LETTERS

THE NEED FOR SCIENTIFIC RIGOR IN STUDIES OF COMPLEMENTARY AND ALTERNATIVE MEDICINE

Weze et al. submitted 76 patients with musculoskeletal pain to 4 sessions of spiritual healing. A before–after comparison of questionnaire data provided "strong circumstantial evidence of benefit."[1(p51)] I would challenge this conclusion on at least 2 grounds. First, the placebo response alone could fully explain the result. We have shown in a randomized clinical trial that pain sufferers' response to sham healing is indistinguishable from their response to "real" healing of a similar type.[2] Second, the possibility exists that patients completed the questionnaires overoptimistically to please the team of investigators and researchers simply because they were kind and empathetic. My main point is that clinical trials, particularly those in controversial areas such as healing,[3] should be conducted according to accepted standards of scientific rigor. Uncontrolled studies using questionnaires or other soft endpoints are prone to create more confusion than knowledge. ■

Edzard Ernst, MD, PhD, FRCP, FRCPEd

About the Author

Requests for reprints should be sent to Edzard Ernst, MD, PhD, FRCP, FRCP(Ed), Complementary Medicine, Peninsula Medical School, 25 Victoria Park Rd, Exeter, Devon EX2 4NT, United Kingdom (e-mail: edzard.ernst@pms.ac.uk).

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LETTERS

WEZE ET AL. RESPOND

We are grateful for Edzard Ernst's interest in our recent brief paper on healing by gentle touch and for opportunity to respond to his criticisms. He is correct to advocate caution in the interpretation of outcomes of "open" trials and to argue for scientific rigor in clinical trials, and we were circumspect in the interpretation of our findings.

First, he asserts that our study was of spiritual healing, but that is not how we described it. Space did not allow for a fuller description of healing by gentle touch, but it differs substantially from that found ineffective by Abbott et al.[1] It involves noninvasive touch on the head, chest, arms, legs, and feet, with varying extents of health-related conversation, for approximately 40 minutes—usually while the subject lies comfortably on a treatment bed—followed by a 10-minute rest. Although a simple, repeating pattern of touch is followed by the therapist at each session, successful treatment depends not on physical routine but on the therapist's sensitive response to the altering circumstances of the subject; concentration, as in meditation or contemplative prayer; and the therapist's ability to listen sympathetically to both the voice and the body of the subject. This healing treatment is more truly defined by relationship than by technique.[2]

Second, Ernst claims that a placebo response alone could fully explain our results, but the extent of benefit to virtually all participants greatly exceeds the rate of placebo response (around 35%) generally associated with physical illness.[3] We believe that this, together with other considerations discussed, does provide strong circumstantial evidence of benefit.

Third, Ernst states that the patients may have completed the questionnaires overoptimistically to please the team of investigators and researchers. This seems unlikely. Why would patients record improvements on some of the scales but not others if their intent were other than to inform the research?

Regarding rigor in clinical trials, it is normal for open studies to precede randomized controlled trials because it would be foolhardy to implement the latter without preliminary evidence of the effectiveness, safety, and suitable dose of the treatment being evaluated. We believe that through various open studies[2,4,5] we now have the necessary evidence to justify a randomized controlled study. The so-called soft endpoints of sufferers' own perceptions of parameters of their health are exactly what this research needs. Substitution of apparently "hard" surrogate markers is a more likely source of obfuscation. ■

Clare Weze, MSc,
Helen L. Leathard, PhD,
Gretchen Stevens, BA

About the Authors

Clare Weze and Helen L. Leathard are with St Martin's College, Lancaster, United Kingdom. Gretchen Stevens is with The Centre for Complementary Care, Cumbria, United Kingdom.

Requests for reprints should be sent to Clare Weze, MSc, Faculty of Health and Social Care, St Martin's College, Lancaster LA1 3JD, United Kingdom (e-mail: clare.weze@ic24.net).

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BREASTFEEDING AND THE WEANLING'S DILEMMA

Wolf rightly calls attention to the low breastfeeding rates in the United States and emphasizes the many advantages associated with breastfeeding.[1] We agree that every mother has a fundamental right to breastfeed her child, that human milk is the natural diet for infants, and that breastfeeding should be strongly promoted globally. We would like to add that breastfeeding should be safe and not affected by risks due to chemical pollutants.

Some persistent environmental chemicals, notably polychlorinated biphenyls (PCBs), dioxins, brominated flame retardants, and many pesticides, accumulate in the body and are transferred from the mother to the infant via human milk.[2] These substances have caused contamination of human milk only during the last half century, and long-term health impacts are now being discovered. At birth, the infant carries some of the maternal burden of PCBs and related substances, but after about 4 months of breastfeeding, the child's serum concentration of these substances may exceed that of the mother.[3]

The somewhat equivocal benefits demonstrated in relation to duration of breastfeeding longer than 4 months[4] may in part be explained by geographical and temporal variations in human milk contamination.[2] Recent studies suggest that prolonged breastfeeding in populations exposed to increased amounts of persistent organochlorine compounds may lead to adverse effects, including delayed physical growth,[5] delayed development of the nervous system,[6] and genotoxicity[7] in the infant. These findings are in agreement with the notion that the developing organism is likely to be particularly vulnerable to toxicant exposures. Likewise, the maternal advantage of decreased breast cancer risk[1] could well be related to elimination via milk of substances that could promote development of breast cancer.[8]

Therefore, efforts in support of breastfeeding need to address environmental pollution that can cause contamination of human milk. Unfortunately, this consideration was missing from the documentation provided by the World Health Organization to the World Health Assembly[9] in support of extending the duration of exclusive breastfeeding from 4 months to 6 months. Owing to varying levels of drinking water quality, nutrients supplied from breastmilk substitutes, and exposures to persistent pollutants, the risk–benefit consideration in regard to extended breastfeeding will necessarily vary.

The documentation on human milk contaminants suggest that mothers in the United States and elsewhere may need to consider an additional aspect of the weanling's dilemma[10]: Does human milk contamination limit the advantage of extended breastfeeding? ■

Philippe Grandjean, MD, PhD
Allan Astrup Jensen, PhD

About the Authors

Philippe Grandjean is with the Harvard School of Public Health, Boston, Mass, and the Institute of Public Health, University of Southern Denmark, Odense, Denmark. Allan Astrup Jensen is with Force Technology, Copenhagen, Denmark.

Requests for reprints should be sent to Philippe Grandjean, MD, PhD, Harvard School of Public Health, Department of Environmental Health, Landmark 3E-110, 401 Park Dr, Boston, MA 02215 (e-mail: pgrand@hsph.harvard.edu).

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WOLF RESPONDS

I agree with Grandjean and Jensen that supporters of breastfeeding must address the environmental pollutants contaminating human milk. Feeding babies should be a risk-free venture, which is why the American propensity to formula-feed is so troubling. We need to solve this international public health problem. However, limiting infants' exposure to human milk is no solution.

Formula—which increases children's rates of respiratory, gastrointestinal, and middle ear infections, as well as meningitis, allergies, asthma, obesity, diabetes, leukemia, lowered IQ, and sudden infant death syndrome (SIDS)[1]—is not contamination-free either. Lead levels in milk-based formula are higher than those in breast milk.[2] Although some colostrum samples have higher levels of mercury than formula, mature breast milk has levels of mercury equal to or lower than those of formula.[3] And while heavy metal–contaminated formula may be relatively chemical-free, the water it is mixed with is not.[4]

Recently, the Technical Workshop on Human Milk Surveillance and Research for Environmental Chemicals in the United States concluded that research overwhelmingly supports the value of breastfeeding and that there has been no clinical or epidemiological demonstration of adverse effects of consumption of human milk containing background levels of environmental chemicals. If there is risk, its nature and magnitude are unclear. Thus the workshop's expert panel took care

to emphasize that current research should not have a negative impact on breastfeeding.[5] Besides, few mothers know what contaminants are in their breastmilk and at what levels. If women make the decision to formula-feed when there are so many unknowns, there will be increased infant morbidity and mortality rather than improved infant health.

An obvious solution to the problem of contaminated human milk does exist. Surveys taken by the Mothers' Milk Centre in Stockholm, Sweden, which has monitored human milk for more than 30 years, show that when persistent organic pollutants are banned, their levels in breastmilk fall quickly.[6] Studies in other countries corroborate this.[7,8] Similarly, restricting dioxin emissions in Europe has produced cleaner breastmilk there.[9]

Weighing the risks of feeding babies formula versus the risks of feeding babies contaminated human milk poses an intolerable dilemma. As ecologist Sandra Steingraber argues, the contamination of human milk violates a basic human right: the right of children to attain maximum health.[10] Indeed, the contamination of mothers' milk should make environmental activists of us all. ■

Jacqueline H. Wolf, PhD

About the Author

Requests for reprints should be sent to Jacqueline H. Wolf, PhD, Department of Social Medicine, Ohio University, Athens, OH 45710 (e-mail: wolfj1@ohio.edu).

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SMOKING AND FIRE

Thank you for printing the outstanding collection of articles about tobacco and health disparities in the February 2004 issue of the Journal. Although most of tobacco's deleterious health effects are long-term, smoking materials remain the leading cause of fatal fires in the United States, causing roughly one quarter of home fire deaths. One study compared the demographic characteristics of smokers whose cigarettes had started a fire with those of smokers who had not had a fire. Households with incomes of less than $10 000 accounted for 45.6% of smokers who had had fires and only 16.6% of smokers who had not. Smokers who were not high school graduates accounted for 38.3% of smokers who had had fires and only 18.4% of those who had not.[1]

Not surprisingly, states with larger percentages of adults lacking high school diplomas and households below the poverty level tend to have higher fire death rates.[2] Barbeau et al. showed that these factors are also correlated with smoking.[3]

Smoking bans protect health, but they also protect property. Fee and Brown described the positive effect that hospital smoking bans had on the hospital environment and the smoking behavior of hospital employees.[4] Hospital fires started by smoking materials fell by 96%, from 3200 in 1980 to 130 in 1998. In 1980, these fires accounted for 40% of hospital fires. In 1998, the figure was only 8% (Ahrens M, unpublished data, 2004).

I had to do a mental shift when reading Fairchild and Colgrove's article on the "safer" cigarette.[5] The fire safety community is strenuously advocating legislative requirements for self-extinguishing cigarettes. While such cigarettes would not eliminate all cigarette fires, they would substantially reduce the number of fires caused by smoldering cigarettes. The National Fire Protection Association is in the harm reduction camp. Until smokers quit, we want them to use a product with reduced risk. Because quitting often takes numerous attempts, we advocate cigarettes that are less prone to ignition, products that are less flammable, and education about smoking practices that are less likely to start fires.

Difficult questions arise when someone receiving supplemental medical oxygen continues to smoke. The Joint Commission on Accreditation of Healthcare Organizations discussed the root causes of 11 fires involving home medical oxygen in the article "Lessons Learned: Fires in the Home Care Setting."[6] Many caregivers, agencies, and fire departments are struggling with this issue.

Smoking is a significant part of the fire and injury problem. Preventing smoking will prevent fire deaths. We applaud the efforts taken to identify the most effective strategies and hope that Journal readers will consider including fire prevention in their programs. ■

Marty Ahrens, MSW

About the Author

Requests for reprints should be sent to Ms Marty Ahrens, MSW, Fire Analysis and Research Division, National Fire Protection Association, One Batterymarch Park, Quincy, MA 02169-7471 (e-mail: mahrens@nfpa.org).

Acknowledgment

Dr John R. Hall Jr, assistant vice president of fire analysis and research, National Fire Protection Association, reviewed this letter and made suggestions.

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THE NORTH AMERICAN FREE TRADE AGREEMENT AND PUBLIC HEALTH AT THE US–MEXICO BORDER

In their article on public health on the US–Mexico border following the passage of the North American Free Trade Agreement (NAFTA),[1] Homedes and Ugalde begin with a flawed premise—that free trade agreements, and globalization more generally, should have positive impacts on public health, in step with increased commerce and an invigorated spirit of international cooperation.

This hypothesis is faulty for at least 2 reasons. First, NAFTA is only 1 of many milestones in a decades-long process of US–Mexican economic integration. To link NAFTA per se to the state of, or changes in, public health along the border is overstated. Second, NAFTA contained no provisions nor subagreements for medical services, let alone public health, as it did for environmental mitigation.

The authors' interviews with public health stakeholders on both sides of the border reveal a disappointing lack of concrete public health accomplishments, as well as barriers to public health cooperation that have existed for many decades. As the authors accurately point out, these barriers include the obvious ones of different languages and vastly different health systems and infrastructure but also legal barriers to cooperation in sharing resources, cross-border travel, and even sharing of basic health information.

However, strides have been made. The US–Mexico Border Health Commission, created in 2000, has gradually begun to address some of the important public health problems and the barriers to their solution through advocacy and limited funding.[2] The establishment of the commission is only 1 of many steps in what will be a long process of improving the institutional setting of cross-border cooperation in public health.

Without a carefully negotiated public health agreement between the 2 governments that lifts legal and administrative barriers and commits ongoing resources, such as were allocated to the North American Development Bank and the Border Environmental Cooperation Commission through NAFTA, advances in public health along the border will likely continue to lag. ■

Stephen Waterman, MD, MPH
Chandler Stolp, PhD

About the Authors

Stephen Waterman is with the Division of Global Migration and Quarantine, Centers for Disease and Prevention, Atlanta, Ga. Chandler Stolp is with the Inter-American Policy Studies Program, LBJ School of Public Policy, University of Texas, Austin.

Requests for reprints should be sent to Stephen Waterman, MD, California Office of Binational Border Health, PO Box 85524, Mail Stop P-511B, San Diego, CA 92138-5524 (e-mail: shw2@cdc.gov).

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HOMEDES AND UGALDE RESPOND

We would like to thank Waterman and Stolp for their interest in fostering the discussion on US–Mexico border health issues, and the Journal for allowing us to clarify one of the most important concepts developed in our December 2003 article.

As we mentioned (p2017, first paragraph), and as Waterman and Stolp say in their letter, there was nothing purposely included in NAFTA to enhance collaboration on health-related issues with counterparts on the other side of the border. But this issue is beside the point. The argument we make is that NAFTA has not facilitated the erasing of the constraints that impede collaboration between health workers. We show that in a few instances it has increased them. Our conclusion is that globalization, as exemplified by NAFTA, benefits not the health of the people, but that of the transnational corporations. Looking at the impact of NAFTA in Canada, Labonte has arrived at similar conclusions.[1]

The contribution of our fieldwork is to detail how this occurs at the US–Mexico border. Other free trade agreements—the Free Trade Area of the Americas Agreement, the US–Central American Free Trade Agreement, the US–Australia Free Trade Agreement, the pending US–Morocco Free Trade Agreement, and others—do include health-related clauses, and the overwhelming assessment by experienced health organizations and observers in the field is that if Congress approves these agreements the damage to the health of these countries will be great.[2–8]

The need for binational collaboration is well recognized, and several agencies have invested considerable resources with different levels of success. Witnesses to these efforts agree on the slowness of these processes. A good example is the US–Mexico Border Health Commission: the idea was conceived in 1990, the creation of such a commission was approved by the US government in 1994, the commission was established in July 2000, its first official meeting was held in November of the same year, and the bylaws were approved in February 2003. As we explained in our article, executives of binational agencies need to take a deeper look at the context in which they are operating to be successful. If contextual constraints to their success are not systematically addressed, progress in US–Mexico border health will continue to be slow, marred with difficulties, and expensive in terms of both human and economic resources. ■

Núria Homedes, MD, DrPH
Antonio Ugalde, PhD

About the Authors

Núria Homedes is with the School of Public Health, University of Texas, Houston, at the El Paso regional campus. Antonio Ugalde is with the Department of Sociology, University of Texas, Austin.

Requests for reprints should be sent to Núria Homedes, MD, DrPH, School of Public Health, 1100 N Stanton, Suite 110, El Paso, TX 79902 (e-mail: nhomedes@utep.edu).

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Stephen Waterman, MD, MPH
Chandler Stolp, PhD

About the Authors

Stephen Waterman is with the Division of Global Migration and Quarantine, Centers for Disease and Prevention, Atlanta, Ga. Chandler Stolp is with the Inter-American Policy Studies Program, LBJ School of Public Policy, University of Texas, Austin.

Requests for reprints should be sent to Stephen Waterman, MD, California Office of Binational Border Health, PO Box 85524, Mail Stop P-511B, San Diego, CA 92138-5524 (e-mail: shw2@cdc.gov).

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The need for binational collaboration is well recognized, and several agencies have invested considerable resources with different levels of success. Witnesses to these efforts agree on the slowness of these processes. A good example is the US–Mexico Border Health Commission: the idea was conceived in 1990, the creation of such a commission was approved by the US government in 1994, the commission was established in July 2000, its first official meeting was held in November of the same year, and the bylaws were approved in February 2003. As we explained in our article, executives of binational agencies need to take a deeper look at the context in which they are operating to be successful. If contextual constraints to their success are not systematically addressed, progress in US–Mexico border health will continue to be slow, marred with difficulties, and expensive in terms of both human and economic resources. ■

Núria Homedes, MD, DrPH
Antonio Ugalde, PhD

About the Authors

Núria Homedes is with the School of Public Health, University of Texas, Houston, at the El Paso regional campus. Antonio Ugalde is with the Department of Sociology, University of Texas, Austin.

Requests for reprints should be sent to Núria Homedes, MD, DrPH, School of Public Health, 1100 N Stanton, Suite 110, El Paso, TX 79902 (e-mail: nhomedes@utep.edu).

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OCCUPATIONAL RISK FACTORS FOR SELECTED CANCERS

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Although there are different magnitudes of association between risk factors and diseases among racial groups,[2,3] few biological risk factors cause a specific cancer in 1 race but not in another race. In addition, the incidences of non-Hodgkin's lymphoma and Hodgkin's disease are lower in African American men than in White men in the United States, though the overall cancer incidence for African American men is about 24% higher than that of White men.[2,3] It is unlikely that racial predispositions play a major role in the occurrence of these cancers.

The chemical natures of chromium and wood dust are harmful to human cells, but the results of their associations with lymphoma and soft-tissue sarcoma are inconsistent.[4-7] For example, significantly increased risks for both non-Hodgkin's lymphoma and Hodgkin's disease among White firefighters but not among African American firefighters have been reported.[5]

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Ping Wei, PhD

About the Authors

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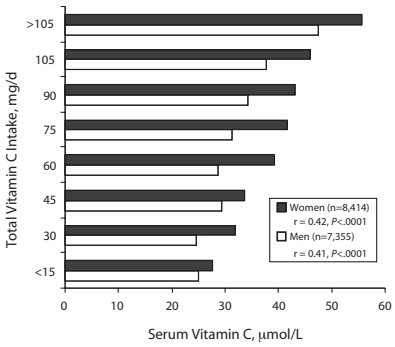
ERRATA

In: Contents. *Am J Public Health.* 2004; 94:898–899.

An incorrect title was printed in the table of contents. The correct title of the Public Health Matters article is **Child Custody Determinations in Cases Involving Intimate Partner Violence: a Human Rights Analysis**. The title was printed correctly on the first page of the article.

In: Hampl JS, Taylor CA, and Johnston CS. Vitamin C deficiency and depletion in the United States: the Third National Health and Nutrition Examination Survey, 1988 to 1994. *Am J Public Health.* 2004; 94:870–875.

A figure was printed with typographical errors. In **FIGURE 1—Mean vitamin intakes, stratified by serum vitamin C levels**, page 872, the x axis labels were incorrect. The corrected figure appears below.



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EDITOR'S CHOICE

HIV and Women: When Words Speak Louder Than Actions

Less than 2 years after AIDS was identified among gay men in the United States, cases were diagnosed among women whose only apparent source of exposure was sex with men who had AIDS or who were at high risk, foretelling the horror to come: heterosexual sex transmits the disease too (Harris C, Small CB, Klein RS, et al. Immunodeficiency in female sexual partners of men with the acquired immunodeficiency syndrome. *N Engl J Med.* 1983;308:1181–1184). Ten years later, in 1993, the executive director of the World Health Organization's Global Program on AIDS told the world that women accounted for half of new HIV infections and the majority of people with HIV in sub-Saharan Africa. He attributed women's vulnerability to biological, epidemiological, and social—including economic—inequities. He called upon men everywhere to help end the social traditions that subordinate women (http://vhaaidsinfo.cio.med.va.gov/aidsctr/newsletters/women/women2.htm).

Another decade went by. On International Women's Day, March 8, 2004, Kofi Annan, secretary-general of the United Nations, spoke: "All over the world, women are increasingly bearing the brunt of the epidemic . . . because society's inequalities put them at risk. There are many factors, including poverty, abuse and violence, lack of information, coercion by older men, and men having several partners" (http://www.undp.org.vn/mlist/health/032004/post33.htm). Only a month earlier, the United Nations special envoy for HIV/AIDS in Africa, Stephen Lewis, had put it even more bluntly: "[I]n so many parts of the world, gender inequality and AIDS is a preordained equation of death. There's nothing new in that. It's irrefutably documented in encyclopedic profusion. The culture, the violence, the power, the patriarchy, the male sexual behavior—it's as though Darwin himself had stirred this Hecate's brew into a potion of death for women" (http://www.sarpn.org.za/documents/d0000696/P772-Stephen_Lewis_08022004.pdf).

Research reports in this issue of the Journal remind us that women in the United States are not spared the HIV-related consequences of gender inequities either. Prevention information for adolescent Latinas slips through the information gap left between schools and parents (Zambrana et al., p1152). Past or present exposure to physical or sexual abuse is likely to impair women's access to HIV treatment (Cohen et al., p1147). Even when they receive appropriate HIV medication regimens, women's mental health needs remain unmet (Siegel et al. p1127), while depressed women decline faster and die sooner (Cook et al., p1133).

Lewis railed at the atrocity of HIV infection unchecked by effective treatment, then sounded a hopeful note: "People are dying in Malthusian numbers. . . . And the majority of those people are now women. . . . Women must somehow be given control over a way to protect themselves from HIV, and that way is microbicides." Recognizing that his audience—the world's foremost basic and clinical HIV researchers—might not be familiar with the concept of microbicides, he proceeded to describe products that might be "formulated as a topical gel, film, sponge, lubricant, time-released suppository, or intravaginal ring that could be used for months at a time."

The Journal's readers are likely to be familiar with the concept, because these pages have been among the most hospitable to scientific research reports and policy analyses on topical microbicides. Several contributions to this issue continue this tradition. They sound important cautionary notes.

First, the field is at a crossroads, at risk of lurching down either of 2 possible paths that

would impede its progress. Legitimate concerns about disrupting planned field trials fail to outweigh more serious concerns over plans to test too many "me too" products in a strategically incoherent, indefensibly costly, and risky multitrial program (Gross, p1085). But it is equally important not to permanently institutionalize an ad hoc fix for problems of the past by creating some sort of centralized gatekeeper controlling access to field trials for future candidates. Effective integration of a pharmaceutical-industry approach means that future candidates will benefit from detailed understanding of cellular processes of infection and rigorous screening to discard less promising candidates.

Second, the impact of microbicides on acquisition of HIV needs to be interpreted in the context of behaviors—in particular, whether microbicidal products are applied at all, are used as instructed, and are free of potential inactivation by drying agents or douching—whereas the tower of academic babble known as "behavioral assessment" has exempted itself from the standard required for all laboratory and clinical endpoints. There is no consensus on valid, reliable, reproducible, clinically meaningful metrics and methods; instead, instruments, scales, and variables proliferate. Whether microbicides become available as prescription-only or over-the-counter products, users are more consumers than patients. They must be motivated to achieve consistent, correct use of products that have no immediately obvious health benefit. Drug and cosmetics manufacturers survive by creating and maintaining markets and supply lines for these products. Are their stratagems relevant for microbicides?

Third, patterns of male control over women do not fall away even if rubber and plastic barriers do. If both partners tacitly accept the man's infidelity as normative, then a nonbarrier method compatible with conception and with sexual intimacy could augment protective options. But those men determined not to lose control of their womenfolk—especially control of female fertility or sexuality—may well respond with mistrust, denunciation, and violence. Produce a woman-controlled protective method and men will demand control over which women may access it (Bentley et al., p1159). If men sabotage a technology that empowers women to save their own lives, then the final solution is to disempower men. ■

Michael Gross, PhD
Associate Editor

"Street Medicine": Collaborating With a Faith-Based Organization to Screen At-Risk Youths for Sexually Transmitted Diseases

| Nicholas J. Moss, BA, Alonzo Gallaread, Jacqueline Siller, MPH, and Jeffrey D. Klausner, MD, MPH

Chlamydia and gonorrhea rates among African American youths in San Francisco are far higher than those among young people of the city's other racial and ethnic groups.

A geographically targeted sexually transmitted disease education and screening intervention performed in collaboration with a local faith-based organization was able to screen hundreds of at-risk youths. The screened individuals included friends and sex partners from an extensive social-sexual network that transcended the boundaries of the target population. The intervention also provided an excellent opportunity to practice "street medicine," in which all screening and treatment was effectively conducted in the field.

The San Francisco Department of Public Health (SFDPH) has documented disproportionately high prevalences of chlamydia and gonorrhea in adolescents residing in low-income, predominantly African American neighborhoods in the city. In 2001, the case rate among adolescents aged 14 to 20 years in one neighborhood, West Hunter's Point, was 5300 per 100 000 for chlamydia and 3200 per 100 000 for gonorrhea, compared with 2000 per 100 000 for chlamydia and 690 per 100 000 for gonorrhea among all adolescents citywide.[1]

Because of these high rates of sexually transmitted diseases (STDs) among adolescents in West Hunter's Point and an adjacent neighborhood, Bayview, in 1997 the SFDPH STD Prevention and Control Services implemented an HIV and STD peer-education program, Youth United Through Health Education (YUTHE), in the Bayview/Hunter's Point area (box on page 1083). In 2002, YUTHE expanded peer education to include field-based STD screening in the area.

The YUTHE director invited a local faith-based organization, the Providence Foundation, to seek an SFDPH grant for youth STD education and to participate in the screening initiative. The Providence Foundation is affiliated with the Providence Baptist Church, which has been serving the African American community in San Francisco since 1945. The foundation's mission is to help the low-income residents of Bayview/Hunter's Point to develop the resources to improve their quality of life. YUTHE and Providence staff worked together in the management of the initiative. Collaborations between public health organizations and community organizations have facilitated urine-based screening for STDs in nonclinical settings.[2] Using faith-based organizations to reach targeted ethnic communities has been successful in other public health initiatives,[3,4] but there are scant reports of adolescent STD screening collaborations with faith-based organizations.

STD SCREENING: "STREET MEDICINE"

Between May and December of 2002, we began screening persons in Bayview/Hunter's Point aged younger than 25 years for chlamydia and gonorrhea. The Providence Foundation provided staff to work with YUTHE to facilitate access to local youths. Three afternoons per week, outreach workers encountered youths along 4 geographic routes in Bayview/Hunter's Point. The YUTHE supervisor designed the outreach routes to cover separate gang turf areas in Bayview/Hunter's Point so that all potential participants would be included.

Outreach workers recruited youths to STD prevention education workshops and screenings at local venues secured by the Providence Foundation. These included one employment program and one after-school program, a YMCA, and hangout spots such as a local barber college and eateries. YUTHE staff conducted 38 education workshops and urine screenings between May and December 2002 (box on page 1083).

TABLE 1—Results of a Faith-Based Collaborative Screening Initiative for Chlamydia and Gonorrhea in Bayview/Hunter's Point, San Francisco, 2002 (n = 470)

	No. (%)	CT Positive, No. (%)	GC Positive, No. (%)	CT or GC Positive, No. (%)
Race/Ethnicity				
African American	431 (91.7)	15 (3.5)	3 (0.7)	16 (3.7)
Other[a]	39 (8.3)	3 (7.7)	0	3 (7.7)
Age,[b] y				
< 25	393 (83.6)	16 (4.1)	2 (0.5)	16 (4.1)
> 25	71 (15.1)	2 (2.8)	1 (1.4)	3 (4.2)
Residence				
Within Bayview/Hunter's Point	304 (64.7)	13 (4.3)	2 (0.7)	13 (4.3)
Outside Bayview/Hunter's Point	166 (35.3)	5 (3.0)	1 (0.6)	6 (3.6)
Total screened	470 (100)	18 (3.8)	3 (0.6)	19 (4.0)

Note. CT positive and GC positive indicate urine positive for *Chlamydia trachomatis* and *Neisseria gonorrhoeae*, respectively, by nucleic acid amplification test (ProbeTec, BD Diagnostic, Sparks, Md). Percentages in last 3 columns are based on numbers shown in second column; for example, 15 of 431 African Americans (3.5%) were CT positive.

[a]Asian, Hispanic, Pacific Islander, White, Native American, and unknown.

[b]We lacked age data for 6 participants.

TABLE 2—African American Youths Aged Younger Than 25 Years Residing in Bayview/Hunter's Point, San Francisco, Screened for Chlamydia and Gonorrhea, by Selected Testing Sites, May to December 2002

	Chlamydia, n (%)		Gonorrhea, n (%)	
	Screened	Positive	Screened	Positive
Bayview/Hunter's Point screening initiative	282	11 (3.9)	282	2 (0.7)
SFDPH clinics[a]	377	44 (11.7)	273	10 (3.7)
City jails[a]	223	14 (6.3)	151	2 (1.3)
Youth detention facility[a]	150	6 (4.0)	45	3 (6.7)
All sites	1032	75 (7.3)	751	17 (2.3)

Note. SFDPH = San Francisco Department of Public Health. A positive test result indicates that urine was positive for *Chlamydia trachomatis* or *Neisseria gonorrhoeae* by nucleic acid amplification test (ProbeTec, BD Diagnostic, Sparks, Md).

[a]Traditional San Francisco city-run sexually transmitted disease screening sites.

The Providence Foundation also organized 6 youth rallies to raise STD awareness among Bayview/Hunter's Point youths. These events took place in the Providence Baptist Church parking lot and featured food and entertainment, as well as STD screening and education provided by the YUTHE and Providence outreach staff.

The SFDPH laboratory tested all urine samples. YUTHE staff confidentially notified positive individuals, delivered appropriate therapy, and offered partner treatment packs. The STD Prevention and Control Section has found field-delivered therapy to be an effective and safe way to treat individuals diagnosed with STDs.[5]

COSTS

All costs were assumed by the SFDPH directly or through the grant to the Providence Foundation. Staff pay was the most significant expenditure. Other costs included flyers, incentives for participants, condoms, and youth rallies. The SFDPH provided the screening tests, but the manufacturer donated antibiotics for chlamydia treatment (Azithromycin, Pfizer Inc, New York, NY).

DISCUSSION AND EVALUATION

Our initiative represented a unique collaboration between a traditional African American faith-based organization and a local health department to educate, screen, and treat youths for STDs. We averaged about 15 participants per screening and had valid screening results for 470 individuals, of whom 360 (83.5%) were African Americans aged younger than 25 years. According to the 2000 US census, there are approximately 2500 African Americans aged 15 to 25 years actually residing in Bayview/ Hunter's Point, of whom we screened 188 (7.5%). Additional results are summarized in Table 1.

Our faith-based partner secured screening venues and created events that were central gathering places for youths living within and outside of Bayview/Hunter's Point. Outreach staff encouraged contacts to bring friends and sex partners to screenings, and 166 (35.3%)

Youth United Through Health Education (YUTHE) and Providence Foundation outreach workers walk the street in Bayview/Hunter's Point.

The Bayview Barber College, a local screening venue.

of all screened individuals actually resided in other neighborhoods, indicating that the Bayview/Hunter's Point youth social-sexual network extends beyond the geographic boundaries of the neighborhood. It has been suggested that targeting networks of friends and sex partners may aid in risk reduction interventions.[6]

The initiative also benefited from our ability to treat all individuals outside of a clinic. Nineteen people (4.0%) tested positive for chlamydia, gonorrhea, or both. All received field-delivered therapy, and 5 accepted treatment for sex partners.

At $150 000, the initiative cost about $320 per person educated, counseled, and screened for chlamydia and gonorrhea and $7900 per new case identified. Since these infections were in asymptomatic persons, they would have gone undetected and further transmission would have been likely. Case detection through screening is an essential aspect of STD control. Our Bayview/Hunter's Point initiative screened on only 38 occasions during the study period and still reached a significant number of youths, including 282 African Americans aged younger than 25 years who actually resided in Bayview/Hunter's Point. We compared this result with the number of individuals, mainly symptomatic, tested at traditional city-run venues (Table 2).

THE FUTURE

The YUTHE program continues to educate and screen for STDs in Bayview/Hunter's Point and has begun a new initiative in a second neighborhood. As our outreach workers gain more experience, they target their efforts to youths engaged in more high-risk behavior. New screening instruments include questions about risk behaviors, and the resulting data may help us tailor future initiatives to high-risk individuals. Future costs can be lowered by relying on community partners primarily for access to their constituency, access to screening sites, and endorsement of

YOUTH UNITED THROUGH HEALTH EDUCATION (YUTHE) PROGRAM, SAN FRANCISCO

- The goal of the YUTHE program is to lower sexually transmitted disease (STD) rates among the approximately 2500 adolescents and young adults in Bayview/Hunter's Point.
- Peer-educators are recruited from target communities and are permanent San Francisco Department of Public Health employees.
- Peer-educators are high school graduates or hold a general equivalency diploma.
- Each peer-educator receives 60 hours of standardized training in:
  - Sexual health outreach;
  - STD and HIV prevention;
  - Skills necessary to work with youths in an economically disadvantaged neighborhood.
- Peer-educators have continuously performed sexual education outreach in Bayview/Hunter's Point and other neighborhoods since the YUTHE program's inception in 1997.

VENUE-BASED URINE SEXUALLY TRANSMITTED DISEASE SCREENING

- The Youth United Through Health Education (YUTHE) team sets up a tent outside of the venue to attract attention.
- All specimen collection materials are brought to the site and stored in a cooler.
- Participants must fill out a brief demographic form with contact information before testing.
- YUTHE staff provides specimen collection instructions and a urine cup in a paper bag for privacy.
- Venues must have a bathroom available for urine self-collection.
- Participants receive 2 movie passes for their time.

screenings, but not for staffing the initiatives.

One of the lasting and important effects of our project is the diversification of the Providence Foundation's community support programs in Bayview/Hunter's Point to include sexual health programs for teens and young adults. The participation of an influential local faith-based organization will hopefully continue to validate the importance of STD screening within the youth community in Bayview/Hunter's Point. ■

About the Authors

The authors are with the San Francisco Department of Public Health, STD Prevention and Control Services, San Francisco, Calif.

Requests for reprints should be sent to Jeffrey D. Klausner, MD, MPH, 1360 Mission St, Suite 401, San Francisco, CA 94103 (e-mail: jeff.klausner@sfdph.org).

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Contributors

N.J. Moss performed some data analysis and wrote the report. A. Gallaread supervised the YUTHE team operations. J. Siller helped conceive the initiative and managed its implementation. J.D. Klausner conceived the screening and treatment protocols and arranged financial support for the program. All authors reviewed drafts of the report.

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Human Participant Protection

As a public health screening and education initiative, the description of this project was designated public health practice and nonresearch.

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KEY FINDINGS

- The San Francisco Department of Public Health was able to collaborate with a local faith-based organization to perform sexually transmitted disease (STD) screening for African American adolescents.
- Our community health initiative successfully relied on "street medicine" techniques, where all STD education, screening, and treatment took place outside of a clinic environment.
- Targeted STD screening in a single neighborhood, Bayview/Hunter's Point, accessed a social-sexual network of young people from all over San Francisco who came there to socialize with their peers.

HIV Topical Microbicides: Steer the Ship or Run Aground

Six HIV candidate microbicides are scheduled to enter 6 large-scale effectiveness trials in the next year. The selection of products for testing and the design of this group of trials should be reconsidered to provide an answer to a key question now before the field: Does a sulfonated polyanion, delivered intravaginally as a gel, block HIV attachment to target cells with sufficient potency to protect women from sexually acquired HIV infection?

Paradoxically, entering more candidates into more trials may confuse or compromise efforts to identify an effective product. Instead, a single trial of the most promising product(s) best serves the current candidates while also preserving resources needed to promptly advance innovative new protective concepts into future large-scale trials. (*Am J Public Health.* 2004;94:1085–1089)

Michael Gross, PhD

I TOLD MY FRIEND I WAS thinking of referring to microbicides—in comparison with preventive HIV vaccines—as "the other white meat." Without a moment's hesitation, she waggishly shot back, "Yes, but vaccines have all the pork."

As soon as HIV was isolated in the early 1980s and methods were devised for producing large quantities of the virus for diagnostic tests and laboratory studies, preventive vaccines emerged as a paramount research goal because they were considered the optimal means of controlling the HIV pandemic. Topical microbicides—vaginally/rectally administered agents designed to block HIV access or attachment to or insertion in the genome of susceptible target cells—for the most part languished: unfamiliar, unpronounceable, marginalized, typically ignored or neglected in public by officials who played a predominant role in establishing research priorities and discounted or trivialized in private. Although, like vaccines, microbicides can interrupt mucosal transmission of HIV in animal models, they long remained overshadowed as a biomedical means of preventing HIV infection.

With the annual National Institutes of Health (NIH) budget for HIV vaccine research projected to exceed half a billion dollars in the upcoming fiscal year, routine increases in the vaccine budget in the neighborhood of $50 million[1] per year approximate the entire amount annually designated for microbicides, estimated at $68 million in fiscal year 2003.[2] In the past decade, NIH has spent tens of millions more on preparations for HIV vaccine efficacy trials that have never taken place than on the few microbicide trials that have. Federal bureaucrats learn to recite the magic sentence that exorcises complaints of insufficient resources: current funding is adequate to support any research worth pursuing. Because availability of funds motivates researchers to take risks and devote the substantial effort required to apply for grants and contracts, lack of funding and lack of ideas worth funding stall a research field in a vicious circle of apathy.

MORE IS LESS?

However, by early 2004, persistence in the face of an unremitting pandemic affecting ever larger proportions of women finally seemed to have paid off. Six new microbicide candidates that had been painstakingly brought through preclinical and early clinical development were poised to enter large-scale effectiveness trials in the subsequent 12 months. Sponsors had secured sufficient funding from government and foundation donors—the Department for International Development of the United Kingdom, the Bill and Melinda Gates Foundation, NIH, and the US Agency for International Development—to launch the trials, with the expectation that donors who provided the down payment would follow through with the $250 million or more likely to be required for their completion.

Sponsors have worked closely with donors to secure the extensive resources required for such a costly undertaking. Field sites have been identified and prepared to begin the trials, and communities have been informed about and mobilized to support these studies. Unless plans change, more than 20 000 women, mostly in developing countries, will be asked to volunteer for these trials in the next several years and to sustain participation for periods of up to 2 years and, sometimes, even longer (Table 1).

At a historical moment that seems well worth celebrating, microbicide research has reached a crossroads where the momentum of a decade or more of effort is sending it down the wrong path. By testing too many products in too many separate clinical trials, the field is mortgaging its future. Not only is the multitrial strategy flawed, but the scope and duration of these trials may stall the evaluation of even more promising, innovative candidates now progressing through preclinical and early clinical development. The field stands to benefit from pausing to compare available candidates and to consider proceeding only with the best-performing one(s). Sound research design and resource management imply that such a portfolio review should in turn lead to a better coordinated, more efficient clinical testing strategy.

A 6-PRODUCT, 6-TRIAL PILEUP

Five of the 6 products about to enter large-scale trials belong to

TABLE 1—Microbicide Effectiveness Trials Scheduled to Begin in 2004

Sponsor (Manufacturer)	Product	Sample Size (Design)	Country (City/Region)	Estimated Start
NIAID/HPTN (Indevus; Reprotect)	Pro2000/5; BufferGel	3100 (phase IIb; 4 arm)	India (Pune) Malawi (Blantyre, Llongwe) South Africa (Durban, Hlabisa) Tanzania (Moshi) Zambia (Chililabombwe, Lusaka) Zimbabwe (Chitungwiza, Harare)	Q3
USAID (Biosyn)	Savvy (C31g)	4284 (2-arm phase III × 2)	Ghana (Accra, Kumasi) Nigeria (Lagos, Ibadan)	Q1
USAID/GMP (CONRAD)	Cellulose sulfate	2500 (2 arm)	India (Chennai) Kenya (Nairobi) Uganda (Kampala) Benin	Q2–3
USAID/GMP (CONRAD)	Cellulose sulfate	2700 (2 arm)	Cameroon (Yaounde)	Q4?
Population Council	Carraguard	6260 (2 arm)	South Africa (Cape Town, Durban, Soshanguve)	Q1
DFD/MRC (Indevus; ML Labs)	Pro2000/5; Emmelle (dextrin-2-sulfate)	6000 (3 arm)	South Africa (Durban, Johannesburg, Mtubatuba) Zambia (Mazabuka) Tanzania (Mwanza) Uganda (Masaka) Cameroon (Yaounde)	Q2–3

Note. NIAID = National Institute of Allergy and Infectious Diseases; HPTN = HIV Prevention Trials Network; Q = quarter; USAID = US Agency for International Development; GMP = Global Microbicide Program; DFD = Department for International Development (United Kingdom); MRC = Medical Research Council.

the same class of compound, sulfonated polyanions. Their protective activity depends on the same mechanism of action: interference with HIV attachment to susceptible immune cells. One of the 5 also lowers pH in the vaginal milieu to levels expected to be virucidal. The detergent action of the sixth compound, a surfactant, purportedly will disrupt the envelope of HIV yet spare the membranes of healthy cells (Table 1).

The first product scheduled to enter a large-scale trial is the surfactant Savvy. Only 4 years ago, the field recoiled from news that even at the lowest dose tested, a previous surfactant candidate, nonoxynol-9 (N9), increased susceptibility to HIV infection among the most frequent users of the product.[3] The same detergent action that disrupts the HIV envelope also may cause lesions in the vaginal epithelium, the principal physical barrier between HIV and susceptible immune cells. Published studies suggest that Savvy may[4] or may not[5] be as injurious to healthy tissue as N9.

It is impossible to overstate the potential harm to future microbicide research and perhaps other research on preventive biomedical technologies—not to mention the very real risks to participants in the trials—should field testing of another surfactant product reveal an adverse safety profile. Safety assessment procedures used in N9 trials will remain unchanged in upcoming trials of Savvy, which means that thousands of women might be exposed for months or even years before such adverse effects became identifiable. No evidence of superior efficacy relative to other advanced microbicide candidates counterbalances concern about Savvy's potential toxicity.

HOW NOT TO SELECT AMONG "ME TOO" PRODUCTS

No industrial sponsor would commit the extensive resources required for efficacy trials to 5 products of the same type. Rather, the most promising candidate would be sought through comparative preclinical and early clinical tests—considered the most plausible indicators of clinical safety and efficacy. Development of the 5 polyanions has been supported by separate sponsors in vertical alliances that have precluded or discouraged cross-product comparisons. When a single donor has supported multiple products, the donor has not always had the independent scientific capacity to assess the comparative merits of products it supports. Although almost all trial funding comes from public coffers, the available data on these products have not been brought together in a single forum that would allow direct head-to-head comparisons.

Carraguard is the only product in this category to have completed a stand-alone phase II trial. The product and placebo arms registered the same number of infections.[6] Although an insufficient number of cases are available to provide definitive evidence that Carraguard lacks protective efficacy, this finding supports further comparative testing versus other products of the same class. In vitro assays of multiple products indicate that they are not equivalent in their virucidal potency,[7] suggesting that comparative preclinical data would support selection of the most promising from among the group.

New insights into the fundamental molecular mechanisms of HIV infection indicate that the laboratory-adapted variant of HIV used in previous preclinical efficacy studies differs importantly from the variant of HIV most often implicated in sexual transmission. This difference is pivotal, because polyanions may be less effective in inactivating the sexually transmitted variant (known as CCR5) than the laboratory-adapted variant (CXCR4). Suitable viral stocks now make it possible to evaluate candidate microbicides using CCR5 variants for both in vitro studies and a low-dose, multiple-challenge non–human-primate test, one considered to be a more relevant

model for human sexual transmission than previous such tests.[8]

HOW NOT TO COMPARE MULTIPLE PRODUCTS

The question to be answered at the present stage of product development for this particular concept—nonspecific blocking of HIV attachment to target cells—is whether the most compelling candidate in the class, based on comparative preclinical efficacy and preclinical and early clinical safety, protects uninfected women from HIV acquisition during unprotected vaginal intercourse. Testing more than one product of the same class requires an explicit rationale, including analyses assessing cross-product differences to inform the field and guide further product development.

If multiple products are to be tested, they should be entered into a single randomized trial that ensures equal distribution among all products of any factors that may influence effectiveness other than the product itself. Only a single trial that randomizes all products can distribute confounding factors—measured and unmeasured—equally among all products. Testing multiple products in multiple trials simply because they are ready, the sites are ready, and the funding agencies have signed the checks does not exemplify good science, sound policy, or responsible ethics.

In the case of a patchwork of trials, there seems no evident rationale for decisions to test some candidates in multiple trials and others in only a single trial or to test some products in concurrent trials with different designs and other products in paired trials with identical protocols. Differences among trials may complicate, and even preclude, direct comparisons. For example, products may perform differently not because of differences in their biological efficacy but because of differences among women enrolled in different trials in terms of, for example, product acceptability or consistency or contexts of condom use. Comparative analyses will be especially difficult, because these separate trials lack common methods and instruments with which to measure such key behavioral indicators.

Some trials have been designed in conjunction with the input of regulators and are based on plans for submitting applications for licensure based on specified study outcomes. Other trials have no clear linkage to a plan for subsequent regulatory review. In countries with rampaging epidemics and an underdeveloped public health infrastructure, regulators are apt to look to the Food and Drug Administration or the European Agency for the Evaluation of Medicinal Products for guidance. But few of these trials have been designed to address specifications for US or European licensure or registration, leaving a policy vacuum. Consequently, the outcome of a single trial, for instance, may indicate enough of a protective benefit from an experimental microbicide to suggest that it would contribute usefully to HIV prevention efforts, even though the results may lack the strength of evidence required to convince regulators to approve such a candidate for licensure.

HOW TO AVOID BETTER SAFETY ASSESSMENT METHODS

Researchers acknowledge weaknesses of the key outcome measure used to monitor product safety: pelvic examinations with visual inspection and colposcopy to detect lesions. A method that depends on clinical examinations is difficult to standardize, labor intensive, burdensome for study participants, and very costly. Furthermore, the N9 experience suggests that this is not an optimally sensitive way to monitor product safety. Although sponsors have sought to standardize colposcopy by including the same trainers for all trials, plans for periodic assessments of "drift" from the prescribed clinical examination procedure and implementation of corrective mechanisms have not been elaborated with an equal amount of comprehensiveness.

Large-scale trials with HIV infection as a primary outcome provide the best opportunity to assess the performance of biomarkers that may be superior safety indicators. Specimens required for such studies can be collected readily, sometimes even by study participants themselves without the assistance of a clinician. Because laboratory-based biomarkers involve the use of reproducible assays, they are intrinsically more reliable than clinical observations made by multiple practitioners. They can be selected so as to be more sensitive than overt tissue damage detectable during clinical examinations. From the perspective of quality control, they are simpler to assess, and inconsistencies in implementation can be more easily remedied.

Pressured by a sense of urgency to move their studies into the field, reluctant to incur even marginal added costs, and unwilling to task already overburdened field sites with any additional procedures required for such "ancillary studies," sponsors have made no provisions to exploit a unique opportunity to improve the efficiency and increase the sensitivity of safety monitoring in future trials. Selecting fewer products, which would reduce the total required sample size, and consolidating operations in a single multicenter trial might provide a more suitable context for any additional specimen collection and storage required to support such studies.

MORTGAGING THE FUTURE

More worrisome than a group of trials in which all fail to demonstrate the efficacy of any single candidate would be a trial program that generates ambiguity while delaying entry of the next generation of candidates into large-scale trials. These risks are all too real, because the proposed set of trials places unprecedented demands on individual clinical trial sites.

Few of the sites that are slated to participate in these trials have previously attempted the massive effort required to recruit and retain 500 to 2000 women in a study. Few sites have conducted prior studies intended to support a regulatory submission for registration or licensure. These requirements translate into the need for flawless conduct of study procedures, accuracy of data capture, integrity of specimen management, and administration of regulated investigational products.

When the next generation of compounds—now progressing into late preclinical or early clinical testing—become available for entry into large-scale trials, the sites that are now being committed may still be engaged in completing the current generation of studies. With new clinical trial

capacity just beginning to be cultivated, inadequate infrastructure may result in the next generation of candidates remaining in limbo while the current set of trials draw to a close. Yet, these candidates are apt to be more promising than the current group of advanced candidates because they benefit from insights and opportunities unavailable even a few years ago.[9]

Much more now is known about the process of HIV infection secondary to sexual exposure, particularly the importance of R5 versus X4 coreceptor usage. In vitro challenge studies with subtypes representative of those in circulation in the regions where products are to be tested and an improved non–human-primate model can provide more useful guides to potential field efficacy. New agents specifically active against HIV at diverse stages of its replication cycle have joined the array of compounds available for evaluation. At last, products being considered as microbicides have induced participation in the field by some of the industry giants that have, until now, scrupulously refrained even from licensing abandoned compounds for public sector development as HIV preventive products.

Knowledge of principles and techniques for developing topical formulations fundamental to the cosmetic and skin care industries now informs microbicide development. Long-acting delivery systems such as relatively unobtrusive vaginal rings that may require replacement monthly or even less often are being carefully scrutinized; these systems would greatly reduce adherence burdens on users while offering a truly inactive placebo that will simplify clinical trial design. Increasingly, product designers appreciate (and development strategies anticipate) that the most effective products are likely to combine multiple active ingredients and mechanisms of protection to achieve broad coverage.

However, the proposed trials have enlisted virtually every potential field site believed to have access to suitable populations of high-risk trial participants and capable of ensuring that their participation meets the highest scientific and ethical standards. These sites will be engaged in enrolling or following participants through 2006 to 2008, or even longer if accrual is slower or retention more problematic than currently contemplated in ambitious study parameters and timetables. It typically requires 2 or more years to identify, develop, and qualify new clinical sites that can participate in efficacy trials.

THE PAUSE THAT REFRESHES

Sponsors might argue that the additional delay in implementing large-scale microbicide trials required to reconsider product selection and rework clinical trial design also will delay progress by 1 to 2 years. Certainly, it will take time to assemble data, perform any additional preclinical studies that seem especially critical for decisionmaking, finalize a revised trial protocol, secure regulatory review, and implement a different field site distribution than that currently planned. The time required depends on how quickly people can mobilize and become motivated to address the future instead of defending well-intentioned decisions made years ago that no longer serve the field.

Any pause is vexing. It imposes major disruption on field sites, host communities, sponsors, and donors. Imposing a further cycle of scrutiny or wholesale revision of research protocols is especially difficult for sponsors who sacrificed much and struggled long and hard to bring a candidate to this most advanced stage of product development. But the risks and costs of pausing must be contrasted with the risks and costs of proceeding. On both sides, imponderables weigh heavily. People may die because research delays defer answers that could have spared them. People also may die because research proceeds down a blind alley or stalls progress in more promising avenues of investigation. Perfection may be the enemy of the good. But hunkering down in dogged determination to proceed, while refusing to take the measure of obstacles that threaten further progress, is called a shipwreck.

POSTSCRIPT

As this paper was going to press, both of the developments alluded to above subsequently unfolded. In February, as informal discussions with donor organizations moved toward some sort of mobilization to review the overall research strategy being implemented, the potential challenge to existing plans became known to trial sponsors. Sponsors of 2 of the proposed trials redoubled efforts to insure that accrual would begin without any further delays, just in time for word to spread at the biennial Microbicides 2004 meeting of virtually every investigator and organization committed to this area of research and development. There can be no more effective way to discourage a modification of the study design or data collection instruments and methods than to begin enrolling volunteers based on the existing protocol and case report forms.

Nevertheless, the Alliance for Microbicide Development and Gates Foundation did orchestrate a consultation April 12–13, 2004 on behalf of the trial donors (Polly F. Harrison, PhD, Executive Director, Alliance for Microbicide Development, Silver Spring Md, oral communication, May 12, 2004). The program (Memorandum from Renee Rizdon and Polly Harrison to Participants in Funder's Consultation April 5, 2004) implied no challenge to the selection of products entering testing or the assemblage of trials being implemented, seeking instead to "extract the maximum possible benefit out of the trials going forward." Despite the complexity of issues associated with the existing menu of trials, the brief meeting also sought to "seek consensus on next best steps for development and testing of future microbicide candidates." ■

About the Author

Michael Gross is an independent consultant, Long Beach, Calif.

Requests for reprints should be sent to Michael Gross, 315 W 3rd St #712, Long Beach, CA 90802 (e-mail: m144@earthlink.net).

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Triangle Park, NC); and the National Institute of Allergy and Infectious Diseases, National Institutes of Health (through BL Seamon Associates, Rockville, Md).

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Improving Topical Microbicide Applicators for Use in Resource-Poor Settings

With more than 60 potential microbicides being assessed in preclinical or clinical trials, most attention has been centered on products intended for topical application, with much less research conducted on the applicators that will be used to deliver the microbicides. However, applicator design relates to safety, efficacy, and acceptability.

As the foundation for a more systematic approach to evaluating and possibly improving designs for topical microbicide applicators, we conducted a literature review and a series of interviews with microbicide developers, trial investigators, and trial sponsors. Our findings indicate that issues concerning applicator safety, reuse, and cost warrant further investigation. (*Am J Public Health.* 2004;94:1089–1092)

Janet G. Vail, MPH, MBA, Jessica A. Cohen, MHS, and Kimberly L. Kelly, MPA

IN THE MIDST OF THE growing AIDS pandemic, safe and effective microbicides could provide urgently needed options for women and men seeking protection from HIV and other sexually transmitted infections. At present, more than 60 potential microbicides are being tested in preclinical or clinical trials. Most attention has been focused on the products themselves, with much less research addressing the devices (applicators) that will be used to deliver most of the microbicides now in the advanced clinical development stage. Applicator design relates to safety (e.g., relationship with product purity and stability, avoidance of local trauma associated with insertion or use), efficacy (e.g., consistent delivery of the required amount of product in the intended location), and acceptability (comfort, ease of use, convenience, aesthetic appeal).

According to interviews and literature reviews conducted by the Program for Appropriate Technology in Health (PATH), approximately 6 different applicators are in use in current microbicide trials. Most of these applicators, prefilled with a single dose to reduce dose variability among trial participants, have been adapted from applicators already marketed for other products. The Global Microbicide Project, directed by The Contraceptive Research and Development Program (CONRAD), a sponsor of several microbicide clinical trials, recently conducted physical tests on applicators and polled physicians and consumers regarding the appearance of these products. This work resulted in a prefilled applicator produced by HTI Plastics (Lincoln, Neb) that has been or will be used in evaluations of 8 different microbicides.

The Population Council has used the prefilled Micralax applicator, designed to deliver rectal laxatives, in its trials of the microbicide Carraguard. The Population Council conducted a 2-month study involving 22 women to evaluate the feasibility and acceptability of that applicator as a microbicide/placebo delivery system.[1] Finally, one microbicide developer based at Laval University in Canada has patented an applicator specifically for use with his product.

METHODS

We conducted a literature review as the foundation for a more systematic approach to evaluating existing applicators and assessing the need for improved applicator designs. The literature covered vaginal and rectal applicators, along with inserters for microbicides, spermi-

TABLE 1—Studies Addressing Vaginal and Rectal Product Applicator Acceptability, Dosage Delivery, Ease of Use, Reuse, or Size

Study, Setting, and Participants	Study Intervention	Product
Barnhart et al.[8]: US university medical center; 1 woman	Magnetic resonance imaging; 7 pelvic scans	Gynol-II mixed with a 1:100 concentration of gadolinium-based magnetic resonance contrast material, with "standard clinical applicator" (not specified)
Barnhart et al.[9]: US university medical center; 1 woman	Magnetic resonance imaging; 1 pelvic scan	Gynol-II mixed with a 1:100 concentration of gadolinium-based magnetic resonance contrast material, with "standard clinical applicator" (not specified)
Bentley et al.[2]: 2 hospitals in Rhode Island; 27 low-risk women aged 18–45 years	Product use once daily for 14 days and twice daily for 14 days (patient choice)	BufferGel with reusable applicator
Coetzee et al.[1]: 2 primary health care centers in South Africa; 28 women 18 years or older who were HIV negative	Product use every other day and up to 1 hour prior to vaginal intercourse over 2 months	Micralax applicator prefilled with methyl cellulose gel
Coggins et al.[6]: 5 sites (Cote d'Ivoire, Thailand [2 sites], United States, Zimbabwe); 145 women	Product use of each type for 4 weeks with each act of vaginal intercourse	Apothecus Vaginal Contraceptive Film; Ortho Conceptrol Vaginal Inserts (suppository); Ortho Conceptrol Gel in a prefilled applicator
Gross et al.[7]: Washington State; 35 seroconcordant male couples (25 HIV-negative and 10 HIV-positive)	Product use once or twice daily and with anal sex at least 3 times a week	Advantage 24 in a prefilled single-use applicator
Hammett et al.[3]: 3 sites (Connecticut, Rhode Island, Puerto Rico); 84 drug-involved women aged 25–44 years	Use of each product during sexual intercourse at least twice during a 3-week period	Lubrin Inserts (suppository); Replens Vaginal Moisturizer in a prefilled disposable applicator; Moist Again with a reusable applicator
Hardy et al.[4]: Brazil; 635 women aged 15–45 years	Individual interviews using a structured, precoded questionnaire; no product use	Clotrimazole plastic applicator; KY Plus applicator; clotrimazole aluminum applicator; Advantage 24 prefilled single-dose applicator; single-use envelope prepared by researchers
LePage et al.[5]: United States (not specified); 20 healthy women with vulvovaginal candidiasis	1 product use per evening for 3 consecutive nights	Femstat (2% butoconazole cream) in a prefilled applicator
Morrow et al.[10]: 4 sites (United States [2 sites], South Africa [2 sites]); 50 HIV-negative and 13 HIV-positive women aged 18–45 years	Product use once or twice daily for 14 consecutive days	Pro 2000 gel in single-dose tubes with individually wrapped single-use plastic applicators

cides, contraceptive devices, and therapies. Ten published articles provided information specific to applicator acceptability,[1–7] dosage delivery,[1,7–9] ease of use,[1–3,5–7,10] reuse versus single use,[3–5,7,10] or size[4,5,7] (see Table 1 for more information about the applicators and products included in each study, along with sample sizes, research settings, and study interventions). This information was used as the basis for a subsequent series of interviews with lead investigators of microbicide clinical, preclinical, and acceptability trials.

The 17 interviewees were identified from the Alliance for Microbicide Development's "microbicides product database," as well as by referrals made during interviews with potential respondents and referrals from the Global Campaign for Microbicides. They included clinical and behavioral scientists, microbicide developers and funders, trial designers, and sponsors representing approximately 30 trials and 7 applicator designs. Respondents provided information regarding applicator type and selection criteria; ease of use, comfort, features, cost, dosage delivery, and reuse; suggested improvements; and alternative delivery mechanisms (tablets, film, vaginal ring, cervical cup).

A number of researchers participated in more than one clinical trial, preclinical trial, or both and were able to discuss several trials and corresponding applicators during a single interview. Four researchers discussed information obtained from trials conducted in developing countries. This series of interviews highlighted the importance of more systematic field research on applicators to guide possible design and manufacturing improvements that will address the needs of future microbicide users in resource-poor settings.

RESULTS AND DISCUSSION

Our findings indicate that issues surrounding applicator safety, reuse, and cost warrant further investigation. These areas were identified on the basis of their importance in terms of acceptability and accessibility among developing-country populations and the fact that they had not been thoroughly investigated in previous research. In particular, safety, reuse, and cost issues need to be examined in relation to one another and how together they affect preferences of women in developing countries.

Safety

Given the potential for frequent and sustained use of microbicides and their intended use as a disease prevention method, applicator safety is a

paramount consideration in product design. Some researchers noted that the size and shape of applicators as well as methods for insertion may lead to cervical, vaginal, or rectal trauma and commented that additional research should be conducted to provide a more complete understanding of applicator use and its effect on user safety.

Researchers noted that women participating in trials in developing countries expressed concerns about the risks that might occur from washing and storing reusable applicators in unsanitary conditions. These concerns included recontracting sexually transmitted infections, HIV infections, or both; contracting diseases such as cholera; and transmitting sexually transmitted infections, HIV, or both to partners and other family members. In one study, HIV-positive women in the United States reported their belief that cleaning an applicator would be unsanitary and would cause infection.[10] Although the literature has not shown any evidence of infections being transmitted via reusable applicators, perceptions of such risks need to be addressed.

The US Food and Drug Administration categorizes vaginal applicators as class I medical devices, meaning that they present minimal potential for harm to the user and are simpler in design than other medical devices. Examples of other class I devices include elastic bandages, examination gloves, and hand-held surgical instruments. Vaginal applicators are exempt from premarket notification, as are most class I devices. Therefore, new stand-alone vaginal applicators can be marketed in the United States without prior Food and Drug Administration clearance.

Reuse

Our literature review indicated that, when asked, US users reported a preference for prefilled disposable applicators.[3,5,7] In a survey of Brazilian women, most preferred the concept of a single-use device.[4] In a study of women from the United States and South Africa, 44% of the respondents preferred the idea of a single-use applicator as well.[10] In interviews, respondents reported that they favored using prefilled single-use applicators in clinical trials to simplify user participation requirements (eliminating the need for women to fill and clean the applicator themselves) and to reduce potential dose variability and user compliance errors associated with reusable applicators.

Outside of clinical research, decisions about reusable versus single-use applicators are intertwined with considerations of safety and cost, as well as convenience, portability, storage, undisclosed use, and disposal. According to 2 of the researchers interviewed, some women in developed countries have voiced concern over adding to environmental waste with disposable applicators, while others prefer single-use, disposable applicators as a result of their convenience. Conversely, 2 other researchers noted that women in developing countries were concerned about privacy of disposal and that they would prefer applicators that could be safely incinerated after use. This issue will have implications for determining the types of materials from which to make applicators.

According to a study conducted in the United States, women who have frequent sexual relations away from their homes found the characteristics of applicator storage and portability to be important.[3] Interviews with researchers suggested that women in developing countries may have greater concerns related to both discreet use and storage than women in industrialized countries, who may have more personal privacy. The inconvenience of having to wash an applicator in public places visible to neighbors or family members, as well as lack of accessible and clean water and fear of not being able to adequately clean the applicator, might lead women in developing countries to prefer single-use disposable applicators. Ultimately, both prefilled single-use and reusable applicators are likely to be needed to accommodate different user preferences and markets.

Cost

Cost will probably be one of the key determinants affecting access to microbicide products. Although one study has estimated single-use applicator prices[11] and 2 studies have explored what women in developing countries would be willing to pay for a microbicide,[12,13] the issue of cost as it relates to single-use versus reusable applicators has not been explored in developing-country populations. While users in some settings may prefer single-use products, the presumed higher cost of single-use applicators is an important decisionmaking factor in resource-poor settings. Nevertheless, alternative designs, less costly raw materials, and streamlined or simplified production processes could reduce manufacturing costs.

RECENT FIELD STUDIES AND ANALYSES

On the basis of the needs identified in this research, PATH, along with collaborating agencies, initiated 2 microbicide applicator field studies in September 2003, one to evaluate microbicide applicator safety and one to explore applicator acceptability. In the first study, PATH collaborated with Profamilia in the Dominican Republic to conduct a clinical evaluation of 3 microbicide applicators. The objective of this safety study was to assess and compare the applicators' effects on symptoms and signs of vaginal irritation as observed via colposcopy. The 3 applicators evaluated were a single-use applicator manufactured by HTI Plastics, a reusable applicator manufactured by HTI Plastics, and a single-use applicator (the Micralax applicator, manufactured by Norden-Pac International, Kalmar, Sweden). All applicators were empty and therefore not delivering any substance during use.

The second study was conducted in the Dominican Republic and South Africa in collaboration with Profamilia and the Reproductive Health Research Unit, respectively. The objective of this acceptability study was to characterize and prioritize women's needs as they relate to vaginal applicator features. The specific parameters explored were cost, reuse, and perceived applicator safety. In each country, approximately 450 interviews were conducted with randomly sampled participants from selected clinic populations. Actual applicator use was not part of the study.

Conjoint analysis, a quantitative method involving structured surveys and closed-ended inter-

views, was used to estimate preferences among potential microbicide users in the 2 populations sampled. Conjoint analysis is typically applied in economics and marketing fields; its application to health care interventions is more limited. However, a study applying conjoint analysis to HIV testing provides a good overview of the methodology and how it can be applied to the health field.[14] The methodology has also been applied to microbicide research and development.[15]

In conjunction with these 2 field-based studies, PATH conducted an analysis of different materials and applicator designs in an effort to characterize comparative features in the areas of cost, reuse, and disposal. This analysis assessed biodegradability of materials, effectiveness with which applicators could be cleaned, and alternative materials and fabrication techniques designed to decrease product cost.

Data collection is complete for all studies, and results are expected to be published later in 2004. If results of the safety study, acceptability study, and material/design analysis indicate a need for further refinement or adaptation of applicators for use in resource-poor settings, PATH will first assess existing products marketed by the private sector in both developed and developing countries, where numerous applicator products have been created for a variety of cosmetic and medicinal purposes (e.g., cardboard applicators manufactured for tampon use and medicine delivery). If these products require further research and development, PATH will work with its industry partners to adapt their products in an effort to ensure the availability of low-cost applicators that will meet user needs as well as microbicide delivery requirements. ■

About the Authors

The authors are with the Program for Appropriate Technology in Health, Seattle, Wash.

Requests for reprints should be sent to Kimberly L. Kelly, MPA, Program for Appropriate Technology in Health, 1455 NW Leary Way, Seattle, WA 98107 (e-mail: kkelly@path.org).

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Contributors

J.G. Vail conceived the study, synthesized the findings, and revised the article. J.A. Cohen supervised all aspects of study implementation and led the analysis. K.L. Kelly implemented the study and assisted with the data analysis and the writing of the article.

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Citizen Rights and State Responses

Legal and Public Policy Responses of States to Bioterrorism

William Martin, MPA

In late 2001, during the aftermath of the anthrax letter attacks, model legislation was proposed to relevant state agencies to update their states' public health laws to meet the threat of bioterrorism. This legislation was the Model State Emergency Health Powers Act.

A concern underlying this and related efforts to address future bioterrorism threats was the perceived inadequacy of state laws to respond effectively when such threats occur. We evaluated how 4 states—Utah, Maine, South Dakota, and Indiana—addressed this concern in the context of the model legislation.

The conclusion is that the model legislation generally served as an important catalyst for state action in the field of bioterrorism preparation. (*Am J Public Health.* 2004;94: 1093–1096)

THE ANTHRAX ATTACKS IN the fall of 2001 raised the question of whether each level of government in the United States had adequate authority and resources to respond to future attacks. In the US defense against bioterrorism, state and local agencies will most likely be on the front lines because these levels have the primary responsibility for public health.[1] The Center for Law and the Public's Health at Georgetown and Johns Hopkins universities wrote model legislation for states seeking to update their laws relating to public health emergencies because these laws are arguably outdated.[2] The Model State Emergency Health Powers Act (MSEHPA) highlights those powers the center found should be granted to states to detect and respond sufficiently to future bioterrorist attacks.

States received copies of the MSEHPA in late 2001, and many initiated legislative or administrative efforts to adopt part or all of its text.[3] This study examines how 4 states—Utah, Maine, South Dakota, and Indiana—interpreted the MSEHPA to try to achieve the goals of effective bioterrorism detection and response. These states are in different regions of the country, and they addressed the challenges presented by the threat of bioterrorism differently. The general conclusion of this article is that the MSEHPA usually served as a catalyst for health care providers, law enforcement personnel, political leaders, and citizens at large to discuss how to improve their public health laws.

THE SUBSTANCE OF THE MSEHPA

The MSEHPA has 2 broad operational goals relevant to infectious disease—effective detection of the problem and effective response.[4] In terms of detection, the MSEHPA places pharmacies, hospitals, and outpatient service providers on the front lines against bioterrorism. Before the MSEHPA, many states prevented private businesses like pharmacies from sharing information with health authorities and prohibited health authorities from sharing information with state police. The MSEHPA requires pharmacists who notice peculiar increases in specific medicines to contact state or local health authorities. If public health officials think it necessary, the pharmacist is even required to supply names and addresses of specific individuals. When public health authorities learn of a case they "reasonably believe" to be the result of bioterrorism, the MSEHPA directs them to inform public safety authorities immediately.

Once public health authorities detect a possible bioterrorist attack, they must then develop an effective response to the emergency. Under article II of the MSEHPA, states should already have coordinated their response measures to public health emergencies. After a governor declares a public health emergency, she may suspend any regulatory statute if strict compliance with such laws would "prevent, hinder or delay necessary action" to respond to the threat. The public health authorities coordinate the state's response to the emergency, and the state legislature can terminate the state of public health emergency at any point.

One potentially controversial response measure is the isolation and quarantine of potentially infected individuals.[5] The MSEHPA gives the state broad power to do so, on the condition that isolation and quarantine are the "least restrictive means" to prevent the spread of infectious disease. Failure to abide by the state's directions in isolation or quarantine would constitute a misdemeanor. Additional response measures include mandatory vaccinations, and seizure of private property. At the same time, the MSEHPA guarantees affected individuals some due process to demand release from isolation or quarantine. Specifically, individuals can request a court hearing for the state to show cause for the isolation or quarantine or for affected individuals to argue that the state

has breached conditions of the isolation or quarantine order.

Perhaps the foundational achievement of the MSEHPA is its articulation of how to balance social goals served by police powers with individual freedom. Absent such ex ante articulation, the state may quickly lose credibility and public trust after a bioterrorist attack and thus complicate efforts to mitigate the spread of infectious disease. For example, local officials in Muncie, Indiana, did not effectively communicate with citizens during a smallpox outbreak in 1893. Local officials sought quarantines, isolations, seizure of property, and mandatory vaccinations, but soon confronted violent resistance. More recently, the spread of severe acute respiratory syndrome (SARS) and the Chinese government's response to the disease likely diminished public trust in that government.[6] These experiences should encourage government leaders at all levels to discuss and develop effective detection and response strategies for bioterrorist and nonterrorist occurrences of infectious disease.

CASE STUDIES

The 4 states evaluated in this article present a useful comparison of how different states approach the same problem of the threat of bioterrorism. The Utah legislature addressed only detection issues, given the pressing need to prepare for the 2002 Winter Olympics in Salt Lake City. Maine largely ignored detection and focused instead on strengthening response powers. South Dakota also focused primarily on response in addition to clarifying jurisdictional issues between the state and county departments of health. Finally, confident in existing state powers to handle bioterrorist attacks, Indiana did not reform its public health laws.

Utah

After receiving the MSEHPA in late fall of 2001, Utah Department of Health officials decided to propose some reforms of the state's public health laws. However, it was an open question whether the agency should pursue a comprehensive—yet lengthy and time-consuming—set of reforms or a more modest version. Although the state might have benefited from both detection and response reforms, Utah health officials ultimately pursued only detection reforms for 2 reasons. First, the agency had already missed the deadline for submitting bills to the legislature for its 2002 session. As a result, the agency was more dependent than usual on individual legislators to draft and promote legislation, and a comprehensive set of reforms would likely have been too ambitious an undertaking. The agency could either have waited for almost a year to submit a comprehensive version or support a more modest version immediately. Second, the Winter Olympics in February 2002 strongly encouraged officials to choose the latter. It was deemed better to have a partial set of reforms in place before this potential terrorist target than nothing.

Utah's reforms focused on health care providers' expedited reporting of relevant information and the appropriate dissemination of that information. Preexisting state law mandated that physicians, pharmacists, and hospitals immediately report selected diagnoses to public health officials. However, "immediate reporting" could take as long as 14 days after a diagnosis. Waiting for a firm diagnosis before reporting the patient's conditions to public health authorities could worsen the bioterrorism attack's potential impact.[7] In addition to the mandatory reporting of diagnosed conditions, the changes authorized the voluntary reporting of syndromes and conditions. For example, pharmacists could report to the Department of Health that they had received an unusual number of requests for over-the-counter drugs. In addition, Utah followed the MSEHPA by authorizing public health officials to share information with law enforcement agencies.

Yet, the Department of Health and its allies in the legislature made several concessions to opponents. Originally, the department sought mandatory reporting conditions and syndromes. After several hospitals, pharmacists, and the Utah Medical Association argued that such extensive reporting requirements might pose serious administrative burdens on health care providers, the department agreed to the mandatory/voluntary distinction described previously. In response to concerns about individual privacy, the bill included a 2-year sunset provision and a clause mandating that the department must destroy any personal information within 180 days of its collection.

In the end, Utah did not change its quarantine laws or other response measures as part of this effort. The legislature had recently reformed these laws to help the Department of Health address cases of recalcitrant patients with tuberculosis or other infectious diseases. However, the new laws refer only to individuals, not groups, so it is unclear whether the Utah Department of Health has the full extent of quarantine authority envisioned in the MSEHPA. In terms of due process, the state is required to give quarantined individuals a hearing to determine the necessity of continuing such conditions within 10 business days. It is uncertain whether the state has the legal authority to mandate vaccinations for uncooperative individuals.

Maine

Unlike Utah, Maine focused primarily on bioterrorism response instead of detection. Maine already had some emergency powers, such as holding individuals for up to 48 hours for "public health purposes." A court could order such holding even if the individual did not come to court. However, the legislature considered these powers inadequate to respond to a bioterrorist attack.

Maine accorded its public health department new powers that would come into effect only after the governor declared an "extreme public health emer-

gency." Powers granted to the public health department included taking "a person into custody and order[ing] prescribed care."[8] The term *prescribed care* was defined broadly to include isolation, quarantine, mandatory vaccination, and medical examination and treatment ordered by the department. This covers many of the "response" powers detailed in the MSEHPA, including controversial issues like mandatory vaccinations. Yet, Maine sought to balance a need for public protection with respect for individual rights. For example, although the MSEHPA allows 10 days of quarantine and isolation before the affected individual receives a hearing, Maine authorized only 48 hours before such judicial intervention. In addition, Maine's law did not include the sections of the MSEHPA detailing how the state can handle the remains of infected or possibly infected individuals.

The Maine legislature did not address most detection issues to the extent envisioned in the MSEHPA. Maine law protecting personal health information would likely have conflicted with certain provisions in the MSEHPA. Specifically, legislators feared that a proposal to grant public health officials unrestricted access to individual-level health information regardless of the circumstances would encounter stiff political opposition. Instead, Maine allowed disclosure for the purpose of "protect[ing] the public health and welfare," which could be interpreted as allowing health care providers to share information in aggregate form. In addition, after declaration of an extreme public health emergency, the public health department can demand individual-level information related to that emergency.

Despite these changes, some concerns remain regarding the capacity of the public health system in Maine to respond to any attack. In particular, Maine may have insufficient institutional capacity to handle such public health emergencies. Maine has no county public health departments, and the state's 2002 application for Centers for Disease Control and Prevention (CDC) funds to augment the state's bioterrorism response capabilities pointed to a Department of Justice/CDC survey indicating that "immediate attention" was needed in 49 of the 88 key public health essential service dimensions.[9] This illustrates the need for many states to go beyond making only legal changes in enhancing community preparedness for bioterrorism and other public health emergencies.

South Dakota

The South Dakota legislature passed 2 bills in 2002 giving the governor several new powers to respond to bioterrorist attacks. One set of powers would come into effect after any "disaster, war, act of terrorism as defined by state law, or emergency that is beyond local government capability."[10] One of these powers is the governor's ability to "procure, acquire, store, distribute and dispense" pharmaceutical agents within the state's borders to respond to the event in question. This language is broader than the text of the MSEHPA, which would allow such actions only in times of a "shortage or threatened shortage" of pharmaceutical agents. Another key provision of the law is the ability of the governor to "appoint . . . out-of-state health care providers"[11] to respond to bioterrorist attacks, presumably in case the local supply of such providers appears insufficient. This language derives from the MSEHPA, which specifies how long providers may be licensed and their liability protections for civil damages.

One overarching change is the clarification of the South Dakota Department of Health's authority after the declaration of a public health emergency. Legislators and public health officials feared that time-consuming disputes between state and county health officials over each level's powers would occur. The legislature amended South Dakota laws relating to the emergency powers of both levels of the public health infrastructure and declared that the state shall have the "primary jurisdiction, responsibility, and authority for responding to a public health emergency."[12] Yet, there are some areas the South Dakota bills do not address. Specifically, state law already mandated reporting infectious diseases such as tuberculosis, and legislators did not seek to grant the state power to mandate vaccinations of individuals.

Indiana

Although many states reformed their laws regarding public health emergencies to detect or better respond to bioterrorist attacks, the Indiana legislature and public health officials believed they already had enough authority to respond to these situations. The Indiana legislature had already sought to balance the individual's interest in keeping health information confidential with the state's need to detect emerging infectious diseases quickly, regardless of whether these diseases were part of a bioterrorist attack. Usually, under Indiana state law, individual health information is confidential, and any person who violates this confidentiality is guilty of a misdemeanor. However, physicians and hospitals must report certain communicable disease information to the health department, and the department may track this information to respond effectively to these public health threats. These provisions may provide an adequate foundation for the detection of a bioterrorist attack, but the state could still reform its existing law and bolster improvements in public health. For example, Indiana could take steps similar to Utah's in monitoring the frequency with which health care providers actually report communicable diseases.

In terms of response, Indiana law grants significant emergency power to the public health commissioner, not the governor. In particular, the commissioner has the right to "establish quarantine[s] and may do what is reasonable and necessary for the prevention and suppression of disease." Another broad power granted to the commissioner is the "right to issue an order condemning or abating conditions

causative of disease."[13] Unlike the MSEHPA, Indiana law does not specify what due process a quarantined individual has.

CONCLUSION

All the states in this study considered the MSEHPA, but each eventually approached concerns about bioterrorism differently. Multiple factors—including the states' political dynamics, social characteristics, and existing legal frameworks—likely shaped these approaches. Although these states did not provide the consistency sought by the Center for Law and the Public's Health, their efforts still addressed some critical needs regarding bioterrorism detection and response.[14]

Study of this issue sheds light on the interaction between law and public policy in solving a complex and contemporary national, state, and local problem—bioterrorist attacks on civilian populations. Consistent and clarified law that minimizes time-consuming lawsuits in the event of a crisis is 1 aspect of a solution to this problem. Building on efforts to update their laws, states and localities should now direct their attention, other aspects—including funding and personnel.[15] ■

About the Author

Requests for reprints should be sent to William Martin, The University of Chicago Law School, 1111 E 60th St, Chicago, IL 60637 (e-mail: martinw@uchicago.edu).

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Ethical Challenges in Preparing for Bioterrorism: Barriers Within the Health Care System

Matthew K. Wynia, MD, MPH, Lawrence O. Gostin, JD

Preparedness for bioterrorism poses significant ethical challenges. Although public health ethics and preparedness have received attention recently, health care ethics must also be considered.

In epidemics, the health care system assists public health in 3 tasks: detection, containment, and treatment. Detection might fail if all patients do not have access to care, or if physicians do not understand their obligation to report infectious diseases to public health authorities. Containment might fail if physicians view themselves only as advocates for individual patients, ignoring their social obligations as health professionals. Treatment might fail if physicians do not accept their professional duty to treat patients during epidemics.

Each of these potential ethical barriers to preparedness must be addressed by physicians and society. (*Am J Public Health.* 2004;94:1096–1102)

THE INTENTIONAL DISPERSAL of anthrax spores in the United States demonstrates the need for preparedness for bioterrorism, and the recent outbreak of severe acute respiratory syndrome (SARS) has renewed fears of unintentional or naturally occurring infectious epidemics. In responding to these threats, the public health system has rightfully garnered much of the attention,[1]

after decades in which government has starved public health agencies of needed resources.[2–4] However, an effective response also will require the health care system to fulfill critical roles. By the term *health care system*, we mean those professionals (e.g., physicians and nurses) and institutions (e.g., hospitals and health plans) obliged to diagnose, treat, and care for individuals exposed to or infected with contagious diseases. We specify *contagious* diseases because although anthrax is not transmissible from person to person, many experts reserve their deepest fears for transmissible agents such as smallpox, plague, hemorrhagic fevers (e.g., the Ebola, Marburg, Lassa, and Crimean-Congo hemorrhagic fever viruses), and new (e.g., SARS) or designer viruses and bacteria.[5]

Thinking systematically, what are the obligations of the health care system in handling contagious diseases? The health care system should rapidly identify threats, help to prevent the spread of disease in the population, and care for infected patients. These 3 tasks—detection, containment, and treatment—are vital to the efficient handling of contagious epidemics. To prepare for each task, policymakers have emphasized training,[6–9] clarification of public health quarantine powers,[10,11] facilities improvements, and pharmaceutical stockpiling.[12–14] Although these steps are important, we wish to draw attention to several challenges related to medical ethics and professionalism that might hinder detection, containment, and treatment and that have been much less discussed. Ours is not an exhaustive compilation of the many ethical issues associated with bioterrorism, but the issues we raise have received relatively little attention recently and are at risk of being lost in the highly publicized debates over, for example, the ethics of smallpox vaccination. These issues also illustrate that contagious diseases raise critical questions about the ethical relationship between medicine and public health.[15]

DETECTION: REPORTING AND ACCESS TO CARE

In some bioterror scenarios, such as an aerosol release into a crowd, simultaneous widespread infections would mark an attack; if this were the case, then limiting the outbreak through early detection might provide little benefit (though early recognition and treatment of the illness might still save lives). But smaller-scale attacks are potentially much easier for terrorist organizations to organize, finance, and carry out.[16] As the anthrax mailings of October 2001 demonstrated, even relatively small attacks can provoke widespread anxiety and disruption. In a stealth attack, early detection becomes critically important, as it is in stemming naturally occurring outbreaks.

To improve detection, the United States is expanding the public health system's capacity for surveillance. However, public health surveillance relies largely on reports from health care professionals. Persons with symptoms arrive first in physicians' offices, clinics, or hospital emergency departments. For this system to work, therefore, patients must first have access to the health care system, and their illnesses must then be reported to the public health system.

The health care system must improve its reporting performance. Many physicians are unaware of reporting requirements, complain of the administrative burden of reporting, do not see reporting as important to patient care, or are unconvinced that reporting is of value.[17] Reporting must be made easier (or even automatic, through electronic links), and physicians should be given feedback on how their reports are used to safeguard public health, reinforcing the value of the physician–public health partnership. Examination of the physician's role in reporting contagious illnesses should be included in new curricula on professionalism[18] in the context of exploring the social roles of the medical profession—an issue to which we will return.

In the area of patient access to health care, more challenging dilemmas arise. Strong ethical reasons have long been recognized as supporting universal access to a decent minimal set of health care services,[19] yet our nation has been unable or unwilling to accomplish this.[20] Perhaps if policymakers understand that inadequate access to care poses a threat to national security, progress can be made.[21,22] In the United States, more than 40 million Americans lack health insurance, and this number is rising.[23,24] Although some uninsured individuals use emergency rooms to obtain care when they are acutely ill, many of the uninsured and underinsured avoid the health care system for as long as possible.[20] Some have argued that bioterror-related illnesses are so severe that anyone affected would surely seek care.[25] But uninsured patients discriminate poorly between appropriate and inappropriate care and tend to avoid both equally.[26] Numerous studies demonstrate that the uninsured are more likely to present in an advanced stage of illness, and many die without ever being evaluated.[27–29]

Terrorists undoubtedly recognize that even a small-scale release of an infectious agent into a community with a high rate of uninsurance might be devastatingly effective. Because most of the uninsured are employed and working throughout cities, suburbs, and rural areas, starting an outbreak in such a community—using a low-tech approach, such as an infected "martyr"—would reduce the likelihood of early detection and raise the odds of broad spread of the disease.[30] Unfortunately, this scenario is not mere speculation: "natural experiments" that simulate such an attack have demonstrated the vulnerability of poor, especially uninsured immigrant, populations and their ability to spread disease throughout the population.[31,32] Many naturally occurring infectious diseases, including tuberculosis, food-borne illnesses, and HIV/AIDS, disproportionately burden the uninsured and

subsequently spread to the community at large.[33]

Maintaining barriers to accessing health care in the face of today's threats should be unacceptable, morally and politically. In the aftermath of the September 11 attacks, New York ordered its health care system to provide care to all possible victims[34] and the state health commissioner, Antonio Coello Novello, declared to providers: "Thou shalt not ask who will pay for this."[35] Over the next 4 months, New York's special Disaster Relief Medicaid program enrolled and cared for almost 400 000 people.[36] New York dramatically streamlined the application process for Medicaid and obtained additional funding for the state pool for the uninsured. The public, government, and the medical community widely approved these actions as appropriate, given the threat.[37,38]

Learning from this experience, federal and state officials should make clear that individuals with symptoms that suggest infection with a contagious illness should present for evaluation and ensure that those who do can be treated without prejudice. Funding must be provided to cover screening and treatment of patients with contagious illnesses; in particular, funding for hospital emergency departments that see large volumes of uninsured patients must be increased.[39] Because patients cannot be expected to know in advance whether their illness is infectious, programs can be targeted toward contagious illness but ultimately, they will need to be broad based. Finally, funding alone might not guarantee ready access to care for certain populations, especially recent immigrants and those who mistrust the health care system.[22] The current policy focus on addressing racial and ethnic health disparities should be used to build a culturally sensitive primary care system in which all patients feel welcome.[40]

CONTAINMENT: ISOLATION BEFORE QUARANTINE

In late October 2001, the secretary of the US Department of Health and Human Services asked the states to increase their legal preparedness for potential epidemics.[41] Twenty-two states and the District of Columbia have since enacted laws based on the Model State Emergency Health Powers Act, drafted by the Center for Law and the Public's Health at the request of the Centers for Disease Control and Prevention.[42,43] These laws seek to ensure that when facing a clear emergency, the public health system can carry out screening, vaccination, quarantine, and treatment.[44] Even with these powers, however, the public health system cannot contain an outbreak as rapidly as might health care professionals who are willing and empowered to use short-term involuntary isolation when needed.

Of course, most contagious patients will comply voluntarily with an isolation request; but recent bioterror training scenarios assume that not everyone will cooperate with treatment and quarantines,[45,46] and this assumption is borne out in experiences with SARS.[47–49] Illness and fear can hinder clear thinking. Physicians should know this and be prepared to intervene if necessary. Under what legal authority might health care professionals isolate a potentially contagious patient *in advance* of a public health quarantine? Health care professionals have a general obligation to prevent patients from harming themselves or others and may use compulsion when necessary.[50] The most common application of this power might be to "hold" psychiatric patients thought to pose a suicide or homicide risk.[51] Such short-term physician holds usually require judicial review within 24 to 48 hours, but this kind of short-term legal authority could serve as an early stop to an outbreak in the event that one or more patients decline necessary interventions before the public health authority enforces quarantine.

In general, public health officers, not one's physician, should declare quarantine, because separation of these roles allows physicians to attend to individual patients' interests. Indeed, using professional powers to hold patients involuntarily poses a fundamental ethical challenge for physicians, because it entails overriding an individual patient's wishes in deference to the community's needs—balancing respect for patient autonomy against public health benefit. Challenging though it may be, however, mediating the tension between individual and community needs is integral to the role of the medical profession in society—and demonstrates why the profession must maintain some independence from both the state and patient interests.[52]

There are significant risks in physicians' acting as agents of the state,[53–55] yet attention to civic obligations is as ancient a part of professionalism as is attention to patients' interests. Plato bluntly recognized this balancing act when he wrote that physicians are "statesmen" who are to do what "is best for the patients *and* for the state."[56(p6)] More recently, Creuss and Creuss noted that during the 19th century

> legal measures for the first time granted medicine a broad monopoly over health care—along with both individual and collective autonomy—with the clear understanding that in return medicine would concern itself with the health problems of the society it served and would place the welfare of society above its own.[57(p943)]

The original 1847 Code of Medical Ethics of the American Medical Association noted that a physician's skills "are qualities which he holds in trust for the general good,"[58(p318)] and one of its 3 chapters—entitled, "Of the Duties of the Profession to the Public, and of the Obligations of the Public to the Profession"—dealt explicitly with physicians' social duties.[58(p333)]

In the era after 1955, however, medicine began to move away from balancing social obligations, tilting toward a more restricted advocacy position.[59,60] Obligations regarding public health were minimized, and physicians were eventually urged to

ignore civic considerations altogether and to think only of the welfare of the patient before them. In 1984, Norman Levinsky wrote that "physicians are required to do everything that they believe may benefit each patient, without regard to costs or other societal considerations."[61(p1574)] This statement reflected the domination of medical ethics by respect for patient autonomy and the loss of a cardinal feature of professionalism: mediation between private and community interests.[53,62] But, bereft of its role as a social protector, medicine was left with only technical expertise to support its claims to professional prerogatives, which are granted by society and have since steadily eroded.[63,64] Recognizing this chain of events, recent scholars of the medical profession are returning to a civic understanding of professionalism as necessary to maintaining public trust and, with it, professional privileges.[65,66] Dr William Sullivan wrote of this return to a classic role for the professions in society: "Historically, the legitimacy, authority, and legal privileges of the most prestigious professions have depended heavily on their claims (and finally their demonstration) of civic performance, especially social leadership in the public interest."[63(p11)]

Ethically, therefore, when time is limited, physicians should be empowered and willing to use short-term holds to prevent immediate spread of disease, because physicians' professional duty sometimes should tilt toward protecting the public—although not incidentally, of course, most individuals will also benefit from enforced isolation and treatment. Some physicians and patients, raised on the medical ethics of the last 50 years, will chafe at the paternalism of this statement, but we find that professionalism requires meaningful attention to civic duties such as protecting the public health. Because the power to hold patients involuntarily can be abused,[67] constraints such as requiring 2 physicians to concur, ensuring the short-term nature of the hold (24 hours or less), and ensuring rapid judicial review, should be applied. Legally, in jurisdictions where it is not clear whether physicians' authority to hold patients for dangerousness applies outside the psychiatric setting, clarification is required. Bioterror training should reinforce physicians' ethical obligations regarding isolation of dangerously infectious patients, and there should be open debates on appropriate limits to this power, as well as to address practical considerations regarding quarantine, such as when public health authorities should enforce community quarantine and how to respectfully care for those under quarantine.

TREATMENT: THE DUTY TO TREAT

Recent discussions of treatment barriers during bioterror-related outbreaks tend to focus on potential shortages of antibiotics and vaccines. But stockpiles can be calculated with reasonable certainty and increased as needed. More challenging in these scenarios is that 1 treatment variable is critically important yet very difficult to estimate: how many health care professionals will fail to show up for work because they fear contracting the illness?[68]

It is almost certain that some will not willingly face the risk. At least 1 hospital in China had difficulty maintaining services because of absenteeism in the face of SARS.[69] Some hospitals in New York have announced they will not care for victims of bioterror attacks.[70] Physician performance during epidemics, from the black plague to the HIV epidemic, has been notoriously spotty.[71–73] And relatively few physicians have volunteered to receive smallpox vaccination, despite high-level government requests.[74,75]

There is legitimate reason for trepidation on the part of health professionals. More than one third of health care personnel treating patients after the sarin gas attack in Tokyo became ill from cross-contamination.[76] Health care workers are common second-wave victims of Ebola[77] and SARS.[78] In the United States, there are 56 documented cases of health care workers' becoming infected with HIV due to needlestick injuries,[79] and countless more have contracted hepatitis B or C, tuberculosis, and other potentially deadly infections. Into the 1950s, exposure to and infection with tuberculosis was a near-ubiquitous medical training experience, especially for pulmonologists.[80,81]

Several ethical and practical bases for a "duty to treat" have been proposed that taken together provide a strong justification for its reaffirmation today.[82,83] Health care professionals receive special training, which increases the general obligation to render aid to others in need, because it increases the value of the aid and may reduce the risk associated with providing it.[84] Physicians have long subscribed to explicit codes of ethics that demand the duty to treat,[85,86] codes that the public assumes to be binding. In 1991, despite recent interprofessional wrangling over the treatment of patients with HIV,[70] 72% of the public agreed with the statement that physicians are obligated to "treat all sick people."[87] Physicians also receive social standing and trust as part of a social contract, which includes an obligation to place the welfare of patients above self-interest.[57]

When professional associations last confronted this issue, in the early years of the AIDS epidemic, early wavering gave way to consensus that a duty to treat still exists.[88] According to the Infectious Diseases Society of America and the American College of Physicians, health care professionals "must provide high-quality nonjudgmental care to their patients, even at the risk of contracting a patient's disease."[89(p576)] The American Medical Association's recently (December 2001) adopted Declaration of Professional Responsibility states that physicians must "treat the sick and injured with

competence and compassion and without prejudice," and "apply our knowledge and skills when needed, though doing so may put us at risk."[90]

Two steps should be taken to reinforce this obligation. First, language in professional codes of ethics addressing treatment during epidemics was largely removed in the 1970s, at a time when epidemics appeared to be on the wane.[91] Subsequent statements focused almost exclusively on HIV/AIDS and often were framed in terms of antidiscrimination principles rather than professional obligations.[92] Professional associations should make clear their current stances on physicians' obligations to care for patients during epidemics. Ideally, the inspiring spirit and language of the early American Medical Association Code of Medical Ethics should be reaffirmed today: "When an epidemic prevails, a physician must continue his labors for the alleviation of suffering people, without regard to the risk to his own health or to financial return."[93(p354)]

Second, to justify and strengthen this obligation, special efforts should be made to ensure that health care professionals receive all reasonable preventive and treatment measures in the event of an outbreak, such as vaccines, prophylactic therapies, and safety training.[94] Such preferential treatment makes practical sense, because only healthy practitioners will be of value in responding to any ongoing threat.[95] Ethically, when health care professionals tend to patients in epidemics, healthy people place themselves (and often their families) at risk to benefit the common good. The state must recognize that this burden, in some manner, should be shared by the community as a whole. This value was implicitly recognized in policy discussions regarding early smallpox vaccination for health care workers. However, beyond smallpox, health care workers should be assured that in the event of an attack, all that is possible will be done to protect them—and their families. Local stockpiles of vaccines and other therapies should be set aside for health care workers, ensuring that those who may be at greatest risk will receive early and effective protection. In addition, the families of health care workers who perish in epidemics should receive predictable compensation. By offering fair compensation, the government can further spread the burden of pursuing the public interest.

CONCLUSIONS

Defense against bioterror and naturally occurring infectious epidemics requires a strong public health system. But the public health system cannot function without an effective health care system to detect, contain, and treat infectious diseases. Hence our national defense against bioterrorism must ensure universal rapid access to knowledgeable and compassionate health care professionals who in turn can and will evaluate and care for potentially contagious patients. When ethical barriers in the health care system stand in the way of detection, containment, and treatment, they must be confronted and resolved, because undiagnosed, unconfined, and untreated infections pose a risk to individuals and the community. ■

About the Authors

Matthew K. Wynia is with the Institute for Ethics, American Medical Association, Chicago, Ill. Lawrence O. Gostin is with the Center for Law and the Public's Health, Georgetown University, Washington, DC.

Requests for reprints should be sent to Matthew Wynia, MD, MPH, Director, the Institute for Ethics, American Medical Association, 515 N State St, Chicago, IL 60610 (e-mail: matthew_wynia@ama-assn.org).

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Contributors

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Asthma Inhalers in Schools: Rights of Students with Asthma to a Free Appropriate Education

Sherry Everett Jones, PhD, JD, MPH, and Lani Wheeler, MD

Students who possess and self-administer their asthma medications can prevent or reduce the severity of asthma episodes. In many states, laws or policies allow students to possess and self-administer asthma medications at school.

In the absence of a state or local law or policy allowing public school students to possess inhalers and self-medicate to treat asthma, 3 federal statutes may require public schools to permit the carrying of such medications by students: the Individuals With Disabilities Education Act, Section 504 of the Rehabilitation Act of 1973, and Title II of the Americans with Disabilities Act. Local policies and procedures can be based on these federal laws to ensure that students with asthma can take their medicines as needed.

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MORE THAN 6 MILLION AMERICAN children aged younger than 18 years have asthma, making it one of the most common chronic diseases among children.[1] In 2001, more than 4 million children younger than 18 years had an asthma episode in the previous year (a rate of 57/1000), suggesting that many young people with asthma may not have their asthma under control.[1] As many as an estimated 1.4% of all American children experience some level of limitation owing to asthma, such as an inability (or limited ability) to engage in school or play activities.[2] Young people with asthma miss an estimated

14 million days of school each year because of the disease,[3] and some children's school performance consequently suffers.[4]

Provided parents or guardians and a health care provider, preferably with input from the child's school and especially the school nurse, deem it appropriate for a student to self-medicate and have granted authorization, it is beneficial to students with asthma to have unobstructed access to their medication before, during, and after school.[5,6] Students who self-administer their asthma medications can prevent or reduce the severity of asthma episodes.[7] However, some schools perhaps as part of a drug use prevention program or in hopes of minimizing liability claims, do not allow students to carry their inhalers in school.[8,9] In 2000, students were allowed to self-medicate with prescription inhalers in 68% of all schools nationwide (79% of middle/junior and senior high schools).[10]

Restrictions on students carrying their inhalers may preclude the immediate use of medication at the onset of symptoms. For example, the room in which the medication is kept may be too far from the student's classroom or playing field, some students may believe it is too disruptive to go to another part of the school building to take their medication,[11] and many students are embarrassed about needing to take medications.[12] Restrictions on the use of inhalers may ultimately compromise medication adherence, increase the risk of a full-blown asthma episode, and cause unnecessary suffering, emergency treatment, and asthma-related school absences.[2,8,13]

In 2000, approximately 223 children aged 0 through 17 years died as a result of asthma (a rate of 0.3/100 000).[1] Furthermore, asthma results in substantial increased use of the health care system. In 2000, children aged 0 through 17 years had an estimated 4.6 million asthma-related outpatient visits to doctors' offices and hospital outpatient departments (a rate of 649/10 000), approximately 728 000 asthma-related emergency department visits (a rate of 104/10 000), and approximately 21 000 asthma-related hospitalizations (a rate of 30/10 000).[1] Asthma-related missed school days among children aged 5 through 17 years resulted in an estimated cost of $726.1 million in caretakers' time lost from work.[14]

By knowing the rights of students with asthma, school administrators, educators, physicians, and other health care providers can help ensure that students have appropriate access to medications. This article explores state laws and policies that allow students to carry and self-administer asthma inhalers in school and federal statutes that may, under certain circumstances, require schools to allow students to do so.

STATE LAWS AND POLICIES ALLOWING INHALERS

As of April 2004, 38 states allow self-medication among students at school. Twenty-three states (Alabama,[15] Delaware,[16] Florida,[17] Georgia,[18] Illinois,[19] Kentucky,[20] Maine, [21] Massachusetts,[22] Michigan,[23] Minnesota,[24] Mississippi,[25] Missouri,[26] New Hampshire,[27] New Jersey,[28] New York,[29] Ohio,[30] Oklahoma,[31] Rhode Island,[32] Tennessee,[33] Texas,[34] Utah,[35] Virginia,[36] and Wisconsin[37]) have enacted legislation specifically to allow students with asthma to possess and self-administer inhaled asthma medications while at school. These laws require parental consent and permission from a physician or other health care provider. Also, the School Health Policies and Programs Study 2000 found that an additional 10 states (Kansas, Louisiana, Maryland, Nebraska, New Mexico, North Dakota, South Carolina, South Dakota, Vermont, and Washington) have adopted policies allowing students to self-medicate at school with prescription inhalers.[38] Five other states (California,[39] Connecticut,[40] Indiana,[41] Iowa,[42] and Oregon[43]) have laws broadly providing for the self-administration of medications. Because state laws are often changing, interested readers can access the National Conference of State Legislatures Web site to monitor legislative action related to asthma, including self-medication laws (http://www.ncsl.org/programs/esnr/asthmamain.htm).

ASTHMA AS A DISABILITY: FEDERAL STATUTES

In the absence of a state or local law or policy allowing students to possess inhalers and self-medicate, health care providers and parents might be able to use 1 of 3 federal statutes that, under certain circumstances, will provide the legal justification requiring schools to allow students with asthma to do so. Those laws are the Individuals With Disabilities Education Act (IDEA), Section 504 of the Rehabilitation Act of 1973 (Section 504), and Title II of the Americans With Disabilities Act (Title II of ADA).

INDIVIDUALS WITH DISABILITIES EDUCATION ACT

The purpose of IDEA is to partially fund states to develop special education programs "to ensure that all children with disabilities have available to them a free appropriate public education that emphasizes special education and related services designed to meet their unique needs and prepare them for employment and independent living."[44]

IDEA applies only to children who meet the definition of a *child with a disability,* that is, a child with "mental retardation, hearing impairments (including deafness), speech or language impairments, visual impairments (including blindness), serious emotional disturbance (hereinafter referred to as emotional disturbance), orthopedic impairments, autism, traumatic brain injury, *other health impairments,* or specific learning disabilities; and who, by reason thereof, needs special education and related services" (italic added).[45]

The implementing regulations further define *other health impairment* as "having limited strength, vitality or alertness, in-

cluding a heightened alertness to environmental stimuli, that results in limited alertness with respect to the educational environment, that–(i) *Is due to chronic or acute health problems such as asthma* . . . ; and (ii) Adversely affects a child's educational performance (italic added)."[46]

To be classified as disabled under IDEA, a child with asthma must fall under the *other health impairment* category and require special education because of the asthma or have some other disabling condition under IDEA and require special education because of that disability. In either case, modifications must be made for that student that are determined necessary by the child's individual education program team and allow the student to receive a "free appropriate public education" (defined as education and related services provided at the public's expense, which meet the standards of the state educational agency, include an appropriate preschool, elementary, or secondary school education in the state involved, and are consistent with the student's individual education plan[47]), including "related services" designed to meet the child's unique needs.[44,48-50] Such related services might include allowing a student to carry an asthma inhaler.

SECTION 504 OF THE REHABILITATION ACT OF 1973

The purpose of Section 504 is to eliminate discrimination on the basis of a disability: "No otherwise qualified individual with a disability in the United States . . . shall, solely by reason of her or his disability, be excluded from the participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance. . . ."[51] Under this law, *disability* is more broadly defined than under IDEA and, consequently, covers a large number of youths with disabilities who attend federally funded programs not covered under IDEA. The federal regulations promulgated under Section 504 define a disabled person as one who "(i) has a physical or mental impairment which substantially limits one or more major life activities, (ii) has a record of such an impairment, or (iii) is regarded as having such an impairment."[52] The term *physical impairment* encompasses respiratory disorders or conditions. *Major life activities* refers to functions such as caring for oneself, breathing, and learning.[52] Section 504 is broader than IDEA because it applies to not only the education program, but also to other nonacademic and extracurricular activities.[53,54]

As with IDEA, the regulations promulgated under Section 504 require school districts to provide a "free appropriate public education" to children with disabilities.[55] In the context of Section 504, this requirement means that "the provision of regular or special education and related aids and services . . . designed to meet individual educational needs of handicapped persons [must be as adequate as those designed to meet] the needs of nonhandicapped persons. . . ."[56] Of note, some case law is in conflict with the Section 504 regulations requiring a free appropriate education. Some courts, including the US Supreme Court, have held that Section 504 does not impose an obligation for a free appropriate public education despite federal regulations to the contrary.[57] What this conflict means for future lawsuits is unclear. In accordance with the language of Section 504, courts consistently hold, however, that Section 504 requires that schools make reasonable accommodations to allow disabled students to gain equal access to educational opportunities provided at that school.[57]

TITLE II OF THE AMERICANS WITH DISABILITIES ACT

ADA extends Section 504 to public accommodations in the private sector and state and local public agencies that do not receive federal funding (the discussion of which is beyond the scope of this article).[58] In the context of disabled students attending public schools, Section 504 and Title II of ADA are similar. Title II of ADA prohibits any public entity (e.g., public schools) from discriminating on the basis of a disability.[59,60] Congress intended Title II of ADA and its implementing regulations to be consistent with Section 504,[54,61–63] although the federal regulations and the US Department of Education, Office for Civil Rights have interpreted Section 504 more broadly than Title II of ADA.[57] Under both Section 504 and Title II of ADA, recipients of federal funds and public entities must address the disability-related needs of disabled students so they can participate in services or programs to the extent necessary to avoid discrimination.[54] The definition of *disability* under Title II of ADA is identical to that of Section 504. Under the regulations of Title II of ADA, a school must "make reasonable modifications in policies."[54] A school that refuses to administer medication because of a student's disability would be in violation of Title II of ADA.[48]

HOW THESE FEDERAL STATUTES HAVE BEEN APPLIED

A clear demarcation indicating at what point a child's asthma rises to the level of a disabling condition is not available. Presumably, when a child's asthma significantly interferes with breathing, the child would be considered to have a disability.[58] Parents and the child's health care provider, along with teachers, the school nurse, and other school officials, are in the best position to evaluate the effect a child's asthma has on a child's health and academic performance. Gelfman and Schwab recommend that health professionals document the following: "(1) how the disability interferes with 1 or more life functions [e.g., breathing, learning]; (2) how the disability affects the student's functioning (e.g., energy level, exercise needs, medication effects, etc); and (3) what individualized

supports or accommodations in school the student requires in order to access an appropriate education."[58(p337)]

When a child's asthma is disabling to the extent that the child needs "special education and related services,"[45,46] under IDEA a school is obligated to offer that student sufficient specialized services (e.g., allowing a student to carry an asthma inhaler) so that the student may benefit from his or her education.[50,64] During 2000–2001, the US Department of Education estimated that 292 000 children aged 3 to 21 years were served under IDEA as a result of a disability categorized as "other health impairment."[65] The US Supreme Court, in *Cedar Rapids Community School District v Garret F,* established that under IDEA, those services may go as far as providing a full-time, one-on-one nurse or health assistant.[66] If a student has no other disability and the student's asthma does not affect his or her educational performance, IDEA does not apply.[67] However, students who need access to an asthma inhaler because their asthma places a substantial limitation on major life activities (i.e., the child is disabled because of his or her medical condition) but do not need special education remain qualified under Section 504 and Title II of ADA[68,69] and may avoid being labeled as children who need special education.

To succeed in a Section 504 or Title II of ADA claim alleging that an accommodation was not granted, the claimant must show that the accommodation was denied because of the student's disability (i.e., was discriminatory).[54,70,71] In *East Helena (MT) Elementary School District # 9,* the school district refused to either administer or ensure that the student took asthma medication prescribed and filled by a naturopathic physician.[70] Instead, the school offered to allow a family member to administer the child's medication. In refusing to administer the medication, the school district was following a state law that prohibited the administration of medication unless the prescription was filled by a pharmacist. In that case, the court upheld the policy because the refusal applied to all students regardless of disability status.

Similarly, in *DeBord v Board of Education of the Ferguson-Florissant School District*[54] and *Davis v Francis Howell School District,*[71] schools refused to administer a prescription medication (methylphenidate [Ritalin] for attention deficit hyperactivity disorder) because the doses exceeded that recommended by the *Physicians' Desk Reference.* Both school districts had policies prohibiting schools from administering such prescriptions, although both were willing to let a parent or designee come to the school to administer the medication. The schools argued that the policies were to protect students' health and minimize potential liability. Courts in both cases found that because the school policies were neutral and applied to all students regardless of disability status, no discrimination had taken place. *DeBord, Davis, and East Helena* are examples of situations in which the claimant could not show that the school district's refusal to accommodate the child was based solely on a disability; therefore, no violations of Section 504 or Title II of ADA were found.[54,70,71]

Although some school policies that forbid staff to administer medications to students have been upheld by courts if uniformly applied, it is unlikely that a "no medications" policy (i.e., a policy that denies the administration of any and all medications at school) applied to all students would stand up in court because those policies have the effect of denying children with disabilities the free appropriate public education to which they are entitled under IDEA and perhaps Section 504, or reasonable accommodations under Section 504 and Title II of ADA.[57,72,73] A free appropriate public education must be specifically designed to meet the unique needs of the child,[74] and consequently, related services, including medications, must accompany that design.[55,56,66] Likewise, under Section 504, health services provided as part of related services must be individually evaluated and prescribed.[58]

INDIVIDUAL EDUCATION PROGRAMS

Under IDEA, a "child with a disability" must be provided with an appropriate individualized educational program (IEP).[49,75] Federal regulations promulgated under Section 504 indicate that schools may use IEPs or other plans as a means of meeting free appropriate public education requirements included in those regulations[55] (whether Section 504 includes such requirements is less clear[57]). An IEP is a written statement designed to identify a child's educational needs and other programs and related services the child requires to progress in the general curriculum.[49] IEPs are developed by an IEP team that typically includes the disabled child's parents, regular and special education teachers, and other representatives from the local education agency who are best suited to assist the child in meeting his or her educational needs.[49] A school nurse may be part of the IEP team when school health services (e.g., administration of medications) are necessary.[76] This team, created specifically for each individual child, ensures that all aspects of the child's educational and related services needs are tailored to that child. This team, along with consultation from the child's health care provider, is best equipped to determine on a case-by-case basis whether self-medication using asthma inhalers is appropriate.

For students with asthma, an *asthma management plan* (Table 1) is an appropriate part of an IEP.[5] Health care providers give instructions on how best to manage the child's asthma during the school day. For a student with asthma, it is helpful if part of the IEP (or 504 plan or individual health service plan or asthma management plan) includes specific information about where, when, and how each asthma medication is to be taken, including when medication possession

TABLE 1—Elements of Typical Asthma Management Plan

- Student's asthma history
- Student's asthma symptoms
- How to contact student's health care provider and parent or guardian
- Signatures of physician and parent or guardian permitting use of medications in school
- List of factors that make student's asthma worse
- Student's best peak flow reading (if student uses peak flow monitoring)
- List of student's asthma medications
- Student's treatment plan, including actions school personnel can take to help handle asthma episodes

Source. NIH Publication 95-3651.[5]

and self-administration provisions are appropriate.

It is best if asthma management plans are on file in the school office or health services office and available to teachers and coaches. From a legal perspective, it is recommended that the asthma management plan include parental permission for the plan to be shared with relevant school personnel to avoid possible violations of the Family Education Rights and Privacy Act of 1974 (FERPA), which prohibits the unauthorized disclosure of confidential information in education records (including school health records in most cases).[77,78] However, under FERPA education records may be released to school officials without written consent of students' parents, including to teachers within the educational institution or local education agency, who have a "legitimate educational interest."[79] Under FERPA, it is important to note a narrow emergency exception whereby a school may disclose personally identifiable information to appropriate parties in connection with an emergency if knowledge of the information is necessary to protect the health or safety of the student.[77,80]

OVERCOMING POTENTIAL DISADVANTAGES

Although many advantages to self-medication exist, families and schools need to recognize some theoretically possible disadvantages of students' being responsible for carrying and administering their own medication. These disadvantages can be minimized, however. First, students may unintentionally leave their inhalers at home or misplace their inhalers at school. One possible solution is to keep a spare inhaler in a school nurse's office or health room.

Second, self-medication may make it more difficult for the school to keep medication records. Such documentation ensures that medication adherence can be communicated to parents and children's health care providers; documentation might be required as part of an IEP or Section 504 plan or might be recommended by school boards as a way to monitor the health and safety of students. To solve this problem, schools could require that students report each inhaler use to a school nurse or record each medication use in a diary.

Third, students may not be well educated about when to take their medications,[8,81] may be embarrassed to take their medications in front of peers,[8] or may lack the maturity to use their medications appropriately (e.g., most elementary school students). Health care providers and parents are primarily responsible for teaching children about administering asthma medications and determining on a case-by-case basis whether the student has reached a level of maturity necessary for self-medication. School-based programs can supplement student education by helping students with asthma understand their disease and the importance of asthma self-management[82,85] as well as destigmatize the need for using asthma inhalers during the school day.[83]

CONCLUSION

Not all students with asthma have their asthma under good control.[1,4] Patient education and medical management about the proper use of asthma medication are crucial to preventing asthma morbidity and mortality.[86,87] For optimal asthma management, it is important that students with asthma not be denied appropriate access to their medications in school.[5,6,11,88,89] Many states have laws or policies that allow students to self-medicate with asthma inhalers at school (there is no evidence on whether state laws or polices are more effective to ensure immediate access for students in schools). In addition, 3 federal laws require schools to accommodate students whose asthma qualifies as a disability under IDEA, Section 504, or Title II of ADA. Such accommodations may include allowing students to carry their asthma inhalers so they can self-medicate as indicated in their asthma management plan. Of note, the US Department of Education, Office of Safe and Drug-Free Schools has issued guidance clarifying that "a student's prescription drugs, and related equipment, are not illegal drugs and are not prohibited by the [Safe and Drug-Free Schools and Communities Act]."[90]

Although these laws and policies are important, they cannot provide an individualized answer to asthma management. Ideally, parents or guardians, the child's health care provider, and school personnel, including the school nurse, will work together as a team to determine the best way to manage a student's asthma in school. Table 2 outlines some factors that should be considered in determining the appropriateness of self-carrying and self-administering inhalers in school. For example, whether a child with asthma should be permitted to self-medicate ought to be determined on a case-by-case basis, based on a child's abilities and interest and maturity and the situation at the school. When that team deems the child skilled and mature enough, the student with

TABLE 2—Elements to Consider When Determining Appropriateness of Self-Carrying and Self-Administering of Inhaler Medication in Schools

Student factors
- Asthma severity and morbidity (hospitalizations, emergency department visits, severe episodes, types of triggers)
- Student's asthma knowledge, attitude, skills, and behavior (awareness of asthma signs and symptoms, desire to self-carry inhaler, willingness to self-administer and report use of inhaler, understanding of importance of not sharing inhaler with other students, correct peak flow and inhaler technique)
- History of asthma episodes at school
- Adherence to school rules regarding medication administration
- Inhaler self-carrying experience in other settings (child care, camp, after-school care, at friends' homes)

Family factors
- Desire of parents/guardians for student to self-carry and self-administer medications with an inhaler
- Collaboration of parents/guardians with school team; permission for physician and school to share information

School factors
- Health staff availability (whether or not there are full-time school nurses or health assistants)
- School size (whether or not there is quick and easy access to health room)
- Ability to reduce student's triggers at school
- Proximity and availability of inhalers from local emergency medical services

Health care provider factors
- Completion of physician's or other health care provider's written asthma management plan and all required forms
- Student's education by physician or other health care provider about asthma generally, controlling asthma, and proper use of inhalers, spacers, and peak flow meters
- Assessment by physician or other health care provider of student's technique for inhaler, spacer, and peak flow meter use

asthma should be allowed to keep asthma inhalers in his or her possession[11,88] to reduce the chances of a full-blown asthma episode, asthma-related school absences, and the need for emergency medical care.[8,86,87] Some students may not want or need to carry their inhalers, for example, when the school building is very small and health staff are available during all school hours. Each student needs individual assessment as part of the implementation of that student's personal asthma management plan.

In some circumstances, parents may need assistance from the child's physician or other health care provider in advocating for the student to gain the right to self-carry an asthma inhaler. By knowing the rights of students with asthma, physicians and other health care providers can help ensure that students have appropriate access to medications at school. An informed health care provider can bring to the attention of school administrators and educators, as well as parents, the legal requirements of schools with students with asthma, and the benefits of self-administration and adequate control of asthma (e.g., improved health and fewer school absences). For example, health care providers can obtain parental permission to send a written asthma management plan to schools including specific guidance about the student's skill and maturity regarding self-administering the asthma inhaler. They can personally contact the principal if there is reluctance to permit self-carrying of inhalers. Students are more likely to be able to control their asthma when school personnel, parents or guardians, and health care providers know about disability laws and about appropriate asthma management. ■

About the Authors

The authors are with the Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Division of Adolescent and School Health, Atlanta, Ga.

Requests for reprints should be sent to Sherry Everett Jones, PhD, MPH, JD, Centers for Disease Control and Prevention, 4770 Buford Hwy NE, Mail Stop K-33, Atlanta, GA 30341 (e-mail: sce2@cdc.gov).

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Contributors

S. Everett Jones collected, analyzed, and synthesized the literature and wrote the article. L. Wheeler assisted in synthesizing the literature and contributed to the writing the article.

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causative of disease."[13] Unlike the MSEHPA, Indiana law does not specify what due process a quarantined individual has.

CONCLUSION

All the states in this study considered the MSEHPA, but each eventually approached concerns about bioterrorism differently. Multiple factors—including the states' political dynamics, social characteristics, and existing legal frameworks—likely shaped these approaches. Although these states did not provide the consistency sought by the Center for Law and the Public's Health, their efforts still addressed some critical needs regarding bioterrorism detection and response.[14]

Study of this issue sheds light on the interaction between law and public policy in solving a complex and contemporary national, state, and local problem—bioterrorist attacks on civilian populations. Consistent and clarified law that minimizes time-consuming lawsuits in the event of a crisis is 1 aspect of a solution to this problem. Building on efforts to update their laws, states and localities should now direct their attention, other aspects—including funding and personnel.[15] ■

About the Author

Requests for reprints should be sent to William Martin, The University of Chicago Law School, 1111 E 60th St, Chicago, IL 60637 (e-mail: martinw@uchicago.edu).

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Ethical Challenges in Preparing for Bioterrorism: Barriers Within the Health Care System

Matthew K. Wynia, MD, MPH, Lawrence O. Gostin, JD

Preparedness for bioterrorism poses significant ethical challenges. Although public health ethics and preparedness have received attention recently, health care ethics must also be considered.

In epidemics, the health care system assists public health in 3 tasks: detection, containment, and treatment. Detection might fail if all patients do not have access to care, or if physicians do not understand their obligation to report infectious diseases to public health authorities. Containment might fail if physicians view themselves only as advocates for individual patients, ignoring their social obligations as health professionals. Treatment might fail if physicians do not accept their professional duty to treat patients during epidemics.

Each of these potential ethical barriers to preparedness must be addressed by physicians and society. (*Am J Public Health.* 2004;94:1096–1102)

THE INTENTIONAL DISPERSAL of anthrax spores in the United States demonstrates the need for preparedness for bioterrorism, and the recent outbreak of severe acute respiratory syndrome (SARS) has renewed fears of unintentional or naturally occurring infectious epidemics. In responding to these threats, the public health system has rightfully garnered much of the attention,[1]

after decades in which government has starved public health agencies of needed resources.[2–4] However, an effective response also will require the health care system to fulfill critical roles. By the term *health care system*, we mean those professionals (e.g., physicians and nurses) and institutions (e.g., hospitals and health plans) obliged to diagnose, treat, and care for individuals exposed to or infected with contagious diseases. We specify *contagious* diseases because although anthrax is not transmissible from person to person, many experts reserve their deepest fears for transmissible agents such as smallpox, plague, hemorrhagic fevers (e.g., the Ebola, Marburg, Lassa, and Crimean-Congo hemorrhagic fever viruses), and new (e.g., SARS) or designer viruses and bacteria.[5]

Thinking systematically, what are the obligations of the health care system in handling contagious diseases? The health care system should rapidly identify threats, help to prevent the spread of disease in the population, and care for infected patients. These 3 tasks—detection, containment, and treatment—are vital to the efficient handling of contagious epidemics. To prepare for each task, policymakers have emphasized training,[6–9] clarification of public health quarantine powers,[10,11] facilities improvements, and pharmaceutical stockpiling.[12–14] Although these steps are important, we wish to draw attention to several challenges related to medical ethics and professionalism that might hinder detection, containment, and treatment and that have been much less discussed. Ours is not an exhaustive compilation of the many ethical issues associated with bioterrorism, but the issues we raise have received relatively little attention recently and are at risk of being lost in the highly publicized debates over, for example, the ethics of smallpox vaccination. These issues also illustrate that contagious diseases raise critical questions about the ethical relationship between medicine and public health.[15]

DETECTION: REPORTING AND ACCESS TO CARE

In some bioterror scenarios, such as an aerosol release into a crowd, simultaneous widespread infections would mark an attack; if this were the case, then limiting the outbreak through early detection might provide little benefit (though early recognition and treatment of the illness might still save lives). But smaller-scale attacks are potentially much easier for terrorist organizations to organize, finance, and carry out.[16] As the anthrax mailings of October 2001 demonstrated, even relatively small attacks can provoke widespread anxiety and disruption. In a stealth attack, early detection becomes critically important, as it is in stemming naturally occurring outbreaks.

To improve detection, the United States is expanding the public health system's capacity for surveillance. However, public health surveillance relies largely on reports from health care professionals. Persons with symptoms arrive first in physicians' offices, clinics, or hospital emergency departments. For this system to work, therefore, patients must first have access to the health care system, and their illnesses must then be reported to the public health system.

The health care system must improve its reporting performance. Many physicians are unaware of reporting requirements, complain of the administrative burden of reporting, do not see reporting as important to patient care, or are unconvinced that reporting is of value.[17] Reporting must be made easier (or even automatic, through electronic links), and physicians should be given feedback on how their reports are used to safeguard public health, reinforcing the value of the physician–public health partnership. Examination of the physician's role in reporting contagious illnesses should be included in new curricula on professionalism[18] in the context of exploring the social roles of the medical profession—an issue to which we will return.

In the area of patient access to health care, more challenging dilemmas arise. Strong ethical reasons have long been recognized as supporting universal access to a decent minimal set of health care services,[19] yet our nation has been unable or unwilling to accomplish this.[20] Perhaps if policymakers understand that inadequate access to care poses a threat to national security, progress can be made.[21,22] In the United States, more than 40 million Americans lack health insurance, and this number is rising.[23,24] Although some uninsured individuals use emergency rooms to obtain care when they are acutely ill, many of the uninsured and underinsured avoid the health care system for as long as possible.[20] Some have argued that bioterror-related illnesses are so severe that anyone affected would surely seek care.[25] But uninsured patients discriminate poorly between appropriate and inappropriate care and tend to avoid both equally.[26] Numerous studies demonstrate that the uninsured are more likely to present in an advanced stage of illness, and many die without ever being evaluated.[27–29]

Terrorists undoubtedly recognize that even a small-scale release of an infectious agent into a community with a high rate of uninsurance might be devastatingly effective. Because most of the uninsured are employed and working throughout cities, suburbs, and rural areas, starting an outbreak in such a community—using a low-tech approach, such as an infected "martyr"—would reduce the likelihood of early detection and raise the odds of broad spread of the disease.[30] Unfortunately, this scenario is not mere speculation: "natural experiments" that simulate such an attack have demonstrated the vulnerability of poor, especially uninsured immigrant, populations and their ability to spread disease throughout the population.[31,32] Many naturally occurring infectious diseases, including tuberculosis, food-borne illnesses, and HIV/AIDS, disproportionately burden the uninsured and

subsequently spread to the community at large.[33]

Maintaining barriers to accessing health care in the face of today's threats should be unacceptable, morally and politically. In the aftermath of the September 11 attacks, New York ordered its health care system to provide care to all possible victims[34] and the state health commissioner, Antonio Coello Novello, declared to providers: "Thou shalt not ask who will pay for this."[35] Over the next 4 months, New York's special Disaster Relief Medicaid program enrolled and cared for almost 400 000 people.[36] New York dramatically streamlined the application process for Medicaid and obtained additional funding for the state pool for the uninsured. The public, government, and the medical community widely approved these actions as appropriate, given the threat.[37,38]

Learning from this experience, federal and state officials should make clear that individuals with symptoms that suggest infection with a contagious illness should present for evaluation and ensure that those who do can be treated without prejudice. Funding must be provided to cover screening and treatment of patients with contagious illnesses; in particular, funding for hospital emergency departments that see large volumes of uninsured patients must be increased.[39] Because patients cannot be expected to know in advance whether their illness is infectious, programs can be targeted toward contagious illness but ultimately, they will need to be broad based. Finally, funding alone might not guarantee ready access to care for certain populations, especially recent immigrants and those who mistrust the health care system.[22] The current policy focus on addressing racial and ethnic health disparities should be used to build a culturally sensitive primary care system in which all patients feel welcome.[40]

CONTAINMENT: ISOLATION BEFORE QUARANTINE

In late October 2001, the secretary of the US Department of Health and Human Services asked the states to increase their legal preparedness for potential epidemics.[41] Twenty-two states and the District of Columbia have since enacted laws based on the Model State Emergency Health Powers Act, drafted by the Center for Law and the Public's Health at the request of the Centers for Disease Control and Prevention.[42,43] These laws seek to ensure that when facing a clear emergency, the public health system can carry out screening, vaccination, quarantine, and treatment.[44] Even with these powers, however, the public health system cannot contain an outbreak as rapidly as might health care professionals who are willing and empowered to use short-term involuntary isolation when needed.

Of course, most contagious patients will comply voluntarily with an isolation request; but recent bioterror training scenarios assume that not everyone will cooperate with treatment and quarantines,[45,46] and this assumption is borne out in experiences with SARS.[47–49] Illness and fear can hinder clear thinking. Physicians should know this and be prepared to intervene if necessary. Under what legal authority might health care professionals isolate a potentially contagious patient *in advance* of a public health quarantine? Health care professionals have a general obligation to prevent patients from harming themselves or others and may use compulsion when necessary.[50] The most common application of this power might be to "hold" psychiatric patients thought to pose a suicide or homicide risk.[51] Such short-term physician holds usually require judicial review within 24 to 48 hours, but this kind of short-term legal authority could serve as an early stop to an outbreak in the event that one or more patients decline necessary interventions before the public health authority enforces quarantine.

In general, public health officers, not one's physician, should declare quarantine, because separation of these roles allows physicians to attend to individual patients' interests. Indeed, using professional powers to hold patients involuntarily poses a fundamental ethical challenge for physicians, because it entails overriding an individual patient's wishes in deference to the community's needs—balancing respect for patient autonomy against public health benefit. Challenging though it may be, however, mediating the tension between individual and community needs is integral to the role of the medical profession in society—and demonstrates why the profession must maintain some independence from both the state and patient interests.[52]

There are significant risks in physicians' acting as agents of the state,[53–55] yet attention to civic obligations is as ancient a part of professionalism as is attention to patients' interests. Plato bluntly recognized this balancing act when he wrote that physicians are "statesmen" who are to do what "is best for the patients *and* for the state."[56(p6)] More recently, Creuss and Creuss noted that during the 19th century

> legal measures for the first time granted medicine a broad monopoly over health care—along with both individual and collective autonomy—with the clear understanding that in return medicine would concern itself with the health problems of the society it served and would place the welfare of society above its own.[57(p943)]

The original 1847 Code of Medical Ethics of the American Medical Association noted that a physician's skills "are qualities which he holds in trust for the general good,"[58(p318)] and one of its 3 chapters—entitled, "Of the Duties of the Profession to the Public, and of the Obligations of the Public to the Profession"—dealt explicitly with physicians' social duties.[58(p333)]

In the era after 1955, however, medicine began to move away from balancing social obligations, tilting toward a more restricted advocacy position.[59,60] Obligations regarding public health were minimized, and physicians were eventually urged to

ignore civic considerations altogether and to think only of the welfare of the patient before them. In 1984, Norman Levinsky wrote that "physicians are required to do everything that they believe may benefit each patient, without regard to costs or other societal considerations."[61(p1574)] This statement reflected the domination of medical ethics by respect for patient autonomy and the loss of a cardinal feature of professionalism: mediation between private and community interests.[53,62] But, bereft of its role as a social protector, medicine was left with only technical expertise to support its claims to professional prerogatives, which are granted by society and have since steadily eroded.[63,64] Recognizing this chain of events, recent scholars of the medical profession are returning to a civic understanding of professionalism as necessary to maintaining public trust and, with it, professional privileges.[65,66] Dr William Sullivan wrote of this return to a classic role for the professions in society: "Historically, the legitimacy, authority, and legal privileges of the most prestigious professions have depended heavily on their claims (and finally their demonstration) of civic performance, especially social leadership in the public interest."[63(p11)]

Ethically, therefore, when time is limited, physicians should be empowered and willing to use short-term holds to prevent immediate spread of disease, because physicians' professional duty sometimes should tilt toward protecting the public—although not incidentally, of course, most individuals will also benefit from enforced isolation and treatment. Some physicians and patients, raised on the medical ethics of the last 50 years, will chafe at the paternalism of this statement, but we find that professionalism requires meaningful attention to civic duties such as protecting the public health. Because the power to hold patients involuntarily can be abused,[67] constraints such as requiring 2 physicians to concur, ensuring the short-term nature of the hold (24 hours or less), and ensuring rapid judicial review, should be applied. Legally, in jurisdictions where it is not clear whether physicians' authority to hold patients for dangerousness applies outside the psychiatric setting, clarification is required. Bioterror training should reinforce physicians' ethical obligations regarding isolation of dangerously infectious patients, and there should be open debates on appropriate limits to this power, as well as to address practical considerations regarding quarantine, such as when public health authorities should enforce community quarantine and how to respectfully care for those under quarantine.

TREATMENT: THE DUTY TO TREAT

Recent discussions of treatment barriers during bioterror-related outbreaks tend to focus on potential shortages of antibiotics and vaccines. But stockpiles can be calculated with reasonable certainty and increased as needed. More challenging in these scenarios is that 1 treatment variable is critically important yet very difficult to estimate: how many health care professionals will fail to show up for work because they fear contracting the illness?[68]

It is almost certain that some will not willingly face the risk. At least 1 hospital in China had difficulty maintaining services because of absenteeism in the face of SARS.[69] Some hospitals in New York have announced they will not care for victims of bioterror attacks.[70] Physician performance during epidemics, from the black plague to the HIV epidemic, has been notoriously spotty.[71–73] And relatively few physicians have volunteered to receive smallpox vaccination, despite high-level government requests.[74,75]

There is legitimate reason for trepidation on the part of health professionals. More than one third of health care personnel treating patients after the sarin gas attack in Tokyo became ill from cross-contamination.[76] Health care workers are common second-wave victims of Ebola[77] and SARS.[78] In the United States, there are 56 documented cases of health care workers' becoming infected with HIV due to needlestick injuries,[79] and countless more have contracted hepatitis B or C, tuberculosis, and other potentially deadly infections. Into the 1950s, exposure to and infection with tuberculosis was a near-ubiquitous medical training experience, especially for pulmonologists.[80,81]

Several ethical and practical bases for a "duty to treat" have been proposed that taken together provide a strong justification for its reaffirmation today.[82,83] Health care professionals receive special training, which increases the general obligation to render aid to others in need, because it increases the value of the aid and may reduce the risk associated with providing it.[84] Physicians have long subscribed to explicit codes of ethics that demand the duty to treat,[85,86] codes that the public assumes to be binding. In 1991, despite recent interprofessional wrangling over the treatment of patients with HIV,[70] 72% of the public agreed with the statement that physicians are obligated to "treat all sick people."[87] Physicians also receive social standing and trust as part of a social contract, which includes an obligation to place the welfare of patients above self-interest.[57]

When professional associations last confronted this issue, in the early years of the AIDS epidemic, early wavering gave way to consensus that a duty to treat still exists.[88] According to the Infectious Diseases Society of America and the American College of Physicians, health care professionals "must provide high-quality nonjudgmental care to their patients, even at the risk of contracting a patient's disease."[89(p576)] The American Medical Association's recently (December 2001) adopted Declaration of Professional Responsibility states that physicians must "treat the sick and injured with

competence and compassion and without prejudice," and "apply our knowledge and skills when needed, though doing so may put us at risk."[90]

Two steps should be taken to reinforce this obligation. First, language in professional codes of ethics addressing treatment during epidemics was largely removed in the 1970s, at a time when epidemics appeared to be on the wane.[91] Subsequent statements focused almost exclusively on HIV/AIDS and often were framed in terms of antidiscrimination principles rather than professional obligations.[92] Professional associations should make clear their current stances on physicians' obligations to care for patients during epidemics. Ideally, the inspiring spirit and language of the early American Medical Association Code of Medical Ethics should be reaffirmed today: "When an epidemic prevails, a physician must continue his labors for the alleviation of suffering people, without regard to the risk to his own health or to financial return."[93(p354)]

Second, to justify and strengthen this obligation, special efforts should be made to ensure that health care professionals receive all reasonable preventive and treatment measures in the event of an outbreak, such as vaccines, prophylactic therapies, and safety training.[94] Such preferential treatment makes practical sense, because only healthy practitioners will be of value in responding to any ongoing threat.[95] Ethically, when health care professionals tend to patients in epidemics, healthy people place themselves (and often their families) at risk to benefit the common good. The state must recognize that this burden, in some manner, should be shared by the community as a whole. This value was implicitly recognized in policy discussions regarding early smallpox vaccination for health care workers. However, beyond smallpox, health care workers should be assured that in the event of an attack, all that is possible will be done to protect them—and their families. Local stockpiles of vaccines and other therapies should be set aside for health care workers, ensuring that those who may be at greatest risk will receive early and effective protection. In addition, the families of health care workers who perish in epidemics should receive predictable compensation. By offering fair compensation, the government can further spread the burden of pursuing the public interest.

CONCLUSIONS

Defense against bioterror and naturally occurring infectious epidemics requires a strong public health system. But the public health system cannot function without an effective health care system to detect, contain, and treat infectious diseases. Hence our national defense against bioterrorism must ensure universal rapid access to knowledgeable and compassionate health care professionals who in turn can and will evaluate and care for potentially contagious patients. When ethical barriers in the health care system stand in the way of detection, containment, and treatment, they must be confronted and resolved, because undiagnosed, unconfined, and untreated infections pose a risk to individuals and the community. ■

About the Authors

Matthew K. Wynia is with the Institute for Ethics, American Medical Association, Chicago, Ill. Lawrence O. Gostin is with the Center for Law and the Public's Health, Georgetown University, Washington, DC.

Requests for reprints should be sent to Matthew Wynia, MD, MPH, Director, the Institute for Ethics, American Medical Association, 515 N State St, Chicago, IL 60610 (e-mail: matthew_wynia@ama-assn.org).

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Contributors

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Asthma Inhalers in Schools: Rights of Students with Asthma to a Free Appropriate Education

Sherry Everett Jones, PhD, JD, MPH, and Lani Wheeler, MD

Students who possess and self-administer their asthma medications can prevent or reduce the severity of asthma episodes. In many states, laws or policies allow students to possess and self-administer asthma medications at school.

In the absence of a state or local law or policy allowing public school students to possess inhalers and self-medicate to treat asthma, 3 federal statutes may require public schools to permit the carrying of such medications by students: the Individuals With Disabilities Education Act, Section 504 of the Rehabilitation Act of 1973, and Title II of the Americans with Disabilities Act. Local policies and procedures can be based on these federal laws to ensure that students with asthma can take their medicines as needed.

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MORE THAN 6 MILLION AMERICAN children aged younger than 18 years have asthma, making it one of the most common chronic diseases among children.[1] In 2001, more than 4 million children younger than 18 years had an asthma episode in the previous year (a rate of 57/1000), suggesting that many young people with asthma may not have their asthma under control.[1] As many as an estimated 1.4% of all American children experience some level of limitation owing to asthma, such as an inability (or limited ability) to engage in school or play activities.[2] Young people with asthma miss an estimated

14 million days of school each year because of the disease,[3] and some children's school performance consequently suffers.[4]

Provided parents or guardians and a health care provider, preferably with input from the child's school and especially the school nurse, deem it appropriate for a student to self-medicate and have granted authorization, it is beneficial to students with asthma to have unobstructed access to their medication before, during, and after school.[5,6] Students who self-administer their asthma medications can prevent or reduce the severity of asthma episodes.[7] However, some schools perhaps as part of a drug use prevention program or in hopes of minimizing liability claims, do not allow students to carry their inhalers in school.[8,9] In 2000, students were allowed to self-medicate with prescription inhalers in 68% of all schools nationwide (79% of middle/junior and senior high schools).[10]

Restrictions on students carrying their inhalers may preclude the immediate use of medication at the onset of symptoms. For example, the room in which the medication is kept may be too far from the student's classroom or playing field, some students may believe it is too disruptive to go to another part of the school building to take their medication,[11] and many students are embarrassed about needing to take medications.[12] Restrictions on the use of inhalers may ultimately compromise medication adherence, increase the risk of a full-blown asthma episode, and cause unnecessary suffering, emergency treatment, and asthma-related school absences.[2,8,13]

In 2000, approximately 223 children aged 0 through 17 years died as a result of asthma (a rate of 0.3/100 000).[1] Furthermore, asthma results in substantial increased use of the health care system. In 2000, children aged 0 through 17 years had an estimated 4.6 million asthma-related outpatient visits to doctors' offices and hospital outpatient departments (a rate of 649/10 000), approximately 728 000 asthma-related emergency department visits (a rate of 104/10 000), and approximately 21 000 asthma-related hospitalizations (a rate of 30/10 000).[1] Asthma-related missed school days among children aged 5 through 17 years resulted in an estimated cost of $726.1 million in caretakers' time lost from work.[14]

By knowing the rights of students with asthma, school administrators, educators, physicians, and other health care providers can help ensure that students have appropriate access to medications. This article explores state laws and policies that allow students to carry and self-administer asthma inhalers in school and federal statutes that may, under certain circumstances, require schools to allow students to do so.

STATE LAWS AND POLICIES ALLOWING INHALERS

As of April 2004, 38 states allow self-medication among students at school. Twenty-three states (Alabama,[15] Delaware,[16] Florida,[17] Georgia,[18] Illinois,[19] Kentucky,[20] Maine, [21] Massachusetts,[22] Michigan,[23] Minnesota,[24] Mississippi,[25] Missouri,[26] New Hampshire,[27] New Jersey,[28] New York,[29] Ohio,[30] Oklahoma,[31] Rhode Island,[32] Tennessee,[33] Texas,[34] Utah,[35] Virginia,[36] and Wisconsin[37]) have enacted legislation specifically to allow students with asthma to possess and self-administer inhaled asthma medications while at school. These laws require parental consent and permission from a physician or other health care provider. Also, the School Health Policies and Programs Study 2000 found that an additional 10 states (Kansas, Louisiana, Maryland, Nebraska, New Mexico, North Dakota, South Carolina, South Dakota, Vermont, and Washington) have adopted policies allowing students to self-medicate at school with prescription inhalers.[38] Five other states (California,[39] Connecticut,[40] Indiana,[41] Iowa,[42] and Oregon[43]) have laws broadly providing for the self-administration of medications. Because state laws are often changing, interested readers can access the National Conference of State Legislatures Web site to monitor legislative action related to asthma, including self-medication laws (http://www.ncsl.org/programs/esnr/asthmamain.htm).

ASTHMA AS A DISABILITY: FEDERAL STATUTES

In the absence of a state or local law or policy allowing students to possess inhalers and self-medicate, health care providers and parents might be able to use 1 of 3 federal statutes that, under certain circumstances, will provide the legal justification requiring schools to allow students with asthma to do so. Those laws are the Individuals With Disabilities Education Act (IDEA), Section 504 of the Rehabilitation Act of 1973 (Section 504), and Title II of the Americans With Disabilities Act (Title II of ADA).

INDIVIDUALS WITH DISABILITIES EDUCATION ACT

The purpose of IDEA is to partially fund states to develop special education programs "to ensure that all children with disabilities have available to them a free appropriate public education that emphasizes special education and related services designed to meet their unique needs and prepare them for employment and independent living."[44]

IDEA applies only to children who meet the definition of a *child with a disability,* that is, a child with "mental retardation, hearing impairments (including deafness), speech or language impairments, visual impairments (including blindness), serious emotional disturbance (hereinafter referred to as emotional disturbance), orthopedic impairments, autism, traumatic brain injury, *other health impairments,* or specific learning disabilities; and who, by reason thereof, needs special education and related services" (italic added).[45]

The implementing regulations further define *other health impairment* as "having limited strength, vitality or alertness, in-

cluding a heightened alertness to environmental stimuli, that results in limited alertness with respect to the educational environment, that–(i) *Is due to chronic or acute health problems such as asthma* . . . ; and (ii) Adversely affects a child's educational performance (italic added)."[46]

To be classified as disabled under IDEA, a child with asthma must fall under the *other health impairment* category and require special education because of the asthma or have some other disabling condition under IDEA and require special education because of that disability. In either case, modifications must be made for that student that are determined necessary by the child's individual education program team and allow the student to receive a "free appropriate public education" (defined as education and related services provided at the public's expense, which meet the standards of the state educational agency, include an appropriate preschool, elementary, or secondary school education in the state involved, and are consistent with the student's individual education plan[47]), including "related services" designed to meet the child's unique needs.[44,48-50] Such related services might include allowing a student to carry an asthma inhaler.

SECTION 504 OF THE REHABILITATION ACT OF 1973

The purpose of Section 504 is to eliminate discrimination on the basis of a disability: "No otherwise qualified individual with a disability in the United States . . . shall, solely by reason of her or his disability, be excluded from the participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance. . . ."[51] Under this law, *disability* is more broadly defined than under IDEA and, consequently, covers a large number of youths with disabilities who attend federally funded programs not covered under IDEA. The federal regulations promulgated under Section 504 define a disabled person as one who "(i) has a physical or mental impairment which substantially limits one or more major life activities, (ii) has a record of such an impairment, or (iii) is regarded as having such an impairment."[52] The term *physical impairment* encompasses respiratory disorders or conditions. *Major life activities* refers to functions such as caring for oneself, breathing, and learning.[52] Section 504 is broader than IDEA because it applies to not only the education program, but also to other nonacademic and extracurricular activities.[53,54]

As with IDEA, the regulations promulgated under Section 504 require school districts to provide a "free appropriate public education" to children with disabilities.[55] In the context of Section 504, this requirement means that "the provision of regular or special education and related aids and services . . . designed to meet individual educational needs of handicapped persons [must be as adequate as those designed to meet] the needs of nonhandicapped persons. . . ."[56] Of note, some case law is in conflict with the Section 504 regulations requiring a free appropriate education. Some courts, including the US Supreme Court, have held that Section 504 does not impose an obligation for a free appropriate public education despite federal regulations to the contrary.[57] What this conflict means for future lawsuits is unclear. In accordance with the language of Section 504, courts consistently hold, however, that Section 504 requires that schools make reasonable accommodations to allow disabled students to gain equal access to educational opportunities provided at that school.[57]

TITLE II OF THE AMERICANS WITH DISABILITIES ACT

ADA extends Section 504 to public accommodations in the private sector and state and local public agencies that do not receive federal funding (the discussion of which is beyond the scope of this article).[58] In the context of disabled students attending public schools, Section 504 and Title II of ADA are similar. Title II of ADA prohibits any public entity (e.g., public schools) from discriminating on the basis of a disability.[59,60] Congress intended Title II of ADA and its implementing regulations to be consistent with Section 504,[54,61–63] although the federal regulations and the US Department of Education, Office for Civil Rights have interpreted Section 504 more broadly than Title II of ADA.[57] Under both Section 504 and Title II of ADA, recipients of federal funds and public entities must address the disability-related needs of disabled students so they can participate in services or programs to the extent necessary to avoid discrimination.[54] The definition of *disability* under Title II of ADA is identical to that of Section 504. Under the regulations of Title II of ADA, a school must "make reasonable modifications in policies."[54] A school that refuses to administer medication because of a student's disability would be in violation of Title II of ADA.[48]

HOW THESE FEDERAL STATUTES HAVE BEEN APPLIED

A clear demarcation indicating at what point a child's asthma rises to the level of a disabling condition is not available. Presumably, when a child's asthma significantly interferes with breathing, the child would be considered to have a disability.[58] Parents and the child's health care provider, along with teachers, the school nurse, and other school officials, are in the best position to evaluate the effect a child's asthma has on a child's health and academic performance. Gelfman and Schwab recommend that health professionals document the following: "(1) how the disability interferes with 1 or more life functions [e.g., breathing, learning]; (2) how the disability affects the student's functioning (e.g., energy level, exercise needs, medication effects, etc); and (3) what individualized

supports or accommodations in school the student requires in order to access an appropriate education."[58(p337)]

When a child's asthma is disabling to the extent that the child needs "special education and related services,"[45,46] under IDEA a school is obligated to offer that student sufficient specialized services (e.g., allowing a student to carry an asthma inhaler) so that the student may benefit from his or her education.[50,64] During 2000–2001, the US Department of Education estimated that 292 000 children aged 3 to 21 years were served under IDEA as a result of a disability categorized as "other health impairment."[65] The US Supreme Court, in *Cedar Rapids Community School District v Garret F,* established that under IDEA, those services may go as far as providing a full-time, one-on-one nurse or health assistant.[66] If a student has no other disability and the student's asthma does not affect his or her educational performance, IDEA does not apply.[67] However, students who need access to an asthma inhaler because their asthma places a substantial limitation on major life activities (i.e., the child is disabled because of his or her medical condition) but do not need special education remain qualified under Section 504 and Title II of ADA[68,69] and may avoid being labeled as children who need special education.

To succeed in a Section 504 or Title II of ADA claim alleging that an accommodation was not granted, the claimant must show that the accommodation was denied because of the student's disability (i.e., was discriminatory).[54,70,71] In *East Helena (MT) Elementary School District # 9,* the school district refused to either administer or ensure that the student took asthma medication prescribed and filled by a naturopathic physician.[70] Instead, the school offered to allow a family member to administer the child's medication. In refusing to administer the medication, the school district was following a state law that prohibited the administration of medication unless the prescription was filled by a pharmacist. In that case, the court upheld the policy because the refusal applied to all students regardless of disability status.

Similarly, in *DeBord v Board of Education of the Ferguson-Florissant School District*[54] and *Davis v Francis Howell School District,*[71] schools refused to administer a prescription medication (methylphenidate [Ritalin] for attention deficit hyperactivity disorder) because the doses exceeded that recommended by the *Physicians' Desk Reference.* Both school districts had policies prohibiting schools from administering such prescriptions, although both were willing to let a parent or designee come to the school to administer the medication. The schools argued that the policies were to protect students' health and minimize potential liability. Courts in both cases found that because the school policies were neutral and applied to all students regardless of disability status, no discrimination had taken place. *DeBord, Davis, and East Helena* are examples of situations in which the claimant could not show that the school district's refusal to accommodate the child was based solely on a disability; therefore, no violations of Section 504 or Title II of ADA were found.[54,70,71]

Although some school policies that forbid staff to administer medications to students have been upheld by courts if uniformly applied, it is unlikely that a "no medications" policy (i.e., a policy that denies the administration of any and all medications at school) applied to all students would stand up in court because those policies have the effect of denying children with disabilities the free appropriate public education to which they are entitled under IDEA and perhaps Section 504, or reasonable accommodations under Section 504 and Title II of ADA.[57,72,73] A free appropriate public education must be specifically designed to meet the unique needs of the child,[74] and consequently, related services, including medications, must accompany that design.[55,56,66] Likewise, under Section 504, health services provided as part of related services must be individually evaluated and prescribed.[58]

INDIVIDUAL EDUCATION PROGRAMS

Under IDEA, a "child with a disability" must be provided with an appropriate individualized educational program (IEP).[49,75] Federal regulations promulgated under Section 504 indicate that schools may use IEPs or other plans as a means of meeting free appropriate public education requirements included in those regulations[55] (whether Section 504 includes such requirements is less clear[57]). An IEP is a written statement designed to identify a child's educational needs and other programs and related services the child requires to progress in the general curriculum.[49] IEPs are developed by an IEP team that typically includes the disabled child's parents, regular and special education teachers, and other representatives from the local education agency who are best suited to assist the child in meeting his or her educational needs.[49] A school nurse may be part of the IEP team when school health services (e.g., administration of medications) are necessary.[76] This team, created specifically for each individual child, ensures that all aspects of the child's educational and related services needs are tailored to that child. This team, along with consultation from the child's health care provider, is best equipped to determine on a case-by-case basis whether self-medication using asthma inhalers is appropriate.

For students with asthma, an *asthma management plan* (Table 1) is an appropriate part of an IEP.[5] Health care providers give instructions on how best to manage the child's asthma during the school day. For a student with asthma, it is helpful if part of the IEP (or 504 plan or individual health service plan or asthma management plan) includes specific information about where, when, and how each asthma medication is to be taken, including when medication possession

TABLE 1—Elements of Typical Asthma Management Plan

- Student's asthma history
- Student's asthma symptoms
- How to contact student's health care provider and parent or guardian
- Signatures of physician and parent or guardian permitting use of medications in school
- List of factors that make student's asthma worse
- Student's best peak flow reading (if student uses peak flow monitoring)
- List of student's asthma medications
- Student's treatment plan, including actions school personnel can take to help handle asthma episodes

Source. NIH Publication 95-3651.[5]

and self-administration provisions are appropriate.

It is best if asthma management plans are on file in the school office or health services office and available to teachers and coaches. From a legal perspective, it is recommended that the asthma management plan include parental permission for the plan to be shared with relevant school personnel to avoid possible violations of the Family Education Rights and Privacy Act of 1974 (FERPA), which prohibits the unauthorized disclosure of confidential information in education records (including school health records in most cases).[77,78] However, under FERPA education records may be released to school officials without written consent of students' parents, including to teachers within the educational institution or local education agency, who have a "legitimate educational interest."[79] Under FERPA, it is important to note a narrow emergency exception whereby a school may disclose personally identifiable information to appropriate parties in connection with an emergency if knowledge of the information is necessary to protect the health or safety of the student.[77,80]

OVERCOMING POTENTIAL DISADVANTAGES

Although many advantages to self-medication exist, families and schools need to recognize some theoretically possible disadvantages of students' being responsible for carrying and administering their own medication. These disadvantages can be minimized, however. First, students may unintentionally leave their inhalers at home or misplace their inhalers at school. One possible solution is to keep a spare inhaler in a school nurse's office or health room.

Second, self-medication may make it more difficult for the school to keep medication records. Such documentation ensures that medication adherence can be communicated to parents and children's health care providers; documentation might be required as part of an IEP or Section 504 plan or might be recommended by school boards as a way to monitor the health and safety of students. To solve this problem, schools could require that students report each inhaler use to a school nurse or record each medication use in a diary.

Third, students may not be well educated about when to take their medications,[8,81] may be embarrassed to take their medications in front of peers,[8] or may lack the maturity to use their medications appropriately (e.g., most elementary school students). Health care providers and parents are primarily responsible for teaching children about administering asthma medications and determining on a case-by-case basis whether the student has reached a level of maturity necessary for self-medication. School-based programs can supplement student education by helping students with asthma understand their disease and the importance of asthma self-management[82,85] as well as destigmatize the need for using asthma inhalers during the school day.[83]

CONCLUSION

Not all students with asthma have their asthma under good control.[1,4] Patient education and medical management about the proper use of asthma medication are crucial to preventing asthma morbidity and mortality.[86,87] For optimal asthma management, it is important that students with asthma not be denied appropriate access to their medications in school.[5,6,11,88,89] Many states have laws or policies that allow students to self-medicate with asthma inhalers at school (there is no evidence on whether state laws or polices are more effective to ensure immediate access for students in schools). In addition, 3 federal laws require schools to accommodate students whose asthma qualifies as a disability under IDEA, Section 504, or Title II of ADA. Such accommodations may include allowing students to carry their asthma inhalers so they can self-medicate as indicated in their asthma management plan. Of note, the US Department of Education, Office of Safe and Drug-Free Schools has issued guidance clarifying that "a student's prescription drugs, and related equipment, are not illegal drugs and are not prohibited by the [Safe and Drug-Free Schools and Communities Act]."[90]

Although these laws and policies are important, they cannot provide an individualized answer to asthma management. Ideally, parents or guardians, the child's health care provider, and school personnel, including the school nurse, will work together as a team to determine the best way to manage a student's asthma in school. Table 2 outlines some factors that should be considered in determining the appropriateness of self-carrying and self-administering inhalers in school. For example, whether a child with asthma should be permitted to self-medicate ought to be determined on a case-by-case basis, based on a child's abilities and interest and maturity and the situation at the school. When that team deems the child skilled and mature enough, the student with

TABLE 2—Elements to Consider When Determining Appropriateness of Self-Carrying and Self-Administering of Inhaler Medication in Schools

Student factors
- Asthma severity and morbidity (hospitalizations, emergency department visits, severe episodes, types of triggers)
- Student's asthma knowledge, attitude, skills, and behavior (awareness of asthma signs and symptoms, desire to self-carry inhaler, willingness to self-administer and report use of inhaler, understanding of importance of not sharing inhaler with other students, correct peak flow and inhaler technique)
- History of asthma episodes at school
- Adherence to school rules regarding medication administration
- Inhaler self-carrying experience in other settings (child care, camp, after-school care, at friends' homes)

Family factors
- Desire of parents/guardians for student to self-carry and self-administer medications with an inhaler
- Collaboration of parents/guardians with school team; permission for physician and school to share information

School factors
- Health staff availability (whether or not there are full-time school nurses or health assistants)
- School size (whether or not there is quick and easy access to health room)
- Ability to reduce student's triggers at school
- Proximity and availability of inhalers from local emergency medical services

Health care provider factors
- Completion of physician's or other health care provider's written asthma management plan and all required forms
- Student's education by physician or other health care provider about asthma generally, controlling asthma, and proper use of inhalers, spacers, and peak flow meters
- Assessment by physician or other health care provider of student's technique for inhaler, spacer, and peak flow meter use

asthma should be allowed to keep asthma inhalers in his or her possession[11,88] to reduce the chances of a full-blown asthma episode, asthma-related school absences, and the need for emergency medical care.[8,86,87] Some students may not want or need to carry their inhalers, for example, when the school building is very small and health staff are available during all school hours. Each student needs individual assessment as part of the implementation of that student's personal asthma management plan.

In some circumstances, parents may need assistance from the child's physician or other health care provider in advocating for the student to gain the right to self-carry an asthma inhaler. By knowing the rights of students with asthma, physicians and other health care providers can help ensure that students have appropriate access to medications at school. An informed health care provider can bring to the attention of school administrators and educators, as well as parents, the legal requirements of schools with students with asthma, and the benefits of self-administration and adequate control of asthma (e.g., improved health and fewer school absences). For example, health care providers can obtain parental permission to send a written asthma management plan to schools including specific guidance about the student's skill and maturity regarding self-administering the asthma inhaler. They can personally contact the principal if there is reluctance to permit self-carrying of inhalers. Students are more likely to be able to control their asthma when school personnel, parents or guardians, and health care providers know about disability laws and about appropriate asthma management. ■

About the Authors

The authors are with the Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Division of Adolescent and School Health, Atlanta, Ga.

Requests for reprints should be sent to Sherry Everett Jones, PhD, MPH, JD, Centers for Disease Control and Prevention, 4770 Buford Hwy NE, Mail Stop K-33, Atlanta, GA 30341 (e-mail: sce2@cdc.gov).

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Contributors

S. Everett Jones collected, analyzed, and synthesized the literature and wrote the article. L. Wheeler assisted in synthesizing the literature and contributed to the writing the article.

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Characterizing Perceived Police Violence: Implications for Public Health

Hannah Cooper, ScD, Lisa Moore, DrPh, Sofia Gruskin, JD, MIA, and Nancy Krieger, PhD

Despite growing recognition of violence's health consequences and the World Health Organization's recent classification of police officers' excessive use of force as a form of violence, public health investigators have produced scant research characterizing police-perpetrated abuse.

Using qualitative data from a study of a police drug crackdown in 2000 in 1 New York City police precinct, we explored 40 injection drug using and 25 non–drug using precinct residents' perceptions of and experiences with police-perpetrated abuse. Participants, particularly injection drug users and non–drug using men, reported police physical, psychological, and sexual violence and neglect; they often associated this abuse with crackdown-related tactics and perceived officer prejudice.

We recommend that public health research address the prevalence, nature, and public health implications of police violence. (*Am J Public Health.* 2004;94: 1109–1118)

Despite the emerging understanding of violence as a public health issue, the recent classification by the World Health Organization (WHO) of police officers' excessive use of force as a form of violence,[1] and the exploration of excessive police violence by disciplines such as sociology,[2–4] law,[5–9] and psychology,[10–12] public health investigators have produced scant research characterizing police-perpetrated abuse and its significance for public health. Drawing on the results of a qualitative study of a police crackdown on drug users in 1 New York City precinct in 2000, we seek to redress this silence by exploring injection drug using and non–drug using precinct residents' perceptions of and experiences with police violence. Because initial analyses indicated that perceived unwarranted police violence often arose from conflicts between participants' and officers' definitions of local places, we have drawn on social geography to understand the conditions in which this phenomenon occurs.

PUBLIC HEALTH AND EXCESSIVE POLICE VIOLENCE

In its landmark 2002 report on violence, WHO defined violence as "the intentional use of physical force or power, threatened or actual, against oneself, another person, or against a group or community, that either results in or has a high likelihood of resulting in injury, death, psychological harm, maldevelopment or deprivation."[1(p5)] The report defined "intention" as the desire to commit the act rather than the wish to cause harm, thus distinguishing violence from unintentional injury while simultaneously indicating that an act can be classed as violent regardless of an individual's desire to cause damage.[1] WHO's report also noted that individuals and entities wielding power can cause violence through the absence of assistance, as in the case of neglect.[1] WHO has identified 4 domains of violence: physical, sexual, psychological, and neglectful.[1]

While public health researchers have extensively documented multiple health problems associated with physical, sexual, and psychological violence,[1,13–15] research regarding the health implications of police violence has stayed at the margins of public health. However, the small but important body of work addressing police violence begins to provide an outline of its repercussions. Police violence has been implicated as a leading cause of assault-related ear damage in a sample of clinic attendees in Kenya,[16] a principal source of violence experienced among patients in a Chilean clinic,[17] and, in a qualitative study, a major cause of spinal cord injuries among African residents of Soweto, South Africa, who used wheelchairs.[18] A *Lancet* editorial has described the internal injuries suffered by Abner Louima after his torture in a New York City police precinct.[19] Research also suggests that children living in the streets of Brazil experience lethal violence at the hands of police.[20]

Populations that have experienced police-perpetrated abuse may hesitate to summon police assistance in cases of civilian-on-civilian violence, fearing the police might exacerbate the violence or further traumatize victims.[21,22] Research also suggests that particular tactics used in policing illegal drug use, including those perceived as abusive (the authors' unpublished data), may adversely affect injection drug users' ability to reduce the harm of their drug use.[23–30] Collectively, this research suggests that police-perpetrated abuse has an impact on health.

According to data from the New York City Civilian Complaint Review Board, a body empowered to investigate allegations of police misconduct in the city,[31] between 1996 and 2000, civilians annually registered between 3269 and 5174 allegations of officers' improper use of force and between 6564 and 8919 allegations of abuse of authority or of offensive or discourteous language or behavior.[31] On the basis of New York City demographics, a disproportionate number of these complainants were African American.[31] Governmental and nongovernmental investigations of police misconduct in New York City support this finding,[7,9,32] as has a New York City–based study of police–adolescent relations.[33] These reports suggest that substantial numbers of city residents, particularly people of color, have experienced police-perpetrated abuse.

We seek to extend public health inquiry into police violence, and to encourage links with other disciplines addressing this violence, by exploring the experiences of residents of one New York City precinct with police-perpetrated abuse and identifying the particular policing tactics that participants associated with this phenomenon. To situate the analysis, we begin by describing police "drug crackdowns," the policing strategy at the heart of this inquiry, and relevant elements of social geography.

POLICE DRUG CRACKDOWNS

Since the mid-1980s, the United States has shifted its domestic drug-related enforcement efforts from upper-level dealers and distributors to lower-level dealers and users.[34–36] A "drug crackdown," a strategy exemplifying the current enforcement focus, is a centrally organized, rapidly initiated, sustained policing effort to reduce the possession and sale of illicit drugs through heightened surveillance and arrest of drug users and street-level dealers.[37,38] New York City has undergone 2 waves of drug crackdowns since the mid-1990s. The first wave, implemented in stages between 1996 and 1999, consisted of a series of precinct-specific crackdowns, each lasting 2 years or more, in 27 of the city's 76 precincts (Assistant Chief C. Kammerdener, New York City Police Department, written communication, November 29, 1999, and May 15, 2000). In these precincts, officers work in modules called tactical narcotics teams (TNTs), which target narcotics crimes; each team is composed of 1 sergeant, 6 investigators, and 2 undercover officers (C. Kammerdener, written communication, May 15, 2000). Hundreds of patrol officers may be added to the target precincts as well[39]; in order not to deprive other precincts of patrol officers, the department draws on recent police academy graduates ("rookies").[39] Patrol officers not assigned to TNT modules may attend more closely to quality-of-life crimes such as public alcohol consumption (C. Kammerdener, oral communication, July 2000). As determined by US census data, the New York City precincts targeted by crackdowns have typically been home to impoverished communities of color.[40]

The second crackdown wave began in January 2000 when the New York City Police Department (NYPD) implemented Operation Condor, an initiative encompassing all of New York City. Initially, the heightened police presence was achieved by asking TNT officers to work an extra day of overtime each week[40]; in May 2000, the NYPD expanded the request to include patrol officers.[41] Patrol officers were to focus on quality-of-life crimes and patrols.[41]

This dual wave of crackdowns occurred within the broader context of "zero tolerance" policing in New York City, initiated in the mid-1990s.[37,42–44] Zero tolerance strategies seek to prevent serious crime by arresting individuals committing any infraction, including misdemeanors.[37,42–44] The combination of crackdowns and zero tolerance encouraged officers, who routinely exercise discretion in deciding whether to enforce particular laws,[45,46] to target street-level drug-related crime.[37]

SOCIAL GEOGRAPHY: POLICING PUBLIC SPACES

Integral to this analysis is the notion of place. "Place" is understood in social geography as a space endowed with particular meaning(s) by individuals and groups[47–50]; place is thus literally and metaphorically peopled space. Testifying to this subjective construction, an early definition of "place" is "a portion of space in which people dwell."[51(p926)] A single space may be the site of multiple places. A corner of an urban public park, for example, might simultaneously serve as a playground for children, a home for people without houses, and a work site for parks department employees. Diverse constructions of place may not happily coexist within the same space. For example, heated and occasionally violent struggles have erupted between the individuals and communities who call parks home and those who seek to enforce definitions of those spaces as exclusively recreational places or landscapes.[52–54]

Within limits, the state endows police with power to arbitrate legitimate and illegitimate conduct in public spaces[55,56]—in other words, to define place. Social geographers and sociologists have maintained that officers identify suspicious behavior or characteristics by crafting "cognitive maps" of their precincts along intersecting axes of space, time, and social activity.[55–58] Officers hold in their minds 2 sets of cognitive maps: those defining what is acceptable and those defining what is unacceptable; they then use these maps to decide what individuals and activities merit further investigation.[55–58] Officers charged with targeting drug-related crimes may rely on such cognitive maps quite extensively; drug-related activity is a consensual crime, meaning that neither user nor dealer is likely to summon police assistance to complain about the transaction, and thus officers may largely draw on situational cues to identify such activity in the streetscape. This analysis suggests that conflicts between officers' cognitive maps and residents' definitions of local places often establish conditions for police-perpetrated abuse.

METHODS

As a part of an investigation into the relationship between a drug crackdown and local drug use, we queried injection drug using and non–drug using individuals about police–community relations. When using and nonusing participants voiced high levels of concern regarding police violence, we further explored this topic during interviews and crafted an analysis devoted to this subject.

Data Collection

The first author spent August through December 2000 in New York City's 46th precinct interviewing 40 precinct residents who injected drugs ("injectors") and 25 precinct residents who had not used an illicit drug such as heroin or cocaine in the past year ("nonusers"). The 46th precinct was selected as a study site because the deputy inspector of narcotics of the NYPD noted that the crackdown in this precinct was particularly active (C. Kammerdener, oral communication, July 2000).

Individuals eligible for the study were aged 18 years or older at the time of the screening, had resided in the precinct for at least 1 year prior to the screening, and were able to speak

English with sufficient fluency to understand the screening and consent processes. Injection drug using participants were those who reported typically injecting an illicit drug on at least 3 occasions a week during the past year; nonusing participants were those who reported not using an illicit drug such as cocaine or heroin in the past year. In keeping with theoretical sampling methods,[59] the sampling strategy was designed to recruit a group of participants that varied with regard to qualities believed to shape the relationship between police and the community, including race/ethnicity, age, sex,[60–62] and, where relevant, legal syringe exchange program enrollment status and injection location (i.e., whether injection typically occurred in public or private spaces). (When the study was conducted, it was illegal to acquire or possess syringes without a prescription unless one obtained them from a state-sanctioned syringe exchange program. As of January 2001, individuals could acquire and possess up to 10 syringes without a prescription.) Eligibility criteria were ascertained through a screening process. Study participants received a $21 stipend and a community resource guide.

Snowball sampling methods were used to invite residents into the study.[63,64] "Snowballs" were initially started with nonusing residents identified by a local city council member and community board staff. As time passed, the first author met individuals on local stoops and park benches and at soup kitchens. Four key informants also introduced her to community members. The sample was thus created through a patchwork of connections that permitted the inclusion of multiple social networks.

Interviews lasted between 60 and 90 minutes and consisted of an open-ended segment followed by a short survey. The open-ended interview explored police–community relations, police contributions and threats to local safety, the role of officer type (e.g., patrol vs TNT) and officer and resident social position in shaping police encounters, and local drug use practices, all in relation to the 46th precinct. The short survey gathered information regarding police encounters and, where applicable, drug use behaviors. With the participant's permission, each interview was audiotaped; in the few instances in which a participant denied permission to be taped, the interviewer took detailed notes. Taped interviews were transcribed verbatim.

Additionally, we reviewed articles about policing strategies published in *The New York Times* between August and December 2000. We attempted to interview patrol and TNT officers in the 46th precinct to explore their perspectives on the drug crackdowns, but the NYPD refused to grant our requests for interviews.

Analysis

We used "grounded" theory methods to identify salient categories and their interrelationships within and across transcripts.[59] "Grounded theory" is a qualitative analytic method designed to inductively derive theories about a topic. There are typically 3 stages of analysis: 1) "open coding," in which concepts in the text are identified, labeled, and defined; 2) "axial coding," in which the connections between these concepts are explored to build categories and explore the categories' interrelationships with one another; and 3) "selective coding," in which the emerging theory is refined.[59] As the data were collected, transcripts were coded by open coding methods and an initial coding list with accompanying definitions was created.[59] As new data emerged and were analyzed, this coding dictionary was revised. Using axial coding methods,[59] the first author grouped similar codes into categories relevant to the conditions in which participants experienced excessive police violence and the nature of this violence and explored the categories' relationships within and across transcripts, examining diversity of experiences along the lines of drug-use status, sex, race/ethnicity, and age. Throughout this process, the 4 authors discussed emerging codes, categories, and their relationships. Given the salience of place in the participants' narratives of police violence, we drew extensively on social geography. Findings were discussed with 2 injecting and 3 nonusing study participants to check the interpretive validity of the analysis (referred to hereafter as "member check").[65] Because African American and Hispanic participants reported the same level and perceived causes of police-perpetrated abuse, we report the findings for these 2 groups together.

Because states endow the police with the ability to use force to promote public safety if necessary,[66–68] identifying instances of officers' excessive use of force is complex. Accordingly, scant consensus exists concerning the definition of officers' excessive use of force or police brutality.[66–68] Here, we have defined an abusive police encounter as one in which the participant maintained that officers employed gratuitous force, initiated sexual contact, spoke or behaved disrespectfully, or interceded without apparent cause. This definition largely concords with that of the Civilian Complaint Review Board.[31] To describe the nature of this violence, we have contextualized WHO's 4 violence domains within the realm of police-perpetrated abuse (Table 1).

Ethics

Because interviews often involved discussions of illicit activity, extra steps were taken to protect participants' rights. We obtained a National Institute of Mental Health federal certificate of confidentiality to protect interview materials from subpoena. Additionally, in approving the project, the Harvard School of Public Health human subjects committee authorized the use of oral rather than written consent; participants' names were thus not recorded in the interview materials.

RESULTS

The 46th precinct is located in Bronx County, New York City, and bounded by the Cross-Bronx Expressway, Webster Avenue, Fordham Road, and the Harlem River. According to the 2000 US census, the precinct is home to approximately 77 000 people, the vast majority of whom are African American or Hispanic (Table 2).[40] The precinct is deeply impoverished and suffers a disproportionate number of violent crimes,[69] suggesting that its residents direly need services addressing local violence.

The crackdown targeting this precinct, which began in April 1996, initially involved the addition of 15 TNT modules; 8 modules patrolled the area at the start of data collection (C. Kammerdener, written communication, August 25, 2000). TNT modules and patrol officers worked an additional day each week under Operation Condor.[41]

TABLE 1—Domains and Definitions Employed in Analysis of Police Violence: 46th Precinct, New York City

Category	Definition
Excessive physical violence	Participant maintained that the police gratuitously hit, punched, kicked, dragged, beat, or used some other type of physical force against the participant or another civilian.
Psychological violence	Participant maintained that the police engaged in excessive nonphysical aggression toward the participant or another civilian, including cursing at them; using slurs based on their race/ethnicity, sex, sexual orientation, religion, or disability; or unduly threatening or intimidating them. Police-initiated stops that the participant believed lacked probable cause were classified as harassment and deemed psychological violence, as were instances of police-initiated gratuitous prolonged discomfort.
Sexual violence	Participant maintained that the police forced inappropriate sexual contact on the participant or another civilian; such contact included conducting searches of genitals in public places.
Neglectful violence	Participant maintained that she/he or another civilian summoned the police for assistance and the police did not respond, responded too late to be of assistance, or responded inappropriately.

Source. Categories of police violence are derived from a World Health Organization report.[1]

TABLE 2—Sociodemographic and Violent Crime Characteristics: 46th Precinct and of New York City, 2000

Characteristic	46th Precinct	New York City
Population[40]	76 775	8 008 278
Living below federal poverty level in 1999,[40] %	40.0	21.2
Racial/ethnic composition,[40] n (%)		
Hispanic, any race	46 041 (60.0)	2 160 554 (27.0)
Black or African American, non-Hispanic	27 208 (35.4)	1 962 154 (24.5)
All other racial/ethnic groups	3 526 (4.6)	3 885 570 (48.5)
Crimes against people (crude rate per 100 000)[69]		
Murder and nonnegligible manslaughter	29.9	8.5
Forcible rape	46.8	20.3
Robbery	865.7	406.6
Felonious assault	834.5	323.9

Note. The 46th precinct roughly corresponds to the 10453 zip code census tabulation area.

The sample of nonusing and drug-injecting precinct residents was diverse with respect to characteristics believed to shape police–community relations, including gender, race/ethnicity, age, and legal syringe exchange program membership (Table 3). Both injecting and nonusing participants had deep roots in the area, with an average residence in the precinct of 12 years. When asked in the closed-ended survey whether they were close with anyone who had experienced a violent or frightening police encounter, 64% of nonusers and 54% of injectors said yes.

Characterizing Police Violence

Qualitative interviews substantiated New York City statistics on violent crime in the precinct; many participants reported witnessing shootings, losing friends to fights, and enduring sexual violence. They expressed concern about civilian-instigated violence in the area and profound ambivalence about whether officers fulfilled their duty to protect them from this violence.

Users and nonusers alike reported that the police had "cleaned up the neighborhood" in recent years. In particular, residents caring for children lauded the police for reducing drug-related activity in the streets and playgrounds in which children walked and played. Drug-injecting women viewed such policing efforts as extensions of their own struggles to protect their children from their personal drug use. As one mother, a 34-year-old Hispanic injector, said, "I don't want the . . . drug stuff to go on because of the easy access [to drugs]. I guess my having children and not wanting them to go through what I [went through] has made me want more police protection."

Additionally, many participants reported that officers accompanying ambulances and attending to crimes affecting young children were unfailingly helpful and respectful.

Neglect. However, at the same time, 18% of injectors and 36% of nonusers lamented the conduct of the police when they were summoned to address local civilian-instigated violence among adults and older children. Injecting and nonusing men focused on police inaction with respect to shootings and other physical violence occurring among men in public spaces, noting that the police did not respond to their calls for help or responded too late to be of assistance. Women maintained that, when they sought police help for physical or sexual violence inflicted by men, officers often did not come when called; that they came but suggested interventions the women deemed inappropriate, such as taking a walk or having sex with their abusive partner; or that they did not believe them. One African American woman, a 43-year-old injector, said,

> This guy was drunk . . . and was pushing me and hitting me in my chest . . . just being really abusive but I . . . told my friend to hurry up and call a cop . . . they didn't do anything when they were called . . . [they were] talking about "oh they didn't see no visible marks on me." I said, "I'm black—what visible [marks]? . . . I'm dark-skinned. It's not going to show" . . . It's crap, it really is.

Physical, sexual, and psychological violence. A total of 65% of injectors and 40% of nonusers reported directly experiencing or

TABLE 3—Injection Drug Using and Non–Drug Using Study Participants in Qualitative Study of Police Violence: 46th Precinct, New York City

Characteristic	Nonusers (n = 25)	Injectors (n = 40)
Age, y		
Mean	38	41
Median	36	41
Range	19–60	24–59
Gender, n (%)		
Female	11 (44)	19 (48)
Male	14 (56)	21 (53)
Race/ethnicity, n (%)		
African American, non-Hispanic	9 (36)	14 (35)
Hispanic	8 (32)	20 (50)
Hispanic and African American	3 (12)	4 (10)
All other races/ethnicities	5 (20)	2 (5)
Highest educational level, n (%)		
Less than high school	9 (36)	24 (60)
High school graduate	9 (36)	9 (23)
More than high school	7 (28)	7 (18)
Data missing	1 (4)	0 (0)
Homeless, n (%)	2 (8)	14 (35)
Length of residence in 46th precinct, y		
Mean	12	12
Median	7	10
Range	2–28	1–33
Membership in legal syringe exchange program, n (%)	NA	22 (55)
Close to someone who experienced violent or frightening police encounter, n (%)	16 (64)	21 (53)

Note. NA = not applicable.

witnessing perceived excessive police physical violence. This violence ranged from unnecessary kicks delivered during a stop to beatings that resulted in broken ribs and teeth. Additionally, some participants had known Anthony Baez, a local "college boy" killed by the police in 1994 after bouncing a ball against 2 squad cars.[7] Injecting men described the direst gratuitous physical violence. One 36-year-old African American man, an injector, said,

> I was carrying a pair of scissors and I got stopped and [the officer] said, "Do you have anything in your pocket that could stick me?" At first I was thinking of a needle . . . [so I said] "nah nah nah." [He] put his hand in my pocket [and found the scissors]. He broke 4 of my ribs right on this side. Four. He broke them. Boom. Boom. Boom . . . Then he took the scissors and jabbed them in my face in the middle of my forehead . . . I was scared to damn death. They just left me [for] dead . . . They could have locked me up [but they didn't]: trespassing, drug paraphernalia, possession of drugs . . . It hurt to breathe. What the hell.

Thirty-three percent of injectors and 12% of nonusers reported experiencing or witnessing police-perpetrated sexual violence. Injection drug using women, particularly sex workers, bore the brunt of this abuse. At the extreme end of the spectrum of sexual violence, 1 sex worker reported that an officer had raped her. Additionally, during frequent searches in the streets and other public spaces, officers delved into men's and occasionally women's underclothes in a protocol presumably designed to locate contraband. One man, a 35-year-old Hispanic injector, said,

> They pulled my pants down past my knees . . . to search me [on the sidewalk]. The only thing that they needed to do was stick their finger up my ass. I think that was very degrading. That was very low. If I was clean . . . why you got to pull my pants down in front of everybody? . . . You got women and children walking by and you doing this . . . . [Then they] let us go. They didn't even say, "Excuse us. Sorry." Nothing.

Police stops could also involve psychological violence, typically in the form of name-calling, unnecessary physical threats, and the infliction of gratuitous prolonged discomfort, including hours-long journeys to the police station while in handcuffs; 63% of injectors and 44% of nonusers reported such abuse. Participants reported that officers referred to their "black asses" and called local women "bitches." One participant noted that an officer had threatened to "stick [his] foot up [the participant's] ass" when he tried to intercede in perceived police misconduct.

Participants, particularly injectors and younger nonusing men, described frequent police stops that they felt had little probable cause, describing them as "for no reason" and "for nothing." According to one African American man, a 45-year-old nonuser, the police

> just drove by and they saw people minding their own business sitting in front of their building and . . . they backed [the car] up [and got out]. And we're standing on one side of the street saying, "Now they're going to mess with them for no reason at all—they're just sitting in front of their homes."

Approximately two thirds of injectors and nonusers reported stops for "no reason." The accumulation of such encounters left many residents, particularly nonusing young men and injectors, feeling "insecure" and "uncomfortable" when outside; this insecurity was compounded for people who feared that unnecessary violence or life disruption was imminent during every police stop.

Discussing frequent stops, one male participant, a 27-year-old Hispanic nonuser, said,

> When I'm outside . . . sometimes I fear for my well-being because I could just be on my way to the grocery store . . . and get caught up in something. . . . Just because of the way [the police] are doing things now, I could be sent through the system. I might have to see a judge 24 hours later and all I wanted was a loaf of bread.

Given their frequency and resulting fear, we labeled stops "for nothing" as "perceived harassment" and classified them as a form of psychological abuse. For the vast majority of participants, then, officers simultaneously served as both sources of violence and much-needed assistance.

Conditions for Excessive Police Violence

Salient conditions animating police-perpetrated abuse were perceived to include (1) profiling, (2) perceived pressure of officers to make arrests, and (3) discrimination.

Profiling: "hotspots" and social interactions. Participants identified 2 major contexts in which harassing stops occurred: near dealing locations (i.e. "hotspots") and during or just after a social interaction.

The interviews suggested that officers identified particular places in the precinct as dealing locales or "hotspots" and viewed people inhabiting these spots, however temporarily, with suspicion. Observation and participant interviews bore witness to the existence of such dealing places. Rather than being diffuse, dealing was concentrated in particular corners, buildings, and parks. Testifying to officers' accurate identification of some hotspots, injection drug using participants described the outside spaces in which dealing occurred as heavily monitored.

The potential for stops "for nothing" lay in participants' conflicting use of these places. The corners, buildings, and parks in which dealing occurred were the same places in which nonusers, injectors, and their families lived, played, and conducted the licit tasks of daily life. The dissonance between officers' and participants' definitions of place, coupled with officers' ability to enforce their definition, produced harassing stops.

As one 20-year-old African American and Indian man, a nonuser, said, "The corner is known for selling drugs so the cops always been over there so . . . they see me standing over there so they think 'oh that corner, we stop people over there so let's go stop him.' They think I'm selling drugs or something."

Participants also noted that officers stopped them during or after social interactions. The interviews suggested a process through which the police might come to view social interactions with suspicion. In a context of heightened surveillance, participants reported that drug-related commerce was conducted on the "down low": dealers and users camouflaged their transactions so they blended into innocent streetscape social activities, often exchanging drugs for money through hugs, handshakes, and other covert means.

According to participants, officers detected the deception and adapted in turn. If dealers concealed their business behind the trappings of innocent interactions, then officers would come to label interactions occurring in local public spaces as suspect. Both nonusers and injectors lamented the resulting stops "for nothing." As one African American man, a 36-year-old nonuser, said,

> I hugged my man . . . and [the TNT officers] took me through the system for nothing. Just for giving my man the "What's up man, how're you doing buddy?" . . . The officers said, "Oh he passed you something!" . . . I kept walking and [the officers] jumped on me right there. I could see if I'd put my hands in my pocket or [if the officers] could have seen me throw something [but the police] didn't find nothing, didn't see nothing. [They] kept me [in a holding pen] for 24 hours.

Participants generally maintained that officers unfamiliar with the precinct—usually TNT and rookie officers—were particularly guilty of harassment through profiling. In contrast, police officers credited with deeper knowledge of the precinct, its residents, and their use of local places—usually senior patrol officers—were believed to be less prone to making such stops because they relied on "knowing [residents'] faces," rather than assessing their profiles, to determine suspicion.

Perceived pressure to make drug-related arrests. Participants with frequent police contact—injectors and younger, nonusing men—believed that the pressure the police were under to make arrests resulted in sexual and psychological abuse. Many participants maintained that TNT modules had to make 10 drug-related arrests per shift; while rookies had no established arrest quota, they also believed that these officers were intent on making arrests to earn "stripes" or "points" that might further their career. Media reports support this widely held belief: expressing concern that misdemeanor narcotics arrests outnumbered felony arrests 3 to 1, NYPD Commissioner B. Kerik announced in September 2000 that he would review the process through which officers were promoted.[70]

Injecting and nonusing residents linked police-perpetrated abuse to the dynamic between officers' attempts to make an arrest and users' and dealers' efforts to evade arrest. When traversing public spaces closely monitored by the police, injecting participants began concealing drugs and syringes in their most private spaces, including their underwear, rectum, and mouth, to decrease their risk of arrest if stopped and searched. Savvy to this subterfuge, officers reportedly searched participants' undergarments and bodies in the street to find drugs, thus rendering these intimate spaces public. Nonusing and injecting participants reported that this violation of privacy was frightening and humiliating, particularly when they were innocent. Given the gendered nature of physical privacy, women suffered these searches particularly acutely when men either conducted or watched the search. One woman, a 25-year-old African American nonuser, said,

> The lady cop came; she searched me . . . in the building [hallway], the [male] cops were there watching . . . That really hurt me. It made me bug out a little . . . The lady was even in my butt and everything like I might have drugs up there . . . . I was strip-searched in the hallway. And the lady was even in my butt.

TNT officers, charged with addressing drug-related crime, were viewed as particularly likely to employ these drug discovery strategies.

Participants also reported that TNT modules appeared to return to the station only after they had reached their quota rather than taking limited shift time to travel to the station to book each individual upon arrest. Individuals arrested early in the shift thus spent hours locked in the back of the van. Because the van's seats were routinely removed, these hours were spent sitting or lying on the van floor in handcuffs. Reported one African American man, a 21-year-old nonuser,

> This is how it is, right? They got the van. You know what they do to you? . . . [If you are] the first one to get locked up . . . they are going to drive around with you all night, all day long until the van is filled up . . . you're just going to be sitting there with your hands cuffed. And there are no seats; it's just the floor and all!

> And you're going over bumps and all that. That's how it is. They don't care. They don't care. They do not care. They wreck yourself.

Toward the end of the shift, the van could be packed with "close to 15 or 16 people" and conditions were "terrible." Cramped in the van and left without access to a toilet for hours on end, arrested individuals urinated where they lay or sat. A 48-year-old Hispanic woman, an injector, who was held in the van for over 6 hours said

> they were picking up people . . . that's a form of torture. I wanted to piss; my friend he pissed on himself and he almost got his ass kicked because he pissed on the van.

Participants singled out TNT officers, with their vans and quotas, as the sole source of such abuse.

Participants additionally linked pressure to arrest to officers' neglect of local civilian-on-civilian violence. Both injectors and nonusers maintained that officers focused on minor drug-related activity to the exclusion of more egregious crimes. One 34-year-old African American man, a nonuser, said,

> I know you've heard this story before: when you need [the police], they aren't ever around. . . . I've seen people get shot . . . you see guys running through with guns and stuff and [the police] are never around but yet and still . . . if you're standing in front of your building with a beer, they'll jump over . . . and harass you.

Discrimination: community and individual profiling. For many injecting and nonusing residents, extensive searches, frequent stops, and TNT transportation practices occurred within a broader context of perceived discrimination based on the precinct's racial/ethnic and class composition and the suspected drug use or sex work status of individuals.

Because the interviews pertained to experiences within the precinct and because the precinct was largely homogenous with regard to race/ethnicity and class, participants rarely noted that officers singled them out individually for abuse on the basis of their personal race/ethnicity or class. Rather, they considered the relationship between police-perpetrated abuse and sociodemographics to be at a societal level, remarking that the area's "ghetto" status gave officers license to mistreat all residents.

According to a 34-year-old Hispanic man, an injector, the officers

> treat you like shit; I know that I'm a human being but in that moment, he makes you feel like . . . because you're in this community, you're poor, and you're a drug addict . . . you're nobody for the government. It's like a green light to do whatever you want to do with these people. Treat them like pigs.

Homeless individuals were the exception to this rule: they believed that the police targeted them as individuals because of their extreme, visible economic deprivation. Relatedly, some homeless and some housed individuals attempted to deflect police scrutiny by "dressing up," thus perhaps distancing themselves from the precinct's overall class composition and the violence it incurred.

Participants associated officers' poor response to their calls for assistance with the precinct's sociodemographics, maintaining that their lives counted for little. As a 50-year-old Hispanic woman, an injector, asked (and then answered affirmatively), "Why do they do this [e.g., ignore us]? Because we're Hispanic? We're low class and all that?"

Most participants believed African American and Hispanic officers were less prone to engage in abuse than their White counterparts, largely because the former were thought to recognize a shared humanity with the community they policed. However, some participants maintained that minority officers engaged in more violence to distinguish themselves from the community in the minds of their coworkers.

Both injectors and nonusers reported that local injectors sustained more severe and frequent harm from the police than nonusers, testimony that was supported by comparisons of injectors' and nonusers' transcripts. Injecting participants reflected that officers were inclined to "belittle" them verbally, calling them "junkies" and "low lifes" and generally disparaging them, once they saw syringes, drugs, or the telltale "bruises and yellowing, swelling and redness" that can accompany injecting.

Status as an injector also rendered residents vulnerable to physical abuse, particularly when officers happened upon them when they were injecting. According to one 47-year-old African American man, an injector,

> Me and 2 friends were on a roof [injecting] and . . . we were basically cleaning up and [the police] came up, searched us, first thing [one officer] said was "you got any sharp objects or needles in your bag?" and [I] tell him, "yeah." "Pull your pocket inside out" and they took [the syringes], broke them, and commenced beating. . . . They [never took] us in because they didn't have anything to charge us [with] . . . but they did beat us up . . . My back was sore for about 2 weeks after that day.

Among injecting women, sex workers who worked the streets reported far more police-perpetrated abuse than other women. They were frequently subjected to officers' admonishments to leave public spaces when they were not engaging in illegal activities. Additionally, these women reported sexual violence at the hands of the police beyond that incurred during invasive searches: one woman reported that an officer had fondled her breast during a stop and another that an officer had raped her.

A 50-year-old Hispanic woman, an injector, reported that "[The officer] takes me all the way up [to the hotel] and I ask him for the money so we can do something and he pulls out a gun and a badge. He tells me, 'Which way you want it? You want to go to jail, you want a slug [i.e., a bullet] or you want to let me do you?' I had to let him do me."

DISCUSSION

For study participants, excessive police violence was common in their home precinct and was often linked with specific crackdown-related tactics. We find it notable that both nonusers and injectors recounted abusive incidents, given that the crackdowns ostensibly did not target precinct residents who were uninvolved in drug-related activity. The abuse described included excessive physical, sexual, and psychological violence; additionally, participants reported that officers reduced visible drug activity, but often neglected residents' calls for help when civilian-on-civilian violence struck. While disturbing in any context, participants found this perceived neglect particularly distressing in an area with a high rate of violent crime.

When discussing safety and violence during the crackdown, injecting and nonusing participants alike grappled with a paradox:

they lauded the crackdown's objectives of reducing drug-related activity and violence but lamented its methods. Participants viewed the invasive searches and frequent stops conducted when they were engaged in licit social activities as forms of sexual and psychological violence. However, at the same time they embraced the recent reduction in public drug activity, a reduction many partially attributed to the very tactics they deemed objectionable. Crackdown tactics thus left participants, particularly those raising children, feeling they had to relinquish one form of safety to attain another.

Our findings suggest that crackdown-related tactics engendered police-perpetrated abuse in part by challenging participants' understandings of the nature of local public places. Turning to the concept of cognitive maps, forged along the lines of space, time, and social activity, our analysis suggests that officers' maps of the precinct were narrower than residents' actual use of space. Officers therefore apparently classified dealing spaces as principally single-use locales and reacted accordingly while residents experienced these areas as mixed-use locales (e.g., thresholds to shops and paths to school, as well as drug markets). Likewise, police officers apparently came to label social interactions occurring in public places as potentially suspicious and often stopped participants who were genuinely engaging in the licit social activities of daily life. In both cases, officers' maps appeared to reduce the complexities of injecting and nonusing participants' lives to a single, drug-related endeavor.

Relatedly, sexual violence can be understood as developing from resident and officer negotiations over the boundaries of public and private space. When drug-using residents sought to evade arrest by hiding contraband in their bodies, officers extended the perimeter of monitored public spaces to include these most private of spaces, thus creating sexual violence.

As suggested by participants' accounts, it appears that TNT officers were particularly guilty of the spatial reductions and reconfigurations that participants associated with police-perpetrated abuse, a finding in keeping with these officers' exclusive focus on drug-related activity. The temporal and spatial organization of TNT work also appears to have contributed to their role in abuse. Pressured to meet a quota of drug-related arrests during limited shifts, TNT units kept residents, usually injectors, handcuffed in the back of their vans as they traversed the precinct seeking additional drug-related activity.

Many precinct residents invoked race and class as conditions for police-perpetrated abuse. The perceived character of and conditions for excessive police violence resonate with historical patterns in the spatialized nature of race and class relations in the United States, including denying African Americans and impoverished individuals personal sovereignty over their bodies[71–73] and challenging their ability to define and freely inhabit public places.[53,71,72,74–77]

These findings must be understood in the context of certain study limitations. Because all interviews were conducted in English, this study does not include the perceptions of precinct residents who were insufficiently fluent in English to participate. Additionally, at the time the study was conducted it was impossible to gain NYPD permission to interview TNT or patrol officers about their work. We thus could not explore officers' understanding of the role of civilian violence in shaping officer behavior, the conditions in which officers might perceive the need to become unusually violent, or the character of such abuse. We also could not learn officers' motivations for employing the tactics they used or their opinions on whether particular subgroups of officers tend to engage in unnecessary violence. Finally, we could not observe the events that participants described to gain additional perspective on their incidence, nature, and potential origins.

This analysis is thus limited to the perspectives of the precinct residents interviewed. However, these perspectives are significant because they can shape behavior, including reducing the likelihood that an individual will summon police aid if endangered. The study's capacity to address participants' experiences with the local police is strong: the data-collection period was long and permitted familiarity with the precinct and many study participants, interviews were transcribed verbatim, and the injectors and nonusers who reviewed the study findings during the member check supported our findings.

CONCLUSIONS

Recognizing that police abuse is a human rights matter, we suggest that it is also a matter of public health concern. Using WHO's definition of violence as the intentional use or withholding of physical force or power likely to result in harm, participants described widespread and occasionally severe police abuse, often rooted in officer breaches of local definitions of public places and transformations of intimate spaces into public property. Violence of this type has been linked to increased risk of physical and mental illness. Injectors reported the most severe and frequent abuse, suggesting that they may suffer health complications derived from their status as injectors that nonetheless extend beyond their drug use practices. This research also suggests that, because injection drug users are integrally connected to communities that include nonusers, policing strategies adversely affecting users can simultaneously jeopardize nonusers' health.

Evidence regarding police violence gathered to date suggests that public health researchers and other practitioners could support and extend other disciplines' efforts to address police violence by documenting its nature and prevalence, attending closely to variations by both policing strategy and civilian social position; exploring the implications of police violence for population health; and working in partnership with communities and police departments to identify strategies that reduce violence without increasing police-perpetrated abuse. ■

About the Authors

Hannah Cooper is with the Medical Health and Research Association of New York, Inc, at the National Development and Research Institutes Inc, New York, NY. Lisa Moore is with the Department of Health Education, San Francisco State University, San Francisco, Calif. Sofia Gruskin is with the Department of Population and International Health and Nancy Krieger is with the Department of Society, Human Development, and Health, Harvard School of Public Health, Boston, Mass.

Requests for reprints should be sent to Hannah Cooper, ScD, National Development and Research Institutes, Inc, 71 W 23rd St, 8th Floor, New York, NY 10010 (e-mail: cooper@ndri.org).

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Contributors

H. Cooper conceived, designed, and implemented the study and subsequent analyses and wrote the study findings. L. Moore, S. Gruskin, and N. Krieger substantively contributed to the conceptualization and implementation of the study design, analysis and interpretation of results, and preparation of the article.

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The Harvard School of Public Health human subjects committee approved all study protocols. The National Institute of Mental Health granted a Federal Certificate of Confidentiality to protect study documents from subpoena.

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Sociodemographic Differences in Access to Care Among Hispanic Patients Who Are HIV Infected in the United States

Leo S. Morales, MD, PhD, William E. Cunningham, MD, MPH, Frank H. Galvan, PhD, Ronald M. Andersen, PhD, Terry T. Nakazono, MA, and Martin F. Shapiro, MD, PhD

This study evaluated associations between sociodemographic factors and access to care, use of highly active antiretroviral therapy, and patients' ratings of care among Hispanic patients who are HIV infected; we used data from the HIV Cost and Services Utilization Study. Gender, insurance, mode of exposure, and geographic region were associated with access to medical care. Researchers and policymakers should consider sociodemographic factors among Hispanic patients who are HIV positive when designing and prioritizing interventions to improve access to care. (*Am J Public Health.* 2004;94:1118–1121)

Hispanic patients who are HIV infected have worse access to care than do White patients.[1,2] Strategies to remedy this problem necessitate learning the extent to which access to care varies among Hispanic subgroups, so that interventions can be tailored and the most vulnerable population prioritized. In this study, we examined sociodemographic differences in access to medical and dental care, receipt of highly active antiretroviral therapy, and patients' evaluations of care.

METHODS

Subjects

We studied Hispanic patients who completed the HIV Cost and Services Utilization Study baseline survey. The HIV Cost and Services Utilization Study was a representative study of adults who are HIV positive receiving care in the United States.[1,3,4]

Regression Analyses

Dependent variables. We examined 9 dichotomous indicators of access to care, including an access scale (dichotomized at mean),[5] having a usual source of care at HIV diagnosis, having 3 or more outpatient visits in the 6 months before interview, having any emergency department visits not associated with hospitalizations in the 6 months before interview, receiving highly active antiretroviral therapy before December 1996, and receiving highly active antiretroviral therapy by the second follow-up HIV Cost and Services Utilization Study survey.[6] Patients' evaluations of care were assessed by a single rating item (*excellent* vs *very good* to *poor*). Access to dental care was assessed by indicators of having a usual source of dental care and having trouble obtaining needed dental care.[7]

Independent variables. Independent variables were age, gender, educational attainment, income, insurance status, mode of exposure to HIV, geographic location, acculturation,[8–11] survey language, and US citizenship.

Estimation. We estimated 9 logistic regressions, controlling for independent variables and CD4 cell count. All analyses were weighted to account for sampling and survey nonresponse.[12]

RESULTS

Sample Characteristics

The 415 Hispanics included in the HIV Cost and Services Utilization Study represent an estimated 34 180 (95% Confidence Interval = 18 613, 49 747) Hispanics infected with HIV who were receiving care at the time of the baseline survey in the United States (Table 1). Of the Hispanic patients who were HIV infected, 49% were aged 31 to 40 years, 72% were male, 44% had not completed high school, 23% had an annual income of less than $5000, and 25% were uninsured. Forty percent were exposed to HIV by male-to-male sex, 38% were located in the Northeast, 83% were US citizens, 85% answered the English survey, and 58% were highly acculturated.

Descriptive Results

Of the Hispanic patients who were HIV infected, 64% had a usual source of care at

TABLE 1—Sociodemographic Characteristics of Hispanics in the HIV Cost and Services Utilization Study

	Unweighted No.	Weighted % (95% CI)
Age, y		
18–30	89	20 (15, 25)
31–40	198	49 (43, 55)
≥41	128	31 (26, 36)
Sex		
Male	263	72 (63, 81)
Female	152	28 (19, 37)
Exposure		
Male-to-male	155	40 (24, 57)
Injection drug use	110	30 (18, 43)
Heterosexual sex	107	22 (15, 29)
Other	43	8 (4, 11)
Education		
< High school	184	44 (34, 54)
High school graduate	96	23 (20, 27)
> High school	135	32 (21, 43)
Annual income, $		
0–4999	103	23 (17, 30)
5000–9999	116	28 (22, 33)
10 000–24 999	117	29 (23, 34)
≥25 000	79	21 (13, 28)
Region of residence		
West	145	32 (14, 51)
Northeast	160	38 (14, 62)
Midwest	10	2 (0, 3)
South	100	28 (5, 51)
Insurance status		
No insurance	109	25 (16, 33)
Medicaid	163	38 (26, 50)
Private, HMO	55	13 (8, 18)
Private, not HMO	37	11 (3, 19)
Medicare	51	13 (9, 18)
US citizenship		
Yes	341	83 (75, 91)
No	74	17 (9, 25)
Survey language		
English	347	85 (79, 91)
Spanish	68	15 (9, 21)
Acculturation[a]		
More acculturated	195	58 (48, 67)
Less acculturated	143	42 (33, 52)

Note. CI = confidence interval; HMO = health maintenance organization. A total of 415 Hispanics were included in the HIV Cost and Service Utilization Study.
[a]Information on acculturation was missing for 77 respondents.

HIV diagnosis, 34% rated their care as excellent, 72% had 3 or more outpatient visits, and 74% had no emergency department visits without hospitalizations. Seventy-four percent were taking highly active antiretroviral therapy by the second follow-up survey, an increase from 34% by the end of 1996. Fifty-four percent had a usual source of dental care, and 80% had no trouble obtaining needed dental care.

Regression Results

Worse access to care was associated with being male, having no insurance, and receiving care in the South (Table 2). Having no usual source of care at HIV diagnosis was associated with being male and being exposed to HIV by drug use and heterosexual sex. Having 3 or fewer outpatient visits was associated with being male and being exposed to HIV by heterosexual sex. Having 1 or more emergency department visits without hospitalization was associated with being female. Receiving less than excellent care was less likely in the South. Not taking highly active antiretroviral therapy by the second follow-up survey was associated with being female and receiving care in the Northeast. Not having a usual source of dental care was associated with US citizenship. Difficulty obtaining needed dental care was associated with being less acculturated and receiving care in the South.

DISCUSSION

In contrast to prior findings, women in this study reported better access to care than did men.[1] Women had a 67% lower adjusted odds ratio than men of not having a usual source of care at HIV diagnosis. Not having a usual source of care at HIV diagnosis has been associated with delays in care, subsequent hospitalizations, and decreased use of antiretrovirals.[2,13,14] Hispanic persons exposed to HIV by drug use and heterosexual sex also were at increased risk for not having had a usual source of care at HIV diagnosis. These results suggest that Hispanic men and Hispanic patients exposed to HIV by drug use and heterosexual sex should receive special attention when interventions to improve access to care for Hispanic patients who are HIV infected are considered.

We were surprised by the weak associations between access to care and acculturation, survey language, and citizenship status. Language was not significantly associated with any access variable, and acculturation and citizenship status were significant in only 1 regression each. Future research should seek to explain these findings.

This study had limitations. First, data limitations prevented us from identifying the national origin of the Hispanic patients. This limitation was somewhat mitigated by the inclusion of geographic regions that were roughly correlated with concentrations of Hispanic populations of some national origins.[15] Second, Hispanic patients may have been less well represented in the HIV Cost and Services Utilization Study than were other racial/ethnic groups. The HIV Cost and Services Utilization Study sampled noninstitutionalized persons receiving care for HIV, whereas Hispanic persons are overrepresented among the incarcerated and the uninsured (thus, not receiving care).[4]

This study should alert policymakers and researchers to important sociodemographic subgroup differences among Hispanic patients who are HIV positive. Future research should avoid the inclusion of Hispanic patients without characterizing Hispanic subgroups; otherwise, these studies risk obscuring important subgroup variations. ■

About the Authors

Leo S. Morales, William E. Cunningham, Ronald M. Andersen, Terry T. Nakazono, and Martin F. Shapiro are with the University of California at Los Angeles. Leo S. Morales and Martin F. Shapiro are also with RAND Health, Santa Monica, Calif. Frank H. Galvan is with the Charles R. Drew University of Medicine and Science, Los Angeles, Calif.

Requests for reprints should be sent to Leo S. Morales, MD, PhD, UCLA Medicine/GIM, 911 Broxton Ave, Los Angeles, CA 90024 (e-mail: morales@rand.org).

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Contributors

L.S. Morales and W.E. Cunningham led the analysis for this study, with assistance from F.H. Galvan, R.M. Andersen, and T.T. Nakazono. L.S. Morales led the writing of this brief. M.F. Shapiro and W.E. Cunningham conceived the study and supervised all aspects of its implementation. All of the authors helped to conceptualize ideas and interpret findings and reviewed drafts of the brief.

Human Participant Protection

The RAND institutional review board reviewed all procedures, forms, and materials used in this study. Subjects were asked for informed consent for participation in the study.

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TABLE 2—Subgroup Differences in Odds Ratios Among Hispanic Patients for Access to Medical and Dental Care, After Control for All Independent Variables and CD4 Cell Count

	Odds Ratios (95% CI)								
	Poor Access to Care[a]	No Usual Source of Care at Time of HIV Diagnosis	3 Ambulatory Visits in 6 Mo	≥1 Emergency Department Visit(s) Without Associated Hospital Stay	Low Ratings of Quality of Care[b]	No Highly Active Antiretroviral Therapy by December 1996	No Highly Active Antiretroviral Therapy by Second Survey	No Usual Source of Dental Care	Difficulty Obtaining Needed Dental Care
Gender									
Female	0.53 (0.31, 0.90)*	0.33 (0.19, 0.60)*	0.39 (0.19, 0.80)*	2.83 (1.12, 7.15)*	1.36 (0.65, 2.86)	1.04 (0.60, 1.79)	2.20 (1.22, 3.99)*	0.69 (0.35, 1.36)	0.96 (0.53, 1.72)
Male	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00
Age, y									
18–30	1.67 (0.79, 3.51)	2.29 (0.92, 5.68)	0.67 (0.35, 1.32)	1.98 (0.71, 5.50)	1.24 (0.37, 4.15)	1.77 (0.83, 3.79)	1.49 (0.49, 4.49)	1.28 (0.60, 2.77)	1.23 (0.41, 3.65)
31–40	1.33 (0.72, 2.43)	1.36 (0.72, 2.56)	0.91 (0.54, 1.55)	1.15 (0.68, 1.93)	1.15 (0.58, 2.27)	1.60 (0.97, 2.64)	1.16 (0.58, 2.35)	0.93 (0.49, 1.76)	2.22 (0.72, 6.84)
≥41	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00
Education, y									
<12	1.78 (0.92, 3.43)	1.35 (0.72, 2.54)	0.94 (0.60, 1.48)	1.83 (0.82, 4.09)	1.06 (0.66, 1.71)	1.22 (0.75, 2.00)	0.38 (0.15, 1.02)	1.37 (0.71, 2.66)	1.29 (0.78, 2.14)
≥12	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00
Insurance status									
Uninsured	2.24 (1.18, 4.25)*	1.04 (0.49, 2.22)	1.60 (0.93, 2.75)	0.63 (0.38, 1.03)	1.00	1.00	1.00	1.00	1.00
Any insurance	1.00	1.00	1.00	1.00	0.76 (0.41, 1.39)	0.94 (0.44, 2.01)	0.91 (0.38, 2.18)	1.17 (0.76, 1.82)	0.92 (0.47, 1.81)
Exposure to HIV risk									
Injection drug use	0.83 (0.44, 1.58)	4.20 (1.72, 10.24)*	1.46 (0.63, 3.38)	1.04 (0.41, 2.63)	2.05 (0.76, 5.55)	1.68 (0.49, 5.84)	1.86 (0.55, 6.34)	0.99 (0.50, 1.94)	1.58 (0.77, 3.27)
Heterosexual sex	0.71 (0.29, 1.71)	2.73 (1.11, 6.68)*	2.96 (1.24, 7.09)*	0.75 (0.25, 2.27)	0.71 (0.30, 1.68)	1.18 (0.51, 2.75)	0.57 (0.23, 1.38)	1.21 (0.60, 2.44)	1.09 (0.47, 2.50)
Other	1.20 (0.39, 3.72)	1.89 (0.73, 4.92)	2.18 (0.60, 7.84)	0.59 (0.17, 2.09)	1.08 (0.33, 3.54)	2.23 (0.91, 5.43)	0.58 (0.20, 1.69)	2.59 (1.03, 6.48)*	2.65 (0.82, 8.52)
Male-to-male sex	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00
Region									
Northeast	1.91 (0.86, 4.21)	0.53 (0.25, 1.09)	1.38 (0.66, 2.88)	0.86 (0.42, 1.77)	0.97 (0.45, 2.12)	2.00 (0.86, 4.60)	2.33 (1.01, 5.36)*	0.89 (0.52, 1.54)	0.82 (0.45, 1.47)
Midwest	. . .	. . .	. . .	. . .	. . .	. . .	. . .	. . .	. . .
South	2.56 (1.24, 5.30)*	1.90 (0.66, 5.51)	0.94 (0.45, 1.94)	1.32 (0.58, 2.97)	0.49 (0.34, 0.72)*	1.33 (0.63, 2.83)	0.60 (0.30, 1.19)	1.27 (0.77, 2.10)	2.42 (1.02, 5.76)*
West	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00
Acculturation									
Less acculturated	1.35 (0.75, 2.45)	1.00 (0.43, 2.33)	1.07 (0.60, 1.92)	1.24 (0.69, 2.21)	1.35 (0.72, 2.55)	2.11 (0.90, 4.96)	1.03 (0.49, 2.17)	1.33 (0.70, 2.54)	2.01 (1.15, 3.53)*
More acculturated	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00
Survey language									
Spanish	1.91 (0.80, 4.54)	1.14 (0.40, 3.26)	1.42 (0.47, 4.32)	0.57 (0.15, 2.19)	1.38 (0.58, 3.27)	1.22 (0.34, 4.39)	1.71 (0.32, 9.21)	1.21 (0.48, 3.06)	0.77 (0.14, 4.07)
English	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00
US citizenship									
Noncitizen	1.13 (0.63, 2.03)	2.10 (0.84, 5.26)	0.92 (0.51, 1.66)	0.89 (0.31, 2.55)	1.06 (0.58, 1.93)	1.16 (0.44, 3.09)	0.60 (0.21, 1.69)	0.46 (0.24, 0.91)*	1.42 (0.73, 2.78)
Citizen	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00
CD4 cell count, mm^3									
0–49	1.54 (0.45, 5.23)	1.27 (0.64, 2.56)	1.65 (0.75, 3.64)	0.89 (0.42, 1.87)	0.90 (0.29, 2.79)	0.24 (0.11, 0.53)*	0.20 (0.08, 0.51)*	1.04 (0.47, 2.34)	2.93 (0.67, 12.85)
50–199	1.66 (0.54, 5.07)	1.08 (0.57, 2.05)	2.55 (0.67, 9.68)	0.88 (0.36, 2.12)	1.28 (0.53, 3.07)	0.32 (0.14, 0.74)*	0.35 (0.12, 1.02)	1.11 (0.39, 3.19)	3.09 (0.62, 15.48)
200–499	1.68 (0.76, 3.74)	0.96 (0.41, 2.26)	3.06 (1.19, 7.88)*	0.72 (0.32, 1.63)	1.83 (0.64, 5.23)	0.85 (0.44, 1.65)	0.70 (0.34, 1.44)	1.17 (0.46, 2.96)	1.69 (0.47, 6.07)
≥500	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00

Note. CI = confidence interval.
[a]Poor access to care indicated by a score ≤75 on 0–100 scale.
[b]Low ratings of quality care indicated by a score <5 on 1–5 scale.
*P < .05.

Predictors of Risky Sexual Behavior Among Young African American Men Who Have Sex With Men

Trevor Hart, PhD, John L. Peterson, PhD, and The Community Intervention Trial for Youth Study Team

This study examined the prevalence and correlates of unprotected anal intercourse among 758 young African American men who have sex with men. A quarter of the sample reported unprotected anal intercourse in the past 3 months; nonsupportive peer norms and not carrying condoms predicted risky sexual behavior. Effective interventions are needed that promote the use of condoms by changing peer norms and encouraging carrying condoms. (*Am J Public Health.* 2004;94:1122–1123)

After 20 years, the HIV epidemic continues to disproportionately affect men who have sex with men (MSM) in the United States.[1] HIV incidence and prevalence are pronounced among young MSM,[2] especially among African American men.[3–7] We examined the correlates of risky sexual behavior among a large community sample of young African American MSM. Data are presented on the HIV prevalence and associated sexual risks in young MSM.

METHODS

Participants and Procedures

Venue sampling was used to recruit participants (N=778) in the Atlanta, Ga, site of the Community Intervention Trial for Youth between 1999 and 2001 from a variety of venues (e.g., clubs, organizations, coffeehouses, public parks) frequented by African American MSM.[4,8] Participants were aged 18 to 25 years, were African American, and reported sexual contact with a man within the past year. Of the eligible participants (N=921), 84% (n=778) agreed to be interviewed. Analyses reported here are based on the 758 participants who answered all of the questions for the current study. Respondents were interviewed anonymously by trained African American interviewers and received a $15 reimbursement.

Measures

Respondents reported unprotected insertive anal intercourse and unprotected receptive anal intercourse in the past 3 months by answering questions with high test-retest reliability.[9,10] Respondents also reported their sexual identity, their HIV antibody status, whether they were carrying a condom, and their perceptions of peer norms regarding condom use (α=.79).[11]

Statistical Analyses

Univariate and multivariate logistic regressions were used to examine predictors of unprotected insertive and receptive anal intercourse in the past 3 months among those practicing anal intercourse.

RESULTS

Table 1 presents the demographic characteristics of the sample. Regarding risky sexual behavior, 26.5% (n=201) engaged in unprotected anal intercourse. Approximately 16.5% engaged in unprotected insertive anal intercourse, and 18.6% engaged in unprotected receptive anal intercourse. Participants with main partners were more likely than those without main partners to have had unprotected insertive anal intercourse (25.6% vs 12.1%) (odds ratio [OR]=2.50; 95% confidence interval [CI]=1.26, 4.97; $P<.01$) and unprotected receptive anal intercourse (30.8% vs 8.8%) (OR=4.62; 95% CI=2.14, 9.99; $P<.001$).

Demographic variables (age, educational level, and employment status), sexual identity, condom carrying, and peer norms were examined as predictors of unprotected insertive anal intercourse and unprotected receptive anal intercourse. When only participants who engaged in receptive anal intercourse were selected, not carrying condoms was associated with increased likelihood of unprotected receptive anal intercourse (OR=2.75; 95% CI=1.35, 5.60; $P<.01$). Low peer norms were associated with increased likelihood of unprotected receptive anal intercourse (OR=2.14; 95% CI=1.32, 3.47; $P<.05$). Demographic variables and sexual identity did not predict unprotected receptive anal intercourse. When only participants who engaged in insertive anal intercourse were selected, low peer norms were associated with increased likelihood of unprotected insertive anal intercourse (OR=1.90; 95% CI=1.15, 3.14; $P<.05$). All other variables were not asso-

TABLE 1—Demographic Characteristics of the Sample (N=758)

	%
Age,[a] y	
18–21	49.6
22–25	50.4
Education,[b] y	
<12	5.1
12	27.2
13–15	53.5
16	11.2
≥17	3.1
Born in United States	
Yes	94.1
No	5.9
Employment status	
Full-time	60.5
Part-time	22.8
Unemployed	16.6
Sexual identity	
Gay	53.4
Bisexual	32.6
Heterosexual	0.8
Undecided	5.6
Other[c]	7.8
HIV serostatus	
Seropositive	2.0
Seronegative	81.4
Unknown	16.6

Note. Figures may not add to 100% owing to rounding.
[a]Mean = 21.56 y; SD = 2.08.
[b]Mean = 13.58 y; SD = 1.67.
[c]The vast majority of men in this group refused to identify using a sexual label.

ciated with unprotected insertive anal intercourse.

All variables significantly predicting unprotected receptive anal intercourse were entered into a multivariate logistic regression. Both not carrying condoms (OR= 3.48; 95% CI=1.58, 7.66; $P<.01$) and low peer norms (OR=2.43; 95% CI=1.41, 4.22; $P<.01$) predicted increased risk of unprotected receptive anal intercourse. Hierarchical multivariate logistic regressions did not find significant interactions among predictor variables.[12]

DISCUSSION

The prevalence of unprotected anal intercourse was moderately high (26.5%) among our sample of 758 young African American MSM; 18.6% had engaged in unprotected receptive anal intercourse. This is especially notable given the greater relative risk of unprotected receptive anal intercourse compared with unprotected insertive anal intercourse for HIV transmission.[13]

The effect of peer norms on risky behavior indicates the unique contribution of social norms to risky sexual behavior among young African American MSM and is consistent with prior research.[14,15] This finding suggests the need to strengthen social norms for condom use in the communities where the men reside. Interestingly, the effect of carrying condoms was found for reduced risk of unprotected receptive anal intercourse but not for unprotected insertive anal intercourse. These men may be aware of increased HIV risk during unprotected sexual intercourse as a receptive partner. However, this strategy would be less effective for men who expected to engage in insertive anal intercourse but were HIV seropositive and unaware of their serostatus.[16] More interventions are needed that promote knowledge of serostatus among young African American MSM who engage in insertive anal intercourse.

Regarding study limitations, data on sexual behavior were gathered by self-report and therefore were subject to social desirability effects despite efforts to reduce such bias. Despite the strength of our random sampling strategy, the venues sampled may not represent the entire range of settings in which African American men who engage in same-sex behavior may be found. Nonetheless, this study, one of the first to use a large sample of young African American MSM, suggests that changing peer norms to make them more supportive of condom use and encouraging sexually active men to carry condoms may improve HIV intervention in this vulnerable population. ■

About the Authors

Trevor Hart is with the School of Medicine, Emory University, Atlanta, Ga. John L. Peterson is with the Department of Psychology, Georgia State University, Atlanta.

Requests for reprints should be sent to John L. Peterson, PhD, Department of Psychology, MSC 2A1155, 33 Gilmer St SE, Unit 2, Georgia State University, Atlanta, GA 30303 (e-mail: jpeterson@gsu.edu).

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Contributors

All authors contributed equally to the conception of the study, data analysis, and writing of the brief.

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Human Participant Protection

The institutional review board at the Centers for Disease Control and Prevention and at each of the 8 collaborating research institutions reviewed and approved the human subjects protocol for this study.

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Syphilis Testing in Association With Gonorrhea/Chlamydia Testing During a Syphilis Outbreak

Marc B. Rosenman, MD, Stephanie K. Kraft, MD, MPH, Jaroslaw Harezlak, MS, Barbara E. Mahon, MD, MPH, Barry P. Katz, PhD, Jane Wang, PhD, and Janet N. Arno, MD

We used an electronic medical records system retrospectively to evaluate how frequently, in a public hospital and its clinics, combined gonorrhea/chlamydia tests were accompanied by a syphilis test before and during a syphilis outbreak. Among 70 330 gonorrhea/chlamydia tests (1996–2000), the proportion with a syphilis test increased from 13% (preoutbreak) to 50% (intervention period) for men and from 6% to 13% for nonpregnant women. The increased syphilis testing coincided with a multifaceted public health intervention. (*Am J Public Health.* 2004;94:1124–1126)

In 1998, as the Centers for Disease Control and Prevention called for eliminating syphilis from the United States,[1] an outbreak was beginning in Indianapolis, Ind (Marion County). The reported annual case rate in the county peaked in 1999 at 50 per 100 000,[2] whereas the national rate was 2.5 per 100 000.[3]

Because symptoms can be minimal or absent in the early stages of syphilis, screening is central to elimination efforts; inadequate screening has been implicated in syphilis outbreaks.[4–6] In response to the Indianapolis outbreak, the Marion County Health Department and the community implemented a multifaceted program, designed primarily to increase early case detection. Some interventions involved encouraging clinicians who suspected other sexually transmitted diseases (STDs) to test for syphilis also.

We report a longitudinal, descriptive analysis of syphilis tests performed in association with gonorrhea/chlamydia tests before and during the public health response in Indianapolis.

METHODS

Public Health Interventions (1999–2000)

A letter reporting that a syphilis outbreak was in progress was sent to each primary care physician in Marion County (March 1, 1999). A community-based coalition was organized. Media coverage; presentations at major hospitals; and focused efforts at high-prevalence clinics, homeless shelters, substance abuse treatment centers, and hospital emergency departments were key components. At Wishard Hospital, the county's public hospital and a major source of cases, computerized feedback to promote syphilis testing was implemented in the emergency department (September 1999); for patients who resided in a high-prevalence zip code, who had a history of injection drug abuse, or who had an STD or STD symptom entered on the current problem list, the electronic discharge orders system displayed a message asking physicians to consider ordering a syphilis test.

A Marion County Health Department analysis found that many patients with syphilis also had a history of other STDs; one of Marion County Health Department's recommendations, posted in the Wishard Hospital emergency department and mailed to clinicians of selected specialties (June 1999; July 2000), was that clinicians screen for syphilis when they suspected other STDs.

Syphilis Test Data

We studied Wishard Hospital and its neighborhood clinics. Electronic data were extracted from the Regenstrief Medical Records System.[7] We identified all occurrences of combined gonorrhea/chlamydia tests (the tests used to screen for gonorrhea/chlamydia) between January 1, 1996, and November 22, 2000. We then determined the proportion of these tests in which the patient also had a syphilis test within 7 days. Pregnant women and patients younger than 12 years were excluded. Occurrences, not results, of the tests were analyzed. The data were categorized into the preoutbreak period (January 1, 1996, to March 31, 1998), the preintervention outbreak period (April 1, 1998, to February 28, 1999), and the intervention period (March 1, 1999, to November 22, 2000). Syphilis testing was analyzed by clinic location, clinician specialty, and patient race and zip code.

Analyses were performed with SAS, Version 8.1 (SAS Institute Inc, Cary, NC), and SPSS, Version 10.0 (SPSS Inc, Chicago, Ill). Units of analysis were gonorrhea/chlamydia testing encounters. Because the electronic data represent a complete listing of encounters, no variation due to sampling occurred; thus, formal statistical testing was not conducted.

RESULTS

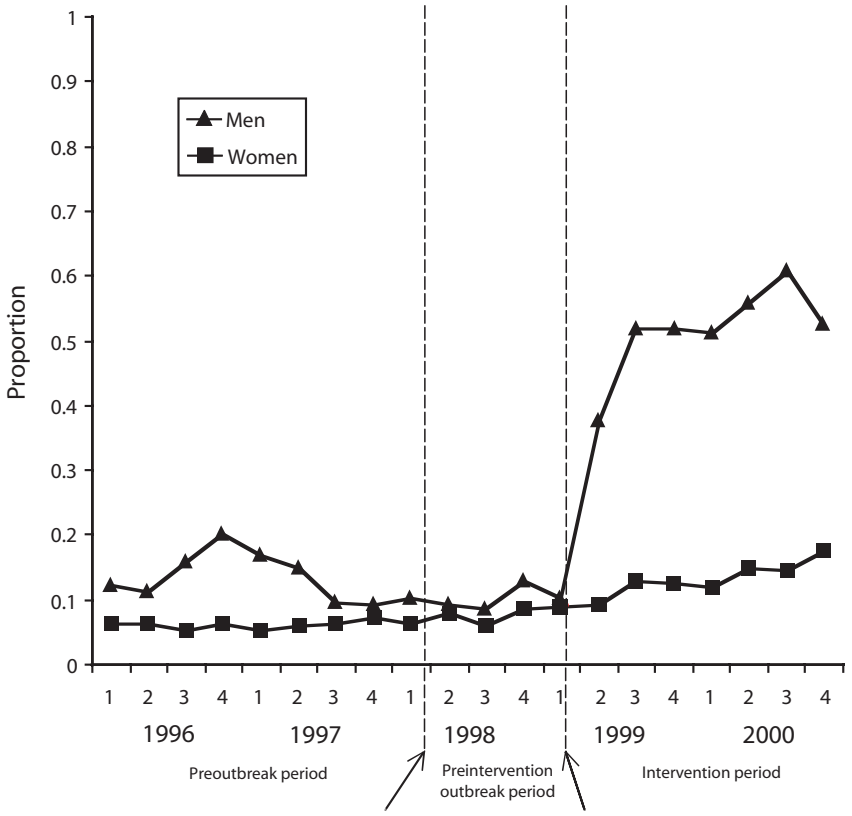
We identified 70 330 gonorrhea/chlamydia testing encounters (38 579 patients; mean age at testing=29 years; 93% women).

The proportion of gonorrhea/chlamydia testing encounters accompanied by a syphilis test increased over time. The trends differed by gender (Figure 1). From the preoutbreak to the intervention period, the syphilis test rate (proportion of gonorrhea/chlamydia testing encounters with a syphilis test within 7 days) increased among women from 6% to 13% and among men from 13% to 50%. Test rates in Hispanic, African American, and White men increased to 58%, 53%, and 40%, respectively (Table 1). During the intervention period, test rates were highest in urgent visit locations (men, 64%; women, 15%).

DISCUSSION

This study of 70 330 gonorrhea/chlamydia testing encounters in a public hospital and its clinics showed that syphilis testing increased during a public health campaign to control a syphilis outbreak. Whether the interventions caused the increase in testing and whether screening for syphilis when testing for other STDs was an effective strategy cannot be answered by this study; additional studies are under way.

Syphilis testing increased most dramatically in men, although they accounted for few of the study encounters. Because chlamydia



Note. The data are for encounters (January 1, 1996, to November 22, 2000) at a large, urban, public hospital in Marion County, Ind, and are divided by calendar quarter and by patients' gender (pregnant women are excluded). The vertical dotted lines divide the study into the preoutbreak period (January 1, 1996, to March 31, 1998), the preintervention outbreak period (April 1, 1998, to February 28, 1999), and the intervention period (March 1, 1999, to November 22, 2000).

FIGURE 1—Proportion of gonorrhea/chlamydia tests that were accompanied by a syphilis test.

screening is routine in women,[8,9] our inclusion criterion—gonorrhea/chlamydia testing—probably identified many asymptomatic women. In contrast, many of the men tested for gonorrhea/chlamydia likely had specific STD symptoms.[10] Such symptoms in men may have prompted clinicians to screen them for syphilis. Although the gender differences observed in syphilis testing might have resulted from baseline differences in symptoms, our syphilis testing rates among patients *evaluated* for gonorrhea/chlamydia are consistent with reports that among those *treated* for other STDs, men more often than women also were tested for syphilis.[11,12]

The higher intervention period testing rate among African American and Hispanic men is only partially explained by local epidemiology. Although the outbreak disproportionately affected heterosexual African Americans, Hispanic men, whose infection rate was not disproportionate, also were tested more frequently.

The largest increase in syphilis testing occurred in urgent visit locations. Other STD studies have suggested that emergency department encounters might represent the only opportunity to diagnose syphilis in some persons at high risk.[13,14] ■

About the Authors

Marc B. Rosenman is with the Department of Pediatrics, Indiana University School of Medicine, Indianapolis. Stephanie K. Kraft is with the Department of Medicine, University of Colorado School of Health Sciences, Denver. Jaroslaw Harezlak is with the Department of Biostatistics, Harvard University School of Public Health, Boston, Mass. Barbara E. Mahon is with the Departments of Epidemiology and Pediatrics, Boston University Schools of Public Health and Medicine, Boston, Mass. Barry P. Katz is with the Department of Medicine, Indiana University School of Medicine, Indianapolis. Jane Wang is with Regenstrief Institute, Indiana University School of Medicine, Indianapolis. Janet N. Arno is with Indiana University School of Medicine, Indianapolis, and the Bell Flower Clinic of Marion County Health Department, Indianapolis, Ind.

Requests for reprints should be sent to Marc B. Rosenman, MD, Indiana University School of Medicine, Riley Hospital for Children, 699 West Dr, Room 330, Indianapolis, IN 46202 (e-mail: mrosenma@iupui.edu).

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Contributors

M.B. Rosenman and S.K. Kraft led the analysis team. J. Harezlak, B.E. Mahon, and B.P. Katz analyzed the data and helped write the brief. J. Harezlak also programmed the data management software. J. Wang extracted the data from the electronic medical records system and assisted with the analyses of the data. J.N. Arno conceived the study and supervised the analyses and the writing of the brief. All authors helped to conceptualize ideas, interpret findings, and review drafts of the brief.

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Human Participant Protection

The institutional review board of Indiana University–Purdue University at Indianapolis approved the study.

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TABLE 1—Proportion (%) of Gonorrhea/Chlamydia Tests With an Accompanying Syphilis Test, by Patient or Clinic Characteristics, Period, and Patients' Gender[a]

	Preoutbreak Period		Preintervention Outbreak Period		Intervention Period	
	Women	Men	Women	Men	Women	Men
Patients' race						
Black	1032/16 234 (6%)	198/1486 (13%)	486/6851 (7%)	69/641 (11%)	2067/15 364 (13%)	744/1401 (53%)
White	530/9407 (6%)	50/373 (13%)	326/3711 (9%)	21/190 (11%)	1114/8325 (13%)	159/400 (40%)
Hispanic	30/593 (5%)	8/62 (13%)	30/488 (6%)	4/43 (9%)	155/1735 (9%)	80/137 (58%)
Other	40/555 (7%)	4/39 (10%)	27/289 (9%)	2/17 (12%)	74/545 (14%)	24/52 (46%)
Missing	34/490 (7%)	6/61 (10%)	28/285 (10%)	3/24 (13%)	65/484 (13%)	9/48 (19%)
Clinic location						
Emergency department/urgent visit	515/8582 (6%)	170/1315 (13%)	285/3727 (8%)	33/503 (7%)	1258/8325 (15%)	682/1060 (64%)
Hospital clinic	540/11 916 (5%)	29/213 (14%)	228/4572 (5%)	26/137 (19%)	775/8934 (9%)	112/282 (40%)
Neighborhood clinic	395/4283 (9%)	41/236 (17%)	302/2450 (12%)	27/153 (18%)	1110/7218 (15%)	77/287 (27%)
Other or missing	216/2499 (9%)	26/257 (10%)	82/875 (9%)	12/123 (10%)	332/1977 (17%)	145/410 (35%)
Clinician specialty						
Internal medicine	168/4145 (4%)	151/1181 (13%)	113/1950 (6%)	43/524 (8%)	572/4333 (13%)	572/1072 (53%)
Obstetrics/gynecology	1217/18 942 (6%)	. . .	666/8021 (8%)	. . .	2308/17 943 (13%)	. . .
Adolescent medicine	6/122 (5%)	14/47 (30%)	16/212 (8%)	24/72 (33%)	59/567 (10%)	47/137 (34%)
Pediatrics	21/164 (13%)	9/49 (18%)	10/91 (11%)	5/41 (12%)	24/283 (8%)	34/97 (35%)
Other or missing	254/3907 (7%)	92/731 (13%)	92/1350 (7%)	27/275 (10%)	512/3327 (15%)	360/719 (50%)
Area of residence						
High-prevalence zip code	476/7163 (7%)	91/641 (14%)	221/2961 (7%)	28/279 (10%)	943/6453 (15%)	318/610 (52%)
Any other or missing zip code	1190/20 116 (6%)	175/1380 (13%)	676/8663 (8%)	71/636 (11%)	2532/20 000 (13%)	698/1428 (49%)

[a]Pregnant women were excluded.

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Psychosocial Characteristics of New York City HIV-Infected Women Before and After the Advent of HAART

Karolynn Siegel, PhD, Daniel Karus, MS, and Laura Dean, MEd

Objectives. We compared level of psychosocial distress of HIV-infected women living in New York City before the advent of highly active antiretroviral therapy (HAART) with level of psychosocial distress reported by women living with the disease after the use of HAART became widespread.

Methods. Data were from HIV-positive New York City women aged 18 to 50 years, enrolled through outreach and self-referral. We compared scores on measures of psychological state and psychosocial adjustment to illness of 74 women interviewed in 1994–1996 with scores of a matched group of 74 women interviewed in 2000–2002.

Results. A significant difference between groups was found only with regard to adjustment to illness in their domestic environment, with poorer adjustment reported, on average, by women in the 2000–2002 sample.

Conclusions. Although new treatments have significantly improved the physical health of those living with HIV/AIDS, no evidence was found that these treatments significantly improved psychological health for women, regardless of history of protease inhibitor use. (*Am J Public Health.* 2004;94:1127–1132)

It is widely assumed that highly active antiretroviral therapy (HAART) has greatly altered the psychological experience of living with HIV/AIDS. HIV disease is now commonly viewed as being a chronic illness rather than acute and life-threatening as new antiviral agents dramatically reduce viral load and increase CD4 cell counts, thereby reducing the risk of opportunistic infections and extending survival.[1,2] For others who do not yet need these medications, their existence nonetheless may offer psychological reassurance that effective therapies will be available when needed. As a result, it has been argued that recent treatment advances have "reinserted the word 'hope' into discussions about AIDS"[3(p161)] and afforded many infected individuals the opportunity for a "second life."[4] The prospect of extended survival and reduced symptomatology has allowed many people to consider returning to work or school and to contemplate either entering into or leaving relationships.[3,5] Although the effect of new treatments on pregnancy decision making remains relatively unexplored, in light of the demonstrated efficacy of the medications, HIV-positive women may now be more likely to choose to become pregnant.[6]

At the same time, opportunities created by new treatments have created new, potentially stressful uncertainties.[4,7] For example, people benefiting from treatments may worry that returning to work will jeopardize their receipt of health insurance and their chances of regaining disability entitlements should their health again begin to deteriorate. In addition, contemplating having a baby might raise concerns that the demands of parenting could compromise one's health.

Furthermore, a substantial proportion of infected individuals will not benefit from new antiviral medications, will do so for only a short period, or will have to terminate treatment because of intolerable side effects. People who do benefit may experience a kind of "survivor guilt" when other people do not benefit.[5,7] Patients unable to tolerate the side effects may engage in self-blame.[5] Furthermore, it has been argued that when treatment benefits are not realized or sustained, patients may experience hopelessness and anger or feel that they were misled about the medications' potential efficacy and may experience even greater psychological distress than in the past.[5,8]

Despite much speculation about the potential effect of HAART availability on the psychosocial well-being of infected individuals, empirical investigations of this issue are recent and few. In one study, investigators interviewed a group of 173 gay/bisexual men with symptomatic HIV/AIDS before and after the availability of protease inhibitors.[9] The sample as a whole showed a clinically modest but statistically significant decline on all measures of psychological distress over time after control for CD4 cell count, HIV symptoms, physical limitations, and social support. When the investigators further compared participants with improved medical markers (i.e., higher CD4 counts or lower viral load) with participants without improvement, they found no significant differences in hopelessness or quality of life. Furthermore, the improved group showed no change in depressive symptoms, whereas the unimproved group exhibited fewer depressive symptoms over time. The investigators offered several possible explanations for these counterintuitive findings: (1) individuals in the improved group were more immunosuppressed at baseline and thus despite showing improvement may have remained more cautious about their medical outlook; (2) the unanticipated opportunity for a "second life" may have created a greater sense of uncertainty; or (3) more of the individuals in the improved group were taking combination therapy, regimens of which are onerous and have distressing side effects.

In another investigation[10] of 456 HIV-infected individuals (433 of whom were men) receiving antivirals, among participants who had completed at least 2 annual surveys (1 before initiating treatment with a protease inhibitor and 1 after), the percentage of patients with a score indicative of probable clinical depression declined, from 52% to 46%. Although this change was not statistically significant, there were also significant declines in scores on the total Center for Epidemiological

Studies–Depression Scale (CES-D), as well as improved scores on the Depressive Affect, Positive Affect, and Somatic/Vegetative State subscales.

In still another study,[11] this time of 125 HIV-infected adults (mostly homosexual or bisexual men), depressive symptoms were assessed at 6-month intervals over a 2-year period. The investigators found a pattern of declining scores (denoting less depression) on the Beck Depression Inventory over time, especially after the third assessment (12 months after baseline), by which time 51% of study participants were receiving HAART. These findings, however, must be interpreted with caution because of study limitations (e.g., substantial dropout by the 6-month assessment) and because of the different number of cases included at each assessment point (although the investigators argue that the same pattern was seen among the 27 cases for which data were available at each assessment point).

The question of whether individuals currently living with HIV experience levels of psychosocial distress comparable to the levels experienced by individuals living with the disease before the advent of HAART is an important one because the widespread perception that such distress has significantly diminished among infected individuals may prompt a reduction in mental health resources targeted to this population. In the case of HIV-infected women, this situation could have particularly unfortunate consequences, given the recently demonstrated association between depressive symptomatology and survival.[12] To investigate this issue, we compared 2 matched samples of women living with HIV/AIDS, the first interviewed between 1994 and 1996 and the second interviewed between 2000 and 2002.

METHODS

Study Design

The data presented here are from 2 samples recruited to examine women's adaptation to living with HIV infection as a chronic illness. The first sample (n=146) was interviewed from October 1994 to November 1996.[13,14] In March 2000, we began interviewing a second group of women to compare their experiences living with HIV/AIDS with the experiences of the sample interviewed earlier, before the availability of protease inhibitors. The same recruitment methods and sources were used to obtain both samples. To protect participant confidentiality, we relied on self-referral. Community-based organizations serving HIV-infected women were given flyers describing the study and the eligibility criteria and listing a telephone number for interested individuals to call. Organizations were asked to post the flyers or to distribute them to potentially eligible women. Advertisements were also placed in the newsletters of prominent HIV-related organizations and in community-based newspapers with a general (non–HIV specific) audience. Some participants referred other participants to the study. Cooperating organizations from the 1994–1996 study were approached to assist with recruitment, and new organizations serving the same population were added to those initially contacted so as to increase the pool of available cases. In both time periods, the study protocol was approved by the sponsoring institutional review board.

In 1994–1996, quota sampling was used to obtain approximately equal numbers of African American, White, and Puerto Rican women and to ensure that within each ethnic/racial group there were approximately equal numbers of women who were asymptomatic, symptomatic, and diagnosed with AIDS. In 2000–2002, quota sampling was again used to yield an aggregate frequency distribution of women comparable to that obtained in the earlier study with regard to race/ethnicity and disease stage. Efforts were also undertaken to achieve a similar distribution with regard to 3 other variables used to match the samples: age (within 5 years), length of time since diagnosis (<2 years, 2–5 years, and >5 years), and injection drug use since 1977. Both groups met the same eligibility criteria.

To investigate the psychosocial effect of the availability of protease inhibitors on living with HIV, we chose to use a matched sample design rather than to attempt to follow the original (1994–1996) sample longitudinally, for a number of reasons. First, had we followed the 2000–2002 sample of women longitudinally into the HAART era and observed change in the outcome variables over time, it would be unclear what accounted for this change. For example, improvements might be attributable to the prospect of longer survival made possible by HAART and the attendant psychological benefits, but these improvements might also be accounted for by the women's accommodating themselves to the stress of HIV infection. Another disadvantage of a longitudinal design would have been significant attrition, both owing to death and to inability to contact women who were marginally housed or homeless. Because women lost to attrition may also have been the most depressed, the sample for the follow-up assessment might have been biased to overrepresent women with better psychological adjustment. The design choice of matching the 2 samples on several variables likely to be associated with psychological and psychosocial adjustment, including time since diagnosis, avoids these potential confounds. It does, however, have the drawback that one can hope to match women in the 2 samples on only a limited number of variables. This limitation leaves open the possibility that 1 or more variables associated with the outcomes of interest, but on which the samples were not matched, might account for any observed differences.

The sampling strategy used in 2000–2002 did not ensure a precise match of participants in both groups with regard to all 5 characteristics guiding the sample selection (i.e., race/ethnicity, disease stage, age, time since diagnosis, and history of injection drug use). However, given the potential importance of all of these variables for women's psychological and psychosocial adjustment, analyses presented here are restricted to women in 2000–2002 for whom such a precise match was found in the 1994–1996 group. Although protease inhibitors were not widely used at the time of the 1994–1996 study, 7 women in that study had received them while participating in clinical trials. Because the effect of the availability of such medications is the focus of this article, only the 139 women in 1994–1996 who had never taken protease inhibitors were used as potential matches. On the basis of these criteria, a precision match was found for a total of 74, or 61%, of

the 121 women interviewed in the later era (2000–2002).

Measures

Participants in both samples completed the same battery of standardized measures to assess psychological symptomatology and psychosocial functioning and adjustment to their illness. Depressive symptomatology was assessed with the CES-D.[15–20] The CES-D has a recommended cutoff point of 16 for identification of probable "caseness."[18] In addition to a summary measure (Cronbach α=.91 in 1994–96; α=.94 in 2000–02), it provides subscale scores on Depressive Affect (α=.86; α=.90), Positive Affect (α=.76; α=.86), Somatic/Vegetative State (α=.73; α=.75), and Interpersonal Distress (α=.78; α=.77). Self-esteem was assessed with the 10-item Rosenberg Self-Esteem Scale (SES), a widely used measure of self-acceptance with demonstrated reliability and convergent, discriminate, and predictive validity.[21,22] Acceptable reliability, as assessed with the Cronbach α, was found in both the 1994–1996 (α=.86) and 2000–2002 (α=.89) samples.

The Mental Health Inventory (MHI),[23] a reliable 38-item instrument, encompasses 8 hierarchically organized measures: the global Mental Health Index (α=.96; α=.97); a Psychological Distress scale (α=.95; α=.95) with subscales of Anxiety (α=.90; α=.90), Depression (α=.86; α=.84), and Loss of Behavioral/Emotional Control (α=.87; α=.88); and a Psychological Well-Being scale (α=.92; α=.95) with subscales of General Positive Affect (α=.91; α=.94) and Emotional Ties (α=.76; α=.87); and a single item assessing Life Satisfaction.

The Psychosocial Adjustment to Illness Scale (PAIS-SR) is a 46-item measure of social functioning and quality of adjustment in several clinically important domains applicable to a broad spectrum of chronic disorders.[24,25] The PAIS-SR yields adjustment scores for 7 specific domains: Health Care Orientation (α=.64; α=.47), Vocational Environment (α=.82; α=.63), Domestic Environment (α=.64; α=.69), Sexual Relationships (α=.75; α=.76), Extended Family Relations (α=.66; α=.72), Social Environment (α=.81; α=.86), and Psychological Distress (α=.82; α=.87).

TABLE 1—Characteristics of Women Before and After HAART: New York City, 1994–1996 and 2000–2002

	1994–1996 (n = 74)		2000–2002 (n = 74)	
	Mean ±SD	%	Mean ±SD	%
Educational attainment				
< High school		28		30
High school graduate		31		30
> High school		40		40
Employed		36		35
Household income > $25 000		22		20
No. of persons in household	2.4 ±1.3		2.4 ±1.2	
1 (respondent alone)		29		26
2		26		33
3		26		24
≥ 4		20		18
Marital status				
Married		19		14
Living with a partner		18		12
Widowed/divorced/separated		30		31
Single		34		43
Mother		74		84
Children live with her (restricted to mothers)		67		67
No. of illness-related symptoms	11.3 ±6.3		11.4 ±6.4	

Statistical Analysis

Paired *t* tests were used to compare scores before and after HAART on the CES-D, SES, MHI, and PAIS-SR. Comparisons of the groups' distributions for categorical variables were made using Pearson χ^2 tests or Fisher exact tests (for the association between pairs of dichotomous variables).

RESULTS

Subject Characteristics

Precision matching resulted in identical distributions in each sample with regard to race/ethnicity (40% African American, 28% Puerto Rican, and 31% White), disease stage (10% asymptomatic, 43% symptomatic, and 47% AIDS), any use of intravenous drugs since 1977 (46%), and length of time since the woman had first learned that she was HIV seropositive (8% <2 years, 23% 2–5 years, and 69% >5 years), and in virtually identical distributions with regard to age (mean ±SD for 1994–1996=36.4 ±5.3; mean ±SD for 2000–2002=36.9 ±5.1). As seen in Table 1, although individual women in each group were not precision-matched on other sociodemographic and disease-related characteristics, both groups had similar distributions with regard to educational attainment, employment status, household income, household size, marital status, parental status, and proportion living with children. The mean number of illness-related symptoms reported by women in the 1994–1996 group was virtually identical to the number reported by women in the 2000–2002 group.

Preliminary Analyses

Before conducting paired comparisons between groups, we used analysis of variance to compare the mean scores on each measure, of women in each time sample for whom a match was identified with the mean scores of the remaining women in that sample for whom no match was found. Analyses of women in each sample found no statistically significant differences ($P<.05$) between mean scores of matched and unmatched women on any scale or subscale of the CES-D, SES, MHI, or PAIS-SR. These findings indicate that in both 1994–1996 and 2000–2002, scores for women included in the paired comparisons were similar to scores for the remaining

TABLE 2—Measures of Depressive Symptomatology, Self-Esteem, and Mental Health Before and After HAART: New York City, 1994–1996 and 2000–2002

	1994–1996, Mean Score ±SD	2000–2002, Mean Score ±SD
Center for Epidemiological Studies–Depression Scale (CES-D)		
Total CES-D (n = 74)	19.17 ±11.49	21.85 ±13.06
CES-D subscales		
Depressive Affect (n = 71)	5.45 ±3.96	5.76 ±4.25
Positive Affect (n = 72)	8.53 ±2.85	7.39 ±3.78
Somatic/Vegetative State (n = 72)	6.71 ±3.86	7.32 ±3.95
Interpersonal Distress (n = 70)	1.01 ±1.52	1.33 ±1.67
Rosenberg Self-Esteem Scale (SES) (n = 74)	3.21 ±0.55	3.14 ±0.63
Mental Health Inventory (MHI)		
Mental Health Index (n = 70)	60.70 ±15.90	59.50 ±17.57
Psychological Distress Scale (n = 73)	35.12 ±16.80	37.47 ±17.53
Psychological Distress subscales (n ≥ 73)		
Anxiety	36.71 ±19.08	38.36 ±18.46
Depression	35.35 ±18.74	37.91 ±20.26
Loss of Behavioral/Emotional Control	31.14 ±17.37	33.81 ±19.53
Psychological Well-Being Scale (n = 70)	53.02 ±17.50	52.96 ±21.97
Psychological Well-Being subscales (n ≥ 72)		
General Positive Affect	52.66 ±18.55	51.78 ±21.94
Emotional Ties	58.89 ±26.14	57.08 ±31.87
Life Satisfaction item	53.24 ±21.52	53.24 ±24.16

women in their respective sample who were not matched.

Paired Comparisons of Matched Cases

Depressive symptomatology. The mean score on the summary CES-D did not differ significantly between the 2 samples; mean scores for both samples were well above the cutoff of 16 for probable caseness (Table 2). More than half of the women in both samples had scores of 16 or higher: 62% in 1994–1996 and 61% in 2000–2002 (Fisher exact test [1 *df*] = 0.054; *P* = .806). The mean scores of women in both groups also did not differ statistically with regard to the Depressive Affect, Positive Affect, Somatic/Vegetative State, or Interpersonal Distress subscales.

Self-esteem. Mean scores on the Rosenberg Self-Esteem Scale for women in the 1994–1996 and 2000–2002 groups are also presented in Table 2. Mean scores were virtually identical for both groups.

Mental health. No statistically or substantively significant difference was found in mean scores on the summary Mental Health Index between women in the 1994–1996 and the 2000–2002 groups (Table 2). Similarly, we observed no difference between group means for the Psychological Distress Scale or its subscales of Anxiety, Depression, and Loss of Behavioral/Emotional Control; the Psychological Well-Being Scale or its subscales of General Positive Affect and Emotional Ties; or the Life Satisfaction item.

Psychosocial adjustment/adaptation to illness. As with the measures of psychological adjustment, the mean scores for 6 of the 7 domains of psychosocial adjustment measured by the PAIS-SR did not differ significantly between the 1994–1996 and the 2000–2002 groups: Health Care Orientation, Vocational Environment, Sexual Relationships, Extended Family Relationships, Social Environment, and Psychological Distress (Table 3). However, a significant difference was found between the groups on the Domestic Environment subscale (paired *t* test [72 *df*] = 2.299; *P* = .024). On average, scores for women in the 2000–2002 group were higher than scores for women in the 1994–96 group, indicating poorer adjustment in the post-HAART group.

Protease Inhibitor Use and Psychosocial Adjustment to Illness

None of the matched women from the 1994–1996 group had ever used protease inhibitors. Among women in the 2000–2002 group, approximately equal proportions of women had never used protease inhibitors (37%), had previously used protease inhibitors but were not currently doing so (28%), or were currently using protease inhibitors (35%). Analysis of variance found no significant differences among these 3 subgroups on any scale or subscale of the SES, the MHI, or the PAIS-SR. Similarly, no significant differences were found among the 3 groups in mean scores for the summary CES-D or for 3 of its 4 subscales. However, a significant difference was found among the 3 groups with respect to scores for the Interpersonal Distress subscale ($F_{2,67} = 3.652$; *P* = .031); women who had previously used pro-

TABLE 3—Measures of Psychosocial Functioning and Adjustment to Illness and Health Care Before and After HAART: New York City, 1994–1996 and 2000–2002

Psychosocial Adjustment to Illness Scale (PAIS-SR) Subscales	1994–1996, Mean ±SD	2000–2002, Mean ±SD
Health Care Orientation (n = 72)	8.14 ±3.73	7.17 ±3.12
Vocational Environment (n = 74)	3.10 ±2.59	2.58 ±1.71
Domestic Environment (n = 73)*	5.30 ±3.28	6.78 ±4.06
Sexual Relationships (n = 73)	4.45 ±3.88	5.81 ±4.09
Extended Family Relationships (n = 73)	3.73 ±3.26	3.92 ±3.32
Social Environment (n = 73)	5.08 ±4.13	6.30 ±4.68
Psychological Distress (n = 66)	10.06 ±4.20	10.14 ±3.85

*$P < .05$.

tease inhibitors reported higher scores (mean ±SD=2.09 ±1.85) than women who had never used protease inhibitors (mean ±SD=0.93 ±1.47) or women who were currently using them (mean ±SD= 1.05 ±1.50).

DISCUSSION

Our findings do not support the notion that women currently living with HIV in New York City experience lower levels of psychosocial distress than similarly situated women who were living with HIV before the availability of HAART. The only statistically significant difference observed between women before and after HAART, which was on scores for the Domestic Environment subscale of the PAIS-SR, indicates greater difficulties in this domain for women in the current era. The Domestic Environment subscale measures several aspects of family living, including finances, relationship quality, communications, and physical disabilities. Our finding of few differences was somewhat surprising, given the improved survival afforded by HAART and the diminished stigmatization of AIDS[26] in the later period (2000–2002). Our findings, however, do not preclude the possibility that HAART availability has improved quality of life and well-being for HIV-infected women in other ways that the study did not measure (e.g., enhanced women's sense of control over the disease).

At least 2 possible explanations exist for the similarity in the scores of women from the 2 eras. One is that in addition to experiencing the stressors associated with living with HIV/AIDS, many of the women in both samples, most of whom were socioeconomically disadvantaged, faced numerous other life stressors independently associated with depression[27–29] (e.g., drug or alcohol addiction, violence, poverty, being the sole caregiver of 1 or more dependent children), some of which posed a more imminent threat to their psychological and physical well-being than did HIV. Indeed, many women who are at risk of contracting HIV or who are already infected do not view the disease as the most challenging stressor they contront.[29–31] For example, 1 study found that for many HIV-infected women, the problems associated with violence, separation from their children, and drug use were far more disruptive than their illness.[30] These multiple chronic stressors may produce such profound psychosocial distress that the availability of more effective treatments for HIV is not sufficient to meaningfully improve these women's psychosocial well-being.

An alternative explanation for the lack of group differences in adjustment is that because of HAART, women in the 2000–2002 group may have had their expectations raised regarding the various roles that they would be able to assume or resume (i.e., regaining custody of children, going back to school or work, becoming pregnant) as a result of improved health or delayed deterioration. However, realization of these goals and dreams may remain elusive, resulting in demoralization. Furthermore, the prospect of performing these roles is also likely to raise new fears and concerns among HIV-infected adults, such as about how the stresses of these roles may compromise their health and whether they will encounter discrimination in the workplace or be unemployable after a long hiatus.[32]

Subgroup analyses among women in the 2000–2002 group revealed similar scores for all but 1 CES-D subscale when women were grouped on the basis of their history of protease inhibitor use (currently using, had used in the past, or never used). Had we enough cases to divide the groups into subgroups, more differences may have emerged. For example, women who had previously used protease inhibitors included those who failed to realize treatment benefits, developed drug resistance, suffered unacceptable side effects, or had insufficient social support or residential stability to sustain adherence to the treatment regimen. These subgroups might differ from each other in important ways that might be related to psychological and psychosocial adjustment; we were not able to investigate such differences because of the relatively small sample size. Similarly, women currently taking protease inhibitors might include those seeing significant benefits; those realizing only modest gains, those experiencing very distressing side effects; and those tolerating the medications well, but for whom the drug's efficacy is low or unknown. Women who have not yet used these medications might include women who do not yet need them as well as women who may need them but reject the use of HAART because of its toxicity. Women who have not yet used protease inhibitors but who would be willing to do so in the future might also be experiencing distress as a result of not knowing whether they will benefit from these medications when they need them or whether they will be able to tolerate the side effects. The possibility of subgroup differences among these categories of infected adults should be explored in future studies with large samples.

Other limitations of the study may also account for the findings. The method used to classify women as having AIDS was based on having ever received a medical diagnosis of AIDS from a health practitioner or having a CD4 count less than 200. Some of the women with AIDS in the 2000–2002 group who are currently using or who had previously used protease inhibitor therapy may have experienced improvements in their immune systems that made them healthier at the time of the interview than the women with AIDS in the earlier period to whom they were matched. However, if this was the case, our finding of only 1 difference between the groups is even more surprising.

Despite the consistent similarity of mean scores in both groups on a wide array of measures, we cannot rule out the possibility that statistically significant differences do exist but could not be detected because of the small sample size. Still, the absence of group differences across such a wide array of measures does lend support to the conclusion that little change has occurred. Therefore, we regard these findings as suggestive and stress that they should be interpreted with caution. In any case, even if statistically significant differences were found, scores of women in both samples would still be indicative of very poor psychosocial adjustment.

Finally, the generalizability of the study findings may be limited by the fact that all of the women lived in the New York City metropolitan area, which has a relatively wide array of social services agencies and treatment facilities for HIV-infected adults. The psychological adjustment of women in more "resource-poor" regions of the country might

be significantly worse. Furthermore, to the extent that New York City is more ethnically diverse and that HIV-infected women living in New York are disproportionately poorer and are more likely to be women of color than HIV-infected women elsewhere, our results might not be reproducible in other geographical locations.

Despite improved treatments for HIV/AIDS, our findings indicate that there is still a very substantial proportion of HIV-infected women who are psychologically distressed and having difficulty adjusting to illness. Yet because of a widely held, unexamined assumption that living with HIV/AIDS in the era of HAART may be significantly less distressing than before the advent of protease inhibitors, there may emerge a growing tendency to overlook the psychological needs of infected individuals or to reduce mental health resources. The data presented here indicate that a substantial proportion of HIV-infected women continue to be at risk for poor psychosocial adjustment to illness and that we must continue to develop, evaluate, and disseminate interventions aimed at improving these women's mental health and quality of life. ■

About the Authors

Karolynn Siegel, Daniel G. Karus, and Laura Dean are with the Center for the Psychosocial Study of Health and Illness, Department of Sociomedical Sciences, Mailman School of Public Health, Columbia University, New York, NY.

Requests for reprints should be sent to Karolynn Siegel, PhD, Center for the Psychosocial Study of Health and Illness, Department of Sociomedical Sciences, Mailman School of Public Health, Columbia University, 100 Haven Ave, Tower 2, Suite 6A, New York, NY 10032 (e-mail: ks420@columbia.edu).

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Contributors

K. Siegel conceived the study and oversaw its implementation. L. Dean directed the study and was responsible for the fieldwork operation. D. Karus completed the data analyses. All authors helped to conceptualize ideas, interpret findings, write sections of the article, and review drafts.

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Human Participant Protection

The study protocol was approved by the Columbia Presbyterian institutional review board.

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Depressive Symptoms and AIDS-Related Mortality Among a Multisite Cohort of HIV-Positive Women

Judith A. Cook, PhD, Dennis Grey, BA, Jane Burke, MS, Mardge H. Cohen, MD, Alejandra C. Gurtman, MD, Jean L. Richardson, DrPH, Tracey E. Wilson, PhD, Mary A. Young, MD, and Nancy A. Hessol, MSPH

Objectives. We examined associations between depressive symptoms and AIDS-related mortality after controlling for antiretroviral therapy use, mental health treatment, medication adherence, substance abuse, clinical indicators, and demographic factors.

Methods. One thousand seven hundred sixteen HIV-seropositive women completed semiannual visits from 1994 through 2001 to clinics at 6 sites. Multivariate Cox and logistic regression analyses estimated time to AIDS-related death and depressive symptom severity.

Results. After we controlled for all other factors, AIDS-related deaths were more likely among women with chronic depressive symptoms, and symptoms were more severe among women in the terminal phase of their illness. Mental health service use was associated with reduced mortality.

Conclusions. Treatment for depression is a critically important component of comprehensive care for HIV-seropositive women, especially those with end-stage disease. (*Am J Public Health.* 2004;94:1133–1140)

Previous research has confirmed associations between depression and immune suppression and other negative health outcomes, such as disability and mortality.[1–3] Recently, attention has turned to the effects of depression on the health of individuals whose immune systems have been affected by HIV infection. Yet, the relationship between depression and HIV disease progression is not well understood. For example, Sambamoorthi et al.[4] found relationships between depression and HIV infection status, declines in immune function, accelerated disease progression, increased disability, shorter survival, and greater probability of death. Conversely, studies by Lyketsos et al.[5] and Vedhara et al.[6] challenge the characterization of depression as an independent or even a significant determinant of HIV disease progression. An additional complicating factor has been suggested by a recent study that found use of protease inhibitors reduces both depressive and clinical symptoms.[7]

The existence of a potential association between women's depression and HIV disease progression is of interest to both health care providers and patients for several reasons. First, women's rate of depression is twice as high as that of men among the general population.[8] Second, HIV-seropositive women who have high levels of depressive symptomatology are significantly less likely to use highly active antiretroviral therapies.[9] Third, depression is associated with poor adherence to antiretroviral treatment regimens,[10,11] which in turn is associated with poor disease outcomes, such as mortality.[12] Finally, depression is a significant predictor of non–AIDS-related deaths (e.g., those caused by accident, drug overdose, violence, and non–AIDS-associated malignancies) among HIV-seropositive women.[13]

Only 1 previous study of a cohort of HIV-seropositive women—the longitudinal study of the 4-site HIV Epidemiologic Research Study (HERS)[14]—has confirmed a link between chronic depressive symptomatology and poor AIDS-related outcomes. Among a cohort of HIV-seropositive women who were followed from 1993 through 2000 (demographic and clinical factors were controlled), the women who had chronic depressive symptoms were twice as likely to die as the women who reported no depressive symptoms or only intermittent ones.

We attempted to replicate and expand the HERS cohort findings by using the same variable definitions and types of statistical analyses and by exploring the effects of 3 additional factors: adherence to highly active antiretroviral treatment (HAART) and other HIV-related therapies, use of mental health services, and occurrence of depressive symptoms during the terminal phase of AIDS-related illness. Three research questions were addressed. First, do depressive symptoms predict time to AIDS-related mortality among a cohort of HIV-seropositive women? Second, does use of mental health services lower the likelihood of AIDS-related mortality? Third, do women in the terminal phase of their AIDS-related illnesses show higher likelihood than surviving women of meeting criteria for depression at the 2 study visits preceding their deaths?

METHODS

Study Background

Between October 1994 and November 1995, 2059 HIV-seropositive women were enrolled in the Women's Interagency HIV Study (WIHS) at 6 medical and university consortia sites nationwide: Brooklyn, NY; Bronx, NY; Chicago, Ill; Los Angeles, Calif; San Francisco, Calif; and Washington, DC. Over the next 7.5 years, participants completed WIHS study visits at 6-month intervals. Specific responses to items in the interview protocol prompted interviewers to offer respondents referrals to medical or psychosocial services, such as gynecologic care or substance abuse treatment.

Measures

Depressive symptoms. We used the Center for Epidemiologic Studies Depression Scale (CES-D),[15] a 20-item Likert-scaled instrument, to assess depressive symptoms. The CES-D

has excellent reliability, validity, and factor structure among numerous subgroups,[15] and it is commonly used in studies of HIV populations, including women.[7] Its sensitivity for the *Diagnostic and Statistical Manual of Mental Disorders, Third Edition*[16] *(DSM-III)*, diagnosis of major depression is excellent, in the 80% to 90% range, with somewhat lower specificity (70%–80%).[17,18] In an earlier analysis of the WIHS cohort's level of depressive symptoms, Cook et al.[9] demonstrated that various ways of analyzing the CES-D (the standard cutoff of 16, a more stringent cutoff of 23, and an interval-level version of the subscale that excluded somatic items similar to HIV symptoms) produced virtually identical associations with antiretroviral therapy use and with the woman's demographic characteristics. Thus, the standard cutoff score of 16 was used in our study.

We used 2 measures of longitudinal depressive symptoms to test the study hypotheses. First, following Ickovics et al.,[19] *depression chronicity* was defined as the proportion of study visits at which the women's self-reported CES-D scores met or exceeded the clinical cutoff for probable cases of depression. In this operationalization, or way of computing a depressive symptom variable, scores that indicated depression at 75% or more of the study visits were classified as *chronic,* 26% to 74% were classified as *intermittent,* and no more than 25% were classified as *none or few.* Second, following Lyketsos et al.'s[5] "conservative" definition, scores of 16 or higher on the CES-D at 2 consecutive study visits were used to define *recent depression.* In our study, this was operationalized as scoring above the cutoff (1) at the last 2 study visits preceding death among women with AIDS-related deaths, and (2) at the last 2 study visits completed for all surviving women. The first operationalization of *depression chronicity* was used to test hypotheses 1 and 2, and the second operationalization of *recent depression* was used to test hypothesis 3.

AIDS-related mortality. Information was collected on all participants' deaths, malignancies, tuberculosis, and AIDS. Cause of death was coded from death certificates and from information obtained electronically via the National Death Index, local death registries, hospital records, physician reports, and families or friends. Deaths were classified as caused by AIDS if the cause was an AIDS-defined opportunistic infection/malignancy (consistent with 1993 Centers for Disease Control and Prevention clinical surveillance conditions), or if the stated cause was organ failure or nonspecific infection and the CD4 count at the last study visit was less than 200 cells per milliliter. This methodology has been described elsewhere.[13]

Independent measures. Women were considered to be on a HAART regimen if they followed the International AIDS Society–USA panel[20] and the US Department of Health and Human Services/Henry J. Kaiser Family Foundation Panel[21] guidelines. All other antiretroviral therapy combinations were defined as *non-HAART combination therapy,* and use of a single antiretroviral therapy was defined as *monotherapy.*

At each study visit, HIV antibody status, HIV-1 RNA, and CD4 T-lymphocyte count were determined with standard flow cytometry at laboratories participating in the National Institutes of Health (NIH) Quality Assurance Program. Viral load was classified as less than 4000 versus greater than 4000. CD4 levels were assessed as low (<200), moderate (200–500), and high (>500).

Study participants' race/ethnicity was categorized as African American, Hispanic/Latina, White, and other. Illicit drug use was categorized as use of crack, cocaine, or heroin at any time during the study. Those with high school degrees or any postsecondary education at baseline were coded as "1" and as "0" otherwise. Age at baseline was measured in decades. Employment status at baseline was defined as any paid work (full- or part-time). Presence of clinical symptoms at baseline included 1 or more HIV/AIDS-related symptoms: fever, diarrhea, memory problems, numbness, weight loss, confusion, and night sweats. Women who reported nonadherence to any HIV treatment at any study visit were classified as nonadherent and as adherent otherwise. This single-item operationalization is similar to one that was used successfully by Wilson et al.[22] in a previous analysis of medication adherence among the WIHS cohort. Those women who reported no HIV-related therapies were included in the adherent classification, because nonadherence is a predictor of mortality distinct from treatment. Mental health service use was defined as receipt of care from a mental health professional or counselor that was self-reported at 1 or more study visits. Indicator variables represented 5 of the 6 study sites; Chicago served as a sixth arbitrary reference category.

Statistical Analysis

We analyzed 13 waves of semiannual data from the HIV-seropositive sample of the WIHS to predict time to AIDS-related death. We used the Kaplan–Meier survival analysis to test for differences in survival function according to depressive symptom chronicity, and we used proportional hazards analysis to examine the effect of depressive symptoms after we controlled for potentially confounding factors. Data from women whose deaths were caused by non–AIDS-related causes (n=144) were retained in the analysis until the time of death, when they were right-censored. We used multiple logistic regression analysis to predict the likelihood of meeting "probable depression" criteria at the final 2 study visits for all women to examine the association between depressive symptoms and end-stage disease.

RESULTS

Sample characteristics. Participants who had less than 3 study visits (n=343) were excluded from the sample so depression chronicity could be assessed longitudinally. When compared with the women who were included in the analysis (n=1716), those with less than 3 study visits were significantly less likely to be employed (13% vs 22%) or to have used a HAART regimen for 12 or more months (1% vs 49%). The 2 groups did not differ significantly on any other variables. The demographic characteristics of the study's 1716 women at baseline closely resembled those of the larger HIV-seropositive WIHS cohort.[23] Two fifths (41%) reported illicit drug use before baseline, and 39% did so during the study. Baseline CD4 counts were below 200 cells for 25% of the women, and viral loads were greater than 4000 for 68%. Use of a HAART regimen for 1 year or more was reported by 49% of the women, and 14% reported use of a non-HAART combination

therapy for 1 year or more. Only 5% reported use of monotherapy for 1 year or more, and 32% reported no use of an antiretroviral therapy or use for less than 1 year.

At baseline, more than half (58%) the women reported HIV-related clinical symptoms. Less than half (45%) were classified as adherent at all study visits; 37% reported perfect adherence, and 8% reported no treatment. For the remaining 55%, the mean number of visits at which nonadherence was reported was 3.

Approximately one third of the women (32%) reported depressive symptoms at a level that exceeded the CES-D clinical cutoff at 75% or more of their study visits. Another third (37%) reported depressive symptoms intermittently, and the final third (31%) reported depressive symptoms at few or none of their study visits. Close to half the women (47%) exceeded the CES-D clinical cutoff at their last study visit, and one third (35%) did so at their last 2 consecutive visits, which indicated recent depression among one half to one third of the cohort. Over two thirds (69%) reported use of mental health services at 1 or more study visits.

Relationship between depressive symptoms and time to death. Two hundred ninety-four (17%) of the women died during the 13 waves of study visits completed over a 7.5-year period by 1716 women: 147 (9%) died from AIDS-related causes, and an additional 147 women (9%) died as a result of other causes (accidents, violent crime, suicide, or non–HIV-related diseases). Of those who died from AIDS-related causes, 66% had CES-D scores greater than or equal to 16 at their last study visit (the mean number of days between death and last visit was 146), and 52% had CES-D scores that exceeded the cutoff at their last 2 visits before death.

Figure 1 shows the Kaplan–Meier survival curves for mortality caused by AIDS for each of the 3 groups of women: those with chronic depressive symptoms, those with intermittent symptoms, and those with infrequent or no symptoms. These curves differ significantly (log-rank test=20.22, $df=2$, $P<.001$), which indicates that chronic depression predicts mortality. Whereas only 6% of the women who had few or no depressive symptoms, and only 7% of the women who had intermittent symptoms, died from AIDS-related causes, nearly double this proportion (13%) of the women who had chronic depressive symptoms did die from AIDS-related causes. We eliminated the somatic symptoms from the depression measure but retained a cutoff of 16 to test a more stringent measure of chronic depressive symptoms, which produced virtually identical results (log-rank test=12.94, $df=2$, $P<.01$) .

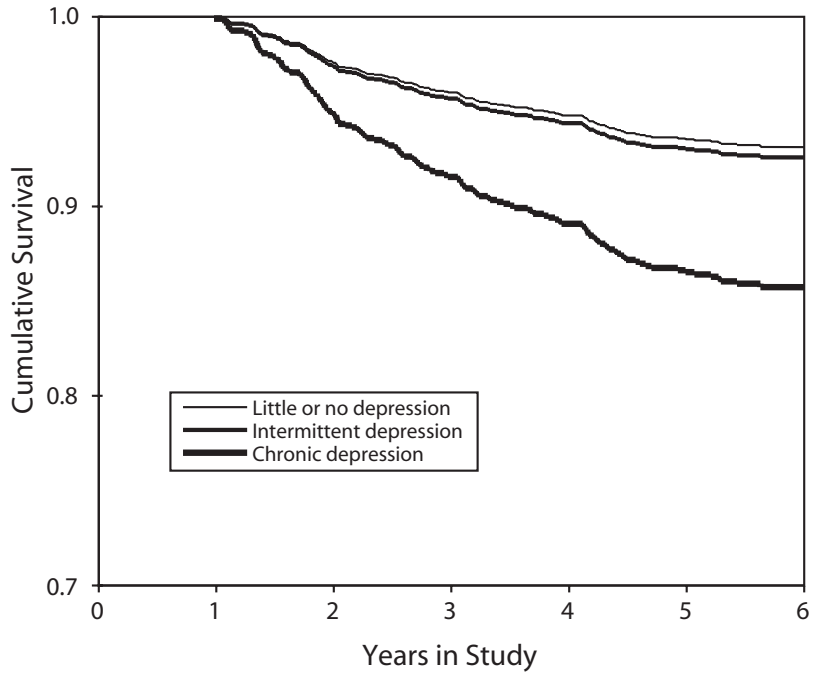

FIGURE 1—Kaplan–Meier survival curves, stratified by level of depressive symptoms.

Relationships among mortality and depressive symptoms and baseline features. The third column of Table 1 shows bivariate odds ratios for AIDS-related mortality and other potential predictors. Women who had chronic depressive symptoms were more than twice as likely to die compared with those who had limited or no symptoms. AIDS-related mortality also was more likely among those who received monotherapy and those who had low baseline CD4 cell counts, high viral loads, and HIV-related symptoms at baseline. Mortality was less likely among those who reported mental health service use and those who were on a HAART regimen or a non-HAART combination therapy. Mortality also was associated with adherence, which was a counterintuitive finding most likely caused by the fact that women who had more advanced disease were more likely to have initiated therapy. None of the other model variables was associated with AIDS-related mortality.

We used a Cox proportional hazards model to estimate the effect of depressive symptom chronicity on mortality after we controlled for all other model variables. As shown in the last column of Table 1, the women who had chronic depressive symptoms were significantly more likely to die compared with the women who had intermittent or fewer symptoms. The remaining results mirror those of the bivariate analysis, except that the positive association between mortality and adherence became nonsignificant (because of its spurious nature), as did relationships between mortality and HIV

TABLE 1—Bivariate and Multivariate Associations Among AIDS-Related Mortality, Depressive Symptoms, and Confounding Factors Among HIV-Positive Women (N = 1716)

Variable	AIDS-Related Deaths, No. (%)	Bivariate Odds Ratio (95% CI)	Multivariate Relative Risk[a] (95% CI)
Level of depression			
Limited/no symptoms (n = 543)	35 (6)	Reference	
Intermittent symptoms (n = 629)	43 (7)	1.1 (0.7, 1.7)	1.0 (0.6, 1.6)
Chronic symptoms (n = 534)	68 (13)	2.2 (1.4, 3.3)	1.7 (1.1, 2.7)
Mental health service utilization			
Used services during study (n = 1187)	82 (7)	0.5 (0.4, 0.7)	0.5 (0.3, 0.7)
No service use (n = 529)	65 (12)	Reference	
Baseline CD4 cell count			
< 200 (n = 409)	104 (25)	27.9 (11.4, 68.6)	36.0 (13.9, 93.8)
200–500 (n = 785)	33 (4)	4.0 (1.6, 10.2)	4.7 (1.8, 12.3)
> 500 (n = 468)	5 (1)	Reference	
Baseline viral load			
≤ 4000 (n = 536)	5 (1)	Reference	
> 4000 (n = 1166)	142 (12)	13.8 (5.6, 33.6)	6.8 (2.7, 16.9)
Baseline HIV symptoms			
0 (n = 714)	42 (6)	Reference	
≥ 1 (n = 999)	105 (11)	1.9 (1.3, 2.7)	1.3 (0.8, 1.9)
Categorized antiretroviral therapy use during study			
Other (n = 554)	81 (15)	Reference	
Monotherapy ≥ 12 mos (n = 93)	27 (29)	2.4 (1.6, 3.7)	0.8 (0.5, 1.3)
Non-HAART combination antiretroviral therapy ≥ 12 mos (n = 231)	17 (7)	0.4 (0.3, 0.7)	0.3 (0.1, 0.5)
HAART ≥ 12 mos (n = 838)	22 (3)	0.1 (0.1, 0.2)	0.1 (0.0, 0.1)
Adherence to HIV treatment regimen			
Adherence reported at every visit (n = 775)	82 (11)	1.7 (1.2, 2.3)	1.5 (1.0, 2.1)
Nonadherence at ≥ 1 visit (n = 938)	65 (7)	Reference	
Crack, cocaine, heroin use during study			
Any use (n = 663)	63 (10)	1.2 (0.9, 1.6)	0.9 (0.6, 1.4)
No use (n = 1053)	84 (8)	Reference	
Baseline age, y			
< 30 (n = 331)	27 (8)	Reference	
30–39 (n = 829)	67 (8)	1.0 (0.6, 1.6)	0.7 (0.4, 1.2)
40–49 (n = 469)	44 (9)	1.1 (0.7, 1.9)	0.7 (0.4, 1.2)
50–59 (n = 75)	8 (11)	1.5 (0.7, 3.2)	0.8 (0.4, 1.9)
≥ 60 (n = 12)	1 (8)	1.1 (0.1, 8.0)	0.7 (0.1, 5.7)
Employment status			
Not employed (n = 1334)	127 (10)	Reference	
Employed (n = 381)	20 (5)	0.8 (0.6, 1.0)	0.9 (0.5, 1.6)
Education			
At least high school or equivalent (n = 1080)	87 (8)	0.8 (0.6, 1.2)	1.1 (0.7, 1.6)
Less than high school (n = 636)	60 (9)	Reference	

Continued

symptoms and mortality and monotherapy. Several potential interactions between model variables were tested and were found to be nonsignificant: an interaction between depression and mental health service use and interactions between adherence and use of different categories of HIV therapies.

Finally, because of the time frame of our study, it is possible that these results are biased by the fact that HAART became available only to those who survived for longer periods of time. To control for this potential bias, we restricted the sample to those women who were alive during the second half of 1996 (because protease inhibitors became commercially available at the beginning of 1996) and repeated the Cox regression analysis. The results (data not shown) were virtually identical to those in Table 1.

Relationships among depressive symptoms immediately preceding death, mortality, and confounding variables. While depressive symptom chronicity is associated with mortality owing to AIDS-related causes, the chronicity measure fails to capture the level of depressive symptoms immediately before death. For example, the chronicity score of a woman who exceeded the CES-D clinical cutoff at the first 2 study visits but not the last 2 visits would be identical to that of a woman who exceeded the cutoff at the last 2 study visits but not the first 2. To examine the effect of depressive symptoms during the immediate premortality period, we computed the proportions of women who met criteria for probable depression at each study visit separately for those who died from AIDS-related causes during the subsequent 6 months versus those who survived until the next study visit. The results (Figure 2) indicated that the proportion of women who had probable depression was higher among those who died during the following 6 months than among those who survived.

Next, we used logistic regression analysis to examine the multivariate statistical association between depressive symptoms and being in the terminal phase of AIDS-related illnesses. Level of depressive symptoms was the dependent measure, and we used Lyketsos et al.'s[5] "conservative" definition of meeting the CES-D cutoff at 2 consecutive study visits. These were the last 2 study visits completed

TABLE 1—*Continued*

Marital status				
Married/living as married (n = 628)	57 (9)	1.1 (0.8, 1.6)		1.3 (0.9, 1.9)
Single (n = 1088)	90 (8)		Reference	
Residential status				
Living in own home (n = 1193)	104 (9)	1.1 (0.8, 1.5)		1.1 (0.7, 1.6)
Living elsewhere (n = 522)	43 (8)		Reference	
Income status				
< $12 000/year (n = 1103)	100 (9)	1.2 (0.8, 1.7)		1.0 (0.6, 1.5)
≥ $12 000/year (n = 613)	47 (8)		Reference	
Race/ethnicity				
African American (n = 962)	97 (10)	1.6 (1.0, 2.4)		1.0 (0.6, 1.7)
Hispanic/Latina (n = 405)	27 (7)	1.0 (0.6, 1.7)		0.8 (0.4, 1.4)
Other (n = 384)	23 (7)		Reference	

Note. N = respondents with 3 or more study visits; CI = confidence interval; HAART = highly active antiretroviral therapy.
[a]Risk estimate was calculated from the Cox proportional hazards model, which associated each variable with mortality while the effects of all other variables in the table and the study site were controlled.

by all women, excluding those who died from non–AIDS-related causes (n = 144).

As shown in the middle column of Table 2, the women who were in the terminal phase of their AIDS-related illnesses were more than twice as likely to report recent clinically significant depressive symptoms. More than half (52%) of the terminally ill women, but less than one third (32%) of the nonterminally ill women, met the "conservative" criteria for depressive symptoms. Clinically significant depressive symptoms also were more likely among those women who used mental health services, who had CD4 counts below 200 cells and viral loads above 4000, who had HIV-related symptoms at baseline, who reported illicit drug use, who were aged 30 to 49 years, who received monotherapy, who had incomes below $12 000 per year, and who were Hispanic/Latina. Depressive symptoms were less likely among women who were on a HAART regimen, who were adherent, who were employed, who had a high school or equivalent education, and who lived in their own homes.

A multivariate logistic regression analysis that controlled for all other factors found that recent clinically significant levels of depressive symptoms were associated with being in the terminal stage of illness, using mental health services, having HIV-related symptoms, and being aged 30 to 39 years. Recent depressive symptoms were significantly less likely among those who had been on a HAART regimen for 12 or more months.

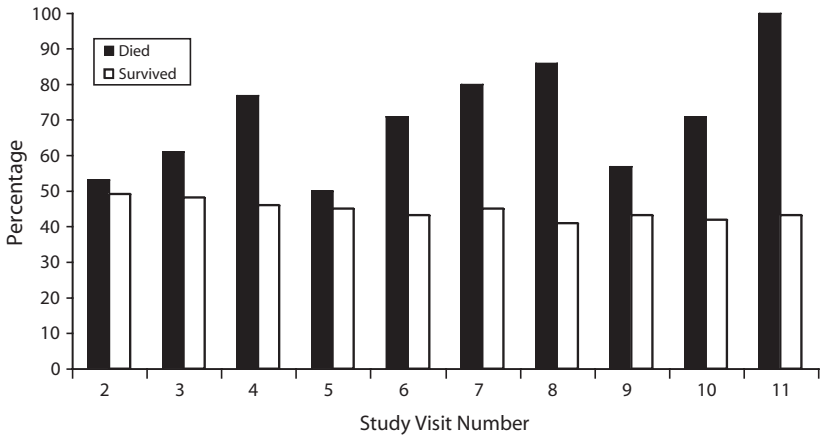

FIGURE 2—Percentage of HIV-positive women who met criteria for probable depression, by subsequent 6-month survival status.

DISCUSSION

Chronic depressive symptoms were significantly associated with a greater likelihood of AIDS-related mortality, even after we controlled for clinical, substance use, and sociodemographic factors. However, despite the impact of depressive symptoms, women who received mental health services were significantly less likely to die from AIDS-related causes during the study period. These results point to the importance of identifying and treating depression—through both pharmacological interventions and psychotherapeutic treatment—as an essential element in the comprehensive clinical care of women who have HIV.

Additionally, not only chronicity but also recency of depressive symptoms was associated with AIDS-related mortality. Of those in the terminal phase of their illnesses, more than half met CES-D–defined clinical criteria for depression at the 2 study visits before their deaths. The high proportion of women who reported depressive symptoms during the terminal phase of their AIDS-related illnesses shows the importance of including treatment for depression in end-of-life care protocols through the use of antidepressants and other treatments in hospice and similar programs.

Antiretroviral therapies clearly affected mortality: those who were on a HAART regimen for a year or more were 90% less likely to experience AIDS-related mortality, and those who were on a combination antiretroviral therapy for a year or more were 70% less likely. Moreover, in our study, the proportion of

TABLE 2—Bivariate and Multivariate Associations Among Depressive Symptoms, AIDS-Related Mortality, and Confounding Factors Among HIV-Positive Women (N = 1569)

Variable	Met Criteria for Clinical Depression, No. (%)	Bivariate Odds Ratio (95% CI)	Multivariate Odds Ratio[a] (95% CI)
Stage of illness			
Teminal (n = 147)	76 (52)	2.3 (1.6, 3.3)	1.8 (1.1, 2.7)
Not terminal (n = 1422)	451 (32)		Reference
Mental health service utilization			
Used services during study (n = 1085)	418 (39)	2.2 (1.7, 2.8)	2.2 (1.6, 2.9)
No service use (n = 484)	109 (23)		Reference
Baseline CD4 cell count			
< 200 (n = 361)	142 (40)	1.4 (1.1, 1.9)	1.2 (0.8, 1.8)
200–500 (n = 720)	232 (32)	1.0 (0.8, 1.4)	1.1 (0.8, 1.4)
> 500 (n = 439)	136 (31)		Reference
Baseline viral load			
≤ 4000 (n = 502)	143 (28)		Reference
> 4000 (n = 1046)	374 (36)	1.4 (1.1, 1.8)	1.2 (0.9, 1.5)
Baseline HIV symptoms			
0 (n = 666)	132 (20)		Reference
≥1 (n = 900)	395 (44)	3.3 (2.6, 4.0)	2.4 (1.8, 3.0)
Categorized antiretroviral therapy use during study			
Other (n = 490)	186 (38)		Reference
Monotherapy ≥ 12 mos (n = 77)	41 (53)	1.8 (1.1, 3.0)	1.8 (1.0, 3.2)
Non-HAART combination antiretroviral therapy ≥ 12 mos (n = 203)	66 (33)	0.8 (0.6, 1.1)	0.8 (0.5, 1.2)
HAART ≥ 12 mos (n = 799)	234 (29)	0.7 (0.5, 0.8)	0.7 (0.5, 0.9)
Adherence to HIV treatment regimen			
Adherence reported at every visit (n = 684)	207 (30)	0.8 (0.6, 0.9)	0.8 (0.6, 1.0)
Nonadherence at ≥ 1 visit (n = 882)	320 (37)		Reference
Crack, cocaine, heroin use during study			
Any use (n = 599)	248 (42)	1.8 (1.4, 2.2)	1.1 (0.8, 1.4)
No use (n = 970)	279 (29)		Reference
Baseline age, y			
< 30 (n = 318)	78 (24)		Reference
30–39 (n = 769)	274 (36)	1.7 (1.3, 2.3)	1.5 (1.1, 2.0)
40–49 (n = 405)	154 (38)	1.9 (1.4, 2.6)	1.4 (1.0, 2.1)
50–59 (n = 59)	21 (36)	1.7 (0.9, 3.1)	1.5 (0.8, 2.8)
≥ 60 (n = 9)	0 (0)	0.2 (0.0, 115.6)	0.1 (0.0, 2942.0)
Employment status			
Not employed (n = 1201)	454 (38)		Reference
Employed (n = 367)	73 (20)	0.5 (0.4, 0.6)	0.8 (0.6, 1.1)
Education			
At least high school or equivalent (n = 1000)	300 (30)	0.6 (0.5, 0.8)	0.8 (0.6, 1.0)
Less than high school (n = 569)	227 (40)		Reference

Continued

women who reported recent depressive symptoms was lowest among those who were on a HAART regimen. The significantly lower proportion of women who had depressive symptoms among users of the most potent antiretroviral therapies shows the possible role of a HAART regimen in combating depression[7,24] along with or in addition to the role of positive mental health in promoting use of a HAART regimen. Also important are associations between depression and AIDS-related mortality in the context of unique factors related to women's use of HAART regimens, such as health insurance status,[25] which could potentially influence their access to both HIV and depression treatments.

Our study's methodology did not allow us to establish a cause-and-effect relationship between depression and mortality, because both may be related to disease progression. However, the multivariate survival analysis controlled for 2 potent clinical indicators of HIV disease status (HIV viral load and CD4 cell count), and the significant relationship between mortality and depressive symptoms remained consistent despite these controls. Furthermore, post hoc analyses (data not shown) of women who did not have AIDS at baseline (i.e., CD4>200) revealed that those who had chronic depressive symptoms were 2.3 times more likely to die than those who had limited or no depressive symptoms ($P<.05$), which indicated that chronic depression was related to mortality even among those who did not have AIDS at baseline. Finally, women who died of AIDS-related causes were significantly more likely to have had CES-D scores that indicated "probable depression" at the 2 study visits immediately preceding their deaths, which established the temporally proximal, if not causal, nature of depression and mortality.

Two caveats to our findings concern the use of the CES-D to measure depressive symptoms and the use of death certificates to determine cause of death. With regard to the first study limitation, operationalization of major depression through research-quality diagnostic tools, such as the Structured Clinical Interview for the *DSM* or the Composite International Diagnostic Inventory, would have yielded a much higher-quality measure of depression as a syndrome, as would diagnostic procedures performed by a clinician who uses

TABLE 2—*Continued*

Marital status			
Married/living as married (n = 587)	186 (32)	0.9 (0.7, 1.1)	1.0 (0.7, 1.2)
Single (n = 982)	341 (35)	Reference	
Residential status			
Living in own home (n = 1096)	344 (32)	0.7 (0.6, 0.9)	0.9 (0.7, 1.1)
Living elsewhere (n = 473)	183 (39)	Reference	
Income status			
< $12 000/year (n = 996)	386 (39)	2.0 (1.5, 2.4)	1.4 (1.0, 1.8)
≥ $12 000/year (n = 573)	141 (25)	Reference	
Race/ethnicity			
African American (n = 865)	295 (34)	1.4 (1.0, 1.8)	1.1 (0.8, 1.5)
Hispanic/Latina (n = 381)	143 (38)	1.6 (1.1, 2.2)	1.2 (0.8, 1.8)
Other (n = 323)	89 (28)	Reference	

Note. N = respondents with 3 or more study visits; CI = confidence interval; HAART = highly active antiretroviral therapy.
[a]Odds estimates were calculated from the logistic regression model, which associated each variable with depression while the effects of all other variables in the table and the study site were controlled.

the *Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV).*[26] All of these approaches are highly preferable to use of a depression screening instrument, such as the CES-D, because of the latter's limited specificity. However, the measure is both valid and reliable and is widely used in studies of HIV-positive cohorts, which enables direct comparisons with the results of previous studies. Moreover, the use of rigorous scientific or clinical diagnostic tools among a population of this size presents considerable logistical challenges and requires substantial interrater and intersite reliability procedures to warrant its expense and its increased subject burden. Our study also was limited by our inability to determine whether the mental health services received by the women were consistent with practice guidelines for the treatment of depression that are based on rigorous research findings.

With regard to the second caveat, the causes of death obtained from death certificates may have been inaccurate. However, once again, death certificate information is commonly used in studies of this type and can provide important epidemiological information that otherwise might not be available. Additionally, the algorithm used in our study enhanced the linkage of AIDS clinical indicators (CD4 cell counts, viral load) to cause of death, which may have accounted for the substantial proportion of deaths classified as non–AIDS-related and most likely reduced chances of false-positive results.[13]

CONCLUSIONS

The findings of our study highlight a number of important and clinically meaningful associations between depressive symptoms and outcomes of women who have HIV. They suggest that antiretroviral therapy alone does not meet best-practice standards of care for this population, and therapy must be augmented by appropriate and sensitive mental health treatment, particularly as HIV disease progresses. Thus, finding ways to reduce depressive symptoms has the potential not only to prolong life but also to enhance its quality among women who have HIV. ■

About the Authors

Judith A. Cook, Dennis Grey, and Jane Burke are with the Department of Psychiatry, University of Illinois at Chicago. Mardge H. Cohen is with the Cook County Hospital, Core Center, Chicago Ill. Alejandra C. Gurtman is with the Department of Medicine, Mount Sinai Medical Center, New York, NY. Jean L. Richardson is with the Department of Preventive Medicine, University of Southern California, Los Angeles. Tracey E. Wilson is with the Department of Preventive Medicine and Community Health, State University of New York Health Sciences Center at Brooklyn. Mary A. Young is with the Department of Medicine, Georgetown University Medical Center, Washington, DC. Nancy A. Hessol is with the Department of Medicine, University of California, San Francisco.

Requests for reprints should be sent to Judith A. Cook, PhD, Mental Health Services Research Program, Department of Psychiatry, University of Illinois at Chicago, 104 S Michigan Ave, Suite 900, Chicago, IL 60603 (e-mail: cook@ripco.com).

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Contributors

J.A. Cook, D. Grey, and J. Burke designed the study, analyzed the data, and prepared the article. M.H. Cohen, A.C. Gurtman, J.L. Richardson, T.E. Wilson, M.A. Young and N.A. Hessol contributed to the data interpretation and the writing of the article. All authors reviewed drafts of the article and contributed revisions.

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Human Participant Protection

The Women's Interagency HIV Study has been approved by the institutional review boards of all institutions involved in our study. Written informed consent was obtained from all participants.

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Changes in Sexual Behavior Among HIV-Infected Women After Initiation of HAART

Tracey E. Wilson, PhD, Mary Elizabeth Gore, PhD, Ruth Greenblatt, MD, Mardge Cohen, MD, Howard Minkoff, MD, Sylvia Silver, DA, Esther Robison, PhD, Alexandra Levine, MD, and Stephen J. Gange, PhD

Objectives. We assessed the association between initiation of highly active antiretroviral treatment (HAART) regimens and sexual risk behaviors among HIV-infected women.

Methods. We analyzed data from 724 women who initiated HAART between January 1996 and January 2001 and who had pre-HAART viral loads at or above 400 copies per milliliter.

Results. Sexually active women were less likely (odds ratio [OR] = 0.79) to report 2 or more partners during a 6-month period after HAART initiation than before HAART initiation. However, the risk for unprotected sex was higher after HAART initiation than before HAART initiation among all sexually active women (both those who reported 2 or more partners [OR = 1.84] and those who reported 1 partner [OR = 1.22]).

Conclusions. Sexual risk behaviors are associated with receipt of therapy but not with therapeutic response, indicating a risk for transmission among female HAART recipients. (*Am J Public Health.* 2004;94:1141–1147)

Since the introduction of highly active antiretroviral treatment (HAART) in the mid-1990s, decreases in AIDS-related morbidity and mortality in the United States[1–2] have coincided with concerns about concomitant increases in sexual risk behaviors both among groups with HIV-1 infection and among the general population.[3] Increases in risk behaviors contribute to the transmission of HIV, including drug-resistant HIV strains, and other sexually transmitted diseases (STDs).[4–5]

Antiretroviral therapy and sexual risk behaviors may be linked through several mechanisms. First, HIV-positive individuals who derive therapeutic benefit from HAART may attain improved quality of life and functional status with the alleviation of physiological, social, and psychological consequences of HIV disease. These gains may be accompanied by increases in sexual risk behaviors among individuals whose illness had previously inhibited those behaviors. Second, individuals may hold unrealistic beliefs about the impact of antiretroviral therapy on disease transmission rates, and thus may perceive the consequences of transmitting HIV as being less serious than in the past. The proven efficacy of HAART in reducing maternal–fetal transmission of HIV may reinforce these beliefs. Individuals who hold such beliefs may be less likely to consistently use condoms or may have a higher number of partners than those who do not. Similarly, individuals at risk for HIV may be less inclined to insist on safe sexual behavior if they perceive the consequences of HIV infection to be somewhat less dire because of the availability of effective antiretroviral therapy.

To help clarify these relationships, we conducted 2 sets of analyses for a national cohort of women with HIV-1 infection. The first analysis examined sexual risk behaviors during the periods preceding and following initiation of HAART regimens, and the second analysis assessed sexual risk behaviors in terms of immunological response to therapy. Behavioral changes in both sets of analyses would imply that attitudes about receiving treatment and the effects of improved immunological parameters were influencing sexual behaviors.

METHODS

Participants

Participants were enrolled in the Women's Interagency HIV Study (WIHS), a multisite longitudinal cohort study established in 1993 to investigate the natural history of HIV infection among women.[6] We collected data from 1168 HIV-positive women who reported receiving HAART at any time from January 1996 through January 2001. In accordance with the International AIDS Society–USA panel and the US Department of Health and Human Services/Henry J. Kaiser Family Foundation[7] guidelines, HAART was defined as a regimen consisting of 1 of the following: (1) 2 or more nucleoside reverse transcriptase inhibitors in combination with at least 1 protease inhibitor or 1 non-nucleoside reverse transcriptase inhibitor, (2) 1 nucleoside reverse transcriptase inhibitor in combination with at least 1 protease inhibitor and at least 1 non-nucleoside reverse transcriptase inhibitor, (3) ritonavir and saquinavir in combination with 1 nucleoside reverse transcriptase inhibitor (but no non-nucleoside reverse transcriptase inhibitors), or (4) abacavir and 3 or more nucleoside reverse transcriptase inhibitors (but no protease inhibitors or non-nucleoside reverse transcriptase inhibitors). Per the guidelines, combinations of zidovudine and stavudine with either a protease inhibitor or a non-nucleoside reverse transcriptase inhibitor were not considered to be HAART regimens because of the drug–drug antagonism between zidovudine and stavudine. Self-reports of HAART use were obtained for the period since the most recent WIHS semiannual visit; participants' recognition of drugs was aided by cards with photographs of different drugs.

The 1168 women in our analysis represented 60.1% of HIV-positive women who were enrolled in the WIHS and who were alive in 1996. Of the women who were alive in 1996 and did not initiate HAART, 32.9% were not receiving any antiretroviral therapy during the study period, and 67.1% were receiving a form of antiretroviral therapy that did

not meet the definition of HAART. To detect significant shifts in therapeutic success as a result of HAART, we further restricted our analyses to 724 participants with viral load levels greater than 400 copies (amount of virus) per milliliter at the time of the study visit and before HAART initiation. This viral load cutoff point represented the minimal threshold for detection of plasma HIV RNA that was available at the beginning of the observation period.

Study Procedures

Participants completed visits at 6-month intervals at study sites in the following areas: Washington, DC, and the surrounding metropolitan area; the San Francisco Bay Area and Los Angeles, Calif; Brooklyn, Bronx, and Manhattan, NY; and Chicago, Ill. Each study visit included an interviewer-administered set of instruments and a physical examination.

At each study visit, participants provided information about the occurrence and the frequency of specific sexual behaviors since the previous study visit. We evaluated 3 separate outcomes related to sexual activities with male partners: (1) any vaginal, oral, or anal sexual activity with 1 or more partners during the past 6 months; (2) among sexually active women, having 2 or more sexual partners during the past 6 months; and (3) among sexually active women who reported vaginal intercourse, consistency of condom use during vaginal sex (always vs not always) in the past six months. We restricted analyses to heterosexual partnerships because of the low proportion of women who reported same-sex relationships.

In addition to information about sexual behavior, a variety of other self-reported variables were included in our analysis: use of crack, cocaine, or heroin; frequency of alcohol use; smoking status; and employment history. Overall quality of life was assessed with scales derived from the Medical Outcomes Study instrument.[8] Depressive symptomatology was assessed with the Center for Epidemiologic Studies Depression scale (CES-D), which has been shown to have high test–retest reliability and to be a good predictor of clinical depression.[9] A conventional definition of depression (total CES-D score >16) was used to identify depressed participants. The presence of AIDS-defining clinical conditions was ascertained through self-report. For example, reported conditions that indicated an AIDS diagnosis, in accordance with the Centers for Disease Control and Prevention definition of AIDS (consistent with 1993 CDC clinical surveillance conditions excluding criteria of low CD4 cell counts)[10] were recorded.

Participants were asked to report the occurrence of clinical symptoms of AIDS (fever accompanied by a temperature higher than 100 degrees Fahrenheit lasting longer than 1 month, memory problems lasting longer than 2 weeks, numbness lasting longer than 2 weeks, unexpected weight loss of more than 10 pounds, mental confusion, and drenching night sweats) and were then classified into 3 groups by number of symptoms (0, 1, and 2 or more). Finally, participants were asked whether a health care provider had told them in the past 6 months that they had gonorrhea, syphilis, chlamydia, pelvic inflammatory disease, genital herpes, genital warts, or trichomonas.

Lymphocyte subsets were quantified with standard flow cytometric methods at laboratories participating in the National Institutes of Health/National Institute of Allergy and Infectious Diseases Flow Cytometry Quality Assessment Program. CD4 cell counts were assessed at 6-month intervals corresponding with study visits. Participants typically were informed of their CD4 status within 2 to 4 weeks of blood sampling.

Statistical Analysis

To investigate whether the initiation of HAART or the immunological changes that occurred after the initiation of HAART were associated with subsequent changes in sexual behaviors, we conducted 2 sets of analyses for each of our 3 outcomes of interest (sexual activity, multiple partners, condom use consistency). Both of these analyses evaluated behavioral trends only among women who had initiated HAART; comparisons of behavioral trends among women who did not use HAART would have been complicated by selection-by-indication biases resulting from the nonrandomized use of HAART in observational studies.[11] Detailed analyses characterizing women in the WIHS who initiated HAART have been published elsewhere.[12]

In our first analysis, we evaluated the percentages of women who engaged in sexual activity, who reported 2 or more male sexual partners, and who reported inconsistent condom use before and after initiating HAART. Trends in these percentages were statistically evaluated with a repeated-measures logistic model that used generalized estimating equation (GEE) methods to investigate associations between HAART initiation and sexual risk behaviors after adjustment for several variables[13] that previous research has linked with the likelihood of engaging in sexual risk behaviors among HIV-positive women,[14–16] including frequency of drug or alcohol use, smoking status, presence or absence of AIDS-defining illness, number of AIDS-related clinical symptoms, presence or absence of depression, quality of life score, and participant's age.

In our second analysis, we assessed whether immunological changes after HAART initiation were associated with subsequent changes in sexual risk behavior. Immunological response to HAART was defined as the amount that CD4 cell counts had increased since the previous visit. These changes were classified into 3 groups: an increase of 33% or more, an increase of 0% to 32%, and no increase. Data from 3 consecutive visits (1-year period) were entered in a model that evaluated changes in sexual behavior. Each of the 3 sexual behavior outcomes of interest was evaluated at the last of these 3 visits, the exposure variables of interest were evaluated at the second of the 3 visits, and immunological response classification was done according to the change from the first and second visits. Because individuals may contribute multiple observations after the initiation of HAART, we used repeated-measures logistic models with GEE methods to determine whether associations between immunological response and sexual risk behaviors remained after adjustment for frequency of drug or alcohol use, smoking status, employment status, presence or absence of AIDS-defining illness, number of AIDS-related clinical symptoms, number of STD diagnoses, presence or absence of depression, quality of life score, and participant's age. For all sets of analyses, participants who were pregnant or trying to get pregnant were excluded.

TABLE 1—Prevalence of Psychosocial and Behavioral Variables Stratified by Sexual Behavior: HIV-Positive Women, Women's Interagency HIV Study, 1996–2001

	Sexual Behavior							
Confounders	Sexually Active	Not Sexually Active	≥2 Partners	1 Partner	Inconsistent Condom Use (1 Partner)	Consistent Condom Use (1 Partner)	Inconsistent Condom Use (≥2 Partners)	Consistent Condom Use (≥2 Partners)
Use crack, cocaine, or heroin, %	13.6	10.2	31.1	10.2	13.5	8.5	33.8	29.6
Smoke, %	51.0	44.8	66.5	48.0	51.0	46.6	73.1	62.2
Consume alcohol, %	19.8	12.7	32.1	17.4	19.6	16.2	33.8	31.1
With depression, %	45.4	47.5	58.3	42.9	41.7	43.3	55.7	60.0
AIDS clinical symptoms, %	40.3	47.8	42.5	39.9	42.5	38.5	39.0	45.2
0	54.1	48.7	44.9	56.0	57.0	55.6	45.8	44.8
1	24.2	23.4	25.5	23.9	23.8	23.9	27.2	23.9
2 or more	21.7	27.9	29.6	20.2	19.3	20.5	26.9	31.3
Any sexually transmitted disease, %	17.2	12.5	26.2	15.4	18.0	14.3	29.4	23.9
Quality of life score (median)	67	65	61	69	69	69	63	61
Person-visits	7423		4841		3997		783	

RESULTS

Study Population

Of the 724 HIV-infected women who had initiated HAART and whose pre-HAART viral loads were more than 400 copies per milliliter, 372 (52.2%) were Black, 195 (26.9%) were Hispanic, and 151 (20.9%) were White or of other races/ethnicities. The median age at HAART initiation was 38.5 years, and 259 (35.8%) of the women reported having less than a high school education. The majority of the sample (87%) reported engaging in sexual activity at some point during the observation period (for our analysis, we defined sexual activity as heterosexual vaginal sex). At the most recent follow-up visit, 8.4% of the sexually active women reported more than 1 sexual partner, and 22.9% of these women did not consistently use condoms. The lifetime occurrences of several potential confounding variables are summarized in Table 1.

We compared the women in our analysis (n=724) with the women who did not receive HAART and were therefore excluded from our analysis (n=767). We found no statistically significant differences between these 2 groups in terms of mean age at baseline or reports of alcohol use during the 6 months before baseline. However, the women who had not initiated HAART were more likely than those who had initiated HAART to report crack, cocaine, or heroin use during the 6 months before baseline (34% vs 22%); to be a smoker at baseline (60% vs 50%); and to be Black (59% vs 52%). Women who had not initiated HAART also had a lower mean CD4 cell count at baseline (343 vs 420 cells) and a higher median viral load (27 000 vs 16 000 copies per milliliter; $P<.05$ for all).

Sexual Behavior Before and After HAART Initiation

We analyzed data from 7423 person-visits to clinics at study sites (2582 pre-HAART and 4841 post-HAART), with a median of 7 post-HAART follow-up visits per person. Figure 1 illustrates the occurrence of each sexual behavior reported at study visits before and after HAART initiation. Although this figure depicts somewhat stable trends, after we adjusted for possible confounders we found some change in sexual behavior since the initiation of HAART. The results of the multiple logistic GEE models are summarized in Table 2. There was a statistically nonsignificant increase in sexual activity reported at post-HAART visits (odds ratio [OR]=1.12, $P=.11$). Other covariates, such as drug use

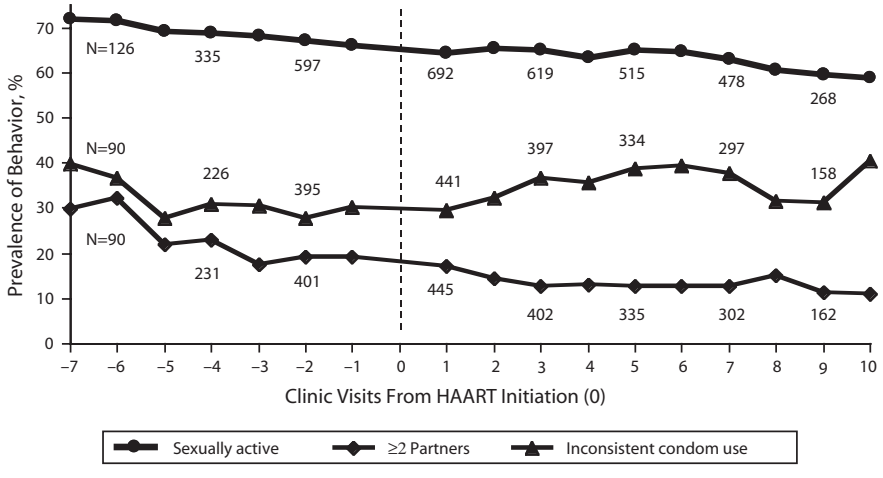

FIGURE 1—Prevalence of sexual behaviors reported at semiannual study visits before and after HAART initiation: HIV-positive women, Women's Interagency HIV Study, 1996–2001.

TABLE 2—Odds of Behavior Change After HAART Initiation Compared With Pre-HAART Time Points: HIV-Positive Women, Women's Interagency HIV Study, 1996–2001

Outcome	Model 1[a] OR (95% CI)	Model 2[b] OR (95% CI)
Sexually active		
No	Reference	Reference
Yes	1.02 (0.89, 1.17)	1.12 (0.97, 1.30)
No. of sexual partners		
1	Reference	Reference
2 or more	0.63 (0.51, 0.77)	0.79 (0.63, 0.98)
Condom use with 1 partner		
Always	Reference	Reference
Not always	1.18 (0.98, 1.43)	1.22 (1.00, 1.47)
Condom use with ≥2 partners		
Always	Reference	Reference
Not always	1.61 (1.13, 2.30)	1.84 (1.26, 2.70)

Note. OR = odds ratio; CI = confidence interval. OR above 1.0 indicates a greater likelihood of the outcome of interest after initiation of HAART.
[a]Adjusted for age.
[b]Adjusted for age; frequency of crack, cocaine, or heroin use; frequency of alcohol use; smoking status; number of clinical symptoms of AIDS; presence or absence of AIDS-defining illness; presence or absence of depression; and quality of life score.

(OR=1.39, *P*=.035), consuming more than 3 alcoholic drinks per week (OR=1.67, *P*< .001), and younger age (measured in 10-year increments; OR=0.42, *P*<.001), were associated with increases in sexual activity.

When we restricted the analyses to women who had engaged in vaginal sex with a male partner, we found that participants were less likely (OR=0.79, *P*=0.03) to report having 2 or more partners in a 6-month period at post-HAART visits than at pre-HAART visits, indicating that having 2 or more partners became less common post-HAART. Drug use (OR= 3.05, *P*<.001), consuming 3 alcoholic drinks per week (OR=1.41, *P*=.027), smoking (OR=1.49, *P*=.004), and every 10-year increase in age (OR=0.62, *P*<.001) were associated with reporting 2 or more sexual partners after the initiation of HAART. Participants who reported inconsistent condom use during vaginal sex were stratified into 2 groups: those who reported having 1 partner and those who reported having 2 or more partners. Participants in both groups were more likely to report inconsistent condom use after HAART initiation than before initiation (1 partner: OR=1.22, *P*=.045; ≥2 partners: OR=1.84, *P*=.002). Drug use was associated with inconsistent condom use in the group that reported having 1 partner (OR=1.65, *P*=.008), whereas smoking was associated with inconsistent condom use in the group that reported having 2 or more partners (OR=1.78, *P*=.008).

Sexual Behavior and Changes in Immunological Parameters

We examined the 724 participants' post-HAART initiation visits to assess whether changes in CD4 cell counts were associated with sexual risk behaviors (3128 person-visits were analyzed). The median number of follow-up visits per participant was 4 [interquartile range=3,6]. Of the 724 women, 14.5% missed 2 or more post-HAART visits. This high percentage was a result of the study design, which required 3 consecutive visits. Missing a study visit was not associated with sexual activity, reporting 2 or more partners, or inconsistent condom use. For 499 women (68.9%), an increase in CD4 cell counts of 33% or higher was observed in at least 1 WIHS visit; for 76 women (10.5%), no increase in CD4 cell count was observed at a post-HAART visit. Immunologic responses were more common: 397 (54.8%) of the WIHS participants had an undetectable level of viral copies (400 or fewer per milliliter) after HAART initiation. Achievement of an undetectable viral load was not associated with subsequent shifts in sexual behavior and was not analyzed further.

The relationships between CD4 cell counts and sexual behaviors are shown in Table 3. As with the first analysis, model 1 was ad-

TABLE 3—CD4 Cell Counts as Predictors of Sexual Behavior After HAART Initiation: HIV-Positive Women, Women's Interagency HIV Study, 1996–2001

	Sexual Behavior							
	Sexually Active		≥2 Partners		Inconsistent Condom Use With 1 Partner		Inconsistent Condom Use With ≥2 Partners	
CD4 change	Model 1[a] OR (95% CI)	Model 2[b] OR (95% CI)	Model 1[a] OR (95% CI)	Model 2[b] OR (95% CI)	Model 1[a] OR (95% CI)	Model 2[b] OR (95% CI)	Model[a] OR (95% CI)	Model 2[b] OR (95% CI)
≥33% increase	1	1	1	1	1	1	1	1
0%–32% increase	1.29 (1.04, 1.61)	1.27 (1.02, 1.59)	0.88 (0.61, 1.28)	0.96 (0.65, 1.40)	1.03 (0.78, 1.36)	1.04 (0.78, 1.38)	0.95 (0.50, 1.83)	0.80 (0.45, 1.40)
Decrease	1.05 (0.88, 1.24)	1.08 (0.90, 1.28)	1.02 (0.75, 1.40)	0.99 (0.70, 1.41)	1.02 (0.81, 1.29)	1.08 (0.83, 1.39)	0.81 (0.48, 1.38)	1.05 (0.51, 2.12)

Note. OR = odds ratio; CI = confidence interval. OR greater than 1.0 indicates a greater likelihood of the behavior of interest relative to the indicated reference groups.
[a]Adjusted for age.
[b]Adjusted for age; frequency of crack, cocaine, or heroin use; frequency of alcohol use; smoking status; number of clinical symptoms of AIDS; presence or absence of AIDS-defining illness; presence or absence of depression; and quality of life score.

justed for participant's age, and model 2 was adjusted for frequency of drug or alcohol use, smoking status, employment status, presence or absence of AIDS-defining illness, number of AIDS-related clinical symptoms, presence or absence of STD diagnoses, presence or absence of depression, quality of life score, and participant's age. Second-order (multiplicative) interaction terms of the confounding factors were examined for all models. Although some were significant, the interaction terms did not change the magnitude or the statistical significance of the primary factors of interest: CD4 cell counts and viral load. Both models indicated that a moderate (0%–32%) increase in CD4 cell count, compared with an increase of 33% or higher, was associated with higher levels of sexual activity (model 1: OR=1.29, 95% confidence interval [CI]=1.04, 1.61; model 2: OR=1.27, 95% CI=1.02, 1.59). Number of partners and inconsistent condom use were not associated with changes in CD4 cell count. Women who reported drug or alcohol use were more likely than those who did not to be sexually active and to report 2 or more partners. Participants were less likely with increasing age to be sexually active or to report 2 or more partners. Smoking was associated with reporting 2 or more partners and with inconsistent condom use among those who reported 2 or more partners. Reports of any STD diagnoses were associated with inconsistent condom use among women who reported having either 1 partner or 2 or more partners. CD4 cell count at the visit preceding HAART initiation was associated with both sexual activity and inconsistent condom use with 1 partner. Women who had cell counts of 200 or fewer (OR=0.56, *P*=.003) and those who had cell counts of 201 to 500 (OR=0.75, *P*=.058) were less likely to be sexually active than were women who had CD4 cell counts higher than 500. Finally, depressive symptoms were associated with reports of 2 or more partners.

DISCUSSION

The HIV-positive women in our study reported higher levels of unprotected vaginal sex post–HAART initiation than pre–HAART initiation. Although women were somewhat less likely to report having 2 or more sexual partners after the initiation of HAART, their overall level of risk may have increased owing to less consistent condom use. Furthermore, the risk for unprotected sex after HAART initiation was somewhat higher among women who reported having 2 or more sexual partners within a 6-month period (OR=1.84) than among those who reported having only 1 partner (OR=1.22). These findings suggest that patterns of increasing sexual risk behaviors are occurring among HIV-infected heterosexual women on HARRT. Even though women reported higher levels of unprotected sex following HAART initiation, a concomitant decrease occurred in the likelihood of engaging in sexual activity with multiple partners.

It appears that these changes in sexual risk behaviors occurred independently of improvements in immune function, suggesting that perceptions of HAART's benefits may be influencing sexual behavior more so than actual improvements in health. We found that sexual activity, number of sexual partners, and condom use consistency were not associated with changes in CD4 cell count classifications occurring after the initiation of HAART. Previous findings from a study of a subgroup of women enrolled in the WIHS also support this interpretation. Thirty percent of the 145 sexually active HIV-infected women enrolled at the Brooklyn site reported either that they believed that they were less infectious as a result of HIV therapy or that they worried less about using condoms after they started HAART. Women who held these beliefs were less likely to report consistent condom use (22.5%) than those who disagreed (50.0%).[17]

The scope of our study was limited by our lack of specific information regarding psychological factors and beliefs that may have influenced risk behavior. Additionally, at the time of data collection we did not have information on the HIV status of the women's sexual partners, on whether these partners were regular or casual partners, or on the rate of change to new sexual partners. Changes in risk behavior among women are not necessarily a function of their views about unprotected behavior in the context of HAART. Because men are the primary users of condoms, it may be the male partners' views or perceptions regarding HIV transmission in the context of HAART that drive changes in sexual risk behaviors. Future research will require delineation of these issues. Furthermore, our sexual risk behavior data are subject to the biases inherent in the collection of any self-reported sensitive behaviors; therefore, the true extent of sexual risk behaviors among our sample may be underestimated. Because we restricted our study sample to women who initiated HAART, we did not have an external reference group; thus, secular changes in behavior may have taken place that we did not appropriately capture.

Finally, although our study protocol required the women in our study to be informed of the results of their virological and immunological tests, it is possible that not all the women were informed early enough to affect subsequent decisions related to sexual behaviors within the next 6 months. Participants at our 6 centers receive HIV care in a number of settings, not all of which are affiliated with WIHS. Those unaffiliated providers monitor participants' status and provide therapy as they deem appropriate. The WIHS, with participants' consent, sends WIHS laboratory results to providers. However, these results may arrive after the results of clinical laboratory tests ordered by participants' private physicians have already been used to guide management. At the time of data collection, WIHS was not structured to measure the provision of testing information to participants.

CONCLUSIONS

Initiation of HAART regimens may be related to continuation of or increases in sexual risk behaviors. It has been estimated that the chance for eradication of an HIV epidemic through widespread antiretroviral therapy use is 85% in the presence of reductions in sexual risk behaviors. In the absence of sexual risk reduction, that chance decreases to 50%, and decreases further in the presence of increased sexual risk behaviors.[18] When we reviewed literature on sexual risk behaviors among people who were HIV positive,[19] we found only 5 studies that examined the relationship between unprotected sex and factors associated with HIV treatment, clinical status, or medical beliefs among women. One of

these studies reported a positive relationship between CD4 cell counts and the risk for unprotected sex,[14] and another supported a positive relationship between having no symptoms of HIV infection and engaging in unprotected sex. Our study provides some of the first evidence that primary and secondary prevention efforts targeting sexual risk behaviors among heterosexual HIV-infected women who receive HAART need to be considered. Our study also suggests that these women and their partners should receive services that will promote the knowledge and skills necessary for effective prevention of transmission of HIV. Such an education program may include addressing the impact of HAART on risks for disease transmission at initiation and continuing similar counseling strategies throughout the course of treatment. ■

About the Authors

Tracey E. Wilson and Howard Minkoff are with the State University of New York Downstate Medical Center, Brooklyn, NY. Mary Elizabeth Gore and Stephen J. Gange are with Johns Hopkins University, Baltimore, Md. Ruth Greenblatt is with the University of California, San Francisco. Mardge Cohen is with Cook County Hospital, Chicago, Ill. Sylvia Silver is with the George Washington University Medical Center, Washington, DC. Esther Robison is with Montefiore Medical Center, Bronx, NY. Alexandra Levine is with the University of Southern California School of Medicine, Los Angeles, Calif.

Requests for reprints should be sent to Tracey E. Wilson, PhD, Department of Preventive Medicine and Community Health, State University of New York, Downstate Medical Center, Box 1240, 450 Clarkson Ave, Brooklyn, NY 11203 (e-mail: tracey.wilson@downstate.edu).

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Contributors

T.E. Wilson formulated the hypothesis, participated in the planning of the study and the interpretation of the results, and wrote the article. M.E. Gore and S.J. Gange conducted the statistical analyses, contributed to the interpretation of the results, and contributed to the writing of the article. H. Minkoff, M. Cohen, R. Greenblatt, S. Silver, and E. Robison participated in the planning of the article and contributed to the writing.

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Human Participant Protection

Protocol approvals were obtained from the participating sites.

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Medically Eligible Women Who Do Not Use HAART: The Importance of Abuse, Drug Use, and Race

Mardge H. Cohen, MD, Judith A. Cook, PhD, Dennis Grey, BA, Mary Young, MD, Lawrence H. Hanau, MD, Phyllis Tien, MD, Alexandra M. Levine, MD, and Tracey E. Wilson, PhD

Objectives. We investigated the prevalence and characteristics of HIV-positive women who do not report highly active antiretroviral therapy (HAART) use.

Methods. We analyzed HAART use among 1165 HIV-positive participants in the Women's Interagency HIV Study.

Results. Between October 1, 2000, and March 31, 2001, 254 women with clinical indications for HAART reported not using it, 635 reported HAART use, and 276 had no clinical indications. In multivariate analysis, using crack/cocaine/heroin and a history of abuse decreased the likelihood of using HAART, whereas being White increased it.

Conclusions. One of 4 women for whom HAART was indicated reported not using HAART. Childhood sexual abuse prevention, more intensive abuse treatment, and continuing drug treatment may enhance HIV disease treatment of women. (*Am J Public Health.* 2004;94:1147–1151)

Women are one of the fastest-growing groups infected with human immunodeficiency virus (HIV) in the United States.[1] When women with HIV use highly active antiretroviral therapy (HAART), dramatic declines in morbidity and mortality have been reported.[2–5] However, both patient and provider characteristics have been shown to influence HAART use in women. As we have previously shown, African American women, those with a history of injection drug use, and those currently using alcohol and illicit drugs were less likely to report initiating HAART.[6] Additionally, women with high levels of depressive symptoms are less likely to use HAART, whereas those receiving mental health treatment are more likely to report use of HAART.[7] Further, women receiving care from HIV specialists are more likely to receive recommended antiretroviral therapy.[8]

As HAART regimens become more varied and convenient, it is important to examine why women who are medically eligible for this therapy remain untreated. We report here on the prevalence and predictors of lack of HAART use in 2000–2001 among medically eligible women enrolled in the Women's Interagency HIV Study (WIHS), a cohort study of women with and at risk for HIV infection, representative of women with HIV in the United States.[9]

METHODS

Subjects

The WIHS is a longitudinal multicenter study funded by the National Institutes of Health, including 6 clinical sites: Bronx/Manhattan and Brooklyn, NY; Chicago, Ill; Washington, DC; and San Francisco and Los Angeles, Calif. After institutional review board approval, participants with or at risk for HIV were enrolled into WIHS between October 1, 1994, and November 30, 1995. Eligible women were aged 13 years or older, gave informed consent, were tested for HIV infection, completed an interview in English or Spanish, and had a clinical examination and extensive laboratory testing every 6 months. The study's methodology, training, and quality assurance activities and the cohort's baseline characteristics have been reported previously.[9]

A standardized interview-based survey was used to collect demographics; medical and psychosocial history; history of cigarette smoking; alcohol use, illicit drug use (including intravenous drugs and noninjected heroin, crack, and cocaine), and drug treatment programs; sexual history; and history of medication use and reasons for not taking medications at each 6-month visit. Participants were shown photographs of all antiretroviral medications to help increase accurate reporting. The Center for Epidemiological Studies Depression Scale measured depressive symptoms, with a score of 16 or greater indicative of a probable depressive disorder.

Women were considered to have experienced abuse if they answered affirmatively to any questions about physical, sexual, or emotional coercion. For this analysis, a history of abuse included domestic violence, defined as physical or sexual abuse or coercion by an intimate partner or spouse; recent abuse, defined as abuse experienced within the past year; and childhood sexual abuse, defined as sexual abuse that occurred before 18 years of age. Abuse data were not collected at the 2 California sites because of reporting requirements, which would have interfered with participant confidentiality.

WIHS recruited women from HIV care, drug treatment, HIV-testing, and sexually transmitted disease clinic programs. Each research site relates to an HIV care program, to which women are referred if they are not already in care. These comprehensive HIV programs offer obstetric and gynecologic services, and many have on-site or connections to mental health and drug treatment. The WIHS protocol specifically calls for flagging responses to survey questions requiring follow-up or referral to specialized care, particularly for illicit drug use, depression, and domestic violence.[10] This ensures that these issues are openly addressed at the end of the interview session.

HIV-1 antibody status, HIV-1 RNA, and CD4 T-lymphocyte (CD4) counts were determined at each visit. HIV-1 RNA quantitation was performed using the isothermal nucleic acid sequence-based amplification method in laboratories certified by the National Insti-

tutes of Health (NIH) Virology Quality Assurance program, and CD4 counts were determined using standard flow cytometric techniques at local laboratories certified by the NIH Quality Assurance Program. Baseline hepatitis C antibody assays were performed locally.

HAART use was determined by self-report and defined as (1) 2 or more nucleoside reverse transcriptase inhibitors (NRTIs) in combination with at least 1 protease inhibitor (PI) or 1 non-nucleoside reverse transcriptase inhibitor (NNRTI); (2) 1 NRTI in combination with at least 1 PI and at least 1 NNRTI; (3) a regimen containing ritonavir and saquinavir in combination with 1 NRTI and no NNRTIs; and (4) an abacavir-containing regimen of 3 or more NRTIs in the absence of both PIs and NNRTIs. Combinations of zidovudine (AZT) and stavudine (d4T) with either a PI or NNRTI were not considered HAART. All other antiretroviral regimens were classified as mono or combination therapy. Participants reporting no HAART use may have used the therapy at some time in the past but were not using it at the analyzed study visit.

HAART was considered to be clinically indicated among those women who reported using HAART and those women with a CD4 count less than 350 or a viral load greater than 50 000 (per the published treatment standards in use during the studied visit).[11]

Statistical Methods

Analysis of variance was used to test for significant differences between 3 groups of women: those using HAART, those for whom HAART was clinically indicated but who were not using it, and those for whom HAART was not indicated, in terms of a series of respondent background features. Next, multiple logistic regression analysis was used to predict lack of HAART use at study visit 13 (i.e., study visits and interviews occurring between October 1, 2000, and March 31, 2001) among all women for whom HAART was clinically indicated at any time before that study visit. Finally, to study a larger "HAART initiation window," multiple logistic regression analysis was used to model predictors of not using HAART at any of the 3 study visits 11, 12, and 13 among all women for whom HAART was clinically indicated at study visit 10. This latter analysis was limited to women who had at least 18 to 24 months to initiate HAART, as opposed to the first analysis, in which women could have had a minimum of only 6 months for HAART initiation. As data on abuse were not available from California participants, they were not included in the multivariate analyses. We performed a χ^2 test to examine the association between current drug use and drug treatment.

RESULTS

During the October 2000 through March 2001 study visit, 1219 HIV-infected women were evaluated for their use of antiretroviral therapy. Missing data prevented classification of 54 participants. Of the remaining 1165, 635 women reported using HAART, 254 women for whom HAART was clinically indicated reported not using HAART (130 women were using no therapy, 15 were using monotherapy, and 109 were using combination therapy), and 276 women for whom HAART was not indicated reported using no therapy or mono or combination therapy. Of the 254 women not using HAART but for whom it was indicated, 163 (64%) had been using HAART at some previous study visit. Of the total 889 women eligible for HAART, 28% reported no HAART use at this study visit.

The demographic and behavioral characteristics for these 3 groups are shown in Table 1. Women in the groups did not differ significantly in median age, in the proportions completing high school, or in having high levels of depressive symptoms. Analysis of variance indicated that a significantly lower percentage of African American women were using HAART, whereas a higher percentage of White women reported using HAART. A lower percentage of women with a history of past and current use of crack, cocaine, or heroin were using HAART. A lower percentage of women with a history of physical or sexual abuse reported using HAART. Similarly, a lower percentage of women with hepatitis C reported using HAART. A higher percentage of women with private insurance and of women currently working reported HAART use.

We performed a multivariate analysis to determine which of these factors were pre-

TABLE 1—Background Features of HIV-Positive Women by Clinical Indication and HAART Use Status (n = 1165): Women's Interagency HIV Study, October 1, 2000–March 31, 2001

	Using HAART (n = 635)	HAART Indicated, But Not Being Used (n = 254)	HAART Not Indicated (n = 276)
Median age at baseline, y	36.3	36.5	35.6
Race			
African American, %*	52	58	62
White, %*	19	12	14
Latina, %	27	27	21
High school graduate, %	65	59	64
CES-D ≥ 16, %	43	50	42
Illicit drug use			
History of crack, cocaine, or heroin use, %**	66	76	67
Current crack, cocaine, or heroin use, %***	10	20	14
Private insurance*	12	5	15
History of physical/sexual abuse, %[a]*	72	80	80
Income < $12 000, %*	46	37	46
Hepatitis C antibody positive, %**	37	49	40
Employed, %*	33	26	38

Note. HAART = highly active antiretroviral therapy; CES-D = Center for Epidemiological Studies Depression Scale.
[a]For this variable, n = 750 because abuse items were not included in the protocols of 2 California sites.
*P < .05; **P < .01; ***P < .001; differences significant in 1-way analysis of variance.

TABLE 2—Multiple Logistic Regression Analysis of HAART Nonuse Among Women for Whom HAART Is Clinically Indicated (After Control for Study Site[a]) (N = 750): Women's Interagency HIV Study, October 1, 2000–March 31, 2001

	Odds Ratio (95% Confidence Interval)
Current crack, cocaine, or heroin use*	2.11 (1.17, 3.79)
History of physical or sexual abuse*	1.72 (1.07, 2.77)
Race	
White*	0.45 (0.22, 0.96)
African American	0.73 (0.45,1.17)
Latina	Reference
Private health insurance	0.83 (0.48,1.45)
Income < $12 000/year	0.82 (0.52,1.28)
Depressive symptoms (CES-D ≥ 16)	0.84 (0.56,1.25)
Hepatitis C antibody positive	1.16 (0.78,1.71)
High school education or more	0.69 (0.46,1.02)
Living in own home	0.65 (0.38,1.13)

Note. HAART = highly active antiretroviral therapy; CES-D = Center for Epidemiological Studies Depression scale.
[a]Two of 6 sites were excluded from the analysis because they did not include abuse items in their study protocols.
*$P < .05$.

dictors of lack of HAART use among clinically eligible women. We controlled for high school education; income below poverty level; health insurance; any crack, cocaine, or heroin use; race; study site; age; housing status; depressive symptoms; any history of abuse; and hepatitis C infection. As shown in Table 2, current crack, cocaine, or heroin use, being non-White, and experiencing any physical or sexual abuse increased the likelihood of no HAART use among clinically eligible women. Women who used crack, cocaine, or heroin in the past year were more than twice as likely to report lack of HAART use, even when indicated (odds ratio [OR]=2.1, 95% confidence interval [CI]=1.17, 3.79). Similarly, women with a history of any physical/sexual abuse were more than 1.5 times more likely to lack HAART (OR=1.72, 95% CI=1.07, 2.77) when clinically eligible. Finally, White women were half as likely to be non-HAART users (OR=0.45, 95% CI=0.215, 0.956).

We next examined lack of HAART use longitudinally over an 18- to 24-month period in a sample of women to determine whether other factors were predictive of HAART use in this group compared with the group studied in the cross-sectional analysis. We identified 159 women who had clinical indications for HAART in 1999 but reported no HAART use for 3 subsequent visits (a total of 18 to 24 months). We used the same multivariate model, which included race, depression, insurance, current drug use, income, hepatitis C, education, housing, abuse, and research site to determine predictors of this continued lack of HAART use (Table 3). Here, too, the model showed that being White predicted using HAART, whereas women with any physical or sexual abuse and with current crack, cocaine, or heroin use were significantly more likely to be HAART nonusers, after we controlled for all other factors.

To determine the availability of drug treatment services for women not using HAART even though it was indicated, we examined reported recent drug use and being in or on the waiting list for a drug treatment program. For the 49 women who had used drugs recently, 41 (84%) were in treatment and 8 (16%) were not in treatment. Another 105 women were in drug treatment but had not used drugs recently.

Women for whom HAART was indicated but who were using no therapy were asked to list the main reason they were not using any therapies. Only 15% reported, "My doctor did not prescribe them," whereas the rest answered that they felt too healthy, wanted to wait, were afraid of side effects, or had difficulty taking the medicines.

TABLE 3—Multiple Logistic Regression Analysis Predicting Women's Clinical Eligibility for HAART But Not Using HAART for Final 3 Study Visits After Indication (After Control for Study Site[a]) (n = 750): Women's Interagency HIV Study, October 1, 1999–March 31, 2001

Variable	Odds Ratio (95% Confidence Interval)
Current crack, cocaine, or heroin use*	2.04 (1.18, 3.60)
History of physical or sexual abuse*	1.72 (1.10, 3.05)
Race	
White*	0.45 (0.21, 0.95)
African American	0.83 (0.46,1.50)
Latina	Reference
Private health insurance	0.82 (0.37,1.79)
Income < $12 000/year	0.96 (0.55,1.70)
Depressive symptoms (CES-D ≥ 16)	0.86 (0.51,1.45)
Hepatitis C antibody positive	0.88 (0.52,1.49)
High school education or more	0.53 (0.21,1.18)
Living in own home	0.75 (0.36,1.57)

Note. HAART = highly active antiretroviral therapy; CES-D = Center for Epidemiological Studies Depression Scale.
[a]Two of 6 sites were excluded from the analysis because they did not include abuse items in their study protocols.
*$P < .05$.

DISCUSSION

When queried in late 2000 and early 2001, 1 of 4 women in WIHS for whom HAART was medically indicated reported not using this therapy. Even after 5 years of continued proof of the efficacy of antiretroviral therapy, with the development of more antiretroviral agents and more convenient regimens, and greater opportunity for access to these medications, a significant number of women remained without the benefits of HAART. History of physical/sexual abuse, current drug use and non-White race were all associated with lack of HAART use.

A history of physical, sexual/childhood abuse is common in women with HIV infection, with up to two thirds reporting a lifetime experience with abuse.[12–14] Considering this high prevalence of abuse, our finding that women who had been abused were more than 1.5 times more likely to report not using HAART is sobering. This association of abuse and not using HAART has not been reported in previous studies. Felitti et al.[15] have shown

the association of childhood sexual abuse and other adverse childhood exposures to increased health risks for alcoholism, drug abuse, depression, and suicide, as well as to the presence in adulthood of heart disease, cancer, lung disease, skeletal fractures, and liver disease. We can now add suboptimal HIV treatment to this list.

Studies have demonstrated that women with a history of abuse characterize their relationships with medical providers as less satisfactory than women without a history of abuse.[16] They are more likely to consider the provider as judgmental, annoyed, and disrespectful and find it difficult to discuss private and emotional issues with their providers. Thus, women with a history of abuse rarely acknowledge this abuse during their medical encounters. These less than satisfactory relationships may explain in part why women with HIV and a history of abuse are more likely not to use HAART. In addition, experiences of abusive relationships may be responsible for damaged self-image, which may become an obstacle to efficacious self-care practices. Leenerts[17] describes how "lingering images" of a damaged self grow out of abuse and can produce disconnection from self-care. This combination of an inability to trust health providers and the personal barriers to effective self-care associated with abuse and the sequelae of posttraumatic stress disorder may lead women to decline HAART when it is offered. It is also possible that medical providers may not offer HAART to these women because of concerns regarding emotional instability/adherence to HAART. Certainly the relationship between a woman with a history of abuse and her medical provider requires more investigation if the impact of abuse on HAART use is to be fully understood.

Our study also found that women who were current users of crack, cocaine, or heroin were twice as likely to report not using HAART when medically indicated. The relation of drug use to lack of HAART has been noted in earlier studies.[18–20] The need to encourage physicians to offer all patients appropriate life-extending therapy while providing resources and plans to address barriers to HIV adherence remains a pressing concern.[21] Although those in drug treatment programs and those with previous drug use seem to respond to HAART similarly to those who have never used illicit drugs, current injection drug users and cocaine users require intensive support to adhere to HAART.[22,23] Studies of women with both drug use and abuse consistently show poorer drug treatment outcomes and the need for more tailored and intensive dual-directed therapy.[24]

In its 2001 discussion of health system challenges, the Institute of Medicine reported: "Some problems—such as substance abuse, AIDS, and domestic violence—are so interrelated that they appear to require a comprehensive rather than problem-by-problem approach."[25(p134)] Although residential drug treatment programs for HIV-infected women are available, the pattern of drug addiction often means that women relapse even when treatment has been available. And although advocacy related to abuse and history of child sexual abuse are available, very few intensive residential treatment programs for abuse exist. Mental health services within the public sector (where most of the women with HIV get their care) are also notoriously inadequate.

The WIHS was designed to allow women to honestly report behaviors they might not otherwise disclose and to provide referrals for identified problems. The remarkably high adherence rates to study visits, more than 80% after 5 years,[26] attest to the success of this approach. WIHS staff continually provide opportunities for advocacy and treatment for psychosocial problems as shown by the high percentage of drug users in treatment programs. For some women, competing priorities prevent them from choosing these options. Thus, even when an observational cohort is followed within the context of women-centered HIV comprehensive programs and is provided with advocacy and treatment referrals for domestic violence and drug use, we found a continuing significant impact of these issues on women using HAART.

Being non-White was also significantly associated with not using HAART when medically indicated. With the burden of HIV in US women borne by African Americans and Latinas, it is particularly striking to document that race remains predictive of lack of appropriate therapy.[27] This predictable but hardly acceptable finding cries out for more effective strategies to overcome this racial gap in HAART use, especially considering that the primary goal of The Healthy People 2010 Initiative is to eliminate disparities in health care in our country.[28] Recent data confirm that the average life expectancy of African Americans is 6 years less than that of Whites in the United States, with HIV infection, hypertension, diabetes, and trauma responsible for most of this disparity.[29]

There are some limitations to our study. The data provided are from self-reports and not confirmed by chart review or provider surveys. We cannot tell from our database if there were other medical or nonmedical conditions that providers considered contraindications to the participants' HAART use. The first cross-sectional analysis only allowed us to evaluate HAART use in 1 time period, from 2000 through 2001, and some of these women had been using HAART in the past and discontinued their medications before the studied visit. However, in the second analysis, we evaluated data longitudinally in the subset of women who were not using HAART between 1999 and 2001, and our conclusions are strengthened by the fact that both analyses yielded similar results.

In conclusion, our study suggests that a history of childhood or adult sexual/physical abuse; current crack, cocaine, or heroin use; and racial status are important predictors of appropriate HIV medication use. Through acknowledgment of these challenges and innovative collaborations with mental health, substance use, and abuse experts, HIV providers have an opportunity to more effectively treat all women with HIV infection. But the public health community has an obligation, as well, to assist these efforts by advocating for more comprehensive drug treatment programs, new intensive residential abuse programs, and more successful childhood sexual abuse prevention campaigns. ■

About the Authors

Mardge H. Cohen is with the CORE Center, Cook County Hospital, Cook County Bureau of Health Services, Chicago, Ill. Judith A. Cook and Dennis Grey are with the Department of Psychiatry, University of Illinois, Chicago. Mary Young is with the Department of Medicine, Georgetown University Medical Center, Washington, DC. Lawrence H. Hanau is with the Department of Medicine, Montefiore Medical Center, Bronx, NY. Phyllis Tien is with the Department of Medicine, University of California, San Fran-

cisco, and San Francisco Department of Veterans Affairs. Alexandra M. Levine is with the Division of Hematology, Keck School of Medicine, University of Southern California, Los Angeles. Tracey E. Wilson is with the Department of Preventive Medicine and Community Health, SUNY Downstate Medical Center, Brooklyn, NY.

Requests for reprints should be sent to Mardge H. Cohen, MD, 2020 W Harrison, Chicago, IL 60612 (e-mail: mcohen@corecenter.org).

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Contributors

M.H. Cohen conceived the study, synthesized analyses, and led the writing. J.A. Cook and D. Grey completed the analyses. M. Young, L.H. Hanau, P. Tien, A.M. Levine, and T.E. Wilson assisted with the study and interpretation of analyses. All authors helped to conceptualize ideas, interpret findings, and review drafts of the article.

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Human Participant Protection

We obtained informed consent from the participants in accordance with procedures and consent materials reviewed and approved by the committee on human experimentation at each of the collaborative institutions.

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Latinas and HIV/AIDS Risk Factors: Implications for Harm Reduction Strategies

Ruth E. Zambrana, PhD, Llewllyn J. Cornelius, PhD, Stephanie Sims Boykin, MD, and Debbie Salas Lopez, MD

Objectives. We examined risk factors for HIV infection among Puerto Rican and Mexican American women aged 15 through 44 years.

Methods. We used data from the 1995 National Survey of Family Growth. Analyses focused on the relation between sex role attitudes, sex education, anxiety, and consistent condom use.

Results. Nearly 60% of Puerto Rican and Mexican American women received no sex education from parents. Twenty-one percent of Puerto Rican and 38.3% of Mexican American women reported no sex education in schools. Women with some sex education in school, less than 13 years of education, or higher sex role attitude scores were more likely than other women to have partners who consistently used condoms.

Conclusions. Harm reduction interventions must be designed to reach multiple Latino audiences by age, gender, and subgroup (*Am J Public Health.* 2004; 94:1152–1158)

Increases in the overall rate of HIV infection/AIDS (HIV/AIDS) in the last 2 decades have disproportionately burdened Latino women (hereinafter referred to as Latinas). HIV/AIDS is the fourth leading cause of death for Latinas aged 25 through 44 years in the United States. In 2000, Latinas represented 11.7% of the total female US population.[1] Women of Mexican origin (54.3%) are the largest subgroup followed by women of Puerto Rican origin (9%).[2] More than half of Mexican origin (51.8%) and Puerto Rican (65.5%) women have completed high school. Mexican American women are more likely to be married than Puerto Rican women but equally likely to be poor because of concentration in low-skilled and low-paying employment sectors.[1–5]

Latinas now represent 20% of women ever diagnosed with AIDS and have an AIDS case rate that is strikingly higher (14.9 per 100 000) than that of non-Hispanic White women (2.3 per 100 000).[6] More than half of all cases are reported to be caused by heterosexual intercourse (64%), whereas 34% are caused by injection drug use.[6,7] Latino men (hereinafter referred to as Latinos) have case rates that are 3 times higher than those of non-Hispanic White men, and the HIV/AIDS status of these men is important for 2 reasons: Latinos are the potential partners of Latinas, and attitudes regarding safe sex practices are particularly important for prevention of the transmission of HIV/AIDS.[7–9] Data on northeastern states suggest that Puerto Ricans have the highest case rates among Latino subgroups. Two of the regions with the highest female AIDS case rates are New York state (where Puerto Ricans are the predominant Latino subgroup) and Puerto Rico (29.9 per 100 000 and 21.2 per 100 000, respectively).[6,7] Among Latinos/as with AIDS, 55% were born on the island of Puerto Rico and 21% were born in Mexico.[8,10]

With few exceptions, prior investigations on risk factors associated with HIV/AIDS have focused on Latino adolescent risk behaviors[11,12]; Latino male sexual behavior associated with alcohol and drug use[13,14]; factors predictive of gay men's risk behavior[15–21]; and perceived vulnerability to risk.[3,16,22] Much less is known about the prevalence and nature of risk behaviors among Puerto Rican and Mexican-origin women.

Four major factors associated with risk for HIV/AIDS include social and cultural factors, such as traditional sex role socialization, low socioeconomic status that is associated with lack of knowledge, limited parent–child communication about contraceptive use, and limited exposure to sex education and health education in school and community-based settings.[23–28] Latinos are less likely to feel comfortable in negotiating the use of condoms and in using condoms than African Americans and non-Hispanic Whites.[29–31] Latinas are less likely than African American women and slightly more likely than non-Hispanic White women to get tested for HIV/AIDS.[32] These factors all constitute barriers to Latinas' ability to take protective steps against HIV/AIDS.

We (1) examined differences in demographics, sex role attitudes, sex education sources, and anxiety among Mexican American and Puerto Rican women; (2) examined differences in demographics, sex role attitudes, sex education sources, and anxiety within subgroups; and (3) assessed predictors of consistent condom use by subgroup. These data provide important information on the sexual behaviors and attitudes of the largest subgroups of Latinas and can guide ethnic-specific interventions that have health-promoting effects.

METHODS

Data were from cycle 5 of the 1995 National Survey of Family Growth.[33] The sample was selected from households that participated in the 1993 National Health Interview Survey. All respondents were asked what their main Hispanic national origin or ancestry was regardless of racial background. All respondents aged 15 through 44 years who identified as Mexican (n=833) or Puerto Rican (n=193) and who had responses for all items were included. The response rate was 79%. Results were weighted to reflect the US population according to the US Census Bureau 1995 March Current Population Survey.[34]

Measures

Data included sociodemographic (8 items), parental and school sources of sexual education (7 items), sexual behaviors (2 items), and

sex role attitude and anxiety scales. Sociodemographic data included age, marital status, annual individual income, educational level, language of interview, place of birth, and number of years in the United States. Two items on place of birth and length of time in the United States were used to group respondents into 3 groups. Group 1 included respondents born in the United States; Group 2 included women not born in the United States but who had resided in the United States for 5 years or less; and Group 3 included women not born in the United States but who had resided in the United States 6 years or more.

Data regarding sources and type of sex education were self-reported by a response of yes or no to specific questions. Four items asked whether respondents had ever had sex education in schools on safe sex, sexually transmitted diseases (STDs), abstinence, or birth control methods. Three items asked whether parents ever talked about STDs, birth control methods, or how pregnancy occurs. An additive scale (0 to 4 sources) was used to summarize the number of information sources reported by the respondent from school and another scale (from 0 to 3) was used to summarize the number of reported information sources from parents.

Two questions about sexual behaviors were asked. One asked for the number of lifetime male sexual partners of both married and unmarried women who reported having sexual intercourse. The other, "How often did you or your partner use condoms for disease protection in the last 12 months" was a self-report item with 5 response options regarding the frequency of condom use by the respondent's male partner. (Self-reported behaviors may not be representative of actual behavior, correctness of the use of the condoms, or the quality of the brand of condom used.)

Two standardized scales on sex role attitudes and anxiety were used. The sex role attitude scale had 18 Likert-type items rated on a 4-point scale (from strongly agree to strongly disagree). Using the National Center for Health Statistics recommendation for summing the scores on the scales, we computed a separate variable based on the distribution of responses. Summed scores ranged from 3 to 55, with higher scores indicating more egalitarian sex role attitudes. Reported scores of 41 or higher out of a possible score of 55 (one third of the responses) were classified as having a high sex role score. The anxiety scale consisted of 9 items (with each of the options recoded so that the response "yes" was coded as 1 and the response "no" was coded as 0). Summed scores ranged from 1 to 9, with higher scores indicating higher anxiety. Data reported are for those who scored 5 or higher by subgroup (this reflected 39% of the Latino subgroup) (oral communication from M.D. Bramlett, PhD, October 2000).

Multivariate Analyses and Tests of Significance

The major dependent variable in the logistic regressions was consistent condom use. It was recoded for all respondents who reported using a condom "all of the time" versus all others. Seven independent variables were included in the logistic regressions: age, income, years of schooling, interview language, high sex role attitude score, sources of sex education (these are dichotomized [1=0, 2=1 or more sources]), and high anxiety score (high=scores of ≥5; low=scores of ≤4). We conducted 2 parallel multiple regressions to acknowledge known differences in risk factors within and between ethnic subgroups.[1,3,5,7]

Tests of significance were conducted (using SUDAAN; Research Triangle Institute, Research Triangle Park, NC) to determine the statistical significance of the findings. SUDAAN is designed to account for the multistage sampling strategies used in National Center for Health Statistics health surveys. The Student *t* test was used to determine the statistical significance of 2% or means being compared in the analysis and to test the significance of the coefficients reported in the regression analyses. Only statistically significant differences ($P<.05$) are discussed.

RESULTS

Table 1 displays selected sociodemographic characteristics of Puerto Rican and Mexican American women. Significant differences between Puerto Ricans and Mexican Americans by age, marital status, educational level, and nativity were observed. Puerto Rican women were more than twice as likely as Mexican American women to be in the youngest age group and were all US born (i.e., in any of the 50 states) compared with only 57.1% of Mexican American women. In contrast, Mexican American women were more likely to have ever been married and to have completed less than 7 years of schooling.

Sources of Sex Education

Table 2 displays the reported number and sources of sex education received by subgroup. Mexican American women were almost twice as likely as Puerto Rican women to report no school-based sex education. More than half of the Puerto Rican and Mexican American women did not receive parental sex education on STDs, birth control, or how pregnancy occurs. Only about one quarter of Mexican American women, compared with about one third of Puerto Rican women, reported that parents talked to them about STDs and birth control.

The lower panel of Table 2 presents selected reported sexual behaviors, anxiety, and sex role scores by subgroup. Thirty percent of Puerto Rican women compared with 19.2% of Mexican American women reported using a condom for disease protection "all of the time." One of the factors that may influence consistent condom use is sex role attitudes. Mexican American women (52.9%) were almost twice as likely as Puerto Rican women (31.4%) to report more traditional sex roles. Slightly over one half (51.5%) of the Puerto Rican women reported high anxiety over the last 6 months compared with 44% of the Mexican American women.

Correlates of Consistent Condom Use

Table 3 displays the odds ratios and confidence intervals of those factors that are associated with consistent use of condoms for disease protection "all of the time" for each group. Similar relations were found between age, educational level, sex role attitudes, sex education, and reported consistent condom use by the male partners of both the Puerto Rican and the Mexican American women. Puerto Rican and Mexican American women—who had some sex education in the schools, completed less than 13 years of education ($P<.01$), or reported higher sex role attitude scores ($P<.001$)—were more likely than other Puerto

TABLE 1—Selected Sociodemographic Characteristics of Puerto Rican and Mexican American Women Aged 14 Through 44 Years: United States, 1995[a]

	Puerto Rican (n = 816), %	Mexican American (n = 3 415), %	Student *t* Test
Age, y			3.22*
14–19	19.7	9.9	
20–29	34.4	38.9	
30–44	45.8	51.2	
Marital status			4.41*
Ever married	55.4	72.6	
Never married	44.6	27.4	
Income, $			NS
< 16 000	39.6	32.7	
16 000–29 999	19.4	30.1	
≥ 30 000	41.0	37.3	
Educational level, y			5.29*
< 7	5.1	15.8	
7–11	35.8	32.3	
12	33.3	31.0	
≥ 13	25.8	21.0	
Language of interview			NS
English	76.3	68.9	
Spanish	7.2	17.3	
Spanish and English	16.4	14.6	
Place of birth and length of time in United States			25.02**
US born	100.0	57.1	
Lived in US < 5 y	0.0	8.9	
Lived in US ≥ 5 y	0.0	34.0	

Note. NS = Not significant.
[a]Total population for each group is in thousands. Results were weighted to proportionately represent the 1995 US population according to the 1995 March Current Population Survey.[34]
*P = .01 ; ** P = .001.

Rican and Mexican American women to have partners who consistently used condoms. In addition, younger (aged 14 through 19 years) Puerto Rican and Mexican American women were more likely than older Puerto Rican and Mexican American women to have partners who consistently used condoms (P<.001).

In contrast, the relation between reported consistent condom use and income, the language of the interview, and the anxiety scale score varied within subgroup. Puerto Rican women who had high anxiety scores (P< .001), whose interview language was not English (P<.05), and who lived in families with incomes between $16 000 and $29 999 ($P$<.05) were less likely than other Puerto Rican women to have male partners who consistently used condoms. Mexican American women who had low anxiety scores (P<.05), whose interview language was English (P<.001), and who lived in families with incomes above $16 000 per year ($P$<.001) were less likely than other Mexican American women to have male partners who consistently used a condom.

DISCUSSION

We sought with this study to enhance our understanding of sexual behaviors among Latinas that may increase the risk of HIV/AIDS transmission. The sociodemographic profile, parent–communication patterns, and sexual behavior patterns appear to be representative and confirm other findings.[3,35–40] The most striking findings are that about 60% of the sample received no sex education from parents, and about one fifth of Puerto Ricans and almost 40% of Mexican Americans reported no sex education in schools. Transmission of information on safe sex practices is viewed as the primary domain of parents and schools. When a mother speaks to her daughter about protective sexual practices, she reduces her daughter's risk of becoming sexually active, becoming pregnant, and contracting an STD.[36,38,41] Latino parents tend not to discuss sexuality with daughters. Several reasons may account for this. Religious beliefs in practices such as abstinence and virginity until marriage, cultural-specific beliefs that sexual knowledge may promote sexual activity, lack of knowledge, and discomfort with the topic are barriers to daughter–parent communication. In addition, traditional religious institutions may not be as significant a source of sex education for Latinas as has been witnessed in other interfaith and denominational organizations.[42]

Receipt of sex and health education in schools is an important source of information to increase knowledge and reduce high-risk health behaviors.[43,44] Standards and types of sex education provided by public schools reveal strong state differences in philosophic orientation to sex education, and few states have a comprehensive sex education program for secondary school students.[45,46] Schools in those states of highest Latino concentration are most likely to not require any sex education or teach abstinence only (7 states). Only 3 states—New Jersey, New Mexico, and California—provide sex education in both abstinence and contraceptive options.[45] Because about half of the people in the study sample did not complete high school, it may be that schools are not the most viable vehicle for sex education.[4] For those who remain in school, sex education is not often required. Thus, an important opportunity to transmit this information is lost.

It is noteworthy that 33% of the Puerto Rican sample and 45% of the Mexican American sample said they do not use condoms at all, which places them at high risk for transmission of HIV/AIDS. For Puerto Rican women, more consistent use of condoms may be associated with more education, higher incomes,

TABLE 2—Sources of Sex Education, Reported Sexual Behaviors, Anxiety, and Sex Role Attitude Scores for Puerto Rican and Mexican American Women Aged 14 Through 44 Years: United States, 1995

	Puerto Ricans (n = 816 000), %	Mexican Americans (n = 3 415 000), %	Student *t* Test
Source of sex education			
Reported number of school sex education sources			2.49*
0	21.0	38.3	
1–2	22.7	19.4	
3–4	56.3	42.3	
Ever had sex education on safe sex?			
Yes	69.0	48.7	
No	31.0	51.3	
Ever had sex education on STDs?			
Yes	70.2	51.7	
No	29.8	48.3	
Ever had sex education on abstinence?			
Yes	60.3	47.8	
No	39.7	52.2	
Ever had sex education on birth control?			
Yes	70.3	53.5	
No	29.7	46.5	
Reported number of parental sex education sources			
0	55.2	64.1	
1–2	20	18.4	
3	24.8	17.5	
Parents ever talked about STDs?			
Yes	31.1	23.5	
Parents ever talk about birth control?			
Yes	32.9	24.3	
Parent ever talk about how pregnancy occurs?			
Yes	39.0	31.5	
Reported sexual behaviors			
Lifetime number of male sexual partners			
1	27.9	50.5	
2	18.2	17.3	
3	19.7	7.5	
4–6	16.5	14.5	
≥7	16.4	10.7	
Condom use for disease protection			3.03*
All of the time	30.0	19.2	
More than half of the time	13.0	12.3	
Half of the time	11.1	11.1	
Less than half of the time	13.2	13.2	
Not at all	32.6	45.3	
Anxiety score[a]			2.98*
High	51.5	44.2	
Sex role attitude scores			4.42*
Low	31.4	52.9	
Medium	34.5	30.1	
High	34.1	17.1	

Note. STD = sexually transmitted disease.
[a]Data reported are for those who scored 5 or higher (considered a "high" score), by subgroup.
*P = .01.

less traditional sex role attitudes, more parental and school sex education information, and presumably more access to health information.[24,35,38] Associated with low rates of condom use and fewer safe sex messages reaching Latinas may be their perceived inability to negotiate safe sex practices with a partner and their culture-specific sex role attitudes.[15,47,48] The negotiation with men to engage in protected sex is a pervasive issue for all women but particularly for low-income Latinas.[24,25]

The relation between anxiety, sex role attitudes, and sexual behaviors is unknown, as life stressors were not measured in this cross-sectional study. However, for Latinas, low education, low income, or immigration may be associated with more anxiety and depression, more traditional sex role attitudes, less knowledge, and less perceived power or assertiveness skills to negotiate safe sexual behavior effectively.[24,35,37,38] Other studies have found that anxiety is associated with the presence of undetected or untreated mental health problems or engaging in risk behaviors that are not culturally sanctioned, such as use of alcohol and drugs.[42,49] As noted previously, 28% of all HIV/AIDS cases reported among Latinas are due to injection drug use.[7] Future studies need to explore a broad set of factors, including substance use, to increase our understanding of the role of cultural-specific protective factors in the transmission of HIV/AIDS.[16,50,51] The intersection of ethnicity, gender, and socioeconomic status appears to be strongly associated with Latinas' increased risk for HIV/AIDS. In effect, low-income Latinas experience multiple challenges to safe sex practices that include less likelihood that they will communicate with providers, financial worries that may overshadow safe sex concerns, lack of access to safe sex education resources, and low perceived vulnerability.[3,16,22,31,32,48,52]

Implications for Harm Reduction Strategies

The question of how to reach the target audience in a culturally appropriate and health-promoting way is compelling. Our data reinforce the distinct differences in predictors of risk reduction and health promotion by Latino subgroup. These findings have important implications for interventions at the community

TABLE 3—Correlates of Condom Use for Disease Protection All of the Time (Odds Ratios and 95% Confidence Intervals) for Puerto Rican and Mexican Women Aged 14 Through 44 Years, by Selected Characteristics: United States, 1995[a]

	Puerto Ricans	Mexican Americans
Age, y		
14–19	1.32** (1.31, 1.33)	2.68** (2.67, 2.69)
20–29	0.80 (0.79, 0.81)	0.92 (0.91, 0.93)
30–44	1.00 . . .	1.00 . . .
Income, $		
<16 000	1.00 . . .	1.00 . . .
16 000–29 999	0.86* (0.85, 0.87)	0.55** (0.54, 0.56)
≥30 000	1.06 (1.05, 1.07)	0.55** (0.54, 0.56)
Educational level, y		
<7	3.16 ** (3.10, .3.22)	1.35 ** (1.33, 1.37)
7–12	2.06 ** (2.05, 2.07)	1.19 ** (1.18, 1.20)
≥13	1.00 . . .	1.00 . . .
Interview language was English		
Yes	1.14 * (91.14, 1.15)	0.58** (0.58, 0.59)
No	1.00 . . .	1.00 . . .
High sex role attitude score		
Yes	1.95 ** (1.94, 1.96)	1.77 ** (1.76, 1.78)
No	1.00 . . .	1.00 . . .
Sources of sex education		
1	1.46 ** (1.44, 1.48)	2.13** (2.12, 2.14)
2	1.00 . . .	1.00 . . .
Anxiety scale score[b]		
High	0.69** (0.67, 0.71)	1.42* (1.41, 1.43)
Low	1.00 . . .	1.00 . . .
No.	193	833
χ^2 test	31563.144	105805.951
df	10	10
P	.0001	.0001

[a]For persons who had at least 1 male sexual partner.
[b]Data reported are for those who scored 5 or higher (considered a "high" score), by subgroup.
* *P*<.05; ** *P*<.001.
Source. National Study of Family Growth.[33]

and school level. Interventions in the Latino community are challenging, and multiple reasons can account for prior ineffective interventions.[25,53,54] For both groups of Latinas, baseline information on sexual knowledge, attitudes, and practices has not been previously available, and it was assumed that parents and schools provided basic knowledge. New emphasis on abstinence as the only option will erode gains made in safe-sex practices. In addition, the higher prevalence of HIV infection among Latinos/as reflects multiple barriers to quality screening and prevention services, including lack of insurance, lack of transportation, discomfort with sex education designed for English-speaking persons, concerns about stigma and confidentiality, and sociocultural and normative beliefs.[16,23–28,55]

Harm reduction interventions must not be individual oriented or Latino generally oriented but designed to reach ethnic subgroup–specific audiences: women, potential male partners, and parents of both male and female youths. Increasingly, the evidence shows that approaches in Latino communities must be intergenerational, ethnic-specific, culturally and linguistically appropriate, and community integrated.[56,57] Information-oriented and skill-building interventions (sex education combined with communication assertiveness, relationship power, and negotiation skills) can promote health-enhancing behaviors among Latinas.[58–62] Community infrastructure resources, such as churches and schools that serve families and youths, are central to improving sex education in Latino communities.[41,63,64]

Overall, the Healthy People 2010 objectives do not have specific targets for harm reduction and prevention of HIV/AIDS for Latinos/as, although targets have been set for gender, developmental age, and mode of transmission. A relevant goal is to increase the proportion of middle, junior high, and senior high schools that provide school health education in priority areas with HIV/AIDS included. The objective is to have the proportion of schools that have the individual health education component of unintended pregnancy, HIV/AIDS, and STD information increase from 65% (1994 baseline) to 90% (2010 target).[65] Two questions require consideration in implementing these goals: How will school districts respond to this priority area in view of new shifts to abstinence-only sex education programs? How will these programs be implemented in a manner that is linguistically, culturally, and literacy appropriate?

Sex education in schools is almost nonexistent.[45] Comprehensive sex education programs have to be based within schools, incorporated into after-school programs, or established in community-based centers to increase opportunities to reach larger numbers of Latino youths and parents.[50,55] Because low-income parents are less likely to discuss sex education with their children than middle-class parents, in future interventions, parents as well as youths need to be targets for sex information and for communication skills. Because Mexican-origin and Puerto Rican women tend to have children at younger ages, these parents would be relatively young, and an intervention would be a primary prevention opportunity that could be used to extend their knowledge on health-promoting sexual behaviors. Schools must tailor their programs to the specific cultural, linguistic, and educational level of Latino ethnic groups in their districts to help meet the 2 most pressing needs in the Latino community—access to health services

and education.[2] Because Latinas have a higher prevalence of 1 or more family members being infected with HIV/AIDS, more attention needs to be focused on family and community interventions.[66]

Caution in the interpretation of these data is warranted. Methodological issues of social desirability and acquiescent responses or Latinas' discomfort in discussing these issues may have influenced reporting of sexual behaviors.[67] Nonetheless, these findings provide valuable insights into risk factors that must be addressed at the individual, family, and community level to prevent the transmission of HIV/AIDS in the next generation of Latinas. ■

About the Authors

Ruth E. Zambrana is with the Department of Women's Studies, University of Maryland, College Park. Llewllyn J. Cornelius is with the School of Social Work, University of Maryland, Baltimore. Stephanie Sims Boykin is with the School of Medicine, Department of Family Medicine, University of Maryland, Baltimore. Debbie Salas Lopez is with the Department of Internal Medicine, New Jersey Medical School, Newark.

Requests for reprints should be sent to Ruth E. Zambrana, PhD, Professor, Department of Women's Studies; University of Maryland, 2101 Woods Hall, College Park, MD 20742 (e-mail: rzambran@umd.edu).

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Contributors

R.E. Zambrana and L.J. Cornelius designed the study plan, analyzed the data, and wrote the article. All authors reviewed the article, contributed to data interpretation, and provided substantial suggestions for revisions.

Human Participant Protection

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Acceptability of a Microbicide Among Women and Their Partners in a 4-Country Phase I Trial

Margaret E. Bentley, PhD, Andrew M. Fullem, MSPH, Elizabeth E. Tolley, MA, Clifton W. Kelly, MS, Neelam Jogelkar, MS, Namtip Srirak, PhD, Liness Mwafulirwa, RN, Gertrude Khumalo-Sakutukwa, MSW, MSc, and David D. Celentano, ScD, MHS

Objectives. We analyzed qualitative and quantitative data for 98 HIV-negative, low-risk women in Malawi, Zimbabwe, India, and Thailand who participated in a safety and acceptability study of BufferGel, a vaginal microbicide to determine the across-country acceptability of vaginal microbicides among women and their partners.

Methods. Quantitative survey data were collected at 7 and 14 days after use among enrolled women, and exit interviews were conducted with women and their partners in separate focus group discussions.

Results. Acceptability was high in all sites (73% of women approved of the microbicide). Women in Africa, where HIV infection rates are highest, were virtually unanimous in their desire for such a product, suggesting that an individual's perception of being at risk for HIV will outweigh concerns about side effects, problems applying a product, or other factors, when products are shown to be efficacious. But men and women reported that use, which was kept secret from an intimate partner, would be difficult and might "break the trust" of a relationship.

Conclusions. Acceptability research across diverse settings through all stages of microbicide research, development, and postlicensure dissemination can help maximize acceptability and use. (*Am J Public Health.* 2004;94:1159–1164)

In the United States and throughout the world, women represent the largest percentage of newly infected HIV-positive individuals,[1,2] yet in many settings their ability to protect themselves is limited. The effectiveness and use of male and female condoms are limited by the need for women to negotiate for use with their sexual partners.[3] Microbicide products that women could electively use, instead of depending on male use of condoms, hold great promise for HIV prevention, particularly among women who perceive themselves to be at high risk of infection.[4]

More than 60 candidate products are currently in various stages of development, and 17 have reached the stage of clinical testing to determine safety, efficacy, and acceptability.[5,6] The Rockefeller Foundation Microbicide Initiative defines *acceptability* as a woman's willingness and ability to use a product or technology in everyday life; it includes her perception of risk and her concerns about or experiences with side effects, alternative products, behavioral choices, cost, and access. Data regarding such perceptions and concerns are needed to identify factors that facilitate or discourage effective microbicide use in diverse settings.[7]

Because approved microbicides are not available, most acceptability research has relied on indirect study designs. Some studies have surveyed potential users about desirable and undesirable product attributes; others have solicited reactions to existing products of similar design, such as spermicides by high-risk women and men individually and in couples.[8,9–17] Recently, some investigators have called attention to social context, as well as physical and clinical attributes of products, with regard to acceptability.[18]

Conducting microbicide acceptability research during clinical trials permits us to assess factors that pertain to actual products being developed for marketing among diverse, at-risk populations and settings. The recent increase in phase I clinical trials has included acceptability research in several settings.[19–27]

We report on the acceptability of a microbicide, BufferGel, developed by ReProtect Inc, Baltimore, Md.[28] This odorless and clear gel with a pH of 3.9 buffers twice its volume of semen to a pH of approximately 5.0, maintaining the protective acidity of the vagina during and after intercourse.[28] BufferGel has no surfactant or detergent properties likely to cause irritation or clinical lesions. Safety data have been reported elsewhere,[29,30] as well as acceptability results among low-risk US women in Rhode Island.[19]

The study enrolled HIV-negative, low-risk women in 4 countries—Malawi, Zimbabwe, India, and Thailand—that have diverse sexual and hygiene practices and varied prevalence of HIV and other sexually transmitted diseases (STDs). Overall acceptability of BufferGel, self-perceptions of HIV risk, ease/convenience of use during sex, and potential for undisclosed use were assessed through semistructured interviews and segregated focus group discussions among women and among male partners of sexually active women participants.

METHODS

The study was conducted under the auspices of the National Institutes of Health (NIH)–funded HIV Network for Prevention Trials (HIVNET). The protocol team consisted of in-country investigators at the study sites in Malawi, Zimbabwe, India, and Thailand; partners at Johns Hopkins University and the University of California at San Francisco; and staff from Family Health International, the Fred Hutchinson Cancer Research Center (FHCRC), and NIH.

Study Design

Participants were asked to apply BufferGel for 14 days, morning and evening, and to wash and dry the applicator after use. Women in the sexually abstinent cohort were requested to refrain from sexual activity for

the duration of the study. Sexually active women were asked to have sex at least twice a week and to use study-provided nonlubricated condoms during all acts of vaginal intercourse during the study period. Women agreed not to douche or clean their vaginas or to apply any other products to their vaginas during the study.

Following the study design and methods used in the Rhode Island safety and acceptability study,[19,29,30] we collected acceptability data for the international sites, using structured interviews and focus groups with men and women. All social scientists and data collectors participated in regional training in Africa and Asia to ensure standardization of methods.

During clinic visits at days 7 and 14, an interviewer administered a questionnaire on product characteristics (e.g., smell, color, texture) and applicator characteristics (e.g. portability, ease of use, comfort, cleaning). Women in the sexually active cohort were asked about partners' reaction to the product and use of the product during sex. At day 14, all study participants answered questions about their willingness to use the product or reasons for being unwilling to use the product if it were approved. After completing the trial, women and their male partners were invited to join gender-specific focus group discussions. The focus group data were collected to provide context and meaning to the quantitative survey data.

Study Participants

Sexually active and sexually abstinent cohorts were recruited from patients visiting Queen Elizabeth Hospital, Blantyre, Malawi; Spilhaus Clinic, Harare, Zimbabwe; and Jahengeer Clinic, Pune, India; and from staff at Chiang Mai University, Chiang Mai, Thailand. Participants were HIV negative, had no history of STDs in the past 6 months, and were either sexually abstinent or in a stable, monogamous relationship. Inclusion and exclusion criteria have been described previously.[29,30] Written informed consent was obtained from all participants before any clinical examinations or questionnaires were administered.

Between July 1998 and April 1999, 288 women were screened, and 98 were enrolled in the study (30 sexually abstinent, 68 sexually active). The average age was 33 years (range: 18 to 44 years). Most women had completed either primary (44%) or some secondary (47%) school and were either unemployed (46%) or employed full-time (42%). Most abstinent (57%) and all sexually active women were married. Three women were dropped from the study because of a diagnosis of *Candida* at the day 7 visit; 2 left because of breakthrough menstrual bleeding; and 1 woman was not able to meet the product use adherence criterion of application on at least 12 of 14 days and elected not to continue. Of the 98 women who completed the study, 85 (93%) met the product use adherence criterion. Transcripts from 17 focus group discussions with 99 people were analyzed (at least 1 group for each women's cohort and 1 men's group from each country).

Data Analysis

Structured questionnaire data were entered with Microsoft Access 1997[32] at the 4 international sites, transferred electronically to FHCRC, and converted into SAS database files.[32] FHCRC statisticians resolved data queries with data managers at each site. Descriptive data were stratified by country and, when applicable, by cohort (sexually abstinent or sexually active). Small cell sizes precluded the use of statistical tests. The primary study endpoint (outcome indicator) for acceptability was the proportion of women who reported at the end of the study that they would be willing to use BufferGel if it were approved for vaginal application.

FDGs were taped, transcribed, and imported into Nud*ist 4[33] for analysis, and a data matrix and display approach was used. Researchers read all transcripts to identify and code themes used by Nud*ist 4 to generate reports of like-coded blocks of text. Text blocks associated with codes were analyzed for dimensions of attitude, perspective, and association with other codes. For central themes, data matrices were used to examine differences by country, gender, and cohort.

RESULTS

Overall Acceptability

Based on structured interview data, all women in the African sites and most (57% abstinent, 65% sexually active) women in Thailand said that they would use the product if approved, compared with much smaller proportions (17% and 60%, respectively) of women in India (Table 1). Men and women in African focus group discussions overwhelmingly expressed a need for protection from HIV and welcomed the possibility of having

TABLE 1—Participant Responses Regarding Product Features Among Sexually Active Women at Day 14, by Site

	No. Responses (%)				
	Malawi	Zimbabwe	India	Thailand	Total
Total	22	25	21	24	92
If approved, would you use BufferGel?					
Yes	20 (91%)	25 (100%)	7 (33%)	15 (63%)	67 (73%)
In some circumstances	2 (9%)	0	3 (14%)	9 (38%)	14 (15%)
No	0	0	11 (52%)	0	11 (12%)
Total	22	25	20	24	91
BufferGel features liked "a lot" or "somewhat":					
Ease of insertion	22 (100%)	24 (96%)	18 (90%)	20 (83%)	84 (92%)
Reusable applicator	18 (82%)	19 (76%)	13 (65%)	10 (42%)	60 (66%)
Color	22 (100%)	24 (96%)	16 (80%)	23 (96%)	85 (93%)
Smell	20 (91%)	23 (92%)	10 (50%)	21 (88%)	74 (81%)
At least sometimes, the product:					
Felt too wet or drippy	10 (45%)	12 (48%)	13 (65%)	10 (42%)	45 (49%)
Soiled clothes	9 (41%)	7 (28%)	2 (10%)	10 (42%)	28 (31%)

new products available that could prevent HIV transmission. By contrast, women in Indian focus group discussions who said that they would not use BufferGel believed that they were not at risk of HIV infection and did not need a protective method.

Perception of Risk

HIV risk perception was not assessed quantitatively. However, most groups in Zimbabwe and Malawi discussed HIV risk at some length in association with sexual risk. A Malawian woman said "I can indeed control my desires for sex and be faithful to my partner, but this may not be the same with him. I can't monitor his movements. . . ." Some men acknowledged that their own wives might use the gel, saying "Considering the warnings that she had been giving me [about being unfaithful], it made me happy that she could use it [the gel]," or, "If you know that you are promiscuous, you have to say that you want to use BufferGel with [your] wife, because you know that you may bring her the virus and give it to her." Other African men worried that encouraging one's wife to use a microbicide would cause her to become promiscuous. One man questioned whether the product should be made available at all, whereas several others said that it should be used only by "these other women who do not have a man they call their own. . . ." Another man proposed selling the gel only to men: "If I want to be promiscuous, I can just take this product and give it to my partner. It shouldn't be sold to women, because they will just use it to have sex with other men."

Women in Africa worried about HIV affecting the next generation. A Zimbabwean woman commented "We have children who are growing up. They should stay alive. We are scared for them." Some Thai women also stated that they felt themselves to be at risk for HIV and envisioned using a product like BufferGel in the future, should it be proven effective. Indian women seemed to distance themselves from personal vulnerability; in their discussions of potential future use of BufferGel, they tended to focus on hypothetical promiscuous women: "Only women who are like that—women who go out, keep outside relations with many men . . . the other women have no reason to use this medicine."

Undisclosed Use

In focus group discussions, few women or men considered undisclosed use to be feasible, given the product's characteristics. Properties of the gel that would make undisclosed product use difficult included increased wetness, stickiness, or telltale signs on men's penises or on condoms. A man from Zimbabwe suggests that the gel cannot be used clandestinely, stating that men might "feel that something [is different]. . . . Why did it get wet so quickly? What is it? . . . So, you would ask what is happening?" However, to avoid a partner's discovery, one Zimbabwean woman said, "you use half as much but insert deeply—and if the partner asks, just tell him it is normal vaginal discharge. He won't know exactly what it is." Some women were not sure that they would be able to apply the product privately before intercourse.

Whether feasible or not, undisclosed use also was viewed as undesirable and potentially risky. African men and women explained in focus group discussions that undisclosed use would be inappropriate "because we are one body" or "we are one when we are in this house." Possible adverse outcomes of a wife's undisclosed use, if such use is detected, included disagreement in the home, being sent to one's parents' house, physical violence, or even divorce. Zimbabwean women anticipated a need to attribute their use of such a product to health concerns that would not impugn their partners' sexual fidelity: "It is better to be honest with him that you are using BufferGel to protect yourself from different infections. Even if you know that it is for preventing HIV, you just tell him that it is protecting you from cancer or other gynecological problems." One woman in the sexually abstinent cohort in Zimbabwe observed that "single women have the right to tell [the man] 'I am using this, whether you like it or not.' It's different for a married woman, who might be sent packing if she does that."

Ease of Insertion and Applicator Features

Almost all participants (92%) found the applicator easy to insert; 31% of women disliked having to clean and reuse it (Table 1). In focus group discussions, concerns about cleaning offset ease of insertion in women's overall appraisal, especially among women who did not have access to running water or feared loss of privacy when using a communal tap. A woman from Malawi worried about leaving it out to dry if droplets "could result in other infections, and you would think it's the gel [that caused the infection, when] it's the applicator." A Thai woman tried to disinfect the applicator with alcohol, although not instructed to do so, and experienced burning sensations on using it. Indian and Thai women worried about storing the gel and applicator away from children who might play with the items or ask questions. Single-dose disposable applicators and tablet or suppository delivery systems were suggested as alternatives, but these suggestions did not entirely resolve storage concerns and evoked questions about cost.

Responses to BufferGel's Physical Characteristics

Women liked many characteristics of BufferGel (Tables 1 and 2), in particular that it is colorless (94%) and odorless (81%). In focus groups discussions, a few participants compared BufferGel's color to that of women's natural discharge: "similar to the fluid that women discharge from their body," as a Zimbabwean man expressed it. The majority of Indian women in the abstinent cohort said that the product's lack of odor was advantageous "because no one can make out that it has been used." In Zimbabwe focus group discussions, 1 man and several women suggested that using the gel could help women prevent odor. A woman from Malawi said that the lack of odor "means that the gel is a strong drug." A few men from Thailand and Zimbabwe requested that a deodorant or nice scent be added to the gel. According to survey data, less than half of women (49%) had some concerns related to the gel's consistency, especially wetness or drippiness (Table 1). In focus group discussions with sexually active women, a few Africans and the majority of Indians and Thais found the gel too thin, slippery, or prone to leaking, sometimes comparing it to the slow trickling that a woman experiences during her menstrual period. Leakage caused 31% of women to report that BufferGel soiled their clothes (Table 1). Some managed to mitigate this

TABLE 2—Participant Responses Regarding Product Characteristics Among Sexually Active Women at Day 14, by Site

	No. Responses (%)				
	Malawi (n = 16)	Zimbabwe (n = 17)	India (n = 15)	Thailand (n = 17)	Total (n = 65)
Strongly or somewhat liked the way BufferGel felt	15 (94%)	17 (100%)	12 (80%)	10 (59%)	54 (83%)
Product never or rarely leaked out:					
Prior to sexual intercourse	15 (94%)	15 (88%)	15 (100%)	15 (88%)	60 (92%)
During sexual intercourse	10 (63%)	16 (94%)	9 (60%)	11 (65%)	46 (71%)
After sexual intercourse	14 (88%)	13 (76%)	11 (73%)	13 (76%)	51 (78%)
At least somewhat agreed that product interrupted:					
Own sexual pleasure	4 (25%)	4 (24%)	2 (13%)	4 (24%)	14 (22%)
Partner's sexual pleasure	7 (44%)	3 (18%)	2 (13%)	3 (18%)	15 (23%)
At least somewhat agreed that product added to:					
Own sexual pleasure	6 (38%)	13 (76%)	8 (53%)	6 (35%)	33 (51%)
Partner's sexual pleasure	4 (25%)	13 (76%)	6 (40%)	5 (29%)	28 (43%)
Strongly or somewhat agreed that they had more communication problems than before the study	1 (6%)	2 (12%)	2 (13%)	11 (65%)	16 (25%)

leakage with pads or cotton wool provided by the study. Other women recommended changing BufferGel so that it was not so liquid or suggested that it could be formulated to be effective in smaller volumes or reformulated as a suppository.

Nevertheless, the majority of sexually active women participants (83%) liked how the product felt (Table 2). Only a few reported significant product leakage before (8%), during (29%), or after (22%) sex (Table 2). One Zimbabwean man commented "I don't despise it, although there were some problems such as it being messy. . . . We can't say it was too messy. It was just like she was having her periods, you see. It is something that can be washed." A couple of men from Zimbabwe reported that this wetness kept them from wanting to touch their partner during sexual foreplay. Some women said that the product was not leaky if it was inserted deeply enough or if the woman waited sufficient time after insertion to have sex.

Several Thai men and one man from Zimbabwe disliked the sticky nature of the gel, although other men and women found this attribute desirable. As explained by a Malawian woman, "BufferGel had a tightening effect and it was not slippery, so I was happy with the product." Another woman from Zimbabwe said: "We did not have any wetness problems, because BufferGel used to sort of dry up and stick. So, it was not slippery. It was perfect." In fact, approximately half of the women from the Zimbabwe sexually active focus group discussion said that the consistency of BufferGel made "sex nicer than on normal days." They explained that dry sex is painful and prolongs the sexual episode: "With BufferGel it is not slippery. It is actually nicely sticky." The perception that the product enhanced sexual pleasure also was reflected in survey data; approximately half of women reported that their own (51%) or their partner's (43%) sexual pleasure was increased (Table 2).

Perceived Side Effects

Some women and men in almost all focus group discussions indicated that they had anticipated side effects, believing, for example, "that I was going to be given harmful products that would burn my vagina." Several Indian women chose to participate in the abstinent cohort to protect their husband's health. An Indian woman in the sexually active cohort said: "All the time we were wondering whether anything would happen to me or my husband. So, sex was dissatisfying." One Zimbabwean man worried about whether the gel "would affect me or my penis, that it would make me sick or something would happen." Another "was afraid that if I remove the condom and have sex without one, it might affect me." Most participants expressed surprise and satisfaction that the gel did not cause the problems they anticipated. One Zimbabwean woman, for example, said, "On the first day, I was surprised because I did not feel anything. I just felt like I did before [using the gel]."

DISCUSSION

Employing the same protocol and methodology previously used among low-risk women in Rhode Island[19] in this multisite study in 4 less-developed countries, we found that overall acceptability of BufferGel was high and that women were unanimous in their belief that such products should be available to women if proven to be safe and effective. The womens' perceptions of being at risk and the stage of the HIV epidemic within each setting placed the results in context for the researchers; in settings in which the HIV epidemic is more advanced (particularly in Zimbabwe and Malawi) and women therefore presumably perceived their risk to be high, acceptability was unanimous.

Across all settings, but particularly in the African sites, both men and women were concerned about not communicating with their partners about using such products. Focus group participants, particularly those from the African sites, concentrated on issues related to partner trust and the dangers—including violence—of undisclosed use in marriages or established relationships. Most participants expressed that even if a product could be used during sex without alerting the partner, it was important for couples to make the decision jointly to use the product. BufferGel's wetness and its appearance on the man's penis would alert men that a woman had inserted something into her vagina before sex. Men from all sites believed that they had the right to participate with their wives in discussing the use of microbicides. However, this discussion might raise questions about the fidelity of either or both partners, depending on which partner introduced the topic and how the rationale was presented. Some men acknowledged that microbicides would be an important option for "other" women—those without a husband or a regular partner or those who are "promiscuous." The availability of microbicide products may threaten some men's perception of their control of women. Some women in

the study anticipated this problem and suggested portraying microbicides as generic vaginal health products when describing their reasons for using them to a male partner.

It will be important, therefore, to anticipate men's concerns and to develop strategies for promoting microbicides among stable partners and in marital relationships. Upon microbicide products' becoming available in the marketplace, site-specific and subgroup-specific acceptability and marketing research can continue to address these issues as the populations increase in risk and cultural diversity. Women at higher risk might devise solutions for maintaining privacy or secrecy of use, but including men in acceptability and marketing research helps to clarify men's major concerns and identify strategies that may effectively preempt or address these concerns. In general, men in this study appeared to be responsive to the need for women to protect themselves. With expanded trials, acceptability research should include community opinion leaders and authorities whose views may affect future dissemination of effective products.

This study had a number of limitations. First, a phase I trial requires the enrollment of women who are at low risk for STDs/HIV, a population not representative of the women at highest risk for infection, whose approval of a microbicide product could be even stronger than that in our study. Second, the trial required condom use during all sexual acts; we did not study BufferGel's acceptability during unprotected sex, when presumably microbicide use would be of greatest benefit. Twice-daily use is at the upper limit of the dose most women would require; therefore, issues related to messiness would likely be diminished for most users. It is difficult to conclude from 2 weeks' use of an investigational product of unknown efficacy whether practical problems would became more troublesome after sustained use by high-risk women or would be resolved. For example, soiling of clothes was addressed by the use of absorbent pads. This solution might become either an acceptable routine or a recurring annoyance. Concerns about cleaning a reusable applicator are being addressed by packaging gels in single-use disposable applicators, but storage may be a consideration for either approach, as well as privacy.

Our data suggest that negative perceptions regarding product characteristics (wetness, drippiness, stickiness) should be identified in microbicide acceptability research. However, users' perception of infection risk may outweigh these "nuisance factors" once microbicide products are proven efficacious, as we previously found in the Rhode Island trial.[19] Larger trials among higher-risk women will provide an opportunity to investigate and address issues related to applicator characteristics, privacy, cleaning, and storage in diverse geographic, demographic, and sociocultural settings.

Microbicide acceptability research can contribute to product development and to messages used for introducing such products before specific products are proven efficacious for HIV prevention. Acceptability research through postlicensure dissemination can facilitate maximum access to products among those populations most in need of additional preventive technologies. This research should include social and contextual research into gender relations, sexuality, and sexual behavior to establish the context within which these products will be promoted and used.[34] ■

About the Authors

Margaret E. Bentley is with the Carolina Population Center, University of North Carolina, Chapel Hill, NC. Andrew M. Fullem is with John Snow Inc, Boston, Mass. Elizabeth E. Tolley is with Family Health International, Durham, NC. Clifton W. Kelly is with the Fred Hutchinson Cancer Center, Seattle, Wash. Neelam Jogelkar is with the National AIDS Research Institute, Pune, India. Namtip Srirak is with the Research Institute for Health Sciences, Chiang Mai University, Chiang Mai, Thailand. Liness Mwafulirwa is with the Johns Hopkins University College of Medicine Research Project, Blantyre, Malawi. Gertrude Khumalo-Sakutukwa is with the Center for AIDS Prevention, University of California, San Francisco. David D. Celentano is with the Department of Epidemiology, Bloomberg School of Public Health, Johns Hopkins University, Baltimore, Md.

Requests for reprints should be sent to Margaret E. Bentley, Carolina Population Center Department of Nutrition, 123 West Franklin St, Suite 308B, Chapel Hill, NC 27516 (e-mail: pbentley@unc.edu).

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Contributors

M.E. Bentley took the lead in designing the study, training the in-country teams, directing the analysis, and writing the article. A.M. Fullem worked closely with M.E. Bentley on study design, analysis, and writing. E.E. Tolley was responsible for analysis of the qualitative data and was a major contributor to the article. C.W. Kelly analyzed the quantitative data. N. Jogelkar, N. Srirak, L. Mwafulirwa, and G. Khumalo-Sakutukwa led implementation of the study in India, Thailand, Malawi, and Zimbabwe, respectively. D.D. Celentano was the principal investigator for the cross-site BufferGel Phase I trial.

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Human Participant Protection

The protocol was reviewed by institutional review boards at Johns Hopkins University and the University of California at San Francisco and in each of the countries in which the study was to be conducted. The appropriate drug control board in each country also reviewed the protocol and approved importation of the study product.

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Efficacy of a Woman-Focused Intervention to Reduce HIV Risk and Increase Self-Sufficiency Among African American Crack Abusers

Wendee M. Wechsberg, PhD, Wendy K.K. Lam, PhD, William A. Zule, DrPH, and Georgiy Bobashev, PhD

Objectives. This study compares 3- and 6-month outcomes of a woman-focused HIV intervention for crack abusers, a revised National Institute on Drug Abuse standard intervention, and a control group.

Methods. Out-of-drug-treatment African American women (n=620) who use crack participated in a randomized field experiment. Risk behavior, employment, and housing status were assessed with linear and logistic regression.

Results. All groups significantly reduced crack use and high-risk sex at each follow-up, but only woman-focused intervention participants consistently improved employment and housing status. Compared with control subjects at 6 months, woman-focused intervention participants were least likely to engage in unprotected sex; revised standard intervention women reported greatest reductions in crack use.

Conclusions. A woman-focused intervention can successfully reduce risk and facilitate employment and housing and may effectively reduce the frequency of unprotected sex in the longer term. (*Am J Public Health.* 2004;94:1165–1173)

One of the devastating consequences of crack cocaine use among African American women is HIV prevalence rates, which range from approximately 1.7% among noninjecting drug users with no sex-trading history[1] to 54% among homeless women who are more likely to trade sex for drugs.[2–5] Although the Centers for Disease Control and Prevention does not track the relationship between crack use and HIV transmission, research indicates that crack use is associated with increased sexual activity,[6,7] sex trading, multiple partners, polysubstance use, and unprotected sex.[8–17]

African American women who use crack are especially at risk because many engage in high-risk behaviors and live in social contexts that increase their vulnerability.[18] Few of these women are self-sufficient, and they report high levels of public assistance, homelessness, and unemployment; low levels of education; and poverty-level incomes.[19–24] The social contexts of substance-using women are also characterized by violence and crime, with high rates of childhood and current victimization.[3,25–31] As a result, they report low self-image; symptoms of depression, anxiety,[32,33] and posttraumatic stress disorder[34]; significant medical problems; frequent emergency room visits[27]; and needs for other resources.[35]

HIV risk-reduction interventions for women can be effective in reducing sex-risk behaviors and increasing HIV/AIDS knowledge and self-efficacy.[36–45] Such interventions should be grounded in social psychological theory; incorporate multiple, women-only sessions led by peers; address gender-related influences; and be culturally sensitive.[36,38]

Recently, researchers have recognized the importance of the multiple social contexts in which women live and have targeted personal empowerment in economic resources and relationships[46] as a vehicle to help women understand and change HIV risk behaviors.[46–58] HIV research grounded in women's empowerment theory recognizes that a woman's ability and willingness to protect herself from HIV is influenced by her sense of empowerment developed through daily interactions and experiences in her social contexts.[52,55–58] This approach moves beyond behavioral skill-building methods emphasized in social cognitively based studies to address power differentials in society and partner influences in relationships that may affect a woman's sexual behavior and negotiation practices.[53,54] These empowerment-based studies acknowledge that women's sexual behaviors may occur within a social context that condones passivity and inequality in sexual matters and oppression by socioeconomic class and race. Interventions targeting African American women need to acknowledge the unique multiple influences on these women and identify strategies to effectively change risk behaviors and life situations.

The health benefits of facilitating empowerment for minority women have only recently received attention in the HIV prevention literature.[50,53,56–59] Incorporating ways for women to increase their personal power within relationship and economic contexts has been critical to the success of HIV risk-reduction interventions.[46,48,51,53,54,58,60] For example, a culturally sensitive HIV prevention intervention designed specifically to facilitate relationship power with inner-city women effectively increased safer-sex intentions and behaviors through follow-up at 6 months.[53] This intervention used skill-building, cognitive rehearsal, and guided imagery to promote women's ownership of their bodies and positive health choices in the social contexts in which their behaviors occurred. A study of HIV risk behavior among Latinas who did not use drugs found that economic resource power, as indicated by employment, had both direct and mediating effects on psychological symptoms and unprotected vaginal sex.[46,60] Becoming employed may reduce women's HIV risk by increasing a woman's resource power and providing behavioral alternatives that foster a healthier sense of self-worth. Similarly, overcoming homelessness, an established risk factor among African American women who use crack,[3,5] may also help women to reduce drug use, to become independent of a drug-

using lifestyle, and to instead make healthier life choices.

We examine the effectiveness (at 3- and 6-month follow-up) of a personalized HIV intervention tailored to gender and culture, compared with a standard intervention and a delayed treatment control group, to reduce sex-risk behaviors and drug use and increase employment and housing status among African American women who use crack.

METHODS

Outreach and Recruitment

The study was marketed on the streets by means of a brochure through indigenous community outreach workers. Out-of-treatment African American women who use crack were recruited according to a prespecified sampling plan through standardized street-outreach techniques[61] and peer-advocate chain-referral procedures that have been used in numerous community studies.[61–64] Outreach occurred in targeted inner-city neighborhood segments to ensure that the sample comprised multiple communities. Outreach workers were trained to approach and engage African American women to market the study and screen them for eligibility. Peer advocates who had participated in previous studies also were trained to work in concert with outreach workers to find prospective participants.

Eligibility Criteria

Women who met preliminary eligibility criteria were referred to field sites for final determination of eligibility. Eligible participants were at least 18 years of age, reported engaging in unprotected sex during the previous 90 days, and admitted using crack on at least 13 of the past 90 days. Women who reported being enrolled in substance abuse treatment within the past 30 days were excluded.

Data Collection

All study participants were assessed by self-report at a 2-part intake occurring 1 to 2 weeks apart and at 3- and 6-month follow-up interviews. Participants received $20 compensation at each intake and $25 and $40 for the 3- and 6-month follow-up interviews, respectively. Urine drug screens for cocaine and opiates were performed on site at intake and at 6-month follow-up to help validate self-report data; HIV antibody testing was conducted at intervention session 1 and at 6-month follow-up. Follow-up interviews also captured data on health services received. Process measures helped determine exposure to interventions (including competing programs), compliance, and costs associated with exposure. They also provided quality checks on protocol fidelity. For additional quality assurance, staff audiotaped every eighth interview session for review by the field supervisor.

Recruitment began in January 1999 and ended in August 2001. A total of 938 women completed intake 1. Seven hundred sixty two women (81%) completed intake 2 and were randomly assigned to study conditions; we controlled for injection drug use history, age (<30 or ≥ 30years), and previous intervention experience. Although the 176 women who did not return for intake 2 were comparable to study participants on most demographic characteristics, they were more likely to report daily crack use (33% vs 22%, $P<.01$), sex trading (56% vs 44%, $P<.01$), and multiple sexual partners in the past 30 days (61% vs 47%, $P<.001$).

Intervention

After intake 2, women were randomly assigned to 1 of 3 study conditions: (1) the woman-focused intervention, (2) a revised intervention modeled on the National Institute on Drug Abuse (NIDA) standard HIV prevention intervention (the standard-R group),[65] and (3) a delayed-treatment control group. African American women indigenous to the community were trained to deliver both interventions to minimize interventionist effects. The field supervisor conducted biweekly supervision meetings with interventionists, observed staff conducting individual sessions, and videotaped group sessions to monitor the fidelity of intervention implementation. The woman-focused and standard-R interventions each comprised 4 modules that included 2 individual and 2 group sessions. Session 1 immediately followed intake 2, and each subsequent session occurred within 2 weeks of the prior session. All women in both the standard-R and woman-focused groups completed at least 1 intervention session, with 67% of women in the standard-R group and 65% of women in the woman-focused group completing all 4 intervention sessions. The woman-focused and standard-R interventions are summarized in the following sections. Table 1 outlines each intervention session in detail.

The woman-focused intervention. The woman-focused intervention development was informed by focus groups with African American women crack users to identify relevant language, issues, and risk patterns. The intervention includes culturally enriched content that is grounded in empowerment theory[57,58] and African American feminism.[30] It acknowledges specific barriers facing African American women and how these barriers affect daily experiences and choices. On the basis of focus group findings, the woman-focused intervention addressed drug dependence as a form of "bondage" and was designed to facilitate greater independence and increase personal power and control over behavior choices as well as life circumstances. The intervention contained psychoeducational information and skills training on reducing HIV risk and drug use, presented within the context of African American women's lives in the inner city, where pervasive poverty and violence limit women's options and increase the likelihood of poor (i.e., high-risk) behavior choices.[3]

The 2 individual sessions focused on pre- and posttest counseling that addressed risk issues specific to the study population and offered personalized feedback about risk that allowed women to develop individualized behavior change plans according to their unique life situations. Group sessions used a support-based format to help women understand how they are affected by the multiple contextual influences in their lives and to teach portable skills to reduce risk and increase a sense of power. Women also received information for developing support networks and linkages to social services. Goal-setting focused not only on drug use and sex-risk behaviors, but also on life issues such as education, employment, housing, and parenting. The goals for women were to reduce risk and to take concrete empowering steps toward independence (e.g., through full-time employment and stable housing).

TABLE 1—Woman-Focused and Standard-R Intervention Sessions: Duration, Format, and Content

Duration	Format	Content	
		Woman-Focused	Standard-R
Session 1, 30–40 min	Individual	Cue cards • AIDS and African-American Women—Wake and Durham counties • Usual course of HIV infection and AIDS • How do women get infected with HIV? • Routes of indirect sharing • Crack or snorting risk among African-American women • Other hurts that cause women to use drugs and be at risk for HIV • Reduce your risk of HIV/AIDS: *Always* use protection • A condom you can control: the female condom • Why clean needles and syringes? • The injecting gold standard: bleach, bleach, water, water • "Walk the talk" (how to talk to your partner about safer sex) • Issues of concern we have learned from women in your community • Benefits of recovery: sister to sister • Ways you can become independent in your community • The HIV antibody test • If you are infected Behavioral skills training • Male and female condoms, dental dam/plastic wrap • Syringe cleaning Materials distributed • HIV/AIDS, condom use literature • Risk-reduction kit • HIV and non-HIV referrals for services • Local services information	Cue cards • What is AIDS? • Usual course of HIV infection and AIDS • How does someone get infected? • Routes of indirect sharing • What behaviors put you at risk • Risks associated with crack or cocaine • Reasons for condom use • What about female condoms? • How to talk with your partner about safe sex • Needle and syringe cleaning and disinfection guidelines and practice • Stopping unsafe drug use • Benefits of drug treatment • HIV antibody test • If you are infected Behavioral skills training • Male and female condoms, dental dam/plastic wrap • Syringe cleaning Materials distributed • HIV/AIDS, condom use literature • Risk-reduction kit • HIV and non-HIV referrals for services • Local services information
Session 2, 30–40 min	Individual	Test results Cue cards • NIDA posttest counseling for HIV-positive or HIV-negative • Review of session 1 cue cards Individualized risk assessment plan • Personalized risk and lifestyle review • Short- and long-term goal setting Behavioral skills training • Male and female condoms, dental dam/plastic wrap • Syringe cleaning Materials distributed • HIV/AIDS, condom use literature • Male and female condoms • HIV and non-HIV referrals for services • Local services information	Test results Cue cards • NIDA posttest counseling for HIV-positive or HIV-negative • Review of session 1 cue cards Behavioral skills training • Male and female condoms, dental dam/plastic wrap • Syringe cleaning Materials distributed • HIV/AIDS, condom use literature • Male and female condoms • HIV and non-HIV referrals for services • Local services information
Session 3, 60–90 min	Group (2–5 women)	Support-based group session: "Sisters Uplifting Sisters Out of Drug-Related Bondage" • Introductions, group rules, session objectives, overview • Identifying the things that keep you in bondage • What's different for women and African American women? Why is it harder?	Didactic general health education: "Learning About Drugs and HIV and How I Can Take Better Care of Myself" • Video: "Drugs and How They Affect Your Body Chemistry" • Lecture: Nutrition and hygiene Review of the Food Guide Pyramid

Continued

TABLE 1—*Continued*

		• Learning how to break free from the various forms of bondage that African American women today find themselves in • Learning how to take the next step • Free yourself! How to make good decisions and take care of yourself • Knowing when and how to change playthings, playmates, and playgrounds (triggers) • Accepting responsibility for and consequences of our decisions • Effective communication and problem solving: gaining freedom in high-risk situations • Solving problems using effective communication and ideal problem-solving method	Basics of hygiene Good hygiene, better self-image leading to better self-esteem
Session 4, 60–90 min	Group (2–5 women)	Support-based group session: "Sisters Uplifting Sisters Out of Drug-Related Bondage" • Introductions, session objectives, overview • First things first: take charge of your physical health • Family issues—succeeding as a parent or partner • Coping with stress in the "hood": being free in our environment • The next step toward freedom: What are *you* going to do to get and stay free? • Community resources to help you get and stay free • Closure: goal setting for 3 and 6 mo • Reaffirmation of women	Didactic general health education: "You Choose—Good Cocaine or Good Physical Health" • Lecture/video: "What is Cocaine/Crack Doing to My Body—Cocaine and Human Physiology" • Lecture/handouts: how you can take responsibility for your physical health Breast self-examination Other examinations for ensuring good health • Lecture/handouts: making quality decisions for reducing your risk of unwanted pregnancy Types of birth control

Note. NIDA = National Institute on Drug Abuse. The complete manual can be obtained from the first author.

The standard-R group. The standard-R group—modeled on the NIDA standard HIV prevention intervention as revised by a cohort of 6 cooperative agreement sites[6,65]—was similar in educational content to the woman-focused intervention but did not incorporate the gender- or culture-specific empowerment approach to develop one's life and change social contexts. After 2 individual sessions focusing on HIV pre- and posttest counseling, 2 group sessions offered general health education lectures and videos in a didactic format.

The control group. The control group received no intervention during the first 6 months of study enrollment. At 6-month follow-up, women in the control group were invited to participate in the standard-R intervention; 35% of these women (n=87) attended at least 1 intervention session.

Study Sample

The present sample comprises 620 (81%) randomly assigned participants who completed either the 3-month or 6-month follow-up interview. HIV prevalence at baseline among those tested was 5.5%, with no seroconversions. Table 2 presents background characteristics of the sample.

The only significant difference among the groups at baseline was that fewer women in the woman-focused group (36%) reported that they had received public assistance benefits in the past year than women in the standard-R (48%) and control (51%) groups (P=.005). Women who completed at least 1 follow-up interview were similar to those who did not, except that noncompleters were younger (35 years vs 37 years, P=.02). Attrition rates were similar for both 3- and 6-month follow-up interviews, with no meaningful or statistical differences in attrition across the 3 study conditions at either assessment period.

Measures

African American women from the community were trained as interviewers to administer the Revised Risk Behavior Assessment (RRBA) and other supplemental assessments at intake 1 and intake 2 with a computer-assisted personal interview. Each session lasted approximately 45 minutes. The RRBA is based on the NIDA-developed Risk Behavior Assessment (RBA) and has demonstrated acceptable levels of reliability with the present study population.[3] The RBA, which has yielded acceptable levels of reliability ($r \geq .7$) and concurrence with urine tests,[68–70] was revised for this project to focus on women's risk issues.[71] The RRBA was the core instrument for assessing the following 10 domains: demographics, drug use (ever, past month), drug injecting, drug use (past 48 hours), drug user treatment, sexual activity, sex trading, health, arrests, and work and income. Outcome measures used in the present study are described in the following paragraphs.

Sex risk. Sex risk was measured as any unprotected sexual acts (vaginal or anal sex, fellatio) and any sex trading in the past 30 days.

TABLE 2—Background Characteristics of Study Sample at Baseline

Characteristic	All Participants (n = 620)
Sociodemographic data	
Age, mean (SD)	36.7 (6.9)
Married or living with partner	25.4%
High school graduate	53.8%
Have children under age 18 years	27.0%
Have any type of health insurance	36.9%
Employed full time	11.0%
Currently homeless	29.9%
Receiving public assistance benefits	45.0%
Drug use	
Age of first alcohol use, mean (SD)[a]	15.4 (4.3)
Age of first crack use, mean (SD)	25.3 (7.0)
No. of days drank alcohol in the past 30 days, mean (SD)	14.8 (12.1)
No. of days smoked crack in the past 30 days, mean (SD)	17.1 (10.0)
Average continuous crack use longer than 24 h	42.5%
Ever injected	10.7%
Sexual behavior	
Less than 1 sexual partner in the past 30 days	45.5%
Engaged in unprotected sex in the past 30 days	88.5%
Ever traded sex for money or drugs	66.7%
Traded sex for money or drugs in the past 30 days	42.8%
Childhood trauma and current psychological distress	
Sexually abused before age 18	30.2%
Physically abused before age 18	29.7%
Depression scale score, mean (SD)[b]	12.9 (4.9)
Anxiety scale score, mean (SD)[b]	11.9 (6.2)
Traumatic stress scale score, mean (SD)[c]	18.2 (10.4)
Tested HIV-positive[d]	5.5%

[a]n = 602; 18 participants had never used alcohol.
[b]Griffith J et al.[66] Symptoms of depression and anxiety in the past 90 days were assessed using the Drug Abuse Treatment Assessment and Research (DATAR) depression and anxiety scales developed at Texas Christian University, which have demonstrated adequate reliability. The DATAR depression scale and the DATAR anxiety scale each consist of 7 items measured on a 5-point Likert scale ranging from never (0) to almost always (4). Possible scores for each scale ranged from 0 to 28. In this sample, coefficient α was 0.76 for the depression scale and 0.84 for the anxiety scale.
[c]Dennis M.[67] Symptoms of traumatic stress were summarized with items from the Global Appraisal of Individual Needs. In this study, the traumatic stress scale consisted of 12 items measured on a 5-point Likert scale ranging from never (0) to always (4). Possible scores ranged from 0 to 48. In the present sample, coefficient alpha for the scale was 0.90.
[d]n = 398, 22 HIV-positive; only women in the standard-R and woman-focused interventions were tested for HIV.

Crack use. Crack use was measured as the number of days crack was used in the past 30 days.

Homelessness. Homelessness was assessed by the question, "Do you consider yourself to be homeless?" This question was included in the RBA and has been established as a measure of homelessness in numerous studies.[3,4,72]

Full-time employment. Employment status was assessed with the question, "Which of the following best describes your current work situation?" Response options included unemployed and looking for work; unemployed and not looking; working full time, 35 hours or more per week; working part time, less than 35 hours per week; employed but on leave; full-time homemaker; retired; student; or disabled. Study participants who selected the response, "working full-time, 35 hours or more per week," were coded as working full time; other responses were coded as not working full time.

Analysis

The initial analysis examined differential attrition, comparing baseline characteristics of women who did not complete either 3- or 6-month assessment by conducting cross-tabulation and statistical testing (*t* test for continuous and χ^2 test for binary data).

Analyses of change compared the differences in the proportions and means of the woman-focused and standard-R intervention groups with controls separately for 3- and 6-month follow-up interviews, accounting for baseline values and within-subject correlation. Statistical significance of changes in crack use was assessed using paired *t* tests; changes in homelessness, full-time employment, and any unprotected sex were assessed using the McNemar test.

We estimated and tested the effects of intervention assignment on major study outcomes at 3 and 6 months. Crack use at each follow-up was assessed using linear regression analysis that included baseline use as a covariate. Intervention effects on binary outcome variables of homelessness, employment, and any unprotected and trading sex were assessed using multiple logistic regression analysis that controlled for baseline status. Group comparisons were performed using an intent-to-treat analysis according to group assignment.

RESULTS

Table 3 presents the baseline, 3-month, and 6-month follow-up data for each of the primary study outcomes by study condition.

Crack Use

All 3 groups reported significant decreases in the number of days of crack use between baseline and 3- and 6-month follow-up (Table 3). In the regression model adjusting for crack use at baseline, days of crack use in both the woman-focused and standard-R groups were significantly lower than in the control group, with woman-focused participants reporting the greatest reduction. At 6 months relative to controls, standard-R group reductions in crack use remained significant, whereas reductions reported by woman-focused intervention participants reached marginal significance.

TABLE 3—Group Means at Baseline, 3-Month, and 6-Month Follow-Up

Variable	Baseline	3 -Mo Follow-Up	6-Mo Follow-Up
No. at each time point			
Woman-focused	213	186	200
Standard	199	186	180
Control	207	190	189
No. of days used crack during the past 30 days, mean (SE)			
Woman-focused	16.9 (0.05)	9.9 (0.05) ***	11.5 (0.06) ***
Standard	16.8 (0.05)	11.4 (0.06) ***	10.8 (0.06) ***
Control	17.7 (0.05)	14.1 (0.06) ***	13.4 (0.06)***
Reporting any unprotected sex in the past 30 days, %			
Woman-focused	88	57***	56***
Standard	90	67***	60***
Control	87	67***	66***
Reporting any sex trading in the past 30 days, %			
Woman-focused	41	26***	26***
Standard	42	23***	23***
Control	43	36*	28***
Homeless, %			
Woman-focused	34	18***	19***
Standard	26	20	20
Control	29	31	23*
Employed full time, %			
Woman-focused	12	25***	24**
Standard	12	17	23**
Control	9	12	17*

Note. *P* values are calculated using paired *t* tests or the McNemar test for comparison to baseline.
*$P < .05$, **$P < .01$, ***$P < .001$.

Table 4 presents the results of the regression model.

Unprotected Sex

All 3 groups reported significant reductions in the proportion of women having any unprotected sex in the past 30 days between baseline and 3- and 6-month follow-up (Table 3). Although the woman-focused group demonstrated greater reductions in unprotected sex than the standard-R and control groups at 3 months, these results were not statistically significant at the .05 level. However, at 6 months this trend was statistically significant relative to controls, with fewer woman-focused group participants reporting any unprotected sex in the past 30 days (odds ratio [OR]=0.62, *P*=.03). The results of the logistic regression model adjusted for baseline involvement in unprotected sex are presented in Table 4.

Trading Sex

All study conditions demonstrated significant reductions in the proportion of women reporting trading sex for money or drugs in the past 30 days between baseline and 3- and 6-month follow-up (Table 3). Both intervention groups showed significant reductions in the percentage of women who traded sex compared with control subjects, with the standard-R group (OR=0.48, *P*=.007) having slightly stronger effects than the woman-focused group (OR=0.58, *P*=.046) at 3-month follow-up. At 6 months, these trends in reduction continued, although they were not statistically significant. The results of the logistic regression model adjusted for trading sex in the past 30 days at baseline are presented in Table 4.

Homelessness

Between baseline and 3-month follow-up, only woman-focused participants demonstrated a significant reduction in homelessness. The standard-R group showed nonsignificant decreases in homelessness, whereas the percentage of control group participants reporting homelessness increased slightly. At 6 months, the woman-focused and control groups showed significant decreases in homelessness, whereas the standard-R group showed nonsignificant improvements in housing status from baseline (Table 3). In multiple logistic regression analysis controlling for baseline homelessness, woman-focused and standard-R groups reported statistically significant decreases in homelessness compared with the control group. At 3 months, the odds of being homeless were the lowest in the woman-focused group (OR=0.35, *P*=.0002). At 6-month follow-up, the woman-focused group continued to report the lowest percentage of homeless women compared with the standard-R and control groups, although the effects were not statistically significant. Results of the logistic regression model for homelessness are presented in Table 4.

Employment

Between baseline and 3-month follow-up, the percentage of participants employed full time increased in all 3 groups, with significant improvements experienced only within the woman-focused group. Between baseline and 6 months, all 3 groups reported significant increases in full-time employment (Table 3). In multiple logistic regression analysis controlling for full-time employment at baseline, the odds of being employed full time at 3 months were significantly higher in the woman-focused group relative to both controls (OR=2.53; *P*=.0027) and the standard-R group (OR=2.02, *P*=.0175). The standard-R group also showed greater increases in employment than controls at 3 months, although this effect was not statistically significant (OR=1.25, *P*=.4871). At 6 months, both the woman-focused and standard-R groups showed relatively greater improvements in full-time employment, although these effects were not statistically significant. Logistic regression model results for full-time employment are presented in Table 4.

TABLE 4—Regression Models for Crack Use, Unprotected Sex, Trading Sex, Homelessness, and Employment at 3- and 6-Month Follow-Up

Outcomes	3 Mo Follow-up		6 Mo Follow-up	
	Estimate (95% CI)	*P* Value	Estimate (95% CI)	*P* Value
Mean no. of days used crack during the past 30 days,[a] coefficient				
Woman-focused vs control	−3.69 (−5.65, −1.74)	.0002**	−1.70 (−3.68, 0.28)	.0918
Standard vs control	−2.18 (−4.13, −0.23)	.0288*	−2.36 (−4.39, −0.33)	.0227*
Woman-focused vs standard	−1.52 (−3.48, 0.44)	.1284	0.66 (−1.34, 2.66)	.5185
Reporting any unprotected sex in the past 30 days, odds ratio[b]				
Woman-focused vs control	0.69 (0.45, 1.09)	.1153	0.62 (0.41, 0.96)	.0335*
Standard vs control	0.95 (0.61, 1.50)	.8319	0.72 (0.47, 1.13)	.1511
Woman-focused vs standard	0.73 (0.47, 1.14)	.1729	0.86 (0.57, 1.33)	.5081
Reporting any sex trading in the past 30 days, odds ratio[b]				
Woman-focused vs control	0.58 (0.34, 1.00)	.0456*	0.94 (0.55, 1.59)	.8144
Standard vs control	0.48 (0.28, 0.82)	.0070**	0.80 (0.46, 1.39)	.4284
Woman-focused vs standard	1.21 (0.70, 2.08)	.4842	1.18 (0.68, 2.04)	.5698
Homeless, odds ratio[b]				
Woman-focused vs control	0.35 (0.20, 0.61)	.0002**	0.69 (0.40, 1.20)	.1931
Standard vs control	0.56 (0.33, 0.96)	.0366*	1.01 (0.57, 1.76)	.9859
Woman-focused vs standard	0.61 (0.34, 1.11)	.1043	0.69 (0.39, 1.22)	.2013
Employed full time, odds ratio[b]				
Woman-focused vs control	2.53 (1.38, 4.66)	.0027**	1.47 (0.87, 2.48)	.1503
Standard vs control	1.25 (0.66, 2.41)	.4871	1.42 (0.83, 2.43)	.2039
Woman-focused vs standard	2.016 (1.13, 3.60)	.0175*	1.04 (0.63, 1.71)	.8892

Note. CI = confidence interval.
[a]Regression analysis with baseline days of crack use as covariate.
[b]Multiple logistic regression models controlling for baseline status.
*$P < .05$, **$P < .01$.

DISCUSSION

Study Limitations

Intervention effects on risk behaviors, employment, and housing were supported statistically; however, the analyses cannot disentangle other unmeasured factors, such as staff attributes that may affect most intervention research. Analyses also cannot distinguish other possible effects of the assessment process on actual behavior change versus response bias (i.e., social desirability). To reduce this potentially confounding effect, for any given participant, no staff member was allowed to serve as both an interventionist and a follow-up interviewer.

Although street outreach targeted a range of neighborhoods, this method limits the sample to women approached by outreach workers and peer advocates and thus does not engender a fully representative sample of African American women who use crack cocaine. Nonetheless, this sample has been found to be similar to other African American, crack-using women in low-income inner-city communities who are at high risk for acquiring HIV.[57,73]

CONCLUSIONS

Results of this study are consistent with previous research findings[42–45] that out-of-drug-treatment African American women who use crack and are at high risk for acquiring HIV who receive either a standard or tailored educational and skill-building intervention made significant reductions in crack use and sex-risk behaviors at 3 and 6 months. In addition, at 3-month follow-up, compared with the standard-R group, women who received the tailored intervention showed greater improvement in both employment and housing status, factors that are associated with improved health outcomes.[74–78] Findings suggest that empowerment-based interventions tailored to develop concrete solutions within personal social contexts, more than standard interventions, can influence other life changes that facilitate independence for African American women. The personalized nature of the risk profile and change plan was likely a key element that increased the saliency of a participant's behaviors and life choices that place her at risk. Discussion of these behaviors and life choices within a woman's multiple contexts allowed for goal-setting and action plans that were concrete and relevant to each woman's life.

Although the woman-focused participants reported significant improvements in risk behaviors, employment, and housing at both 3 and 6 months (Table 3), the gains made by standard-R and control group participants at 6-month follow-up reduced the relative effects of the woman-focused intervention when compared with the control group. The exception to this trend was the percentage of women reporting any unprotected sex. By 6 months, woman-focused participants were significantly more likely than women in the other groups to stop having unprotected sex. Overall, some intervention appears better than no intervention, and a gender-specific and culturally tailored intervention may be more effective than a standard intervention at reducing sex risk over time. Historically, sex-risk behaviors have been difficult for HIV interventions to change, which makes this finding encouraging.

Because, relative to the other groups, significantly fewer participants in the woman-focused intervention received public assistance benefits in the past year, we ran additional models that included this variable. However, post hoc logistic regression analysis with group assignment, baseline employment, and benefits status found no independent effects of benefit status on full-time employment at 3-month follow-up. Similar analysis for homelessness at 3-month follow-up found that benefits status, homelessness at baseline, and intervention group assignment each significantly predicted homelessness at

follow-up. This analysis indicated that women who did not receive benefits at baseline were more likely to be homeless at follow-up, lending further support to the woman-focused intervention effects at helping women empower themselves to find housing.

This study lends credence to the utility of interventions that target women with high-risk behaviors who live in multiple-stressor environments to be individualized and tailored to their culture, gender, and unique life circumstances. Helping women to empower themselves to reduce specific risk behaviors and raise their self-sufficiency through full-time employment and stable housing, which are linked to improved health outcomes, may be one key to sustaining short-term and potentially longer term risk reduction and healthy behaviors. It is essential to conduct further studies to measure long-term durability of intervention effects that specifically address how risk behavior and contextual barriers change over time to affect women's healthy behavior choices. Given the cyclical nature of addiction, additional interventions may be needed to help these women continue the process of reducing HIV risk and attaining independence despite contextual barriers. ■

About the Authors

The authors are with RTI International, Research Triangle Park, NC.

Requests for reprints should be sent to Wendee M. Wechsberg, PhD, RTI International, 3040 Cornwallis Drive, P.O. Box 12194, Research Triangle Park, NC 27709–2194 (e-mail: wmw@rti.org).

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Contributors

W.M. Wechsberg designed the study and the methods, directed the analysis, and wrote the article. W.K. Lam contributed to the interpretation of the data and was instrumental in organizing and drafting the article. W. Zule assisted with the analyses and interpreted the data. G. Bobashev designed and conducted the statistical analyses for the final revised article.

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Modeling the Effects of Different Infant Feeding Strategies on Infant Survival and Mother-to-Child Transmission of HIV

Jay S. Ross, PhD, and Miriam H. Labbok, MD, MPH

Objectives. We investigated how, under various conditions, the risk of mother-to-child transmission of HIV through breastfeeding compares with the risk of death from artificial feeding.

Methods. We developed a spreadsheet simulation model to predict HIV-free survival during 7 age intervals from 0 to 24 months for 5 different infant feeding scenarios in resource-poor settings.

Results. Compared with artificial feeding, breastfeeding during the first 6 months by HIV-positive mothers increases HIV-free survival by 32 per 1000 live births. After 6 months, as the age-specific mortality rate and risk of death caused by replacement feeding both decline, replacement feeding appears to be safer.

Conclusions. Under conditions common in countries with high HIV prevalence, replacement feeding by HIV-infected mothers should not be generally encouraged until after the infant is approximately 6 months old. (*Am J Public Health.* 2004;94:1174–1180)

Each year, HIV infects an estimated 800 000 children, mainly because of transmission from mother to child during pregnancy, delivery, or breastfeeding. Most of these infections could be prevented through the use of antiretroviral drugs taken during pregnancy and delivery and the avoidance of breastfeeding. However, the use of breastmilk substitutes also brings mortality risks that need to be balanced against the risk of HIV transmission. The balance of risks depends on local conditions and should be examined for each situation. For the mother who is HIV-negative or who does not know her status, breastfeeding continues to be recommended.[1] For the mother who knows she is infected and for the health worker advising her, the risks associated with different infant feeding strategies need to be understood.

United Nations agencies currently recommend that: "When replacement feeding is acceptable, feasible, affordable, sustainable and safe, avoidance of all breastfeeding by HIV-infected mothers is recommended. Otherwise, exclusive breastfeeding is recommended during the first months of life."[2(p32)] They also note that the appropriate time to wean depends on both the individual woman's situation and the continuing risks of replacement feeding (including malnutrition and infections other than HIV) and must take into account the possible increased risk of HIV transmission with mixed feeding during the transition period between exclusive breastfeeding and complete cessation of breastfeeding.

Health services worldwide are developing and implementing programs to reduce mother-to-child transmission (MTCT) of HIV, including antiretroviral therapy and artificial feeding. These initiatives increase the urgency of efforts to understand the overall mortality risks associated with different infant feeding strategies under different conditions.

A number of studies have been published that use simulation models to answer such questions.[3–11] These simulations unanimously conclude that under conditions of high infant mortality and a high risk of death from replacement feeding, breastfeeding is the safer infant feeding strategy, despite the risk of HIV transmission. Although many of the factors affecting the risks of HIV transmission through breastfeeding and infant mortality vary dramatically with age, most of these analyses treat the whole of infancy as a single homogeneous period. The exceptions[8,9] lack empirical data on the age-specific risk of death from artificial feeding that are now available.[12]

We developed a simulation model that takes into account such age-related changes to estimate the effect on HIV-free survival at different ages of a range of infant feeding strategies, including efforts to make breastfeeding safer.

METHODS

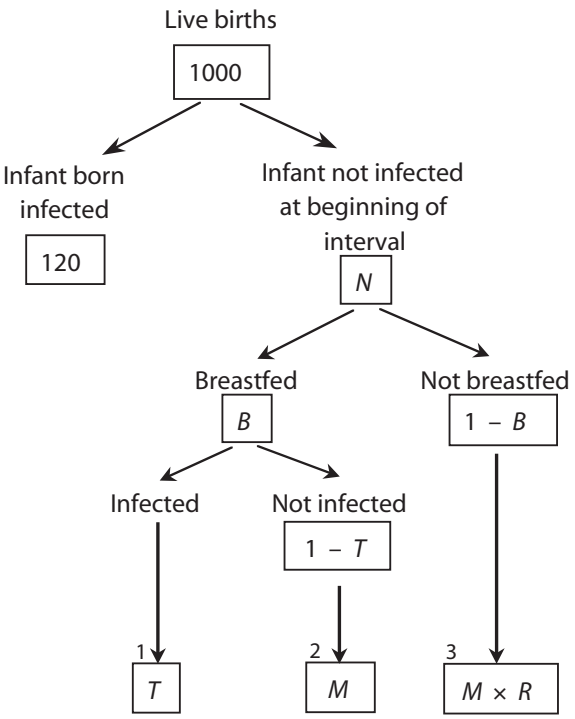
Model Structure and Design

The spreadsheet model, derived from an approach originally presented by Hu et al.,[4] divides infancy into 6 intervals: 0 to 7 days, 7 days to 2 months, 2 to 4 months, 4 to 6 months, 6 to 9 months, and 9 to 12 months; 12 to 24 months was included as a single interval. The model can simulate any scenario represented by the values of 5 variables, all of which can vary across intervals: the number of live infants at beginning of the interval (N), the MTCT rate during breastfeeding (T), the proportion of women breastfeeding (B), the proportion of uninfected breastfed infants who die during the interval (M), and the relative risk of mortality among nonbreastfed infants (R). For each interval in each scenario, the number of deaths and HIV infections in each of 3 mutually exclusive categories is calculated, as illustrated in the decision tree shown in Figure 1.

Model Assumptions

Although the simulation model was designed for whole populations, including uninfected mothers, some of whom become infected while breastfeeding, for the purposes of this analysis, HIV prevalence is set to 1, thus restricting the simulations to mothers who were HIV-positive during pregnancy.

Simulations begin with 1000 live births, the denominator of the infant mortality rate. Current methods of testing for HIV in infants do not permit the timing of transmission to be estimated with precision. The rate of transmission before and during delivery is therefore es-



Note. The formula for infections or mortality in any category is obtained by multiplying the cells in that path of the tree (1. HIV infections = $N \times B \times T$; 2. Non-AIDS deaths among uninfected breastfed infants = $N \times B \times (1 - T) \times M$; 3. Non-AIDS deaths among uninfected nonbreastfed infants = $N \times (1 - B) \times M \times R$). The first interval (shown) begins with n = 880 (1000 live births – 120 infants infected during pregnancy and delivery). For each subsequent interval, *N* is the number of infants surviving HIV-free at the end of the preceding interval.

FIGURE 1—Decision tree with 3 mutually exclusive categories of postnatal infections and deaths: HIV infections, non-AIDS deaths among uninfected breastfed infants, and non-AIDS deaths among uninfected nonbreastfed infants.

timated from the rate of infection observed among infants of nonbreastfeeding women. Because the prevalence of breastfeeding is generally high in poor countries, the transmission rate before and during delivery is estimated mainly from studies in affluent countries. In a large, multicenter study in Europe, transmission among 683 nonbreastfed infants of mothers infected before delivery was 13.6%.[13] In a French study of 801 infected nonbreastfeeding mothers, the rate was 19%.[14] In a meta-analysis reported by Dunn et al.,[15] 16.1% of 1567 nonbreastfeeding mothers in 6 studies transmitted the virus to their infants. Evidence suggests that the rate of transmission through breastfeeding is somewhat higher in countries where malnutrition and other infections are more common.[16–18] In a 2000 review of then-current knowledge about MTCT in poor countries, transmission before and during delivery was estimated to be 15% to 30%.[19] In our analysis, we assumed MTCT during or before delivery was 24%, and perinatal antiretroviral prophylaxis was assumed to reduce this by half, to 12%.[20,21] Of 1000 infants born alive, the number entering the first interval HIV-free (N) is therefore 880. All subsequent intervals begin with the number of live, uninfected infants remaining at the end of the previous interval.

Reported rates of transmission through breastfeeding by a mother infected before delivery (T) range from 0.2% to 0.9% per month.[15,22–27] However, because of the inability to distinguish early postnatal transmission from that occurring before and during delivery, these rates are based on estimates for transmission after the first 6 weeks to 2 months. De Cock et al.[19] estimated that the rate of transmission during the early neonatal period may be several times higher, amounting to a transmission rate over the first 2 months of an additional 5% to 10%. Monthly rates of transmission in the early neonatal period from various studies were 4.5%,[25] 1.9%,[28] 2.9%,[29] and 1.8%,[30] with an arithmetic mean of 2.8%. The value for T used in our analysis for the first 2 months is therefore 2.8% per month. After 2 months, we use the risk of 0.00028 per day reported by Richardson,[26] equivalent to 0.85% per month. These risks yield the age period–specific values for T shown in Table 1. In the absence of effective promotion of exclusive breastfeeding, most breastfeeding mothers begin adding other foods and fluids to the infant diet after the early weeks of life. Exclusive breastfeeding, efforts to prevent and treat breast problems, and prophylactic antiretroviral therapy for the infant or mother during the breastfeeding period are likely to reduce the risk of breastfeeding transmission significantly.[28,31–34]

This model permits manipulation of the breastfeeding rate (B) to estimate the impact of different infant feeding strategies on transmission and overall risk of infant mortality owing to any cause. To obtain unambiguous estimates of the effects of different infant feeding strategies on HIV-free survival at the individual level, breastfeeding rates were set to simulate perfect compliance (0 or 1).

The underlying infant mortality rate among breastfed infants can be estimated from historical values for infant mortality rate for a given country before the HIV epidemic or, if the HIV prevalence remains low, from current statistics. The average infant mortality rate for the 48 poorest countries was 109 in 1996 and 171 in 1960.[35] Mortality rates are known to be higher among younger infants, but the exact relationship depends on the setting. In this study, we used our own unpublished analysis of Demographic and Health Survey data for 31 African countries to derive an infant mortality rate of 91 and the age-specific mortality rates (M) shown in Table 1, expressed as a proportion of children entering the interval HIV-free.

A number of observational studies have documented increased mortality among nonbreastfed infants.[36–43] More recently, an analysis of pooled data from 3 countries has provided age-specific odds ratios for the pro-

TABLE 1—Actual Values, Critical Values, and Confidence Ratios for Key Variables: Simulation of the Effects of Breastfeeding vs Replacement Feeding on the HIV-Free Survival of Infants of HIV-Positive Mothers

		Age Interval						
	Symbol	0–7 d[a]	7 d–2 mo	2–4 mo	4–6 mo	6–9 mo	9–12 mo	12–24 mo
Actual values								
MTCT rate during breastfeeding	T	0.0066	0.0423	0.0169	0.0169	0.0252	0.0252	0.0972
Infant mortality rate (deaths per 1000 live births)	M	0.0293	0.0220	0.0108	0.0101	0.0129	0.0092	0.0356
Additional risk of death from artificial feeding[b]	R	1	4.2	3.6	2.5	1.7	1.4	1.8
Critical values								
MTCT rate during breastfeeding	T_{cv}		0.0799	0.0285	0.0153	0.00913	0.00370	0.0295
Infant mortality rate (deaths per 1000 live births)	M_{cv}		0.0130	0.00646	0.0111	0.0348	0.0593	0.108
Additional risk of death from artificial feeding	R_{cv}		2.69	2.54	2.66	2.93	3.73	3.63
Confidence ratio[b]			0.53	0.59	1.11	2.74	6.71	3.20

Note. MTCT = mother-to-child transmission. The critical value ($_{cv}$) is the value for which the number of HIV-free survivors is the same regardless of whether the mother breastfeeds, holding all other values constant. If the actual value is higher than the critical value for the relative risk (R) and infant mortality (M) and lower than the critical value for the transmission rate (T), breastfeeding (BF) is safer than replacement feeding (RF).

[a]Critical values and the confidence ratio are not calculated for the first week, because the assumed value of R is 1.

[b]To calculate confidence ratios, the additional risk ($R - 1$) is used rather than the relative risk (R) to permit meaningful comparisons. The confidence ratio is the factor by which the actual value would have to be multiplied or divided to achieve an equal number of HIV-free survivors. Confidence ratios less than 1 favor BF; those greater than 1 favor RF.

tective effect of breastfeeding.[12] An unpublished analysis of Demographic and Health Survey data from 17 developing countries confirms this pattern of age-specific protection (Shea Rutstein, oral communication, 1999). For the relative risk of death caused by replacement feeding (R), we used odds ratios including deaths from noninfectious causes from the WHO pooled analysis,[12] which uses the same age intervals during infancy as does our model, given in Table 1.

Infants who died during the first week were removed from that analysis "since breastfeeding is unlikely to have had a marked impact on these deaths (which were mainly from perinatal causes and congenital malformations)."[12(p451)] In our model, we therefore conservatively assumed no protective effect of breastfeeding during the first week.

Analyses

Two types of analyses are presented. The first treats each time period independently, comparing the effects of 3 different infant feeding strategies (replacement feeding, breastfeeding, or safer breastfeeding) on HIV-free survival per 1000 infants entering the period HIV-free. In the second analysis, the cumulative 2-year effects of different infant feeding scenarios are compared. These scenarios, chosen to reflect actual policy alternatives, are as follows:

B_{24}: In this default (or "no intervention") scenario, all HIV-infected mothers breastfeed for 24 months. Other values are given in Table 1.

B_0: All HIV-infected mothers use replacement feeding from birth. Avoidance of breastfeeding reduces B to 0 throughout. All other values remain as in Table 1.

B_6: All HIV-infected mothers breastfeed to 6 months. B is 0 after 6 months, and all other values are as in Table 1.

SB_{24}: All values are as in scenario B_{24}, but safer breastfeeding interventions (exclusive breastfeeding, prevention and treatment of breast problems, postpartum antiretroviral therapy) reduce T by half throughout.

SB_6: All values are as in scenario B_6, but safer breastfeeding interventions reduce T by half.

Critical Values

It is important to know how sensitive simulation results are to plausible variations in the key assumptions, especially because such variations cannot be precisely determined. We addressed this problem by calculating critical values for the transmission risk during breastfeeding (T), the relative risk of death caused by artificial feeding (R), and the underlying mortality rate (M) during each age interval. The critical value is the value a variable would have to take to change the policy conclusion when all other variables are held constant. For this analysis, the critical value is defined as the value that would result in an equal number of HIV-free survivors when all HIV-infected mothers breastfeed as when they do not. Expressions for critical values, derived algebraically from the formulas in Figure 1, are as follows:

$$R_{cv} = (T/M) + 1 - T$$
$$M_{cv} = T/(R - 1 + T)$$
$$T_{cv} = [M \times (R - 1)]/(1 - M)$$

where R_{cv}, M_{cv}, and T_{cv} are the critical values of R, M, and T, respectively.

Breastfeeding is favored by values of T *smaller* than the critical value and by values of R and M *larger* than the critical value. To avoid confusion in comparing critical values with actual values across time periods for different variables, for each period we calculated a "confidence ratio," defined here as the ratio of the critical value used in the model to the actual value (for T), or its inverse (for R and M). Confidence ratios are thus standardized such that ratios less than 1 favor breastfeeding and those greater than 1 favor replacement feeding.

RESULTS

The period-by-period comparison of different infant feeding strategies is presented in Figure 2, which shows the simulated risk

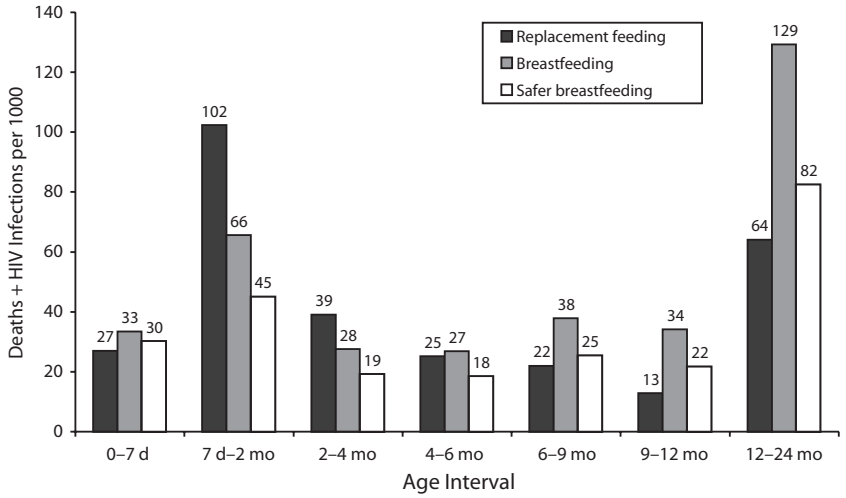


FIGURE 2—Simulated risk of infection or death from other causes in interval for each of 3 infant feeding strategies: replacement feeding (RF), breastfeeding (BF), and safer breastfeeding (SBF), calculated per 1000 infants entering the period HIV-free.

of infection or death from other causes for each interval for each of 3 infant feeding strategies: replacement feeding, breastfeeding, and safer breastfeeding. These risks are calculated per 1000 infants entering the period HIV-free and are therefore independent of the strategy used in the preceding periods. The apparent advantage accorded to replacement feeding in the first week is an artifact of the assumption that there is no protective effect of breastfeeding at this time. During the next 3 periods, safer breastfeeding is safer than replacement feeding, reducing the total of infections and deaths relative to replacement feeding by 56%, 51%, and 27%. Breastfeeding is safer than replacement feeding for the intervals 7 days to 2 months and 2 to 4 months, but for the interval 4 to 6 months, replacement feeding is marginally safer. After 6 months, replacement feeding is safer than both breastfeeding and safer breastfeeding.

The net effects of different infant feeding scenarios on the cumulative total of infections and deaths are shown in Figure 3. Under the conditions simulated here, among the cohort of 1000 infants born to HIV-infected mothers who used perinatal antiretroviral prophylaxis, the safest strategy was SB_6, which resulted in HIV-free survival to 24 months, exceeding that in the B_0 scenario by 65 infants, or 6.5% of the cohort at risk. In comparison with replacement feeding, breastfeeding by HIV-infected mothers during the first 6 months without any intervention to make breastfeeding safer resulted in 68 HIV infections but 100 fewer deaths from other causes, thus increasing net HIV-free survival at 6 months by 32 infants, or 3.2% of the cohort at risk. The most dangerous strategy was continued breastfeeding (B_{24}), which resulted in 391 infants dying or being infected by 24 months. This estimate compares with 291 deaths for the safest strategy (SB_6) and 349 for the "no breastfeeding" strategy (B_0). Although not shown in Figure 3, for mothers who breastfeed without any intervention to make breastfeeding safer, beginning replacement feeding at 4 rather than 6 months is marginally safer under the conditions simulated here, reducing the total number of infections plus deaths at 24 months from 320 (in the B_6 scenario) to 319.

Critical values are shown in Table 1, with the estimates used in the model. For the interval 4 to 6 months, the values used for the 3 key assumptions are close to the critical values, and the confidence ratio is close to 1 (1.11). Plausible variations in the actual values therefore could change our conclusions for this interval. However, for the intervals 7 days to 2 months and 2 to 4 months, confidence ratios of 0.53 and 0.59 strongly favor breastfeeding. After 6 months, the critical values favor replacement feeding by a factor of 2.7 or more. Because such large violations of the model assumptions are highly improbable, our confidence in our results is very strong for all intervals but the interval 4 to 6 months. Under conditions of safe breastfeeding, in which transmission risk is reduced by half, all confidence ratios also would be reduced by half.

DISCUSSION

The risk of death from replacement feeding exceeds the risk of MTCT through breastfeeding during the first 4 months of life under the conditions of poverty and poor hygiene simulated here. Exclusive breastfeeding and efforts to prevent and treat breast problems are likely to make breastfeeding even safer. This information should be provided to HIV-positive mothers who live under conditions of poverty and poor hygiene so that they can make informed infant-feeding decisions. Preliminary evidence from current trials suggest that prophylactic antiretroviral drugs given to the infant or mother during the breastfeeding period reduce HIV transmission.[34] If this finding is confirmed, breastfeeding may become the safest option under a wider range of conditions.

Randomized trials cannot be used to provide information on the risks of different infant feeding strategies under conditions actually prevailing in resource-poor environments. Although random assignment of feeding strategies may be justified on the basis of genuine uncertainty concerning the balance of risks involved, it is unethical to assign replacement feeding without concurrent improvements in the health environment (hygiene, sanitation, water supply, health care) and economic conditions (free or subsidized supplies), though such improvements would in turn limit the applicability of such trials to real conditions. Therefore, estimates of the risk of death from artificial feeding in our analysis were derived

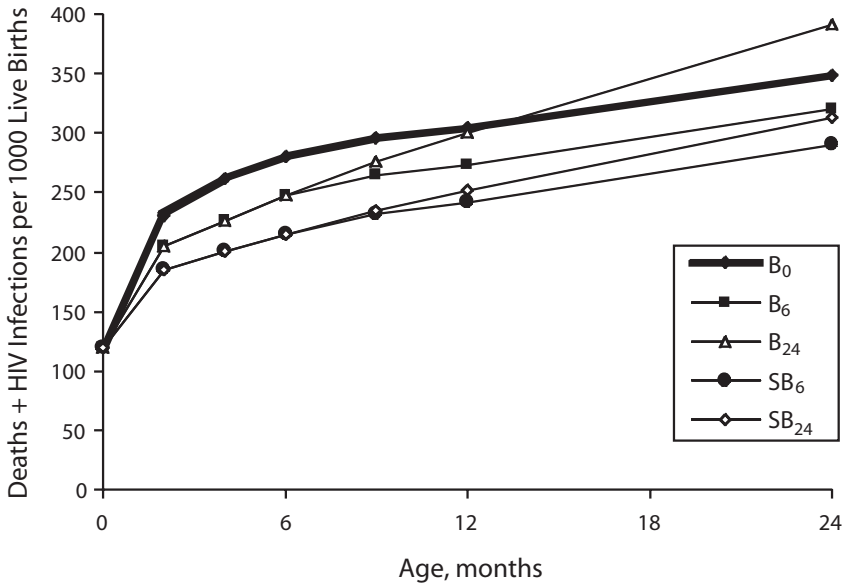


FIGURE 3—Cumulative total of deaths and HIV infections per 1000 live births to HIV-infected mothers who used perinatal antiretroviral therapy and different infant feeding strategies: no breastfeeding (B_0), breastfeeding to 6 months (B_6), breastfeeding to 24 months (B_{24}), safer breastfeeding to 6 months (SB_6), and safer breastfeeding to 24 months (SB_{24}).

from observational studies. These risks probably underestimate the true risk of artificial feeding in this context, because the mothers in the observational studies were not infected with HIV and therefore must have chosen to feed artificially, not from fear of infecting their infants, but because they considered it a safe, affordable, and feasible alternative to breastfeeding.

However, if mothers stop breastfeeding because of severe infant illness—an example of reverse causality—the risks derived from observation studies may overestimate the true risks. Although we do not know what motivates mothers to choose not to breastfeed their infants, studies in the meta-analysis that generated these estimates avoided reverse causality by assessing breastfeeding status before the onset of the fatal disease or, when such information was not available, 7 days before the infant's death.

Although most of the excess risk of death from artificial feeding occurs in the intervals 7 days to 2 months and 2 to 4 months, safer breastfeeding offers a survival advantage during the entire first half of infancy. Even without an intervention to make breastfeeding safer, replacement feeding offers little advantage in the interval 4 to 6 months, improving HIV-free survival only by 1 infant per 1000 live births. Other advantages that favor breastfeeding at this point include saving money, delaying fertility, avoiding the social stigma associated with not breastfeeding a young infant, and avoiding the physical and emotional trauma for both infants and mothers caused by early cessation of breastfeeding. Also, for physiological and developmental reasons, appropriate alternative foods for infants younger than 6 months are less available and more expensive than those for older infants. At the public health level, active encouragement of replacement feeding involves logistical challenges and a risk of undermining breastfeeding practices among the majority of mothers, who are HIV-negative or who do not know their status.

Although our analysis appears to suggest that the infant-feeding decision is of little consequence during the first week after birth, this is an artifact of the exclusion of early deaths by the study that provided the relative risk estimates[12] and of our assumption, therefore, that there is no increased risk of death from replacement feeding at this time. In reality, although most deaths occurring during the first week may be attributed to congenital defects or perinatal problems, lack of breastfeeding in the first 7 days may contribute to immediate postpartum hypothermia and hypoglycemia and to later deaths from the direct effects of artificial feeding. Also, breastfeeding must be initiated early if at all. Including these effects would increase the estimated deaths from artificial feeding, favoring breastfeeding even more.

It has been suggested that an early transition from breastfeeding (which should be exclusive up to 6 months of age) to replacement feeding among HIV-positive mothers may be the best infant-feeding strategy.[19] The optimum timing of this transition depends on the age-related risks associated with available, sustainable replacement-feeding alternatives. Because these risks vary among environments and households, no single recommendation is possible. However, our results suggest that under the conditions simulated here (in which the relative risk of death from artificial feeding is the estimate from the WHO pooled analysis[12] and the baseline infant mortality rate is 91 per thousand live births, the average for sub-Saharan Africa), an appropriate time for an HIV-positive mother to switch from breastfeeding to replacement feeding may be approximately 6 months. As economic and environmental conditions worsen, the relative risk of death from replacement feeding increases, shifting the balance of risks to favor a later transition to replacement feeding. Conversely, better conditions would favor an earlier transition to replacement feeding. The critical values and confidence ratios (Table 1) indicate what conditions favor earlier or later transition. When other variables are held constant, the confidence ratio for the interval 2 to 4 months indicates that mortality would have to be 59% of the current assumed level to make replacement feeding as safe as breastfeeding in this period. This figure corresponds with an infant mortality rate of 54 (91×0.59) per 1000 live births, a level that might be found in many communities affected by HIV. Conversely, in the interval 6

to 9 months, breastfeeding would result in better HIV-free survival than replacement feeding only in countries where the infant mortality rate exceeds 249 (91 × 2.74) per 1000 or, under conditions of safer breastfeeding, 124 (91 × 2.74 / 2) per 1000.

Under virtually all conditions in resource-poor communities, a transition from safer breastfeeding to replacement feeding is advised at some point during infancy. Although our model implicitly assumes that this transition is instantaneous and therefore is itself free of risk, the true risk of transmission during the transition may be increased if the risk is higher during mixed feeding[28,31] or if breast engorgement and poor drainage from rapid cessation lead to mastitis, also a risk factor for HIV transmission.[32,33]

Although our simulation included only infected mothers, if some uninfected mothers who do not know their status but who suspect that they are infected also switch to replacement feeding, this switch would increase overall mortality. Therefore, it is important that any policy derived from our model be based on maternal knowledge of HIV status, with appropriate counseling and breastfeeding support for all women.

This model provides new information for public health decisionmakers. Using recent estimates of the age-specific risks of both HIV transmission through breastfeeding and death from artificial feeding, it demonstrates that under conditions common in countries with high HIV prevalence, breastfeeding by the HIV-infected mother has an advantage in terms of HIV-free survival for infants during the first 6 months after birth, despite the risk of MTCT. Additional studies of the risks associated with different infant feeding strategies are urgently needed to refine and confirm this analysis. ■

About the Authors

Jay S. Ross is with the Academy for Educational Development, Washington, DC. Miriam H. Labbok was with the Nutrition and Maternal Health Division, Global Bureau, US Agency for International Development (USAID) during preparation of the article. She is currently with the Nutrition Section, UNICEF, New York, NY.

Requests for reprints should be sent to Jay Ross, 31 Macken Rd, RR4, Antigonish, Nova Scotia, B2G 2L2 Canada (e-mail: jayross@aed.org).

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Contributors

J. Ross developed the original single-period version of the spreadsheet model, modified the multiple-period version to accommodate new data, developed the scenarios for comparison, and ran the simulations. M. Labbok developed the multiple-period version, derived the age-specific baseline infant mortality estimates, and helped design the simulations. Both investigators wrote the article.

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Human Participant Protection

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Effectiveness of HIV Prevention in Ontario, Canada: A Multilevel Comparison of Bisexual Men

Chad A. Leaver, MSc, Dan Allman, MSc, Ted Meyers, PhD, and Paul J. Veugelers, PhD

Objectives. We examined the effectiveness of community-level HIV prevention programming for men who have sex with men.

Methods. We used multilevel methods to examine unprotected intercourse by bisexual men (n = 1016) with male and female partners in geographic regions with and without HIV prevention programming.

Results. Men living in geographic regions with HIV prevention programming had significantly less frequent unprotected homosexual intercourse with both casual and regular partners. In contrast, no differences were observed for unprotected heterosexual intercourse.

Conclusions. This study provides evidence supporting the effectiveness of community-level HIV prevention programming and the need for its broader implementation. The study also demonstrates the suitability of multilevel methods for examining the effectiveness of community-level public health programs. (*Am J Public Health.* 2004;94:1181–1185)

The influence of contextual factors on disease risk is becoming increasingly important in epidemiological investigations for an understanding of population and individual determinants of health.[1–15] Epidemiological studies examining contextual factors have focused primarily on the influence of such socioeconomic contexts as income inequality, poverty, socioeconomic neighborhood characteristics, and social and cultural environment in explaining individual health outcomes.[4,16–25] Multilevel methods are becoming a standard methodological approach for examining the influence of contextual factors on individual health outcomes.[4,20–25] They also provide the means with which to evaluate contextual changes resulting from public health interventions.[26]

Public health interventions aimed at preventing new HIV infections are essentially designed to promote behavior change toward safer sexual behavior, with the ultimate goal of a decreased HIV incidence at the community level.[27] HIV prevention programming typically takes the form of promotional and educational media initiatives, targeted outreach that often includes distribution of condoms and educational materials, and the provision of various support and counseling services. The various aims of multiple and multidimensional approaches are to change attitudes, awareness, and cultural or community norms and to address access barriers to the provision of such services. Essentially, the overall aim of prevention programming is to change the context of risk behavior practices of at-risk populations at the community level.[28]

Studies in the United States and Canada that have evaluated HIV prevention strategies have focused primarily on behavioral differences in gay and bisexually identified men.[29] To our knowledge, no study among this population has evaluated contextual changes in sexual risk behavior for those residing in communities with and without prevention programming. Bisexual men provide the opportunity to simultaneously investigate the contextual influence of prevention programming in homosexual and heterosexual contexts of sexual behavior, with the former subject to various focused community-level HIV prevention programming initiatives and the latter not.

To further our understanding of contextual changes resulting from HIV prevention programming at the community level, we used multilevel approaches to examine the influence of prevention programming on unprotected intercourse with male and female partners among bisexual men in Ontario, Canada.

METHODS

The BiSex Survey

The BiSex Survey represents one of the few in North America and, until now, the only study in Canada focused exclusively on bisexuality. The Canadian province of Ontario was chosen because it reflects diversity of community size (numerous communities ranging from <500 000 residents to >1 million residents) and the proportion of bisexuals and sexual risk behavior for HIV among bisexual men observed in previous Canadian research.[30] The sampling strategy attempted to obtain a diverse sample of bisexual men via advertisement of a toll-free telephone number and an interviewer-assisted questionnaire.[31,32] Completion of the questionnaire required approximately 1 hour and collected information on personal and sociodemographic characteristics; sexual history; sexuality; sexual behavior with regular and casual male and female partners; sexual events and contexts; HIV testing experiences; health care use; and knowledge, attitudes, and beliefs about bisexuality and HIV/AIDS. No money or in-kind remuneration was provided to respondents. Interviews were conducted between March 11, 1996, and April 23, 1996.

Of the 1314 BiSex survey respondents, 65 (5%) were excluded because they did not provide their postal code information and 14 (1%) were excluded because they did not report sexual intercourse in the past year. An additional 219 (17%) were excluded because of incomplete information, leaving a sample of 1016.

Individual Characteristics

Individual characteristics collected from survey participants included age, marital status, education, employment status, income, self-identified sexual orientation, number of sexual partners by partner type in the previ-

ous year, and HIV testing behavior. The self-reported seroprevalence rate (5 men [0.4%]) was too low to allow for meaningful analyses.

Contextual Characteristics

In Ontario, AIDS Service Organizations (ASOs) are often the primary agencies responsible for HIV prevention programming and service provision. Residing within a catchment area of an ASO was considered as a contextual factor. There are 16 ASOs located throughout the province of Ontario. At the time of BiSex Survey data collection, 9 ASOs provided HIV prevention programming for men who have sex with men (MSM). ASOs were not involved in prevention programming directed toward male-to-female sexual behavior.

Statistical Approaches

The contextual influence of HIV prevention programming toward safer sexual behavior was examined using multilevel logistic regression. Individual characteristics, considered as first-level covariates, and the presence of HIV prevention programming provided by ASOs, considered as second-level covariates, were analyzed for their relationship with unprotected intercourse in the previous year. Specifically, in 4 separate subanalyses, we further examined unprotected intercourse with (1) regular female, (2) casual female, (3) regular male, and (4) casual male sexual partners. In these 4 subanalyses, we included all individual-level covariates that demonstrated a statistically significant association with unprotected intercourse in unilevel logistic regression models.

The analyses were conducted with HLM Version 5.01 (Scientific Software International, Lincolnwood, Ill) and SAS version 6.10 (SAS Institute, Inc., Cary, NC) for Windows 95 (Microsoft Corp., Redmond, Wash).

RESULTS

A total of 633 (62.3%) participants resided in 1 of the 9 ASO catchment areas with HIV prevention programming for MSM. Of the 1016 participants who reported sexual intercourse in the past year, 646 (63.6%) reported having at least 1 episode of unprotected intercourse with a male or female partner or both. A total of 870 (85.6%) reported sexual intercourse with at least 1 regular female partner, among whom 563 (64.7%) reported unprotected intercourse with this partner type. Two hundred thirty-three (22.9%) reported sexual intercourse with at least 1 casual female partner, among whom 47 (20.2%) reported unprotected intercourse. One hundred ninety-four (19.1%) reported sexual intercourse with at least 1 regular male partner, among whom 52 (26.8%) reported unprotected intercourse. Finally, 237 (23.3%) reported sexual intercourse with at least 1 casual male partner, among whom 35 (14.8%) reported unprotected intercourse. Further characteristics of BiSex Survey participants are presented in Table 1. The majority of the subjects in the sample were employed, earned greater than Can $20 000 per annum, and self-identified as bisexual. Approximately 40% of participants were married or living common law with a female partner; 42% were single, never married; and 17% were separated, divorced, or widowed. Participants were equally divided with respect to having been tested for HIV.

The unadjusted risk of unprotected intercourse with a male or female partner or both in the past year was higher in younger age groups. Compared with participants who were single and never married, significantly more unprotected intercourse was reported for bisexual men who were married or living common law or for those who were divorced, separated, or widowed (Table 1).

Table 2 presents the effects of HIV prevention programming on unprotected intercourse by sexual partner type. After adjusting for individual differences, bisexual men who resided in an area with HIV prevention programming engaged in substantially and significantly less unprotected intercourse with casual male partners compared with those residing in areas with no prevention programming. Similarly, bisexual men in areas with HIV prevention programming also engaged in substantially and statistically significantly less unprotected intercourse with their regular male partners. In contrast, unprotected intercourse with female partners (casual and regular) was not substantially or statistically significantly different between areas with or without HIV prevention programming (Table 2).

DISCUSSION

Our results suggest that the presence of HIV prevention programming for MSM is effective toward influencing safer sexual behavior with male but not female sexual partners of bisexual men.

There are various community organizations throughout the United States that provide HIV prevention programming. These US organizations are similar in mission and purpose to Canadian ASOs. Because they are influential community-based agencies, it is important to evaluate the effectiveness of their efforts. The evolution of these organizations primarily began as a community response to a new epidemic; therefore, we have no preintervention observations. It is for this reason that we made comparisons of geographic areas with and without HIV prevention programming for MSM. Participants in areas with prevention programming reported substantially less unprotected homosexual intercourse. These areas, at the time of the study, had no differential programming for the prevention of heterosexual transmission, and we observed no geographic differences for unprotected heterosexual intercourse. Because both observations originated from a single study population of bisexual men, they suggest that, in geographic areas with HIV prevention programming, the context of homosexual risk behavior has changed and the context of heterosexual risk behavior has not.

The effectiveness of HIV prevention programming in changing the context of homosexual risk behavior within communities adds to existing studies that have evaluated behavior changes of individuals.[34–51] To our knowledge, the only other study evaluating the contextual influence of an HIV intervention was undertaken by the Centers for Disease Control and Prevention in five comparison (intervention/nonintervention) US cities. The study demonstrated increased behavior change toward condom use in vaginal sex but did not report on homosexual intercourse.[26] This work represents a substantial contribution to evaluating the effectiveness of community interventions to change the con-

TABLE 1—Individual Characteristics and Presence of HIV Prevention Programming and Odds Ratios (ORs) for Unprotected Intercourse (n = 1016): Ontario BiSex Survey, 1996

	No. (%)	OR (95% Confidence Interval)
Age, y		
≤25	172 (16.9)	Reference
26–35	371 (36.5)	0.22 (0.13, 0.35)
36–45	305 (30.0)	0.34 (0.22, 0.53)
≥46	168 (16.5)	0.56 (0.37, 0.90)
Education		
≤Secondary	429 (42.2)	Reference
College/university	484 (47.6)	0.76 (0.48, 1.21)
≥Graduate/professional	103 (10.1)	0.70 (0.44, 1.11)
Income[a]		
≤$19 999	190 (18.7)	Reference
$20 000–$49 999	494 (48.6)	0.50 (0.35, 0.73)
≥$50 000	332 (32.7)	0.60 (0.45, 0.81)
Employment status		
Employed (full or part time)	789 (77.7)	Reference
Unemployed	108 (10.6)	0.79 (0.53, 1.19)
Other[b]	119 (11.7)	0.83 (0.48, 1.44)
Marital status		
Single	430 (42.3)	Reference
Married/common law	405 (39.9)	6.30 (4.54, 8.74)
Separated/divorced/widowed	172 (16.9)	1.81 (1.26, 2.59)
Self-identified sexual orientation		
Bisexual	763 (75.1)	Reference
Heterosexual	128 (12.6)	1.50 (0.99, 2.26)
Homosexual	47 (4.6)	0.61 (0.34, 1.10)
Other[b]	78 (7.7)	0.99 (0.61, 1.60)
Sexual behavior in the past year		
Women only	69 (6.8)	Reference
Men only	53 (5.2)	0.79 (0.46, 1.34)
Both women and men	894 (88.0)	0.36 (0.17, 0.76)
HIV testing behavior		
Never taken an HIV test	508 (50.0)	Reference
Tested for HIV	508 (50.0)	1.21 (0.93, 1.56)
HIV programming		
No programming	383 (62.3)	Reference
Programming	633 (37.7)	0.96 (0.73, 1.28)

Note. ORs for individual characteristics were calculated with unilevel logistic regression and for the presence of HIV prevention programming with multilevel logistic regression. The dependent variable was unprotected sexual intercourse with male or female partners (or both) in the past year.
[a]In 1996, the Canadian dollar approximated an average value of $0.70 in US dollars.[33]
[b]Other employment status includes individuals who were students and those who received social assistance from government or other sources. Other sexual orientation included those who chose "I do not choose to identify" as well as other responses such as transsexual, transgender, or "fluid."

TABLE 2—Odds Ratios (ORs) for Unprotected Intercourse, by Sexual Partner Type and Presence of HIV Prevention Programming: Ontario BiSex Survey, 1996

Sexual Partner	OR (95% Confidence Interval)
Regular female	
No programming	Reference
Programming	0.98 (0.74, 1.37)
Casual female	
No programming	Reference
Programming	1.41 (0.81, 2.50)
Regular male	
No programming	Reference
Programming	0.32 (0.21, 0.52)
Casual male	
No programming	Reference
Programming	0.39 (0.21, 0.74)

Note. ORs are calculated with multilevel logistic regression. The dependent variable for 4 separate multilevel analyses are unprotected intercourse with specified partner type: (1) regular female, (2) casual female, (3) regular male, and (4) casual male in the past year. The ORs for regular female partner are adjusted for age, marital status, and number of sexual partners in the past year. Those for casual female partner and for regular male partner are adjusted for age, and those for casual male partners are adjusted for age, martial status, and number of sexual partners. The ORs for casual female and regular male partners did not substantially alter when further adjusted for marital status and number of sexual partners. Similarly, none of the ORs changed substantially when further adjusted for potential socioeconomic confounders.

text of sexual risk behavior. The study also addresses the call for new means to assess "change in the HIV prevention fabric of the community."[52(p300)] However, in reality, public health practitioners are not often afforded the opportunity to conduct such detailed and comprehensive evaluations of interventions, particularly community-level interventions, which are often initiated by and from the community before the mobilization of public health initiatives. The present study provides an alternative analytic approach that is suitable for the evaluation of such community-level interventions.

The relatively high prevalence of unprotected intercourse, particularly in geographic regions without HIV prevention programming, is a serious public health concern, particularly in light of the increase in HIV incidence among gay and bisexual men noted in the United States and Canada and in other international studies.[53–59] This finding is also consistent with other studies reporting high levels of unprotected intercourse among bisexual men.[31–36,40–51] These results clearly indicate the importance of addressing homo-

sexual risk reduction for bisexual men and demonstrate the need for inclusive prevention initiatives that also address heterosexual risk behavior.

The BiSex Survey recruitment strategy achieved a large sample size and is one of the few recognized as having accessed the hidden populations of MSM.[31,32,60–63] However, this strategy introduces selection bias, particularly, volunteer bias. For example, participants more receptive to media messages may have an increased awareness of HIV prevention campaigns and the risks of unsafe sex and potentially may be more likely to participate in the study. A selective overrepresentation of such participants in geographic areas with HIV prevention programming could potentially account for the observed differences in homosexual risk behavior. If the mechanism, in this example, was participants' receptivity to media messages, one would then also expect that participants residing in geographic areas with HIV prevention programming would report less heterosexual risk behavior, which we did not observe. It is therefore reasonable to assume a relatively limited effect of volunteer bias on the observed contextual differences and on the inferred supporting evidence for the contextual effectiveness of HIV prevention programming. As a second limitation, we acknowledge the limited means of defining context through postal codes and the limited ability to adjust for contextual confounders. Moreover, as participants may engage in contexts other than those determined by their postal codes, one should be aware of the potential for contextual misclassification and consequent bias in the estimates of the importance of HIV prevention programming.

In summary, this study furthers our understanding of the contextual influence of community-level public health interventions. The significance of HIV prevention programming to influence safer sexual behavior among bisexual men in homosexual but not heterosexual contexts supports the benefits of inclusive and comprehensive programming efforts. This study also demonstrates the suitability of multilevel methods for examining the effectiveness of community-level public health programs. ■

About the Authors

At the time of the study, Chad A. Leaver was a student in the Department of Community Health and Epidemiology, Dalhousie University, Halifax, Nova Scotia. Paul J. Veugelers is with the Department of Community Health and Epidemiology, Dalhousie University. Ted Myers and Dan Allman are with the HIV, Social, Behavioural and Epidemiological Studies Unit, University of Toronto, Toronto, Ontario.

Requests for reprints should be sent to Paul J. Veugelers, PhD, Department of Community Health and Epidemiology, Dalhousie University, 5790 University Avenue, Halifax, Nova Scotia B3H 1V7, Canada (e-mail: paul.veugelers@dal.ca)

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Contributors

C.A. Leaver conceived the study, conducted the statistical analyses, and was the principal author. P.J. Veugelers developed the methodological approach and assisted in the statistical analyses and the development of the article. T.Myers conceived the BiSex Survey from which these data originated and contributed to the interpretation of findings. D. Allman provided feedback to the article.

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Human Participant Protection

This analysis of secondary data was approved by the health sciences human research ethics board of Dalhousie University, Halifax, Nova Scotia.

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Delivery of HIV Prevention Counseling by Physicians at HIV Medical Care Settings in 4 US Cities

Lisa R. Metsch, PhD, Margaret Pereyra, DrPH, Carlos del Rio, MD, Lytt Gardner, PhD, Wayne A. Duffus, MD, PhD, Gordon Dickinson, MD, Peter Kerndt, MD, Pamela Anderson-Mahoney, PhD, Steffanie A. Strathdee, PhD, and Alan E. Greenberg, MD, for the Antiretroviral Treatment and Access Study Group

Objectives. We investigated physicians' delivery of HIV prevention counseling to newly diagnosed and established HIV-positive patients.

Methods. A questionnaire was developed and mailed to 417 HIV physicians in 4 US cities.

Results. Overall, rates of counseling on the part of physicians were low. Physicians reported counseling newly diagnosed patients more than established patients. Factors associated with increased counseling included having sufficient time with patients and familiarity with treatment guidelines. Physicians who perceived their patients to have mental health and substance abuse problems, who served more male patients, and who were infectious disease specialists were less likely to counsel patients.

Conclusions. Intervention strategies with physicians should be developed to overcome barriers to providing counseling to HIV-positive patients. (*Am J Public Health.* 2004;94:1186–1192)

Studies have shown an increase in reported risk behavior among HIV-positive individuals receiving care.[1–5] Similarly, there has been a recent resurgence of syphilis among people with HIV in many cities across the United States.[6–8] These data emphasize the importance of alternative strategies to prevent the continued spread of HIV/AIDS in the United States. National strategies have recognized the importance of incorporating HIV prevention into the medical care setting.[9,10] This approach is consistent with a recent Institute of Medicine report that emphasized the need for prevention services among persons living with HIV and the new HIV prevention strategy of the Centers for Disease Control and Prevention (CDC).[11,12]

Studies consistently demonstrate that patients view their physician as a trusted and authoritative source of health information.[13,14] Studies in other disease prevention areas have shown that brief interventions delivered by physicians can translate into behavior change.[15–17] Recognizing this potential, federal organizations have recommended that physicians play a more active role in delivering prevention messages to their HIV-positive patients.[9–12,18,19] For example, in 1991, the US Public Health Service established as a goal that 75% of primary care and mental health care clinicians provide appropriate counseling regarding prevention of HIV and other sexually transmitted diseases by 2000.[20]

Relatively little is known about the risk reduction practices of HIV care providers with their HIV-positive patients. Earlier studies showed that primary care physicians do not routinely assess or intervene with their patients regarding their risks for HIV infection.[21–23] In 2 studies of HIV-positive individuals,[24,25] approximately 25% and 29% of participants, respectively, reported that a provider had not talked with them about safe sex. However, these studies did not provide information on provider-reported practices, nor did they distinguish delivery of prevention counseling to newly diagnosed and established patients.

To our knowledge, there has been, to date, no comprehensive physician study focusing on the delivery of HIV prevention counseling to HIV-positive patients by physicians within HIV medical care clinics. The current study, which focused on physician practices in 4 major US cities, investigated physicians' delivery of prevention counseling to newly diagnosed and established HIV-positive patients.

METHODS

Participants

We mailed questionnaires to 417 licensed physicians who provided primary care or prescribed antiretroviral treatment to HIV-positive adults in Atlanta, Baltimore, Los Angeles, and Miami between November 2000 and June 2001. We used a variety of sources in compiling clinician lists for each city, including local Medicaid offices, county health departments, state Infectious Diseases Society registries, Ryan White Title I and II programs, and other local medical societies. After preliminary lists had been compiled, all clinician offices were called to verify that contact information was correct and that the listed physicians had seen at least 1 HIV-positive patient in the previous year. The survey population included physicians serving individuals with HIV in community-based outpatient clinics and outpatient clinics associated with large hospitals/medical centers. Physicians in residency training were not included in the sample.

The initial contact included a cover letter, a copy of the questionnaire, and the offer of a small monetary incentive for completing the questionnaire. Names were not included with the questionnaires, and participants were informed that their responses would be confidential. A confidential code was assigned to identify nonresponders for follow-up. Using a modified version of Dillman's total design method for mail and telephone surveys,[26] we continued to follow up with nonresponders for 3 months via postcards, in-person visits, telephone calls, faxes, and questionnaire remailings. At least 5 contacts were attempted before physicians were listed as nonresponders.

Measures

The 61-item survey instrument assessed physicians' demographic and practice charac-

teristics, including the following: perceptions of patient characteristics, attitudes and beliefs regarding patients, perceptions of barriers to providing optimal care, and familiarity and comfort with using current HIV/AIDS treatment guidelines. Physicians were asked to answer questions about HIV-positive patients who were under their care (including hospitalized patients).

To specifically examine the prevention practices of participating physicians, we asked "Of the [newly diagnosed/established] HIV-positive patients you saw in the past month, to what percentage did you provide HIV transmission risk reduction counseling?" This question was asked separately for newly diagnosed and established patients. Providers were given 8 categorical responses from which to choose (0%, 1%–10%, 11%–25%, 26%–40%, 41%–60%, 61%–75%, 76%–90%, and 91%–100%). For the purpose of this analysis, responses were dichotomized: risk reduction counseling provided to more than 90% of patients or 90% or fewer of patients. The 90% cutoff was selected because this was the highest standard listed in the questionnaire. In the present analysis, we were seeking to document the extent to which delivery of prevention counseling was part of every clinical encounter.

Data Analysis

Stata Version 6 (Stata Corp; College Station, Tex) was used in conducting analyses. The outcomes of interest were delivery of transmission reduction counseling to (1) newly diagnosed patients and (2) established patients. Univariate analyses were conducted to assess the relationship between each independent variable and the counseling response variables. Factor analysis and scale construction were used as data reduction tools.

Principal components factor analyses were conducted with 8 items focusing on attitudes toward treatment of HIV-positive patients: (1) provider's perception of whether patients delay seeking HIV care until they experience symptoms, (2) provider's perception that patients want to be active in making decisions about their HIV care, (3) provider's perception that patients understand the meaning of viral load and CD4+ cell count, (4) provider's perception of HIV-positive patients' access to care, (5) provider's perception of the contribution of AIDS Drug Assistance Program support to his or her ability to provide antiretroviral treatment, (6) whether a provider would prescribe highly active antiretroviral therapy (HAART) to an HIV-positive patient who has a problem with illicit drugs, (7) whether a provider would prescribe prophylactic medications to an HIV-positive patient who has a problem with illicit drugs, and (8) whether a provider would see a patient who visited the clinic while high or intoxicated.

The items just described were measured on a 4-point scale ranging from *strongly disagree* to *strongly agree*. Rotated factor loadings ranged from 0.64 to 0.80. A varimax rotation was used in calculating standardized factor scores with a mean of zero; these scores, based on the rotated factors, were used in developing multivariate logistic models. Three factors were identified, and factor scores were calculated: (1) provider's perception of patients' interest and effort in their own care (items 1–3; range: –2.5 to 2), (2) provider's perception of the availability and contribution of community resources to HIV care (items 4 and 5; range: –4.9 to 1.4), and (3) provider's willingness to treat patients with substance abuse problems (items 6–8; range: –4.0 to 1.5).

Two scales were constructed from 9 items addressing providers' perceptions of barriers to HIV care. The original items were measured on a 4-point scale ranging from *not important* (1) to *very important* (4). The resulting scales provided summative scores divided by number of items. Scores ranged from 1 to 4 and measured (1) system barriers (mean=2.5, α=0.69; lack of child care at clinics, inconvenient hours and location, cost of care, transportation problems, unfriendly HIV care setting) and (2) patient barriers (mean=3.0, α=0.75; patients do not want care, lack of social support system, mental health problems, substance abuse problems).

Five items assessed respondents' perceptions of the percentages of their patients with the following problems: depression, other mental illness, alcohol abuse, use of noninjection drugs, and use of injection drugs. The median value for each of these items was 25%. A binary measure was defined to indicate that more than 25% of patients had 1 or more of these problems. In addition, physicians reported the average number of HIV-positive patients seen per month. A categorical measure based on quartiles was created to denote patient load: low (first quartile; 1–18 patients), medium (second and third quartiles; 19–100 patients), and high (fourth quartile; 101–800 patients).

After including in initial models all independent variables that had *P* values of .25 or less in the univariate analysis, we developed multivariate logistic models to allow examination of delivery of transmission reduction counseling to newly diagnosed and established patients. Variables included in initial models but not retained in the final models were type of practice setting (private practice, hospital, other), number of providers, rural/urban location, provider gender, provider race/ethnicity, and years caring for HIV patients. Parsimonious models were then developed through removal of variables that did not significantly contribute to the goodness of fit of initial models according to likelihood ratio tests and Hosmer–Lemeshow goodness-of-fit tests. Covariates were assessed for collinearity and interactions; collinearity was not a problem, and no significant interactions were identified.

RESULTS

Response Rate and Sample Characteristics

Of the 417 questionnaires mailed, 317 were completed, yielding an overall response rate of 76%, higher than those typically reported in physician studies.[27] Response rates at the 4 sites ranged from 62% to 84%. Demographic and practice characteristics of the participating physicians are reported in Table 1. The majority of physicians were male (65.6%), were non-Hispanic White (61.5%), and had been caring for HIV/AIDS patients for more than 8 years (62.2%). Approximately 60% reported caring for more than 25 HIV-positive patients per month. The professional training/background of the physicians varied, with 46.7% board eligible or board certified in infectious diseases, 57.7% board eligible or board certified in internal medicine, 16.1% board eligible or board certified in family practice, and 5.1% in general practice. Among those board eligible or board

TABLE 1—Characteristics of the Participating Physicians (n=317)

	%
Study site	
Atlanta	31.2
Baltimore	14.8
Los Angeles	23.7
Miami	30.3
Male provider	65.6
Provider race/ethnicity	
Hispanic	16.7
Non-Hispanic Black	11.4
Non-Hispanic White	61.5
Other	10.4
Years caring for HIV/AIDS patients	
≤ 4	17.4
5–8	20.5
>8	62.2
Average no. of HIV-positive patients per month (n=292)	
≤10	20.4
11–25	20.1
26–50	20.1
51–100	20.4
>100	19.1
Provider training[a]	
Board eligible/certified in internal medicine	57.7
Board eligible/certified in infectious diseases	46.7
Board eligible/certified in family practice	16.1
General practice	5.1
Other professional training	9.5

[a]Categories of provider training do not sum to 100% because some physicians had more than 1 type of training.

certified in internal medicine, 50.8% were also board eligible or certified in infectious diseases. The mean age of the sample was 44 years.

Overall, physicians reported positive practice characteristics. Most (87.7%) spent more than 15 minutes with each patient, and 65% believed that they had sufficient time to spend with their patients. In addition, most (81.4%) believed that they were very familiar with the current antiretroviral treatment guidelines, and 64.6% relied on these guidelines frequently in their efforts to learn about new treatment options.

Patient populations were largely male (an average of 74% of patients), and approximately half of the providers (55%) reported that more than 25% of their patients had problems relating to depression or other mental illness and alcohol use or other substance abuse.

Delivery of Risk Reduction Counseling

Physicians were more likely to provide HIV risk reduction counseling to newly diagnosed patients than to established patients (60% vs 14%; $P<.0001$). Sixty percent reported that they provided counseling to more than 90% of their newly diagnosed patients; 16.8% reported counseling 76% to 90% of their newly diagnosed patients; 7.1% reported counseling 61% to 75% of their newly diagnosed patients; and only 16.5% reported counseling 60% or fewer of their newly diagnosed patients. In contrast, there was a more dispersed distribution in the case of established patients: 14.0% of physicians counseled 91% to 100% of these patients, 9.2% counseled 76% to 90%, 12.7% counseled 61% to 75%, 17.8% counseled 41% to 60%, 9.2% counseled 26% to 40%, 19.4% counseled 11% to 25%, and 17.5% counseled 10% or fewer (Figure 1).

The multivariate analysis (Table 2) showed that physicians who agreed they had sufficient time to spend with patients (adjusted odds ratio [OR]=1.34 for each 1-unit increase on a 4-point agreement scale; 95% confidence interval [CI]=1.04, 1.72) and physicians who reported being very familiar with current antiretroviral treatment guidelines (adjusted OR=2.54; 95% CI=1.32, 4.89) were more likely to provide counseling to more than 90% of their newly diagnosed patients. Physicians who reported that more than 25% of their patients had mental health or drug problems were less likely to provide counseling to newly diagnosed patients (adjusted OR=0.59; 95% CI=0.36, 0.98).

In addition, physicians who saw fewer patients per month were more likely to provide counseling to newly diagnosed patients. Physicians with low patient loads (1–18 patients per month) were almost 3 times as likely as physicians with high patient loads to provide counseling to their newly diagnosed patients. Similarly, physicians with medium patient loads (19–100 patients per

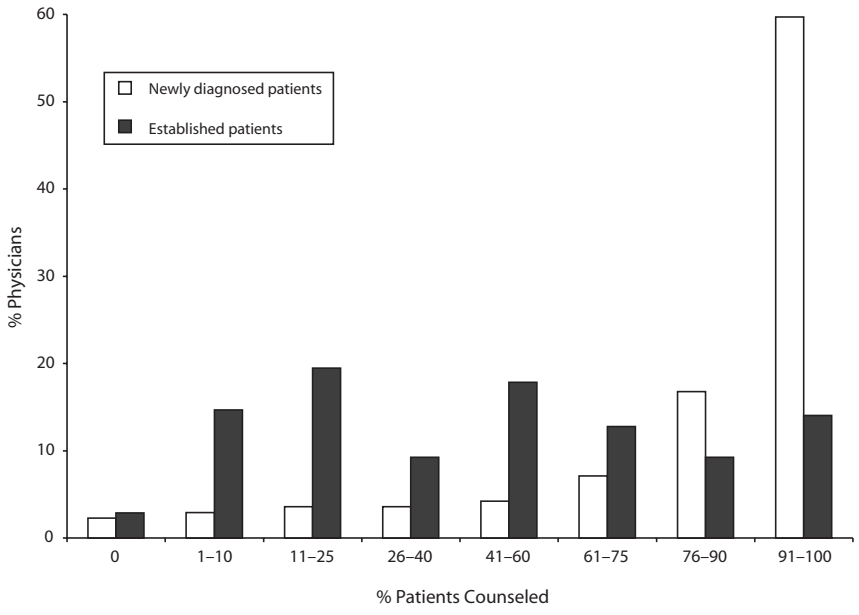

FIGURE 1—Percentages of patients counseled in past month: physicians in 4 US cities.

TABLE 2—Multivariate Logistic Models Focusing on Counseling of More Than 90% of Newly Diagnosed Patients: Adjusted Odds Ratios (ORs) and 95% Confidence Intervals (CIs)

Provider characteristic	OR (95% CI)
Study site	
Atlanta	0.647 (0.353, 1.188)
Baltimore	1.760 (0.758, 4.087)
Los Angeles	0.805 (0.414, 1.566)
Miami	1.000
Average no. of HIV-positive patients per month	
1–18 (low)	2.914 (1.323, 6.415)
19–100 (medium)	1.908 (1.020, 3.571)
101–800 (high)	1.000
Perception that there is sufficient time to provide all care and information needed to patients	1.340 (1.042, 1.722)
Very (vs minimally/moderately) familiar with current antiretroviral treatment guidelines	2.537 (1.317, 4.889)
More than 25% of patients have other health problems (depression or other mental illness, alcohol use, drug use)	0.591 (0.358, 0.975)

TABLE 3—Multivariate Logistic Models Focusing on Counseling of More Than 90% of Established Patients: Adjusted Odds Ratios (ORs) and 95% Confidence Intervals (CIs)

Provider characteristic	OR (95% CI)
Board eligible/certified in infectious disease	0.430 (0.202, 0.916)
Average time spent with patient	
≤30 minutes	1.000
>30 minutes	2.596 (1.153, 5.846)
Frequently uses antiretroviral guidelines to find out about new HIV treatment options	2.292 (1.008, 5.209)
More than 25% of patients have other health problems (depression or other mental illness, alcohol use, drug use)	0.572 (0.278, 1.177)
Patient gender (% male)	0.827 (0.712, 0.961)
Perception that community resources are available and contributed to HIV care	0.804 (0.582, 1.111)
Perception that system barriers are important to HIV care	1.902 (1.104, 3.276)

month) were almost twice as likely as those with high patient loads to provide counseling to these patients.

Physicians who spent an average of more than 30 minutes with patients were more likely to provide counseling to established patients (adjusted OR=2.60; 95% CI=1.15, 5.85); physicians serving more male patients (adjusted OR=0.83 for each 10% increase in male patient percentage; 95% CI=0.71, 0.96) and infectious disease specialists (adjusted OR=0.43; 95% CI=0.20, 0.92) were less likely to counsel such patients (Table 3).

Physicians who frequently relied on antiretroviral treatment guidelines were more likely to provide counseling to more than 90% of their established patients (adjusted OR=2.3; 95% CI=1.01, 5.21). Physicians who perceived health care system characteristics to be important barriers to care seeking among patients also were more likely to provide counseling to a majority of their established patients (adjusted OR=1.90; 95% CI=1.10, 3.28). In contrast to the model describing practices with newly diagnosed patients, study site was not associated with counseling established patients.

DISCUSSION

Medical management of HIV, which is now viewed as a chronic disease, is time consuming because of its complexity, requiring considerable scientific expertise and time for patient assessment. However, unlike most other chronic diseases, HIV is also an infectious disease that can be transmitted to others. Thus, prevention counseling and education regarding strategies to decrease transmission risk should be an integral component—and a priority—of HIV management.

Our data from physicians in 4 US cities suggest that less than optimal HIV prevention counseling is being provided to both new and established patients. Only 60% of physicians reported providing risk reduction counseling to 90% or more of their patients at the first encounter, and this percentage decreased to 14% with established patients. It is possible that patients received prevention counseling from another health care provider during their visit, but previous studies have indicated that physicians are an important source of information regarding HIV transmission and treatment.[3,13] Lack of attention to HIV transmission behavior during a physician visit represents a missed opportunity for delivery of prevention messages.

Several real and perceived barriers exist that contribute to suboptimal provision of transmission reduction counseling to HIV-positive patients. For example, current antiretroviral therapy requires near perfect adherence, and thus providers may be spending a significant amount of time counseling patients about the need to take their medications, leaving little time for discussion of risk reduction. In addition, physicians place different levels of emphasis on provision of this information to newly diagnosed and established patients. In the case of newly diagnosed patients, our findings indicated that perceived time constraints, patient load, and physicians' perception that patients had psychosocial problems were barriers to the delivery of transmission reduction counseling. Consequently, physicians with larger patient loads and those with a higher proportion of patients with mental health or substance abuse problems may have less time to address prevention issues. However, these patients are particularly in need of HIV prevention counseling, in that mental health and substance use problems can have negative effects in terms of medication adher-

ence, viral load suppression, and HIV drug resistance.[28–33]

In regard to established patients, our findings showed that patient gender, physicians' specialty training, and physicians' perception of outside resources available to their patients affected the frequency with which they provided transmission reduction counseling. The finding that physicians with a predominance of male patients were less likely to provide prevention counseling is consistent with other studies showing that female patients communicate more with their physicians, ask more questions than their male counterparts, and are more likely to discuss issues related to sexual matters.[34,35]

The finding that infectious disease specialists were less likely than other physicians to provide prevention counseling to their established patients is consistent with a recent study showing that physicians whose specialty was infectious disease were less confident than physicians with other specialties in assessing patients' sexual risk behaviors.[36] As is the case with many subspecialists, demands on time and effort to keep abreast of their subspecialty may decrease infectious disease specialists' focus on primary prevention. It is also possible that their interest is in management of the complications of HIV and the intricacies of antiretroviral therapy, and they believe counseling is better conducted by other allied health professionals.[37]

Notably, in the case of both newly diagnosed patients and established patients, physicians who reported being very familiar with or who frequently used current antiretroviral treatment guidelines were more likely to provide transmission counseling to the majority of their patients. Although, at the time of the present study, these guidelines did not address prevention, physicians who were more likely to use this resource may also have been more familiar with recent initiatives emphasizing HIV transmission counseling as a priority.

Limitations of our data should be noted. First, nonrespondents may have differed from respondents in terms of their reporting of prevention practices, although this possibility was reduced by the study's response rate. The small number of nonresponders with available data limits the conclusions that can be made regarding nonresponse bias. However, the limited data suggest that response rate did not vary according to gender or type of training. Second, we did not define HIV transmission risk reduction counseling in the survey questionnaire. Future studies similar to the present investigation could refer to the guidelines recently published[10] to define what is meant by prevention counseling so that physicians will have a basis for responding to questions about counseling quality and content.

Third, we asked providers to report on their delivery of counseling practices to patients they had seen in the past month. Providers may have delivered prevention counseling in the past, but not at the most recent medical care visit. Fourth, we lacked data allowing us to evaluate whether delivery of prevention messages led to reductions in new cases of sexually transmitted diseases or in other markers of high-risk transmission behaviors. Finally, the data obtained were self-reported by providers and not confirmed through patient interviews or clinical records. It is unlikely that physicians would underreport their delivery of prevention counseling, given that this is a highly desirable behavior. If any bias had been present, it was most likely in the direction of overreporting, which suggests that overall rates of counseling may be even lower than those observed here.

As we enter the third decade of the HIV/AIDS epidemic in the United States, more people are living with HIV than ever before. At the same time, we are also seeing an increase in risk behaviors among persons living with HIV.[6–8] Physicians caring for HIV-positive individuals have probably been underused as a resource in the national HIV/AIDS prevention strategy. This issue has been recognized in recent national initiatives and studies calling for health care providers to increase the frequency of prevention messages to HIV-positive patients.[9–12,19] However, if they are to provide prevention counseling during medical visits, health care providers will need specific training and tools. Strategies similar to those used in posttest counseling usually delivered to individuals at the time they learn their HIV diagnosis could be incorporated into the medical care visit, including cueing systems that could identify those at highest risk, suggested scripts on how to introduce the topic of prevention,[38] goal-directed counseling,[39] and mechanisms to document patients' progress in reducing high-risk behaviors. Intervention research will also be critical to evaluate different strategies for prevention counseling in the medical care setting.

In addition, it is important to recognize the variability inherent in patient characteristics and clinical care settings.[39] Established patients may have different prevention needs and face different challenges than newly diagnosed patients. For example, some newly diagnosed individuals may be in denial about their HIV and may find it difficult to contemplate and discuss behavior changes related to sexual activity. Established patients may need to be counseled on the interrelationships among risk for HIV transmission, receiving HAART, maintaining adherence, and achieving an undetectable viral load.[40] Some patients, regardless of whether they are newly diagnosed or established, may be engaging in high-risk behaviors, while other patients may not be sexually active. However, individual patient behaviors can change over time and should be assessed at each clinical encounter. Providers also should not make assumptions about the sexual behaviors of their patients without conducting an assessment. Techniques such as stages of change,[41] interactive counseling, and motivational interviewing could be useful in efforts to recognize the individual needs of patients and could allow for tailoring of prevention messages targeted at specific risk behaviors and time periods.[39]

Although there are many constraints placed on physicians who are addressing multiple needs of their HIV-positive patients during a brief encounter, physicians should take an active role in delivering prevention counseling. In turn, physicians can work with other professional clinic staff to ensure that patients receive additional prevention services, if available. New detailed guidelines for physicians and other providers ("Incorporating HIV Prevention Into the Medical Care of Persons Living With HIV"[10]) have recently been released and should be used as a resource. In addition, both public and private forms of insurance might serve as important incentives to compensate physicians sufficiently to allow them to have the time to deliver prevention messages. Incorporating prevention counseling

into the HIV primary care setting and including physicians and other primary care providers in this process represent important new strategies that may assist in targeting populations not reached by current efforts. ■

About the Authors

Lisa R. Metsch and Margaret Pereyra are with the Department of Epidemiology and Public Health, University of Miami School of Medicine, Miami, Fla. Carlos del Rio is with the Division of Infectious Diseases, Department of Medicine, Emory University School of Medicine, Atlanta, Ga. Lytt Gardner and Alan E. Greenberg are with the Division of HIV/AIDS Prevention, National Center for HIV, STD, and TB Prevention, Centers for Disease Control and Prevention, Atlanta. At the time of the study, Wayne A. Duffus was with the Division of Infectious Diseases, Department of Medicine, Emory University School of Medicine. Gordon Dickinson is with the Department of Medicine, University of Miami School of Medicine. Peter Kerndt and Pamela Anderson-Mahoney are with Health Research Association, Los Angeles, Calif. At the time of the study, Steffanie A. Strathdee was with the Johns Hopkins School of Hygiene and Public Health, Baltimore, Md.

Requests for reprints should be sent to Lisa R. Metsch, PhD, Department of Epidemiology and Public Health, University of Miami School of Medicine, 1801 NW 9th Ave, Suite 330a, Miami, FL 33136 (e-mail: lmetsch@med.miami.edu).

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Contributors

L.R. Metsch and M. Pereyra wrote the article and analyzed the data, with collaboration from the remaining authors. L.R. Metsch, C. del Rio, W.A. Duffus, G. Dickinson, P. Kerndt, P. Anderson-Mahoney, and S.A. Strathdee contributed to the study design and directed study activities from their respective sites. L. Gardner and A.E. Greenberg conceived the provider study, and L.R. Metsch developed the prevention focus for the study. All of the authors contributed to interpretation of results.

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Human Participant Protection

This study was approved by the institutional review boards of the Centers for Disease Control and Prevention, the University of Miami School of Medicine, the Emory University School of Medicine, the Johns Hopkins Bloomberg School of Public Health, and the Health Research Association. Voluntary participation was solicited in a cover letter describing the study, and a response to the questionnaire was considered informed consent.

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HIV Risk Behaviors Among Male-to-Female Transgender Persons of Color in San Francisco

Tooru Nemoto, PhD, Don Operario, PhD, JoAnne Keatley, MSW, Lei Han, PhD, and Toho Soma, MPH

Objectives. The authors examined HIV risk behaviors among African American, Asian/Pacific Islander (API), and Latina male-to-female (MTF) transgender persons in order to improve HIV prevention programs.

Methods. Individual survey interviews with MTF transgender persons of color (n = 332; 112 African Americans, 110 Latinas, and 110 APIs) were conducted.

Results. Prevalence and correlates of receptive anal sex and unprotected receptive anal sex (URAS) varied by type of partner (primary, casual, or commercial sex partners). URAS with primary partners was associated with drug use before sex; URAS with casual partners was associated with HIV-positive status and drug use before sex; and URAS with commercial sex partners was associated with African American ethnicity and low income.

Conclusions. Findings on current risk behaviors among MTF transgender persons provided meaningful implications for HIV prevention interventions. (*Am J Public Health.* 2004;94:1193–1199)

Male-to-female (MTF) transgender persons are individuals who experience discomfort with their biological male gender and identify instead as women. Members of this population confront multiple health risks,[1] with HIV/AIDS constituting a particularly overwhelming social and medical issue. Estimates of HIV prevalence in the MTF transgender population range from 11% to 78%.[2–9] However, few evidence-based transgender-specific HIV interventions exist.[10,11]

San Francisco, a city known for acceptance of sexual diversity, has a large, multicultural MTF transgender population. Data from anonymous HIV testing sites in San Francisco indicated an incidence rate of 7.8 per 100 person-years—the highest for any risk group in the city.[12] Ethnic differences in HIV seroprevalence among MTF transgender persons have been reported in studies conducted in San Francisco and Los Angeles.[2,8,12] African Americans showed the highest HIV seroprevalence (44%–63%), followed by Latinas (26%–29%), Whites (16%–22%), and Asian/Pacific Islanders (APIs) (4%–27%). Correlates of HIV-positive status include ethnicity (i.e., being African American), socioeconomic status (i.e., having less than a high school degree), lifetime sexual partners (i.e., >200 partners), and lifetime history of injection drug use.[2] Furthermore, HIV-positive participants were more likely than HIV-negative participants to report unprotected receptive anal sex (URAS) with primary partners and injection drug use in the past 6 months.[2]

Qualitative research has explored the social and ecological context for HIV vulnerability among MTF transgender persons, revealing that socioeconomic and psychological adversity contribute to the high prevalence of HIV-related risk behaviors.[13] Because of discrimination and stigma, many MTF transgender persons lack employment, live below the poverty threshold, and engage in high-risk sex work.[14] Psychosocial consequences of stigma described by MTF transgender persons, including depression and poor self-esteem, contribute to low negotiation power in relationships with primary partners and low self-efficacy to negotiate safe sex.[15] Focus group findings suggested that some MTF transgender persons engage in casual sex with multiple partners to affirm their female gender identities and engage in substance use to cope with stress associated with sex work and depression.[15]

In this article we investigate correlates of recent HIV-related risk behaviors in a sample of African American, Latina, and API male-to-female transgender persons in San Francisco. We focus on understanding current HIV-related risk behaviors to identify factors that can be addressed in behavioral interventions aiming to reduce future infections and transmissions. Many previous studies with MTF transgender persons using HIV status as an outcome have implied causal linkages between participants' risk behaviors and current HIV status; however, it is likely that for many HIV-positive subjects, HIV infection preceded (and may lead to an increase in) recent risk behaviors. One study showed that 65% of MTF transgender persons who tested positive for HIV already knew their HIV status and that 58% of HIV-positive transgender persons were currently receiving HIV antiretroviral therapy.[2] Therefore, treating current HIV status as an outcome may not be appropriate and does not provide meaningful implications for future risk reduction interventions. The authors investigated the association of recent HIV risk behaviors among MTF transgender persons of color with demographic characteristics (including race, age, income, preoperative/postoperative status), sexual behaviors (with primary partners, casual sex partners, or commercial sex partners), sex under the influence of alcohol and drugs, and HIV/sexually transmitted disease (STD) status.

METHODS

Procedure and Sample

This research used a two-stage approach. The first stage involved qualitative research that prepared us for the second stage of individual survey interviews. We held a series of focus groups with 48 MTF transgender persons of color, interviewed key informants in the San Francisco MTF transgender community, and mapped social spaces frequented by MTF transgenders.[16] On the basis of qualitative research findings, we developed a survey that was sensitive to life experiences of MTF transgender persons of color in San Francisco.

Forty MTF transgender persons completed a pilot version of the survey and provided feedback regarding cultural appropriateness, clarity, and ease of completion. On the basis of their feedback, we finalized the questionnaire. The informed consent form and questionnaire were translated into Spanish and unclear parts were back-translated to ensure the comparability between English and Spanish.

Between November 2000 and July 2001, a team of MTF transgender interviewers recruited participants from a range of community venues identified through mapping. Four San Francisco AIDS service organizations with transgender-specific programs referred 46% of the sample. To be considered eligible for the study, each participant had to (1) identify as an MTF transgender person (including pre- and postoperative status); (2) identify as African American, API, or Latina; (3) have a history of exchanging sex for money or drugs; and (4) be 18 years of age or older. Those who fulfilled eligibility criteria voluntarily met with a MTF transgender interviewer (matched by ethnicity) in a private interview space either in the project office or at collaborating agencies. Using a protocol approved by the University of California, San Francisco committee on human research, interviewers obtained informed consent orally and administered the survey. Latinas completed the survey in Spanish or English with the bilingual Latina interviewer. Upon completing surveys, participants received financial reimbursement, a safe-sex kit, and a list of agencies with services for transgenders.

Measures

Sexual behaviors. Participants reported sexual behaviors with 3 types of male partners: primary, casual, and commercial. Primary partners were defined as persons with whom participants had a relationship, such as boyfriends or spouses. Casual partners were defined as nonpaying private partners with whom participants engaged in casual sex, such as 1-night stands. Commercial sex partners were defined as customers who paid for sex.

For each type of partner, participants reported whether in the past 30 days they had engaged in receptive anal sex (partner puts penis in participant's anus) and whether they had ever engaged in unprotected receptive anal sex (URAS) with each type of partner during the past 30 days. Variables were dichotomized as follows: not engaging in the behavior versus engaging in the behavior.

Health outcomes. Participants indicated whether they had ever been tested for HIV and the result of their last test, as well as whether they had ever tested positive for any of 6 STDs (i.e., chlamydia, genital warts, gonorrhea, herpes, syphilis, and trichomoniasis) in the past 12 months. These were dichotomized into 2 variables: HIV status (negative=0, positive=1), and recent STD history (none in the past 12 months=0, any in the past 12 months=1).

Substance use. Measures of substance use were modified from the National Institute of Drug Abuse *Risk Behavior Assessment.*[17] We focused here on only 3 variables; that is, whether they had sex with primary, casual, or commercial partners under the influence of any illicit drug in the past 30 days (no sex under the influence in the past 30 days=0; any sex under the influence in the past 30 days=1).

Statistical Analysis

A Pearson χ^2 test was conducted to assess associations between ethnicity and categorized demographics, HIV status, and STD status. Multivariate logistic regression was performed to identify predictors on each of 6 binary outcome measures: receptive anal sex with primary partner, casual partners, and commercial partners; and URAS with primary partner, casual partners, and commercial partners. Our goal was to achieve a parsimonious model while satisfying good fit. Before modeling, we listed theoretically important and interesting predictors and cross-tabulated them with each of the 6 outcome measures. After the procedures described by Hosmer and Lemeshow,[18] variables with statistically significant levels less than .25 by Pearson χ^2 test were selected as candidates to enter the multivariate logistic model. A backward stepwise procedure was then used to remove those predictors with an adjusted statistically significant level greater than .20. Finally, the Hosmer–Lemeshow goodness-of-fit test was used to assess model fit. All analyses were conducted using SPSS (SPSS Inc; Chicago, Ill).

RESULTS

Demographics

Three hundred thirty-two MTF transgender persons (112 African American, 110 Latina, and 110 API) completed the survey (Table 1). More than half of the sample was foreign born. Among Latinas, most were born in Mexico (52%), followed by the Caribbean (16%), South and Central America (13%), and Spain (1%); 18% of Latinas were born in the United States. Among APIs, most were born in the Philippines (54%), followed by Southeast Asia (26%), South Korea (2%), and China or Hong Kong (2%); 14% of APIs were born in the United States. The average age was 34 years (range 18–60 years of age). Over one third of the sample did not complete high school; 54% earned less than $1000 in the past 30 days, and under half (49%) had permanent housing during the past 6 months. The 3 most common self-identified genders were female (36%), preoperative transgender (31%), and preoperative transsexual (21%). Few had undergone sexual reassignment surgery; among them, 73% identified as female and 24% as postoperative transsexual. A majority identified as heterosexual.

Latinas and APIs were more likely than African Americans to be foreign born (Table 1). African Americans were older (mean=36.5 years) than Latinas (mean=32.9) or APIs (mean=32.9) ($P<.05$). Latinas had relatively little education; 61% of Latinas had not completed high school, whereas 64% of APIs had completed at least some college. Latinas were most likely to currently engage in sex work. APIs were more likely to have a full-time job, higher income, and permanent housing than other ethnic groups. APIs were most likely to have had sex reassignment surgery and to identify as female.

Health Outcomes

Ninety-eight percent of the MTF transgender sample reported having ever tested for HIV. Of those who had been tested, 26% reported being HIV-positive. Another 68% reported being HIV-negative; 4% were unsure and 1% refused to report their status. Fourteen percent reported testing positive for any STD during the past 12 months, including herpes (5%), gonorrhea (4%), genital warts

TABLE 1—Demographics and HIV/STD Prevalence Rates, by Ethnicity

	Total (n = 332), No. (%)	African American (n = 112), No. (%)	Latina (n = 110), No. (%)	API (n = 110), No. (%)	P[a]
Born outside US	191 (58)	6 (5)	90 (82)	95 (86)	.00
Age group, y					.01
18–30	119 (36)	27 (24)	47 (43)	45 (41)	
31–40	137 (41)	50 (45)	39 (35)	48 (44)	
41–60	75 (23)	34 (31)	24 (22)	17 (15)	
Highest education level					.00
Less than high school	122 (37)	35 (31)	67 (61)	20 (18)	
High school/technical/GED	92 (28)	43 (38)	29 (26)	20 (18)	
Some college	84 (25)	27 (24)	9 (8)	48 (44)	
College and above	34 (10)	7 (6)	5 (5)	22 (20)	
Income source(s) in past 6 mo[b]					
Full-time job	92 (28)	18 (16)	24 (22)	50 (45)	.00
Prostitution	170 (51)	56 (50)	79 (72)	35 (32)	.00
Income in past 30 days, $					.00
0–499	64 (20)	15 (13)	36 (33)	13 (12)	
500–999	110 (34)	51 (46)	35 (32)	24 (22)	
1000–1999	70 (21)	31 (28)	15 (14)	24 (22)	
2000 and above	84 (26)	15 (13)	22 (20)	47 (44)	
Housing situation past 6 mo					.00
Permanent housing	157 (49)	43 (40)	46 (43)	68 (64)	
Temporary housing	147 (46)	55 (51)	54 (51)	38 (36)	
Homeless (shelter, street)	16 (5)	9 (8)	6 (5)	1 (1)	
Gender identity					.00
Female	119 (36)	44 (39)	12 (11)	63 (57)	
Preoperative transgender/ transsexual	173 (52)	65 (58)	77 (70)	31 (28)	
Other[c]	40 (12)	3 (3)	21 (19)	16 (15)	
Had sex reassignment surgery	33 (10)	7 (6)	9 (8)	17 (15)	.05
Sexual orientation					.60
Heterosexual	277 (85)	95 (88)	88 (82)	94 (86)	
Homosexual	34 (10)	8 (7)	14 (13)	12 (11)	
Bisexual	15 (5)	5 (5)	6 (6)	4 (4)	
HIV-positive status	86 (26)	47 (41)	25 (23)	14 (13)	.00
Any STD, past 12 mo	46 (14)	20 (18)	21 (19)	5 (4)	.00

Note. GED = general equivalency degree.
[a]*P* values are associated with χ^2 tests with $df = 2(R - 1)$, where R is the number of categories for each variable.
[b]Income sources not mutually exclusive.
[c]Other includes transvestite, androgynous, postoperative transgender, cross-dresser, "gender bender," "drag queen."

(3%), syphilis (3%), chlamydia (2%), and trichomoniasis (1%).

Self-reported HIV status varied significantly by ethnicity (Table 1). African Americans were more likely than Latinas and APIs to report having HIV, and African Americans and Latinas were both more likely than APIs to report having any STD in the past 12 months.

Sex Under the Influence of Drugs

Sex while under the influence of illicit drugs was common. Among participants who reported having a primary partner, 55% engaged in sex with them while under the influence of drugs during the past 30 days; the rate was highest among African Americans (63%) and Latinas (60%) compared with APIs (41%) ($\chi^2 = 6.49$, $P < .05$). Close to half (45%) of the participants who had casual partners reported having sex with them under the influence of drugs during the past 30 days; the rate was highest among African Americans (71%), followed by Latinas (53%) and APIs (43%) ($\chi^2 = 5.98$, $P < .05$). Roughly half (52%) of the participants who had sex with commercial partners reported having sex with them while under the influence of drugs in the past 30 days, with no significant ethnic group differences.

Sexual Behaviors

Receptive anal sex. In the past 30 days, 52% of the sample reported having had a primary partner, 36% at least 1 casual partner, and 40% at least 1 commercial partner. Among those who reported having each respective partner, 77% had receptive anal sex with a primary partner, 71% had receptive anal sex with a casual partner, and 74% had receptive anal sex with a commercial partner. Table 2 shows bivariate associations between these 3 sexual behaviors and demographics, STD history, HIV status, and sexual risk factors in the past 30 days.

Multivariate logistic regression analysis was conducted on each of the 3 outcome variables: receptive anal sex with primary, casual, and commercial partners during the past 30 days (Table 2). Models for primary and commercial sex partners showed adequate goodness of fit. Significant predictors of receptive anal sex with a primary partner were being African American or Latina relative to API, being 18 to 30 years of age relative to 41 to 60 years of age, having an income less than $500 relative to $500 to $999 during the past 30 days, and ever having had sex while under the influence of drugs during the past 30 days. Significant predictors of receptive anal sex with casual partners were being Latina relative to API, not having had sex reassignment surgery, and ever having had sex while under the influence of drugs during the past 30 days. Significant predictors of receptive anal sex with commercial partners were being Latina, having an STD in the past year,

TABLE 2—Receptive Anal Sex in the Past 30 Days, by Partner Type

	Primary			Casual			Commercial		
	No.	% Yes	Adjusted OR (95% CI)[a]	No.	% Yes	Adjusted OR (95% CI)[a]	No.	% Yes	Adjusted OR (95% CI)[a]
Overall	173	76.6		119	71.4		132	74.2	
Demographics									
Ethnicity									
African American	67	**82.1**	6.6**(2.1, 21.3)	35	**71.4**	1.1 (0.3, 3.9)	44	**68.2**	1.7 (0.6, 5.2)
Latina	50	**90.0**	13.4**(3.0, 59.0)	49	**83.7**	4.1*(1.3, 13.6)	59	**84.6**	6.2**(1.8, 21.2)
Asian/Pacific Islander	56	**58.9**	1.0	35	**54.3**	1.0	29	**58.6**	1.0
Age group									
18–30	63	**88.9**	7.4** (1.8, 30.4)	50	**78.0**	[b]	67	74.6	[d]
31–40	69	**73.9**	1.4 (0.4, 4.4)	50	**70.0**		48	77.1	
41–60	41	**63.4**	1.0	19	**57.9**		17	64.7	
Income past 30 days, $									
0–499	32	**90.6**	5.4* (1.0, 29.6)	27	**81.5**	2.2 (0.6, 8.2)	25	**68.0**	0.6 (0.2, 2.1)
500–999	50	**72.0**	1.0	38	**60.5**	1.0	39	**66.7**	1.0
1000 or over	89	**74.2**	3.0 (0.9, 10.0)	54	**74.1**	3.3* (1.1, 10.1)	68	**80.3**	2.4 (0.9, 6.8)
Had reassignment surgery									
Yes	21	**38.1**	1.0	9	**44.4**	1.0	5	60.0	[d]
No	152	**82.2**	2.7 (0.8, 9.2)	110	**73.6**	7.2* (1.2, 42.3)	127	74.8	
STD history									
Any STD past 12 mo									
Yes	30	83.3	[d]	22	**86.4**	[b]	28	**89.3**	4.7* (1.2, 18.2)
No	143	75.5		97	**68.0**		104	**70.2**	1.0
HIV status									
Positive	49	79.6	[d]	27	**81.5**	3.6 (0.9, 14.3)	20	65.0	[d]
Negative/don't know	124	75.8		92	**68.5**	1.0	112	75.9	
Sex risk factors in past 30 days									
Had primary partner									
Yes	173	76.6	[c]	60	70.0	[d]	62	75.8	[d]
No	0	0.0		59	72.9		70	72.9	
Had casual partner									
Yes	60	81.7	[d]	119	71.4	[c]	59	78.0	[d]
No	113	74.3		0	0.0		73	71.2	
Had commercial partner									
Yes	62	**87.1**	[b]	59	**81.4**	2.2 (0.9, 5.9)	132	74.2	[c]
No	110	**70.9**		58	**60.3**	1.0	0	0.0	
Drug use during sex									
Yes	95	**90.5**	6.2***(2.2, 17.2)	66	**81.5**	2.9* (1.1, 7.7)	75	**81.3**	2.5* (1.0, 5.9)
No	78	**60.3**	1.0	53	**58.5**	1.0	57	**64.9**	1.0
Hosmer–Lemeshow goodness-of-fit, χ^2 (df), *P*			7.2 (8), .52			14.1 (8), .08			11.2 (8), .19

Note. OR = odds ratio; CI = confidence interval. Boldface = $P < .25$ in bivariate χ^2 tests and factor is qualified to be entered in multiple logistic model.
[a]Adjusted for those variables in the final model.
[b]Variables are excluded in the final model in backward stepwise selection procedure, adjusted $P > .20$.
[c]Not applicable.
[d]Variables are not entered in the model.
*$P < .5$; **$P < .01$; ***$P < .001$.

and ever having had sex while under the influence of drugs during the past 30 days.

URAS. Of the participants who had engaged in receptive anal sex with each respective partner during the past 30 days, 47% had URAS with a primary partner, 26% had URAS with a casual partner, and 12% had URAS with a commercial partner. Table 3 shows bivariate associations between these 3 sexual behaviors and demographics, STD history, HIV status, and sexual risk factors in the past 30 days.

TABLE 3—Unprotected Receptive Anal Sex in the Past 30 Days by Partner Type

	Primary			Casual			Commercial		
	No.	% Yes	Adjusted OR (95% CI) [a]	No.	% Yes	Adjusted OR (95% CI) [a]	No.	% Yes	Adjusted OR (95% CI) [a]
Overall	133	46.6		85	25.9		98	12.2	
Demographics									
Ethnicity									
African American	55	43.6	[c]	25	**44.0**	[b]	30	**23.3**	4.5*(1.1, 17.9)
Latina	45	42.2		41	**17.1**		51	**7.8**	1.0
Asian/Pacific Islander	33	57.6		19	**21.4**		17	**5.9**	[d]
Age									
18–30	56	44.6	[c]	39	20.5	[c]	50	8.0	[c]
31–40	51	49.0		35	31.4		37	16.2	
41–60	26	46.2		11	27.3		11	18.2	
Income past 30 days, $									
0–499	29	41.4	[c]	22	18.2	[c]	17	**29.4**	8.5*(1.6, 44.2)
500–999	36	50.0		23	34.8		26	**15.4**	2.3 (0.5, 11.8)
1000 or over	66	47.0		40	25.0		53	**5.7**	1.0
Had reassignment surgery									
Yes	8	**25.0**	[b]	4	25.0	[c]	0	0.0	[c]
No	125	**48.0**		81	25.9		95	12.6	
STD history									
Any STD past 12 mo									
Yes	25	56.0	[c]	19	**42.1**	[b]	25	16.0	[c]
No	108	44.4		66	**21.2**		73	11.0	
HIV status									
Positive	39	48.7	[c]	22	**40.9**	3.8* (1.1, 12.4)	13	**23.1**	[b]
Negative/don't know	94	45.7		63	**20.6**	1.0	85	**10.6**	
Sex risk factors in the past 30 days									
Had primary partner									
Yes	131	46.6	[e]	42	**35.7**	2.8 (1.0, 8.3)	47	**17.0**	[b]
No	0	0.0		43	**16.3**	1.0	51	**7.8**	
Had casual partner									
Yes	49	44.9	[c]	85	25.9	[e]	46	8.7	[c]
No	84	47.6		0	0.0		52	15.4	
Had commercial partner									
Yes	54	**53.7**	[b]	48	20.8	[c]	98	12.2	[e]
No	78	**41.0**		35	31.4		0	0.0	
Drug use during sex									
Yes	86	**53.5**	2.2* (1.0, 4.6)	54	**31.5**	3.5* (1.0, 12.4)	61	14.8	[c]
No	47	**34.0**	1.0	31	**16.1**	1.0	37	8.1	
Hosmer–Lemeshow goodness-of-fit, χ^2 (df), *P*			[e]			5.2 (5), 0.39			0.1 (4), 0.99

Note. OR = odds ratio; CI = confidence interval; STD, sexually transmitted disease. Boldface = $P < .25$ in bivariate χ^2 tests and factor is qualified to be entered in multiple logistic model.
[a]Adjusted for those variables in the final model.
[b]Variables are excluded in the final model in backward stepwise selection procedure, adjusted $P > .20$.
[c]Variables are not entered in the model.
[d]Latina and Asian/Pacific Islander are combined as a reference group.
[e]Not applicable.
*$P < .5$; **$P < .01$.

Multivariate logistic regression analysis was conducted on each of the 3 outcome variables: URAS with primary, casual, and commercial partners during the past 30 days (Table 3). Models for casual and commercial sex partners showed adequate goodness of fit. The only predictor of URAS with a primary partner in the past 30 days was having sex while under the influence of drugs during the past 30 days. Significant predictors of URAS with a casual partner were being HIV-positive and having had sex while under the influence of drugs

during the past 30 days. Significant predictors of URAS with a commercial partner were being African American and having an income of less than $500 during the past 30 days relative to $1000 or more.

DISCUSSION

This research offers implications for HIV prevention work for MTF transgender persons of color. Major findings are as follows: (1) about three quarters of the participants had recently engaged in receptive anal sex with primary, casual, and commercial sex partners, with no significant differences between types of partners found; (2) a significantly higher proportion had recently engaged in URAS with primary partners than with casual and commercial sex partners; (3) current URAS with primary and casual partners, but not commercial partners, was significantly and independently correlated with having had sex under the influence of drugs; (4) HIV-positive participants were 3.8 times more likely to have recently engaged in URAS with casual partners than HIV-negative participants, after control for other variables; and (5) although only 12% had reported URAS with commercial partners in the past 30 days, this risk behavior was significantly and independently correlated with African American race (4.5 times more compared with non–African Americans) and lowest income level (<$500 of monthly income).

MTF transgender persons of color in this study reported high levels of HIV and STDs. Self-reported HIV rates in this study were very similar to findings reported in a previous study that used serological HIV testing. Self-reported prevalence here was 41% African American, 23% Latina, and 13% API; serological prevalence in another study in San Francisco was 63% African American, 29% Latina, and 25% others (two thirds of which were APIs).[2] These prevalence estimates are comparable to HIV levels among gay men at the height of the epidemic in the 1980s.[12]

Rates of URAS were highest with primary partners and less so for casual partners and commercial partners, further confirming previous study findings[2] and reports on relationship intimacy as a barrier to condom use and risk reduction.[19] Earlier focus group findings suggested that social and psychological factors contribute to sexual risk behaviors with different partner types.[14,15] In the context of sex with primary partners, focus group participants described intense need for affection and personal connection, and stated that condoms undermined feelings of intimacy and threatened the connection with primary partners. In the context of sex with casual partners, participants described feelings of gender validation and attractiveness associated with receiving sexual attention from men. Most participants endorsed 100% condom use rules with customers, whom they viewed as business clientele rather than intimate partners. However, economic pressures compelled many to compromise their condom rules and engage in unsafe sex for increased money. Quantitative findings thus corroborate the need for prevention strategies to target the relationship context of sex—whether with a primary partner, with a casual date or 1-night stand, or with a partner who pays for sex.

Ethnic differences in HIV-related sexual risk behaviors corroborated previous epidemiological research.[2] African Americans in our sample had the highest rates of HIV and also reported frequently engaging in multiple risk behaviors including sex under the influence of drugs and unprotected sex with commercial sex partners. Latinas were most likely to engage in sex work, reported high rates of having sex while under the influence of drugs, and reported the highest rates of receptive anal sex with all partner types (although this sexual behavior is not risky when condoms are used). It is worth noting that African Americans and Latinas also reported particularly adverse socioeconomic conditions, which should be considered when designing HIV prevention interventions.[8] In an expected finding, APIs showed a protective factor for HIV: they were the least likely among the ethnic groups to report any receptive anal sex with primary, casual, or commercial partners as well as having sex under the influence of substances. Furthermore, only 1 API sex worker reported recent URAS. Lower rates of risk behaviors, HIV, and STDs among APIs may be attributable in part to their higher education and income and lower likelihood of engaging in sex work.

Previous research on MTF transgender persons has shown that African American race was a significant predictor of HIV seroconversion (adjusted relative hazard ratio=5.0).[12] Our findings suggest that this seroconversion rate may be associated with URAS with commercial partners. Although a minority of our study participants reported engaging in URAS with commercial partners, African Americans were disproportionately likely to do so. In addition, low income was independently correlated with URAS with commercial partners. This corroborates our focus group finding that economically disadvantaged MTF transgender persons engage in unprotected sex for survival[15] and confirms that commercial sex clients offer to pay extra for sex without condoms.[20] HIV education programs that address the specific needs of African American MTF transgender persons, such as job training, housing, and substance abuse treatment and mental health services, are critically needed.[16]

Urgent Need for Transgender-Sensitive HIV and Substance Use Interventions

Although MTF transgender persons of color may represent an extremely high-risk strata and a subpopulation within a minority group, practical steps toward addressing these health outcomes are currently underway. Several community-based programs in San Francisco have launched culturally sensitive, transgender-specific HIV/AIDS prevention and care programs and substance abuse treatment programs. Several ethnic-specific community-based agencies (e.g., African American, Latino, and Asian/Pacific Islander AIDS service organizations) have enhanced their transgender-specific outreach, support groups, and educational training programs conducted by transgender staff. Local substance abuse treatment organizations and public health clinics have also increased their sensitivity to transgender health and social issues, and some have hired transgender service providers and counselors to offer transgender-specific programs. Another evidence-based transgender HIV prevention intervention in Minnesota has been well documented.[21,22]

MTF transgender-specific health intervention programs should be implemented in other metropolitan areas (e.g., Los Angeles, New York, Washington, DC, Boston, Chicago).

It is important to train health service providers on transgender sensitivity and health issues.[11,16] This might be particularly important for public health clinics and social service agencies, where transgender persons of color may feel uncomfortable using services because of previous racial and gender insensitivity toward transgender persons.[16] Hiring qualified transgender staff can provide a critical link to the community and enhance trust for transgender clients.

Limitations

This sample may not represent MTF transgender persons in general. Respondents were recruited in San Francisco, where a large transgender community might contribute to a higher prevalence of substance use and sexual activity (including sex work) than elsewhere. Although self-reports of sexual behaviors and drug use tend to be reliable,[23,24] respondents may have minimized their reported risk behaviors. Nevertheless, these data from a large, diverse sample shed light on risk behaviors among a group about which little is known.

CONCLUSIONS

Responses from the public health community are vital to improve the health of MTF transgender persons of color—a population already at risk because of discrimination; victimization; and lack of access to education, employment, health care, and housing. Many public health surveillance measures (e.g., HIV reports issued by the Centers for Disease Control and Prevention) classify MTF transgender persons with homosexual men or men who have sex with men. Our findings suggest they warrant a specific demographic category. Indeed, the San Francisco Department of Public Health has classified MTF transgender persons since 1996. Service organizations must provide programs sensitive to the needs of the multicultural MTF transgender community. In addition, health care and service providers must be trained on the epidemiological, social, psychological, and cultural factors that make this community vulnerable to HIV and substance abuse. To provide effective health services for MTF transgender persons, professionals must accept the diversity within gender identity, appreciate differences associated with culture and sexual orientation, and advocate for transgender clients' basic health and human rights. ■

About the Authors

The authors are with the Center for AIDS Prevention Studies, University of California, San Francisco.

Requests for reprints should be sent to Tooru Nemoto, PhD, Center for AIDS Prevention Studies, University of California, San Francisco, 74 New Montgomery St, Suite 600, San Francisco, CA 94105 (e-mail: tnemoto@psg.ucsf.edu).

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Contributors

T. Nemoto conceived the study and supervised all aspects of its implementation and analysis. D. Operario was involved in analysis, interpretation, and manuscript preparation. J. Keatley coordinated the study implementation. L. Han and T. Soma assisted with data management and analysis.

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Human Participant Protection

This study was approved by the University of California, San Francisco, committee on human research.

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Experiences of Harassment, Discrimination, and Physical Violence Among Young Gay and Bisexual Men

David M. Huebner, PhD, MPH, Gregory M. Rebchook, PhD, and Susan M. Kegeles, PhD

Objectives. We examined the 6-month cumulative incidence of anti-gay harassment, discrimination, and violence among young gay/bisexual men and documented their associations with mental health.

Methods. Gay/bisexual men from 3 cities in the southwestern United States completed self-administered questionnaires.

Results. Thirty-seven percent of men reported experiencing anti-gay verbal harassment in the previous 6 months; 11.2% reported discrimination, and 4.8% reported physical violence. Men were more likely to report these experiences if they were younger, were more open in disclosing their sexual orientation to others, and were HIV positive. Reports of mistreatment were associated with lower self-esteem and increased suicidal ideation.

Conclusions. Absent policies preventing anti-gay mistreatment, empowerment and community-building programs are needed for young gay/bisexual men to both create safe social settings and help them cope with the psychological effects of these events. (*Am J Public Health.* 2004;94:1200–1203)

Recent research involving gay and lesbian individuals has documented associations between psychological distress and both perceptions of discrimination[1,2] and experiences of victimization.[3–5] These findings are consistent with research examining the consequences of mistreatment among other marginalized groups[6–9] and with theories linking minority-specific stress to negative physical and mental health outcomes.[10–13]

Few studies of gay and lesbian populations have been sufficiently large to yield useful information regarding the incidence or prevalence of anti-gay harassment, discrimination, and victimization or to identify demographic subgroups at particular risk. However, a growing literature on violence in high schools does offer some important insights. Population-based studies indicate that gay, lesbian, or bisexual adolescents (defined by sexual behavior, sexual attraction, or self-labeling) are more likely than other adolescents to report being involved in fights or to be the targets of harassment.[14–18] For example, according to 2 such studies, between 25% and 38% of gay, lesbian, and bisexual adolescents reported being involved in a fight in school during the past year, as compared with 7% to 19% of other adolescents.[15,16] It is important to note that existing population-based studies of high school students have not differentiated between violence that occurs because of sexual orientation and violence that occurs for other reasons. They have also tended to exclude nonviolent forms of discrimination.

Little is known about the prevalence or incidence of mistreatment in the years following high school. Herek et al. sampled 2259 gay and lesbian adults and found that, during their adult lifetimes, 28% of men and 19% of women reported some form of violence or other criminal activity directed at them as a result of their sexual orientation.[4] Diaz et al. sampled 912 gay and bisexual Latino men and found that 10% reported anti-gay violence and 15% to 50% reported other forms of anti-gay discrimination and harassment as adults.[1] However, to our knowledge, no large study has used a multiethnic sample to document the extent of anti-gay mistreatment experienced by young gay and bisexual men.

In the present study, we examined the 6-month cumulative incidence of anti-gay verbal harassment, discrimination, and physical violence among a large sample of young gay and bisexual men. We also sought to identify subgroups of young men at particular risk for these experiences and to document associations between such experiences and markers of mental health problems.

METHODS

Study Population

Gay and bisexual men (n=1248) were recruited during 1996 and 1997 in Phoenix, Ariz; Albuquerque, NM; and Austin, Tex, to serve as a baseline sample in a multicity controlled trial of a community-level HIV prevention intervention. Participants were recruited by peers through venues (e.g., gay bars and retail establishments), organizations, and social networks. Detailed descriptions of the sampling methods can be found elsewhere.[19,20] Participants ranged in age from 18 to 27 years, and the average age was 23 years (SD=2.7). Eighty-three percent of the respondents identified themselves as gay, and 16% identified themselves as bisexual. Because our focus was on examining mistreatment based on sexual orientation, participants who did not self-identify as gay or bisexual (n=15) were excluded from the analyses. Participants were predominantly White (59%) or Latino (29%), consistent with the demographic makeup of the study cities.

Research Instrument

Participants completed self-administered questionnaires and returned them to the investigators via mail; they were each paid $10 for their participation. In addition to reporting demographic information, participants indicated whether they had ever been tested for HIV and reported their most recent test result. Untested men were coded as HIV negative in subsequent analyses. Participants also reported how open with other people ("out of the closet") they were about their sexual orientation, using a 5-point scale ranging from *not out to anyone* to *out to almost everyone.*

Experiences with mistreatment were assessed via the question "During the past 6 months, have you experienced any of the following directed at you because you were gay/bisexual?" Participants indicated (yes or no) whether each of the following 3 events had occurred: (a) verbal harassment, (b) discrimination (e.g., in employment, housing, insurance), or (c) physical violence. Self-esteem was assessed with 4 items (α=.78) from the Rosenberg Self-Esteem Inventory.[21] Finally, participants indicated whether they had "thought seriously about committing suicide" in the past 2 months.

RESULTS

Thirty-seven percent of the participants reported that they had experienced verbal harassment during the preceding 6 months because of their sexual orientation (95% confidence interval [CI]=34.3%, 39.7%); 11.2% reported discrimination (95% CI=9.4%, 13.0%), and 4.8% reported physical violence (95% CI=3.6%, 6.0%). Table 1 presents bivariate and multivariate associations between the incidence of these experiences and demographic characteristics, HIV status, and extent of disclosure to others. Table 2 presents the results of regression analyses predicting self-esteem and suicidal ideation from demographic characteristics, HIV status, extent of sexual orientation disclosure, verbal harassment, discrimination, and physical violence.

DISCUSSION

Recent experiences of anti-gay verbal harassment, discrimination, and physical violence were reported by a substantial minority of men in our sample; men aged 18 to 21 years, men who were more open in disclosing their sexual orientation to others, and HIV-positive men most often reported such events. These types of mistreatment were associated with lower self-esteem and a 2-fold increase in the odds of reporting suicidal ideation. Given the potentially life-threatening nature of these acts and their psychological correlates, health care professionals and policymakers should attend to the effects of harassment, discrimination, and violence on young gay men if they hope to improve the lives of this vulnerable population.

The associations observed between experiences of mistreatment and markers of psychological distress are subject to a number of interpretations. The explanation most consistent with existing theory is that discrimination, harassment, and victimization are stress-

TABLE 1—Associations Between Demographic Characteristics and Reported 6-Month Cumulative Incidence of Verbal Harassment, Discrimination, and Physical Violence

		Verbal Harassment			Discrimination			Physical Violence		
	No.[a]	%[b]	OR[c]	95% CI	%[b]	OR[c]	95% CI	%[b]	OR[c]	95% CI
Age, y										
≤21	213	50.2	1.00		14.1	1.00		10.3	1.00	
>21	997	34.3	0.55***	0.40, 0.75	10.6	0.88	0.56, 1.43	3.6	0.32***	0.17, 0.58
Education										
No college	313	43.5	1.00		16.6	1.00		4.0	1.00	
Some college or more	896	34.9	0.81	0.61, 1.08	9.4	0.55**	0.37, 0.81	6.0	1.11	0.60, 2.08
Race/ethnicity										
White	716	39.2	1.00		10.8	1.00		4.6	1.00	
Latino	344	34.6	0.80	0.61, 1.06	12.5	1.18	0.78, 1.77	4.4	0.92	0.49, 1.75
Other	150	32.7	0.73	0.49, 1.07	10.7	1.06	0.59, 1.90	6.7	1.39	0.67, 2.93
HIV status										
Negative/untested	1152	37.0	1.00		10.8	1.00		4.5	1.00	
Positive	41	46.3	1.47	0.78, 2.77	24.4	2.59*	1.23, 5.47	12.2	3.67*	1.34, 10.53
Sexual orientation										
Gay	1015	36.7	1.00		11.0	1.00		4.1	1.00	
Bisexual	195	39.5	1.24	0.88, 1.74	12.3	1.35	0.81, 2.24	8.2	1.87	0.99, 3.59
Openness with others regarding sexual orientation										
Out to half or fewer	328	31.7	1.00		8.5	1.00		5.8	1.00	
Out to more than half	882	39.1	1.45*	1.09, 1.94	12.2	1.73*	1.07, 2.80	4.4	0.89	0.48, 1.65

Note. OR = odds ratio; CI = confidence interval.
[a]The variable sample sizes for each analysis are the result of missing data. Twenty-three participants did not provide data on mistreatment experiences, yielding a maximum sample size of 1210. Multivariate analyses involved a sample size of 1193 owing to missing information on HIV testing.
[b]Percentage of respondents reporting event, unadjusted for other variables.
[c]Adjusted for other demographic variables, HIV status, and extent of openness with others regarding sexual orientation.
*P<.05; **P<.01; ***P<.001 (2-tailed).

TABLE 2—Multivariate Ordinary Least Squares (OLS) and Logistic Regression Analyses Predicting Self-Esteem and Suicidal Ideation From Verbal Harassment, Discrimination, and Physical Violence, After Control for Demographic Covariates

	OLS Regression: Self-Esteem[a] (n = 1191)		Logistic Regression: Suicidal Ideation[a] (n = 1179)	
	b[b] (SE)	95% CI	OR[b]	95% CI
Verbal harassment	−0.19** (0.07)	−0.33, −0.06	1.17	0.82, 1.66
Discrimination	−0.28** (0.10)	−0.49, −0.08	2.13***	1.36, 3.35
Physical violence	−0.20 (0.16)	−0.51, 0.10	2.06*	1.10, 3.86

Note. OR = odds ratio; CI = confidence interval.
[a]Point-biserial correlation between self-esteem and suicidal ideation: −0.42 ($P < .001$).
[b]Regression coefficients and ORs are adjusted for age, education, ethnicity, HIV status, sexual orientation, openness with others regarding sexual orientation, and other mistreatment variables listed.
*$P < .05$; **$P < .01$; ***$P < .001$ (2-tailed).

ful life events that result causally in psychological distress. However, given the limitations inherent in cross-sectional data, we cannot rule out other possibilities. For instance, men with preexisting low self-esteem or suicidal ideation may be more vulnerable to and more likely to be targeted by perpetrators of mistreatment. Alternately, men with greater psychological distress may simply be more likely to report mistreatment or to interpret ambiguous negative events as anti-gay discrimination or harassment. This explanation is less plausible given the research indicating that, under ambiguous circumstances, discrimination is likely to be underreported rather than overreported.[22]

It is important to note that our data represent 6-month cumulative incidences, and therefore the actual lifetime prevalence of anti-gay harassment, victimization, and physical violence is certainly much higher. Moreover, the cumulative effect of multiple experiences may have a more profound association with mental health than the recent experiences with mistreatment assessed in this study. In addition, because we did not examine other forms of mistreatment (i.e., those occurring for reasons other than sexual orientation), we cannot comment on the uniqueness of *anti-gay* mistreatment in its association with psychological distress. The cumulative effects of these varied forms of mistreatment across the life span should be the subject of future research.

It is unclear precisely why certain subgroups of young gay and bisexual men were more likely to report mistreatment. HIV-infected men are probably at increased risk because of the added stigma associated with their disease.[23] Men younger than 21 years of age may be at higher risk for a number of reasons; for example, relative to older men, they may have less independence and control over their lives, making it difficult for them to access safe venues where gay and bisexual men gather. In addition, individuals who self-identify as gay at younger ages may be more gender nonconforming,[24] increasing perpetrators' ability to identify them as targets for anti-gay bias. Finally, studies suggest that perpetrators of anti-gay violence tend to be younger themselves, and thus young men may be targeted more frequently because their peers are more likely to be perpetrators.[25]

Qualitative studies involving younger men and HIV-positive men may further elucidate the contexts in which these experiences of mistreatment occur and may offer more concrete insight into why they are more frequently reported by these subgroups. However, regardless of the reasons identified in such research, the surest means of preventing anti-gay harassment, discrimination, and physical violence is to implement and enforce policies that prohibit and punish these acts. Until such policies are commonplace, existing interventions targeting young gay and bisexual men for other purposes (e.g., HIV-prevention interventions) should consider addressing anti-gay mistreatment. Empowerment or community-building interventions may be particularly well suited to this task, given their emphasis on helping men create safe social settings. Moreover, such interventions could be expanded easily to incorporate education regarding strategies for confronting and coping with anti-gay mistreatment. ■

About the Authors

The authors are with the Center for AIDS Prevention Studies, AIDS Research Institute, Department of Medicine, University of California, San Francisco.

Requests for reprints should be sent to David M. Huebner, PhD, MPH, Center for AIDS Prevention Studies, 74 New Montgomery, Suite 600, San Francisco, CA 94105 (e-mail: dhuebner@psg.ucsf.edu).

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Contributors

D.M. Huebner planned and conducted the analyses and wrote the article. G.M. Rebchook contributed to the writing of the article and supervised data collection. S.M. Kegeles designed the questionnaire, supervised the study, and contributed to the writing of the article and to interpretation of the findings.

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Asian/Pacific Islander Adolescent Sexual Orientation and Suicide Risk in Guam

Thomas K. Pinhey, PhD, and Sara R. Millman, PhD

Objectives. We examined the effects of same-sex orientation on suicide risks for Guam's Asian/Pacific Islander adolescents.

Methods. We used a probability sample and logistic regression analysis to identify suicide risk factors.

Results. Same-sex orientation was associated with a greater risk of suicide attempt, especially for boys. Adolescents who reported suffering physical abuse in the context of a romantic relationship, engaging in binge drinking, and experiencing feelings of hopelessness were at greater risk for suicidal ideation and attempts. Race/ethnicity was associated with suicide risk for both boys and girls, and patterns suggest that membership in the same racial/ethnic group decreased suicide risk for girls and increased risk of suicide for boys.

Conclusions. Gay, lesbian, and bisexual Asian/Pacific Islander adolescents in Guam deserve intervention and counseling programs to reduce suicide risk. (*Am J Public Health.* 2004;94:1204–1206)

Adolescent suicide rates for the Micronesian region of the Western Pacific are particularly high, especially among Micronesian boys.[1] Although previous studies have examined adolescent suicides in Micronesia,[2,3] they did not consider the effects of sexual orientation. Recent national and state research has documented associations between suicide risk and being gay, lesbian, or bisexual.[4–9] However, a literature search reveals no studies documenting the effects of sexual orientation on adolescent suicidality in Guam, an island in the Western Pacific with high rates of adolescent suicides.[1] We examined the effects of sexual orientation, race/ethnicity, binge alcohol consumption, hopelessness, and relationship physical abuse (i.e., physical abuse by a boyfriend or girlfriend) on suicidal ideation and suicide attempts among Guam's Asian/Pacific Islander adolescents, an understudied and underserved population. Our analysis is the first to consider such relationships in an Asian/Pacific Islander context.

METHODS

We used data from Guam's Youth Risk Behavior Survey, which was a high school student survey (grades 9 through 12) conducted during the 2001 spring semester. The sampling frame consisted of the 4 public high schools and the 3 Catholic high schools in Guam. These 7 schools account for approximately 95% of the island's high school students. For the total number of high schools in the sampling frame, we calculated the percentage of students at each grade level and then randomly selected classes (n=95) within each school at each grade level to approximate these proportions. Small amounts of absenteeism on data collection days, parental consent refusals, and exclusions for erroneous response patterns reduced the actual number of completed surveys to 1381, yielding a response rate of 96.6%.

Dependent variables were self-reported measures of suicidal ideation and suicide attempts. All of the variables for the analysis were dichotomous measures. We assessed suicidal ideation by asking respondents the following question: "During the past 12 months, did you ever seriously consider attempting suicide?" Girls were more likely than boys to indicate that they had considered committing suicide (42.0% vs 25.6%, respectively). We measured actual suicide attempts by asking respondents, "During the past 12 months, how many times did you actually attempt suicide?" All nonzero responses were recoded as 1. Girls were more likely than boys to indicate that they had attempted suicide (28.2% vs 14.5%, respectively).

The key independent variable for the analysis was sexual orientation. This measure was binary and was coded 1 for gay, lesbian, and bisexual adolescents (heterosexual, not sure, and don't know responses were coded as 0). We asked respondents, "Which of the following best describes you? Are you (1) gay, (2) lesbian, (3) bisexual, (4) heterosexual, (5) not sure, (6) don't know?" Rates of reporting same-sex orientation were 3.5% for both boys and girls.

Independent variables also included measures of hopelessness, relationship physical abuse, and binge alcohol use. We measured hopelessness by asking respondents a single question: "During the past 12 months, did you ever feel so sad or hopeless almost every day for 2 weeks that you stopped activities?" More girls than boys indicated that they had experienced hopelessness (45.7% vs 36.4%, respectively). We measured relationship physical abuse by asking respondents a single question: "During the past 12 months, did your boyfriend or girlfriend ever hit, slap, or physically hurt you on purpose?" Girls were less likely than boys to indicate that they had experienced physical abuse (7.0% vs 9.1%, respectively). Our measure of alcohol abuse was a single item reflecting binge alcohol consumption. We asked respondents, "During the past 30 days, on how many days did you have 5 or more drinks of alcohol in a row, that is, within an hour?" All nonzero responses were recoded as 1. Female students were less likely than male students to report binge drinking (19% vs 33.8%, respectively).

The logistic regression models also included self-reported race/ethnicity. Racial/ethnic categories were Chamorros (the largest ethnic group in Guam and the excluded comparison category in the logistic regressions), Filipinos, Asians (Chinese, Japanese, Korean, Vietnamese), Micronesians (Chuukese, Yapese,

TABLE 1—Asian/Pacific Islander Adolescent Sexual Orientation and Odds of Suicidality After Control for Ethnicity, Relationship Physical Abuse, Alcohol Abuse, and Hopelessness

	Odds Ratio (95% Confidence Interval)			
	Suicide Ideation		Suicide Attempts	
	Model 1	Model 2	Model 1	Model 2
Boys (n = 674)				
Same sex	1.905 (.809, 4.484)	1.356 (.471, 3.910)	5.005* (2.127, 11.773)	5.057* (1.645, 15.546)
Filipino		.843 (.511, 1.390)		1.089 (.585, 2.026)
Asian		1.335 (.591, 3.017)		1.387 (.416, 3.384)
Micronesian		1.890 (.873, 4.094)		2.259 (.905, 5.636)
White		1.560 (.523, 4.648)		2.251 (.642, 7.889)
Other		.770 (.289, 2.050)		1.150 (.359, 3.690)
Relationship physical abuse		3.127* (1.670, 5.857)		2.222* (1.096, 4.505)
Alcohol abuse		1.877* (1.243, 2.837)		3.539* (2.123, 5.899)
Hopelessness		6.743* (4.475, 10.161)		7.303* (4.213, 12.659)
Girls (n = 707)				
Same sex	1.999 (.875, 4.565)	1.462 (.556, 3.842)	2.645* (1.167, 5.995)	2.173 (.841, 5.619)
Filipino		.750 (.495, 1.135)		1.145 (.734, 1.786)
Asian		.864 (.382, 1.951)		.600 (.224, 1.612)
Micronesian		.401* (.200, .806)		.818 (.399, 1.675)
White		.298* (.097, .914)		.213* (.046, .986)
Other		1.061 (.478, 2.358)		1.767 (.797, 3.916)
Relationship physical abuse		2.414* (1.181, 4.935)		1.278 (.649, 2.517)
Alcohol abuse		1.626* (1.043, 2.536)		1.881* (1.203, 2.942)
Hopelessness		6.956* (4.885, 9.069)		6.846* (4.584, 10.223)

*$P < .05$.

Kosraean, Pohnpeian, Palauan), Whites, and other races/ethnicities (i.e., Hispanic, African American, other Pacific Islanders).

We began by examining the effects of sexual orientation on suicidal ideation and suicide attempts (model 1). We then added race/ethnicity, relationship physical abuse, binge alcohol consumption, and hopelessness to the equation (model 2). Because previous research has shown that Micronesian young men are at greater risk for suicide than are young men of other races/ethnicities,[1–3] we anticipated that male adolescent Micronesians' odds of a suicide attempt would be especially high.

RESULTS

As shown in Table 1, the increase in risk for suicidal ideation associated with same-sex orientation without control for other variables is virtually identical for boys and girls (odds ratio [OR] for suicidal thoughts = 1.999 for girls and 1.905 for boys) and is statistically nonsignificant (model 1). In sharp contrast, the increased risk for suicide attempt associated with same-sex orientation without control for other variables is substantially greater for boys than for girls (OR for suicide attempt = 5.005 for boys and 2.645 for girls) and statistically significant for both boys and girls.

The second model added race/ethnicity and additional suicide risk factors to the sexual orientation measure. Consistent with previous findings,[4] our results showed that among Asian/Pacific Islander adolescents, those who reported hopelessness, relationship physical abuse, or binge drinking were significantly more likely than those who did not endorse these factors to report suicidal thoughts. For boys, these factors also significantly increased suicide attempts. For girls, alcohol abuse and hopelessness significantly increased the risk of suicide attempts, but the effect of relationship physical abuse was not statistically significant. Regarding the effects of race/ethnicity for boys, odds ratios close to 1 (implying little difference from the suppressed category, Chamorros) for both suicidal ideation and suicide attempts dictate a cautious interpretation of these results. Among girls, both White and Micronesian races/ethnicities were associated with decreased risk of suicidal ideation, and White race/ethnicity was associated with decreased risk for suicide attempts. Beyond these findings, a comparison of statistically nonsignificant odds ratios by race/ethnicity between boys and girls raised the intriguing possibility that membership in certain racial/ethnic groups may decrease risks for girls or increase risks for boys. Despite the broad confidence intervals, the pattern of odds ratios of less than 1 (implying decreased risk) for girls and greater than 1 (implying increased risk) for boys holds for both dependent variables (suicidal ideation and suicide attempts) and to Asian, Micronesian, and White race/ethnicity.

DISCUSSION

Early studies examining suicide and sexual orientation used convenience samples,[10] which resulted in outcomes that could not be generalized to larger populations. Our study used a probability sample of Guam's Asian/Pacific Islander youth, an approach that may provide answers to various questions concerning racial/ethnic differences in suicidality.[6] Consistent with conclusions of previous studies, our results suggest robust links between sexual orientation and adolescent suicidal thoughts and suicide attempts.[4] This analysis is the first to document suicidal thoughts and attempts in this Asian/Pacific Islander context with a probability sample. To be sure, our results indicate that same-sex orientation of Asian/Pacific Islander adolescents in Guam presents significant risk for suicide attempts. The risk for suicidal ideation also is higher for adolescents with a same-sex orientation, although not significantly so. Race/ethnicity is related to suicide risk in this Asian/Pacific Islander adolescent community. Although risk for suicidal ideation is not statistically significant among boys, it is higher for Micronesians than for members of all other races/ethnicities. Among girls, the risk of suicidal ideation is reduced both for Whites and for other races/ethnicities (i.e., Hispanic, African American, other Pacific Islanders), whereas the risk of suicide attempt is reduced only for other races/ethnicities. These results may actually understate the effect of Micronesian race/ethnicity for boys, given that other sources have reported that completed suicide attempts are more common among Micronesian boys.[2,3] All suicide attempts reported in this survey were incomplete owing to the self-reported nature of the data.

Relationship physical abuse, binge drinking, and hopelessness were associated with increased risk of suicidal ideation for both boys and girls and with increased risk of suicide attempts for boys. For suicide attempts by girls, the elevation of risk associated with physical abuse was nonsignificant, whereas the associations with binge drinking and hopelessness were significant. The changes in odds ratios for same-sex orientation observed when those risk factors were added to the equation suggest that the adverse effects of same-sex orientation are partially mediated by relationship physical abuse, binge drinking, and hopelessness. This mediating effect applies to suicidal ideation for both sexes and to suicide attempts for girls but not for boys.

Recent research[4] suggests that adolescent girls who identify themselves as lesbian may derive benefit from their sexual identity through the social support they receive from other gay, lesbian, and bisexual individuals or from similar sources. Because our findings indicate that in this setting, female adolescents with same-sex orientation are at greater risk for suicidality compared with their heterosexual peers, it appears that corresponding supportive communities might not exist in Guam or that the effects of such support may not be sufficient to counterbalance the potential detrimental effects of same-sex orientation. Indeed, our findings strongly suggest that both male and female Asian/Pacific Islander adolescents in Guam deserve intervention and counseling programs to reduce suicidal risks. Recent research shows that gay-sensitive HIV programs in schools decrease sexual risks for gay, lesbian, and bisexual adolescents. Similarly, gay-sensitive interventions targeting relationship physical abuse, binge drinking, and feelings of hopelessness might help reduce risks of suicide.

Finally, these patterns of possible gender differences in the effects of race/ethnicity on suicide deserve further investigation, preferably with larger data sets. ■

About the Authors

Thomas K. Pinhey and Sara R. Millman are with the Department of Sociology, University of Hawaii at Hilo.

Requests for reprints should be sent to Thomas K. Pinhey, Department of Sociology, University of Hawaii at Hilo, 200 W. Kawili St, Hilo, HI 96720-4091 (e-mail pinhey@hawaii.edu).

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Contributors

T.K. Pinhey supervised all aspects of the study and led the writing of the article. S.R. Millman assisted with the study and in the writing and reviewing of all parts of the study. Both authors assisted in the data analysis and interpretations of the findings and reviewing the article.

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HIV Seroprevalence Among Homeless and Marginally Housed Adults in San Francisco

Marjorie J. Robertson, PhD, Richard A. Clark, MPH, Edwin D. Charlebois, PhD, MPH, Jacqueline Tulsky, MD, Heather L. Long, MPH, David R. Bangsberg, MD, MPH, and Andrew R. Moss, PhD

Objectives. We report HIV seroprevalence and risk factors for urban indigent adults.

Methods. A total of 2508 adults from shelters, meal programs, and low-cost hotels received interviews, blood tests, and tuberculosis screening.

Results. Seroprevalence was 10.5% overall, 29.6% for men reporting sex with men (MSM), 7.7% for non-MSM injection drug users (IDUs), and 5.0% for residual non-MSM/non-IDUs. Risk factors were identified for MSM (sex trade among Whites, non-White race, recent receptive anal sex, syphilis), non-MSM IDUs (syphilis, lower education, prison, syringe sharing, transfusion), and residual subjects (≥5 recent sexual partners, female crack users who gave sex for drugs).

Conclusions. HIV seroprevalence was 5 times greater for indigent adults than in San Francisco generally. Sexual behavior predicted HIV infection better than drug use, even among IDUs. (*Am J Public Health.* 2004;94:1207–1217)

Homeless and marginally housed persons in the United States are at high risk for HIV owing to high-risk sexual and drug-use behaviors.[1–6] These populations include high-risk groups such as former prison inmates,[7] crack and other cocaine users,[8,9] sex workers,[10] certain racial or ethnic minority groups,[11,12] and persons with major mental illness.[13–15]

Representative studies of HIV among homeless and marginally housed adults are rare,[3] and estimates of HIV infection and other health problems vary dramatically as a function of sampling strategy.[16] Since many indigent adults are unlikely to be included in traditional household or telephone surveys,[17] HIV estimates are often based on convenience samples of high-risk groups (injection drug users [IDUs], female sex workers) or samples from service, treatment, or institutional sites (shelters, medical clinics). Not surprisingly, HIV prevalence rates vary from 0% to 62%, depending on the target population, geographic area, recruitment site, and sampling strategy.[1–3,18–28] Estimates for the larger indigent urban populations are needed.

This report documents HIV seroprevalence, distribution, and risk factors for a large sample of indigent persons in San Francisco and provides the most comprehensive data on HIV among homeless and marginally housed adults to date. We expect the findings reported here to inform both new and existing HIV prevention efforts that serve these high-risk but hidden populations.

METHODS

Sampling Design

The sampling design was a multistage cluster sample with stratification. The target population was homeless and marginally housed adults in San Francisco, and data were collected over a 21-month period (starting in April 1996).

To create a probability sample of homeless and marginally housed adults, we constructed a sampling frame of shelters and free-meal programs throughout the city and county of San Francisco. The sample was drawn from all 7 overnight shelters (housing a minimum of 50 adults per night) and 5 of 6 midday free-meal programs (serving ≥100 adults ≥3 days/week). The great majority of homeless adults in urban areas (usually >85%) are represented by similar sampling strategies.[29–32]

Additional marginally housed adults were recruited from a sampling frame of 83 residential hotels concentrated in low-income neighborhoods (i.e., Tenderloin, South of Market, and Mission districts). Criteria for selecting hotels included the following: a hotel operator's license;[33] rent of $400 per month or less; 20 or more "usually occupied" residential (nontourist) rooms; public availability; no in-house programs (e.g., health clinics); and location within census tracts with a high incidence of tuberculosis (TB) cases in US-born individuals, which excluded Chinatown. Hotels were selected with a probability proportionate to size, and subjects were recruited from 4734 usually occupied residential rooms in 26 hotels. For hotels with fewer than 100 eligible rooms, a geographically contiguous hotel was also selected into the cluster until at least 100 rooms were included. Adults within hotels, meal programs, and shelters were selected by systematic random sampling.

Initial data collection occurred on Mondays (at or near sampling sites) and included an interview, HIV pretest counseling by certified counselors, a blood draw, and TB skin tests. A study identification number and a unique identifier (no names) were used to identify each subject. Shelter/meal program recruits received $10 cash and hotel recruits received $15 cash. Those who returned the following Friday for notification of HIV and TB test results, HIV posttest counseling, and medical referrals received $10.

The completion rate was 66.6% (75.6% in shelters, 74.1% in meal programs, and 62.1% in hotels). No significant gender or racial/ethnic differences were documented for refusals. The return rate for notification was 91.2%. Among 2905 subjects completing interviews and blood tests, 397 duplicates were deleted, for a final sample of 2508.

Data Collection

Serum specimens were screened for HIV-1 antibodies with a licensed enzyme-linked immunosorbent assay (ELISA) with Western Blot assay confirmation. TB was screened with a tuberculin skin test by the Mantoux method with 5-TU (tuberculin units) strength

of partial protein derivative. A positive tuberculin skin test was defined as 10 mm of induration or more for HIV-negative subjects and 5 mm or more for HIV-positive subjects. Subjects who clearly described a past positive TB result were counted among TB positives but not retested.

The structured interview averaged 45 minutes. Sex included oral, vaginal, or anal intercourse. Lifetime sexual risk factors included reported sex with men among biological males (i.e., men who have sex with men, or MSM), sex trade (giving sex for cash or drugs), and prior syphilis diagnosis by a doctor or nurse. Twelve-month factors included a history of receptive anal sex or sex with 5 or more partners.

Drug risk factors included lifetime use of crack, other cocaine, stimulants, or heroin or other opiates. Lifetime injection behaviors included injection drug use, sharing of syringes, and injection in a "shooting gallery" situation. ("Shooting gallery" is a slang term that usually refers to a hidden location within a neighborhood with a high rate of drug use, where multiperson use of injection equipment commonly occurs.)

Lifetime, chronic, and current homelessness (spending the night in a shelter or "on the streets") were assessed. A positive screen for alcohol dependence was indicated with affirmative answers to at least 2 of 4 questions of the CAGE questionnaire.[34] Test-based knowledge of HIV status was collected during the interview, phlebotomy, and posttest counseling.

Biological sex was attributed by interviewers (or asked if unclear) as male or female. Classification as male-to-female transgender included biological males who self-identified as transgender or transsexual or who reported gender identification as women. Current sexual orientation was self-identified as heterosexual (straight), homosexual (gay or lesbian), or bisexual.

ANALYSIS

All analyses were weighted. Subject weights were calculated to adjust for probabilities of selection of stratum (hotel vs shelter/meal program), cluster (specific site), and individual within sites. Analyses were conducted with SPSS (SPSS Inc, Chicago, Ill). Chi-square tests were used for bivariate analysis. Logistic regression was used to identify risk factors independently associated with HIV infection for the total sample and for each of 3 mutually exclusive risk groups. Odds ratios and 95% confidence intervals are reported. Fit for each model was judged by the comparison of the −2 log likelihood of model improvement and Wald statistics of the β coefficients. Each multiple logistic regression initially included variables associated with HIV status ($P<0.10$). Collinear variables and ones with small sample sizes were excluded.

RESULTS

Full Sample

The sample was 75% male, with a median age of 42 years. Blacks and Whites constituted most of the sample (Table 1). Most had lived in San Francisco for 1 year or longer (median = 12 years). About one quarter were veterans (30.5% of males, 3.2% of females; not shown). Most (97.4%) reported current (30-day) income; median income was $585 per month (not shown). Most subjects (72.4%) reported current (30-day) income from public entitlement programs (General Assistance, 40.1%; Supplemental Security Income/Social Security Disability Income, 30.3%; Aid to Families With Dependent Children, 2.6%) or employment (19.3%) (not shown). Only half (50.5%) reported medical coverage; 37.7% had Medicare or Medicaid (not shown).

The majority (78.1%) had experienced homelessness as adults (including 75.2% of hotel recruits and 92.3% of meal program/shelter recruits [not shown], demonstrating the high overlap between these populations). For the previous night, many (43.3%) were homeless, and half (48.1%) reported staying in a single-room occupancy hotel (not shown). Half of the sample reported chronic homelessness.

Current drug use (30 days; not shown) included crack (32.8%), other cocaine (6.9%), heroin (17.3%), and stimulants (12.9%). Nearly half (44.2%) reported current use of any of these drugs. About one third reported injection drug use (34.6%).

The prevalence of TB infection (not necessarily active disease) was 33.4%. TB positives were referred to the San Francisco Department of Public Health TB Clinic for evaluation.

HIV seroprevalence for the total sample. The weighted seroprevalence of HIV infection was 10.5% overall (Table 1). HIV was slightly higher for recruits from single-room occupancy hotels (11.1%) than for shelter and meal-program recruits (7.6%). By mutually exclusive risk groups, the burden of HIV infection was heaviest for men who reported lifetime histories of both sex with men and injection drug use (32% of positive cases), followed by (1) men and women with lifetime histories of injection drug use only (28%), (2) men and women with neither histories of injection drug use nor (for men) sex with men (24%), and (3) men who reported sex with men but did not report injection drug use (16%).

Forty-three percent of HIV-positive subjects disclosed test-based knowledge of their HIV status during the interview. Of these, 74.7% reported current care for HIV and 39.4% reported current HIV/AIDS-related medication. HIV-positive subjects underreported knowledge of HIV status during interviews; an additional 25% disclosed knowledge during phlebotomy or posttest counseling.

HIV seroprevalence in the full sample: bivariate analysis. HIV was significantly higher among males, Whites, younger subjects, longer-term San Francisco residents, TB-negative individuals, gay or bisexual men, bisexual women, and male-to-female transgender persons (Table 1). HIV was significantly higher among behavioral risk groups: MSM, sex traders, and subjects with prior syphilis, recent (12-month) receptive anal intercourse, or 5 or more recent (12-month) sex partners.

Drug use was highly prevalent, and HIV was significantly higher among lifetime IDUs and crack and stimulant users (Table 1). About half of the sample reported lifetime injection, and IDUs were about twice as likely as non-IDUs to be infected. HIV infection was significantly higher among subjects reporting risky injection (including lifetime syringe sharing and injecting in a shooting gallery) and use of a needle/syringe exchange.

TABLE 1—HIV Seroprevalence in Homeless and Marginally Housed Adults (n = 2508), by Risk Factors: San Francisco, 1996–1997

	% of Sample (n)	% HIV+	OR (95% CI)
All subjects	100.0 (2508)	10.5	. . .
Biological sex			
Male	74.8 (1958)	11.8***	1.9 (1.3, 2.7)
Female	25.2 (550)	6.6	1.0
Race/ethnicity (dichotomy)			
White	42.0 (1006)	12.0*	1.0
Non-White	58.0 (1496)	9.4	0.79 (0.6, 1.0)
Race/ethnicity (self-identified)			
White	42.0 (1006)	12.0	1.0
Black/African American	44.2 (1133)	9.7	0.79 (0.60, 1.0)
Latino/Hispanic	5.1 (147)	12.5	1.1 (0.60, 1.8)
Asian/Pacific Islander	4.8 (117)	4.1**	0.32 (0.1, 0.79)
Native American	3.1 (78)	6.4	0.50 (0.2, 1.3)
Other	0.8 (21)	16.7	1.5 (0.4, 5.2)
Age, y			
18–29	9.5 (238)	15.5*	1.5 (1.1, 2.1)
≥30	90.5 (2228)	10.0	1.0
Education completed			
< 12th grade	26.6 (659)	10.6	1.0 (0.8, 1.3)
≥ 12th grade	73.4 (1846)	10.5	1.0
Current sexual preference:			
Among males reporting (n = 1900)			
Heterosexual	80.8 (1568)	6.3	1.0
Gay/bisexual	19.2 (342)	33.8***	7.6 (5.6, 10.3)
Among females reporting (n = 533)			
Heterosexual	73.6 (396)	5.1	1.0
Bisexual	21.6 (110)	11.3*	2.4 (1.2, 4.7)
Lesbian	4.8 (27)	3.3	0.65 (0.08, 4.9)
Transgender male to female[a]			
Yes	2.1 (52)	25.0**	2.9 (1.5, 5.6)
No	97.9 (2456)	10.2	1.0
Prison, ever			
Yes	24.1 (600)	10.8	1.1 (0.8, 1.4)
No	75.9 (1887)	10.3	1.0
Psychiatric hospitalization, ever			
Yes	21.5 (555)	10.8	1.0 (0.8, 1.4)
No	78.5 (1951)	10.4	1.0
Currently homeless[b]			
Yes	14.0 (1084)	8.3	0.74 (0.49, 1.1)
No	86.0 (1419)	10.9	1.0
Chronic homelessness[c]			
Yes	49.6 (1301)	11.5	1.2 (0.9, 1.6)
No	50.4 (1141)	9.7	1.0
San Francisco resident ≥1 y			
Yes	89.2 (2087)	11.2**	2.3 (1.3, 3.9)
No	10.8 (320)	5.0	1.0

Continued

For analysis, the sample was divided into 3 mutually exclusive and exhaustive risk groups: the MSM group, which included all reported MSM (including those with a history of drug injection); the IDU group, which included the balance of reported IDUs; and the residual group, which comprised men and women who reported no history of injection drug use and men who reported no history of sex with other men.

HIV by Risk Group: Bivariate Analysis

HIV infection in the MSM group. MSM had an overall HIV infection rate of 29.6% (Table 2). MSM constituted 18.7% of the entire sample, and most of these (75.5%) self-identified as gay or bisexual. The majority of MSM also had a lifetime history of injection drug use, and HIV was significantly higher in this subgroup. MSM were twice as likely as all other subjects to be lifetime IDUs (58.2% vs 41.7% [$P<.001$]; odds ratio [OR]=2.0; 95% confidence interval [CI]= 1.6, 2.4 [not shown]).

HIV among MSM was significantly higher for subjects who were younger (18–29 years), were San Francisco residents (≥12 months), were TB negative, had had transfusions, reported sexual risk factors (i.e., prior diagnosis of syphilis, lifetime sex trade, and recent [12-month] receptive anal intercourse), and reported drug risk factors (i.e., any injection drug use, stimulant injection, heroin injection, and crack use). Paradoxically, while HIV was higher among MSM with lifetime use of needle/syringe exchange (as part of a risk reduction program), HIV among MSMs was not associated with lifetime syringe sharing or use of shooting galleries.

HIV infection in the IDU group. For the IDU group (lifetime IDUs, excluding MSM), HIV prevalence was 7.7%, with almost identical rates for males and females. HIV was significantly higher among subjects who reported lifetime needle/syringe sharing, injecting drugs in a shooting gallery, previous syphilis infection, blood transfusion, prison stay, or lower education (Table 2). Stimulant users were significantly less likely to be HIV infected than other IDUs. Although 16% of female IDUs reported receptive anal sex in the previous year, their HIV rate was not

TABLE 1—*Continued*

TB-infected in lifetime[d]			
Yes	33.4 (791)	7.5**	1.0
No	66.6 (1496)	11.8	1.5 (1.2, 2.1)
Transfusion blood/products 1978–1985			
Yes	9.0 (187)	13.5	1.4 (0.9, 2.1)
No	91.0 (2291)	10.0	1.0
Drug use risk factors			
Injection drug use, ever[e]			
Yes	44.8 (1033)	14.3***	2.1 (1.6, 2.7)
No	55.2 (1475)	7.4	1.0
Injection of cocaine (not crack), ever			
Yes	26.5 (592)	12.1	1.3 (1.0, 1.7)
No	73.5 (1874)	9.7	1.0
Injection of stimulants, ever[f]			
Yes	27.7 (623)	15.9***	2.1 (1.6, 2.7)
No	72.3 (1848)	8.2	1.0
Injection of heroin, ever			
Yes	38.2 (835)	13.3***	1.7 (1.3, 2.2)
No	61.8 (1640)	8.4	1.0
Injection of speedballs or other heroin mixes, ever			
Yes	19.7 (376)	13.3*	1.5 (1.1, 2.0)
No	80.3 (1954)	9.4	1.0
Needle/syringe sharing, ever			
Yes	26.6 (591)	15.4***	1.9 (1.5, 2.5)
No	73.4 (1828)	8.6	1.0
Shooting gallery, ever			
Yes	12.6 (286)	16.4*	1.8 (1.3, 2.6)
No	87.4 (2130)	9.6	1.0
Needle exchange, ever			
Yes	26.0 (513)	15.5***	1.9 (1.5, 2.5)
No	74.0 (1995)	8.8	1.0
Crack cocaine use, ever			
Yes	63.2 (1535)	11.9***	1.7 (1.3, 2.3)
No	36.8 (941)	7.3	1.0
Stimulant use, ever			
Yes	46.2 (1130)	13.0***	1.7 (1.3, 2.2)
No	53.8 (1349)	8.0	1.0
Sexual risk factors			
MSM, ever[g]			
Yes	18.9 (475)	29.6***	6.4 (4.9, 8.4)
No	81.1 (2033)	6.1	1.0
≥5 sex partners, past 12 mo			
Yes	17.8 (454)	26.9***	1.8 (1.4, 2.5)
No	82.2 (2018)	16.8	1.0
Receptive anal sex, past 12 mo			
Yes	11.0 (285)	30.1***	4.9 (3.6, 6.6)
No	89.0 (2223)	8.1	1.0
Syphilis diagnosis, ever			
Yes	9.2 (211)	25.1***	3.4 (2.4, 4.7)
No	90.8 (2287)	9.0	1.0

Continued

significantly higher than that of other female IDUs (not shown).

HIV infection in the residual group. HIV seroprevalence was 5.0% for the residual group (history of neither injection drug use nor [among men] of sex with other men) (Table 2). In bivariate analysis, HIV rates were significantly higher among subjects who were Black compared with Whites, had prior syphilis, had 5 or more recent (12-month) sexual partners, or had ever traded sex. HIV was also significantly higher for bisexual women than for other women in the group. HIV was significantly lower for veterans (3.6% vs 6.6% for non-veterans; OR=0.54; 95% CI=0.29, 1.0 [not shown]) and subjects with lifetime psychiatric hospitalization. While 11% of women in the residual group reported recent (12-month) receptive anal sex, none of them were HIV positive (not shown). For the total sample, most women infected with HIV were non-IDUs.

Multivariate Analysis of HIV Infection

Logistic regression was used to identify risk factors that independently predicted HIV infection for the overall sample and then for each of 3 risk groups (Table 3). For the total sample, MSM were 4.6 times more likely to be infected than non-MSM. Other significant predictors included previous syphilis infection, interaction between lifetime injection drug use and White race/ethnicity, blood transfusion, non-White race/ethnicity, lifetime sex trade, and recent (12-month) receptive anal sex.

For the MSM group, sexual risk factors were stronger predictors of HIV infection than high-risk drug use. The strongest predictor was an interaction term for White sex traders, who were 5.9 times more likely than other MSM to be infected. Compared with other MSM, those of non-White race/ethnicity were 3.4 times more likely to be HIV infected, and those who reported recent (12-month) receptive anal sex or lifetime syphilis were twice as likely to be HIV infected. Despite the high prevalence of drug use in the MSM group, drug use variables (including lifetime injection drug use and stimulant use) did not independently predict HIV among MSM.

TABLE 1—*Continued*

Sex trade, ever			
Yes	29.7 (679)	18.7***	3.2 (2.5, 4.2)
No	70.3 (1757)	6.6	1.0
Sex for cash, ever			
Yes	26.0 (596)	18.7***	2.9 (2.3, 3.8)
No	74.0 (1857)	7.2	1.0
Sex for drugs, ever			
Yes	14.5 (369)	23.9***	3.6 (2.7, 4.8)
No	85.5 (2079)	8.0	1.0

Note. OR = odds ratio; CI = confidence interval; TB = tuberculosis. Percentages, ORs, and CIs are based on weighted data; sample sizes are unweighted data.
[a]Two female-to-male transgender persons in the sample were not included here; both were HIV negative.
[b]Spent the previous night in a shelter or "on the streets," a set of nonconventional living sites.
[c]Total time accumulated as homeless since age 18 was 12 months or longer.
[d]Positive tuberculin skin test, but not necessarily active disease.
[e]Injection of illicit drugs.
[f]"Speed," "uppers," "crank," amphetamines, methamphetamine, "crystal meth," or "ice."
[g]Men who reported ever having oral or anal sex with another man.
*P<.05; **P<.01; ***P<.001.

For the IDU group (lifetime injection drug use, excluding MSM), previous syphilis infection was the strongest independent predictor of HIV (3.3 times higher risk of infection), followed by low education, prison stay, syringe sharing, and blood transfusion (each associated with at least a twofold risk of infection). In this group of IDUs, having syphilis was a stronger predictor of HIV infection than syringe sharing.

Compared with others in the residual group, female lifetime crack users with histories of trading sex for drugs were 6.1 times more likely to be infected, and those with 5 or more recent (12-month) sex partners were 2.9 times more likely to be infected.

DISCUSSION

In this study, HIV seroprevalence was 10.5% overall, 8.3% among the currently homeless, and 10.9% among marginally housed adults in San Francisco. After adjustment for other risk factors, non-Whites were 1.8 times more likely than Whites to have HIV infection. Recruits from single-room occupancy hotels (11.1%) had higher rates of HIV infection than among those from shelters/meal programs (7.6%). The rate for shelters and meal programs (i.e., excluding the hotel sample) is similar to that of an earlier study (8.5%).[3]

Lifetime histories of injection drug use or (among men) sex with other men put *more than half* of the sample at risk for HIV infection. While more than half of all HIV-infected persons were lifetime IDUs, high-risk sexual activity and its surrogates were stronger predictors of HIV infection than high-risk drug use, even among IDUs.

It is striking that these indigent adults were 5 times more likely to be infected than others in San Francisco,[35] a city with relatively high HIV estimates for the United States. While the number of HIV-infected indigent adults is unknown, the number of homeless persons among all new cases of AIDS in San Francisco has increased each year since 1990 (from 1% to 15%).[35] Our findings, and this trend, are consistent with studies that report HIV and AIDS incidence to be inversely associated with economic resources, even across gender and racial/ethnic groups.[2,36–39]

Sex Drives HIV Infection Among Indigent MSM

HIV was widespread among MSM in this study: 29.6% overall, 34.8% among MSM with lifetime histories of injection, and 22.4% among MSM with no history of injection. The HIV rate for MSM overall is consistent with the 1997 San Francisco Department of Public Health estimate for MSM generally (30%), but high compared with the results of a 1997 San Francisco household survey of MSM (20%).[17] Our prevalence estimates for MSM IDUs (34.8%) and MSM aged younger than 30 years (40.9%) are also close to HIV rates estimated for these groups of MSM in San Francisco generally.[40,41]

Over half (58.3%) of all MSM had lifetime histories of injection drug use. While MSM IDUs were more likely to be infected than non-IDUs, injection drug use did not independently predict HIV infection among MSM. Rather, HIV among MSM was predicted by sexual risk factors, including previous syphilis diagnosis, recent receptive anal sex, sex trade among Whites, and non-White race/ethnicity.

Consistent with previous literature,[42–44] MSM who reported recent (12-month) receptive anal sex or prior syphilis were more than twice as likely as other MSM to be HIV infected. Syphilis, a marker for unprotected sex, has been identified as a predictor of HIV seroconversion,[45] and its presence may increase the transmissibility of HIV.[45,46] Recent outbreaks of syphilis among MSM in California may suggest a resurgence of unprotected sex and a potential increase in HIV incidence.[47] In one study, identifying and treating cases of syphilis and other sexually transmitted diseases decreased the incidence of HIV without changing sexual behavior.[48] Such efforts targeting indigent urban adults may have a similar effect.

Sex trade was prominent among MSM in this study, with half reporting lifetime sex trade for cash or drugs. White sex traders were almost 6 times more likely to be HIV infected than other MSM. Similarly, Canadian researchers have found that sex trade independently predicts both HIV incidence and prevalence among young gay and bisexual men.[49] Sex trade among MSM in this study may owe in part to economic necessity or severe drug abuse (since HIV was more prevalent among those who traded sex for drugs than among those who traded it for cash).

Consistent with previous studies of MSM in San Francisco and other cities,[17,40,50,51] non-White MSM (mostly Blacks) were 3.4 times more likely to be infected than White MSM, after adjustment for other risk factors. Among US MSM, Blacks are burdened with the highest HIV and AIDS incidence and prevalence, the highest HIV-related mortality,

TABLE 2—HIV Seroprevalence Among Homeless and Marginally Housed Adults (n=2508), by Risk Factors, by Risk Groups: San Francisco, 1996–1997

	Risk Groups (Mutually Exclusive)								
	MSM Group[a] (All MSM)			IDU Group (Non-MSM IDUs)			Residual Group (Non-MSM, Non-IDUs)		
	% (n)	% HIV+	OR (95% CI)	% (n)	% HIV+	OR (95% CI)	% (n)	% HIV+	OR (95% CI)
All subjects	(475)	29.6		(772)	7.7		(1261)	5.0	
Biological sex									
Male	100.0 (475)			64.4 (554)	7.8	1.0 (0.61, 1.8)	72.3 (929)	4.7	.80 (0.45, 1.4)
Female				35.6 (218)	7.6	1.0	27.7 (332)	5.8	1.0
Race/ethnicity (dichotomy)									
White	60.4 (262)	28.9	1.0	45.7 (360)	8.0	1.0	32.0 (384)	3.4	1.0
Non-White	39.6 (213)	30.6	1.1 (0.80, 1.4)	54.3 (410)	7.6	.95 (0.60, 1.5)	68.0 (873)	5.7	1.7 (0.91, 3.2)
Race/ethnicity (self-identified)									
White	60.4 (262)	28.9	1.0	45.7 (360)	8.0	1.0	32.0 (384)	3.4	1.0
Black/African American	26.9 (153)	31.0	1.1 (0.70, 1.7)	40.1 (296)	8.2	1.0 (0.61, 1.7)	54.1 (684)	6.2*	1.9 (0.99, 3.6)
Latino/Hispanic	6.8 (32)	34.4	1.3 (0.60, 2.8)	6.8 (61)	8.6	1.1 (0.41, 2.9)	3.2 (54)	0.0	
Asian/Pacific Islander	0.5 (6)	66.7	4.9 (0.44, 55.1)	2.4 (16)	0.0		8.2 (95)	3.1	.90 (0.25, 3.2)
Native American	5.2 (18)	20.8	.65 (0.23, 1.8)	3.9 (30)	0.0		1.8 (30)	0.0	
Other	0.2 (4)	0.0		1.1 (7)	0.0		.8 (10)	33.3**	14.1 (3.2, 62.8)
Age, y									
18–29	14.5 (65)	40.9*	1.8 (1.0, 3.0)	6.5 (54)	1.8	.21 (0.03, 1.5)	9.6 (119)	7.1	1.5 (0.71, 3.3)
≥30	85.5 (404)	28.0	1.0	93.5 (709)	8.2	1.0	90.4 (1115)	4.7	1.0
Education completed									
<12th grade	22.3 (102)	23.8	.76 (0.52, 1.1)	31.0 (231)	13.6	2.7 (1.7, 4.2)	25.2 (326)	3.3	0.61 (0.31, 1.2)
≥12th grade	77.7 (373)	31.2	1.0	69.0 (541)	5.1***	1.0	74.8 (932)	5.5	
Current sexual preference									
Among males reporting (n = 1900)									
Heterosexual	24.5 (127)	13.3	1.0	97.9 (547)	8.0		99.8 (894)	4.2	
Gay/bisexual	75.5 (340)	33.9***	3.4 (1.9, 6.0)	2.1 (7)	0.0		0.2 (2)	0.0	
Among females reporting (n = 533)									
Heterosexual				63.8 (138)	6.7	1.0	82.9 (258)	4.2	1.0
Bisexual				31.7 (69)	9.4	1.8 (0.99, 3.3)	11.7 (41)	16.2*	4.4 (1.5, 12.7)
Lesbian				4.5 (10)	7.1	1.0 (0.13, 8.0)	5.4 (17)	0	
Transgender male to female[b]									
Yes	10.7 (49)	26.0	0.82 (0.42, 1.6)	0.0 (1)			0.2 (2)	0.0	1.0
No	89.3 (426)	30.0	1.0	100.0 (771)	7.7		99.8 (1259)	5.0	
Prison, ever									
Yes	16.2 (93)	26.7	0.86 (0.49, 1.5)	40.4 (282)	12.0***	2.6 (1.6, 4.4)	15.5 (184)	2.2	0.41 (0.15, 1.2)
No	83.8 (381)	29.8	1.0	59.6 (486)	4.9	1.0	84.5 (1051)	5.2	1.0
Psychiatric hospitalization, ever									
Yes	31.2 (154)	28.8	.95 (0.62, 1.5)	26.6 (201)	6.6	0.82 (0.55, 1.5)	14.0 (200)	0.6**	.10 (0.01, 0.73)
No	68.8 (320)	29.8	1.0	73.4 (570)	8.0	1.0	85.0 (1061)	5.7	
Currently homeless[c]									
Yes	11.7 (184)	20.0	0.6 (0.28, 1.1)	13.3 (339)	9.7	1.3 (0.68, 2.6)	15.3 (561)	3.3	0.62 (0.26, 1.5)
No	88.3 (291)	30.7	1.0	86.7 (433)	7.4	1.0	84.7 (695)	5.3	1.0
Chronic homelessness[d]									
Yes	56.6 (261)	31.9	1.3 (0.87, 2.0)	50.7 (402)	7.5	0.88 (0.53, 1.5)	46.1 (638)	4.5	0.87 (0.51, 1.5)
No	43.4 (207)	26.4	1.0	49.3 (348)	8.0	1.0	53.9 (586)	5.2	1.0

Continued

TABLE 2—*Continued*

San Francisco Resident ≥1 y									
Yes	89.9 (405)	31.1*	2.4 (1.1, 5.1)	92.9 (674)	7.6	.66 (0.20, 2.2)	86.2 (1008)	5.6	2.2 (0.81, 6.0)
No	10.1 (13.0)	13.0	1.0	7.1 (71)	5.2	1.0	13.8 (191)	2.6	1.0
TB-infected in lifetime[e]									
Yes	24.6 (122)	1.2	1.0	38.6 (275)	6.0	1.0**	33.1 (394)	5.4	1.0
No	75.4 (311)	33.3	1.7 (1.1, 2.6)	61.4 (429)	7.8	1.3 (0.75, 2.2)	66.9 (756)	4.9	0.91 (0.53, 1.6)
Transfusion blood/products 1978–1985									
Yes	5.6 (28)	53.8**	3.1 (1.4, 7.0)	15.1 (88)	12.5*	1.9 (1.1, 3.5)	5.9 (71)	1.4	0.26 (0.04, 1.9)
No	94.4 (442)	27.1	1.0	84.9 (679)	7.0	1.0	94.1 (1170)	5.4	
Drug use risk factors									
Injection drug use, ever[f]									
Yes	58.3 (261)	34.8**	1.8 (1.2, 2.8)						
No	41.7 (214)	22.4	1.0						
Injection of cocaine (not crack), ever									
Yes	29.1 (138)	33.1	1.3 (0.84, 2.0)	61.0 (454)	6.6	0.66 (0.40, 1.1)			
No	70.9 (336)	27.7	1.0	39.0 (314)	9.7	1.0			
Injection of stimulants, ever[g]									
Yes	46.4 (202)	34.6*	1.6 (1.1, 2.4)	55.4 (421)	7.2	0.85 (0.51, 1.4)			
No	53.6 (273)	25.1	1.0	44.6 (346)	8.5	1.0			
Injection of heroin, ever									
Yes	42.1 (186)	34.5*	1.5 (1.0, 2.3)	88.5 (649)	7.7	0.93 (0.43, 2.0)			
No	57.9 (288)	25.7	1.0	11.5 (121)	8.2	1.0			
Injection of speedballs or other heroin mixes, ever									
Yes	19.3 (71)	33.8	1.3 (0.80, 2.3)	52.2 (305)	9.2	1.3 (0.77, 2.2)			
No	80.7 (353)	27.5	1.0	47.8 (340)	7.2	1.0			
Needle/syringe sharing, ever									
Yes	35.2 (151)	31.8	1.2 (0.79, 1.8)	62.0 (440)	10.2**	2.5 (1.3, 4.7)			
No	64.8 (293)	27.9	1.0	38.0 (274)	4.3	1.0			
Shooting gallery, ever									
Yes	14.6 (72)	37.5	1.5 (0.88, 2.7)	30.8 (214)	11.2*	1.7 (1.0, 2.8)			
No	85.4 (373)	28.1	1.0	69.2 (496)	7.0	1.0			
Needle exchange, ever									
Yes	30.9 (126)	39.3**	1.9 (1.3, 2.9)	59.6 (387)	8.7	1.5 (0.85, 2.5)			
No	69.1 (349)	25.3	1.0	40.4 (385)	6.1	1.0			
Crack cocaine use, ever									
Yes	64.9 (318)	33.7**	2.0 (1.3, 3.1)	87.2 (666)	7.8	1.1 (0.50, 2.3)	48 (551)	5.0	1.3 (0.74, 2.3)
No	35.1 (155)	20.2	1.0	12.8 (104)	7.3	1.0	55.2 (682)	3.9	1.0
Stimulant use, ever[g]									
Yes	67.2 (309)	32.0	1.4 (0.93, 2.2)	69.0 (553)	6.3*	0.54 (0.33, 0.90)	21.1 (268)	4.5	1.0 (0.52, 2.0)
No	32.8 (166)	24.7	1.0	31.0 (218)	11.0	1.0	78.9 (965)	4.4	1.0
Sexual risk factors									
≥5 sex partners, previous 12 mo									
Yes	32.0 (159)	30.0	1.1 (0.70, 1.6)	17.8 (139)	5.3	0.6 (0.29, 1.3)	12.0 (156)	10.9***	3.3 (1.8, 6.2)
No	68.0 (311)	28.7	1.0	82.2 (630)	8.3	1.0	88.0 (1077)	3.6	1.0
Receptive anal sex, past 12 mo									
Yes	43.2 (212)	39.4***	2.3 (1.5, 3.4)	4.9 (34)[h]	7.1	0.91 (0.27, 3.0)	3.0 (37)[h]	0.0	
No	56.8 (263)	22.1	1.0	95.1 (738)	7.8	1.0	97.0 (1025)	4.7	

Continued

TABLE 2—*Continued*

Syphilis diagnosis, ever									
Yes	15.8 (67)	47.3***	2.5 (1.5, 4.2)	9.3 (69)	17.7***	3.0 (1.6, 5.8)	6.6 (75)	11.5**	2.8 (1.3, 5.8)
No	84.2 (406)	26.1	1.0	90.7 (702)	6.6	1.0	93.4 (1179)	4.5	1.0
Sex trade, ever									
Yes	49.7 (242)	40.5***	3.0 (2.0, 4.6)	36.5 (258)	8.9	1.4 (0.82, 2.3)	16.7 (196)	7.9*	2.2 (1.2, 4.1)
No	50.3 (226)	18.4	1.0	63.5 (499)	6.6	1.0	83.3 (1024)	3.8	1.0
Sex for cash, ever									
Yes	43.4 (214)	39.9***	2.5 (1.6, 3.7)	31.7 (210)	8.7	1.3 (0.76, 2.2)	14.8 (172)	8.9**	2.5 (1.4, 4.8)
No	56.6 (256)	21.1	1.0	68.3 (550)	6.8	1.0	85.2 (1051)	3.7	1.0
Sex for drugs, ever									
Yes	26.2 (139)	46.7***	2.9 (1.9, 4.5)	18.9 (148)	11.3	1.7 (0.97, 3.1)	6.6 (82)	13.3***	3.9 (1.9, 8.1)
No	73.8 (330)	23.0	1.0	81.1 (610)	6.9	1.0	93.4 (1139)	3.8	1.0

Note. OR = odds ratio; CI = confidence interval; MSM = men who have sex with men; IDU = injection drug user; TB = tuberculosis. Percentages, ORs, and CIs are based on weighted data; sample sizes are unweighted.
[a]Men who reported ever having anal or oral sex with a man.
[b]Two female-to-male transgender persons in the sample were not included here; both were HIV negative.
[c]Spent the previous night in a shelter or "on the streets," a set of nonconventional living sites.
[d]Total time accumulated as homeless since age 18 was 12 months or longer.
[e]Positive tuberculin skin test, but not necessarily active disease.
[f]Injection of illicit drugs.
[g]"Speed," "uppers," "crank," amphetamines, methamphetamine, "crystal meth," or "ice."
[h]These are all women.
*P < .05; **P < .01; ***P < .001.

and the greatest number of years of potential life lost.[40]

Many MSM (10.7%) self-identified as male-to-female transgender persons; they were no more likely to be HIV infected than other MSM. Their HIV rate was low (26%) compared with that reported in a recent community-based study of transgender persons in San Francisco (35%).[52] Indigent urban male-to-female transgender persons may require highly tailored interventions.

Although sexual risk factors were the best predictors of HIV among MSM, HIV was still more prevalent among MSM IDUs than among MSM non-IDUs. At the bivariate level, HIV infection among MSM was higher among stimulant and heroin injectors, but not among syringe sharers. While the literature suggests that methamphetamine use among MSM is associated with increased risk taking and HIV seroconversions,[42–44] the link between HIV and the use of other drugs by MSM (such as noninjected heroin and crack) is less clear. While drug treatment may decrease sexual risk taking among gay men with substance use disorders,[53] effective treatment options for indigent adults are scarce.[16] Despite widespread injection and noninjection drug use among indigent MSM, HIV interventions targeting this group should reinforce the focus on sexual risk.

Sex Drives HIV Infection Among Indigent IDUs

Almost half of the sample (44.9%) reported lifetime injection drug use, and among all IDUs (including MSM and non-MSM), the HIV rate was 14.3%. This is somewhat higher than the 8.7% reported for IDUs recruited from 2 neighborhoods in San Francisco.[20]

Among the non-MSM IDUs, HIV prevalence was 7.7%, with virtually equivalent rates for men and women (as observed elsewhere[54]). The HIV rate for non-MSM IDUs was lower than those reported in previous studies in San Francisco (10.0%–14.2%)[28,55–58] and nationally (12.7%).[54] The lower rate is probably owing to recruitment of a population-based probability sample that included non-MSM IDUs, rather than a targeted sample of non-MSM IDUs.

Among non-MSM IDUs, prior syphilis was a stronger predictor of HIV infection than lifetime syringe sharing. This finding adds to the literature on non-MSM IDUs that identifies sexual risk as a more important risk factor for HIV infection than drug-use behaviors.[54,55,59–62] Similarly, in a study of urban IDUs that included MSM, Kral and colleagues found that sexual behavior predicts HIV seroconversion better than drug use behavior among both men and women.[62]

Consistent with other studies of non-MSM IDUs,[54] HIV was not related to trading sex for money, cocaine use, or cocaine injection. In contrast to other studies of non-MSM IDUs,[11,55,58–60,63] HIV infection in our study was not related to Black race once we controlled for behavioral risk factors.

Among non-MSM IDUs, those with lower education were 2.5 times more likely to be infected than others, which is consistent with previous studies of HIV seroconversion among non-MSM IDUs.[64,65] Lower education may be a marker for lower socioeconomic status and longer injection careers.

HIV seroprevalence in US prisons is high,[66,67] and there is considerable overlap between the populations of former inmates and the homeless. One quarter of the total

TABLE 3—Logistic Regression Models[a,b] Predicting HIV Infection Among Homeless and Marginally Housed Adults in San Francisco, by Risk Group

Risk Group	Risk Factors	AOR	(95% CI)
Total sample	MSM	4.6	(3.3, 6.4)
	Syphilis, diagnosis ever	2.2	(1.5, 3.3)
	White IDUs (interaction)	2.0	(1.3, 3.3)
	Transfusion	1.8	(1.1, 2.8)
	Non-White race	1.8	(1.1, 2.8)
	Sex trade[c]	1.8	(1.3, 2.4)
	Receptive anal sex, past 12 mo	1.6	(1.1, 2.4)
MSM group (all MSM)	White sex traders[c] (interaction)	5.9	(3.2, 11.1)
	Non-White race	3.4	(1.8, 6.2)
	Receptive anal sex, past 12 mo	2.1	(1.3, 3.3)
	Syphilis, diagnosis ever	2.0	(1.1, 3.5)
IDU group (Non-MSM IDUs)	Syphilis, diagnosis ever	3.3	(1.7, 6.6)
	Less than 12th-grade education	2.6	(1.5, 4.4)
	Prison	2.3	(1.3, 4.0)
	Needle/syringe sharing	2.1	(1.1, 4.0)
	Transfusion (1978–1985)	2.1	(1.1, 3.9)
Residual group (non-MSM/Non-IDUs)	Female crack users × sex for drugs (interaction)	6.1	(2.4, 15.5)
	≥5 sex partners. past 12 mo	2.9	(1.5, 5.5)

Note. AOR = adjusted odds ratio; CI = confidence interval; MSM = men who have sex with men; IDU = injection drug user. Analyses are based on weighted data; sample sizes are unweighted.

[a]When interaction terms in logistic regression models were tested, all covariates were kept in the model regardless of each individual contribution. For the sake of economy, nonsignificant variables were removed from the final models.

[b]All models are adjusted for age (dichotomous), race (White/non-White), and biological sex. Unless otherwise indicated, all variables are lifetime measures.

[c]Sex trade includes ever giving sex for either cash or drugs.

sample reported spending time in prison. Forty percent of non-MSM IDUs reported being in prison, and these were more than twice as likely as other non-MSM IDUs to be HIV infected. In multivariate analysis of non-MSM IDUs, histories of prison and syringe sharing both independently predicted HIV infection, suggesting that prison is not merely a marker for injection drug use or severe drug abuse. Counseling and testing prison inmates may be a cost-effective way to prevent HIV transmission among inmates[68] and may be an important long-term effort to reduce HIV among the urban poor.

Sex Drives HIV Infection Among Other Indigent Adults.

The residual group (no reported history of injection drug use or [among men] of sex with other men) constituted about half of the sample and had a 5.0% HIV prevalence rate. The women's infection rate (5.8%) was high, and more HIV-infected women were in the residual group than in the IDU group. Bisexual women had significantly higher rates (16.2%) of HIV than other women. In multivariate analysis, female crack users who had ever traded sex for drugs were 6 times more likely to be infected than were all others in the residual group, a finding that is consistent with reported high HIV risk for women who trade sex.[10,69] Having 5 or more recent (12-month) sexual partners was also an independent predictor of HIV.

Bisexual women (IDUs and non-IDUs) were more likely to be HIV infected than heterosexual or lesbian women (although only marginally more likely among IDUs.) This finding suggests that besides injection behavior, bisexual women's sexual activity may increase their risk of contracting HIV and requires additional study.

CONCLUSIONS

Findings should be interpreted in light of the study's limitations. Data are cross-sectional, and reporting bias cannot be ruled out.[63] While the demographic profile here closely resembles that of the homeless adults in a recent national survey,[70] findings about general HIV rates and risk factors for infection (e.g., the high prevalence of MSM) may not generalize outside San Francisco or beyond indigent adults who used shelters, meal programs, or low-cost single-room occupancy hotels in San Francisco during the study period.

Despite limitations, it is evident that much of the HIV epidemic in San Francisco is concentrated in a population with numerous complex problems such as extreme poverty, social marginalization, and drug abuse. Indigent urban adults are the "new faces" of HIV in the United States who will carry the heaviest burden of the HIV epidemic into its third decade. Broad structural factors such as poverty, class, racism, and homophobia should be studied to better inform interventions. ■

About the Authors

Marjorie J. Robertson, Richard A. Clark, Heather L. Long, and Andrew R. Moss are with the Department of Epidemiology, University of California, San Francisco. Marjorie J. Robertson is also with the Alcohol Research Group, Public Health Institute, Berkeley, Calif. Edwin D. Charlebois and David R. Bangsberg are with the Epidemiology and Prevention Interventions Center, San Francisco General Hospital, University of California, San Francisco. Jacqueline Tulsky is with the Department of Medicine, University of California, San Francisco.

Requests for reprints should be sent to Marjorie J. Robertson, PhD, Alcohol Research Group, 2000 Hearst Ave, Suite 300, Berkeley, CA 94706 (e-mail: mrobertson@arg.org).

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Contributors

M.J. Robertson and R.A. Clark were primary authors. In addition, Robertson was study director and oversaw development of the study design, sampling strategy, instrumentation, and fieldwork implementation, and contributed to data analysis. Clark also contributed to fieldwork implementation and data management and conducted data analysis. E.D. Charlebois contributed to the study design, instrumentation, sampling strategy, and data analysis. J. Tulsky was medical director for the study and contributed to the study concept, design, and instrumentation, and she designed and oversaw medical staff and protocols for medical data collection. H. Long was the fieldwork manager and contributed to study design, instrumentation, and fieldwork implementation. D.R. Bangsberg contributed to the instrumenta-

tion and fieldwork implementation. A.R. Moss was principal investigator and participated in all aspects of the study, including concept, design, data collection, and analysis.

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Research protocols were approved by the committee for human research at the University of California, San Francisco (no. H924–05739), and all subjects provided signed informed consent for participation in the study, including HIV testing and TB screening.

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Prevalence and Incidence of HIV, Hepatitis B Virus, and Hepatitis C Virus Infections Among Males in Rhode Island Prisons

Grace E. Macalino, PhD, David Vlahov, PhD, Stephanie Sanford-Colby, MPH, Sarju Patel, MSc, Keith Sabin, PhD, Christopher Salas, BS, and Josiah D. Rich, MD, MPH

Objectives. We evaluated prevalence and intraprison incidence of HIV, hepatitis B virus, and hepatitis C virus infections among male prison inmates.

Methods. We observed intake prevalence for 4269 sentenced inmates at the Rhode Island Adult Correctional Institute between 1998 and 2000 and incidence among 446 continuously incarcerated inmates (incarcerated for 12 months or more).

Results. HIV, hepatitis B virus, and hepatitis C virus prevalences were 1.8%, 20.2%, and 23.1%, respectively. Infections were significantly associated with injection drug use (odds ratio = 10.1, 7.9, and 32.4). Incidence per 100 person-years was 0 for HIV, 2.7 for HBV, and 0.4 for HCV.

Conclusions. High infection prevalence among inmates represents a significant community health issue. General disease prevention efforts must include prevention within correctional facilities. The high observed intraprison incidence of HBV underscores the need to vaccinate prison populations. (*Am J Public Health.* 2004;94:1218–1223)

Concerns exist that jails and prisons could serve as reservoirs that could amplify transmission of infectious diseases in the wider community as inmates who become infected behind bars are released. Such reservoirs would be formed by the high prevalence of infections such as HIV, hepatitis B virus (HBV), and hepatitis C virus (HCV) among inmates, particularly those with a history of injection drug use. Injection drug users in the general community have elevated rates of HIV, HBV, and HCV infections compared with the general population.[1,2] Injection drug use, a known risk factor for these infections, has been reported in some studies to be present in as much as one third of convicts entering prison.[3] Of these infections identified in prison, 85% have been associated with preincarceration behaviors.[4] Infections within the reservoir could be amplified by high-risk behaviors occurring in prison, such as drug use and sexual activity. Further amplification in the community might occur as newly infected inmates are released and then infect individuals in different social networks. The restrictive nature of the prison environment and the scarcity of clean syringes and condoms probably heighten the hazards associated with high-risk activities, thus increasing the risk of transmission from infected to uninfected inmates.[5] Rates of drug use and sex within prisons are difficult to estimate with precision. Some previous findings indicated that 12% of inmates injected drugs and 33% were sexually assaulted while incarcerated[6,7]; however, the rate of consensual sex is more difficult to estimate. The effects of intraprison transmission are not limited to those incarcerated: given the average lengths of stay in jails (< 3 months) and in prisons (2–3 years), the risk for continued transmission extends to the general community to which the ex-offender returns. Thus, interventions addressing infection prevention in prisons affect the larger community outside the prison walls.

During the first decade of the HIV epidemic, numerous surveys estimating prevalence rates in different US correctional systems revealed that the highest rates were found among the eastern seaboard states.[8] Several studies that examined HIV incidence within the prison setting (i.e., intraprison transmission) reported rates that were lower than expected, ranging from 0 to 4.2 per 1000 person-years.[9–11] A study of HCV incidence in men in prison found a rate of 1 per 100 person-years.[12] A similar incidence for HBV was reported from studies in both Tennessee and New Mexico prisons.[13,14] These studies indicated that transmission does occur but is probably less frequent than might be expected. In Europe, reports of outbreaks of HIV and other infections in correctional settings have demonstrated that efforts to identify and control infections in this setting are important.[15,16]

Since these earlier studies were completed, the size of the prison population in the United States has more than doubled, and the proportion of inmates held for drug-related crimes also has increased.[17] Concurrently, community HIV prevalence has expanded and the prevalence of hepatitis viruses, especially HCV, has remained elevated among injection drug users, with rates generally exceeding 80%.[18,19] In addition, prison-related outbreaks of hepatitis B have been reported.[20] The purpose of this study was to update and extend information about the prevalence and within-prison incidence of HIV, HBV, and HCV infections among sentenced male inmates in the Rhode Island Correctional Institute.

METHODS

Study Setting

The Rhode Island Adult Correctional Institute has 1 intake processing center for individuals who have been arrested as well as those who have been sentenced, thus functioning as both a jail and a prison facility. Approximately 15 000 men are processed through intake each year, 3000 of whom are sentenced. The average daily census is also approximately 3000. The median age at intake is 41 years, and the racial/ethnic

distribution is 56% White, 29% Black, and 14% Hispanic. The median sentence length is 3 years.

Prevalence Study

Our sample was composed of sentenced inmates who were processed through intake between February 1998 and February 2000. In 1988, HIV testing became mandatory for all sentenced inmates in the state of Rhode Island, although before the mandate more than 90% of inmates consented to HIV testing at intake. For the purposes of this study, excess sera from mandatory HIV testing were collected and stored for all sentenced inmates. Serum specimens were linked to demographic variables (age and race/ethnicity) as well as to standard medical intake data, including self-reported alcohol and drug use, injection drug use, and overt signs of drug use (e.g., being visibly intoxicated, having track marks). HIV results were abstracted from mandatory testing records contained in prison charts. Names and unique identifiers were removed before testing. All testing for HBV, HCV, and human T-cell lymphotrophic virus I and II was done off site after identifiers were removed. Inmates were considered to be HBV seropositive if their serum tested positive for antibody to hepatitis B core (anti-HBc). To estimate how many recent infections were occurring in this population, we also tested samples for hepatitis B surface antigen (HBsAg). A specimen was considered HCV seropositive if it was reactive to at least 2 HCV antigen bands that were encoded by different parts of the HCV genome. Antibody to human T-lymphotrophic virus I/II was assayed from residual sera that were obtained during only the first year of the study because of the low prevalence observed.

Incidence Study

One half of the residual sera collected from each individual was separated, linked to demographic data, and stored untested with an identifier to serve as the baseline blood sample to evaluate incidence. Male inmates with stored baseline specimens who were continuously incarcerated for more than 12 months (without work release) were eligible for the incidence study sample. Incidence was determined by testing serial specimens from each inmate—1 specimen at baseline (intake) and 1 at follow-up. Twelve months postintake was chosen as the follow-up interval both to account for individuals who may have become HIV infected shortly before intake but who were still within the seroconversion window (i.e., the first 6 months following infection) and to ensure that individuals who became HIV infected within the first 6 months of incarceration would be past the seroconversion window at incidence testing (an additional 6 months). Eligible inmates were approached by an outreach worker and underwent informed consent and venipuncture for the follow-up serum specimen. Standard pre- and posttest counseling was administered. Inmates had the choice of having their follow-up test results added to the prison medical records or making an appointment with the prison physician. We offered this option as a service to participants so that it would be clear to them that our study was separate from the prison medical system. We did not document who did or did not choose to take advantage of the option of placing their results in the medical records.

To determine incidence, serial samples were linked before identifiers were removed prior to testing for HIV, HBV, and HCV. Incident case individuals were defined as those who were seronegative at intake and seropositive at follow-up. For individuals with incident cases for whom samples were available the paired samples were subjected to reverse blood type testing to verify that they were indeed from the same person. To determine whether the participant could have been within the period of early infection at intake (when antibodies are negative), baseline samples were retested for HIV RNA and HCV RNA. For inmates with incident HBV cases, IgM anti-HBc marker testing was performed to document recent seroconversion. Institutional review board approval was obtained from all participating institutions.

Laboratory Testing

Testing for antibody to HIV was performed with commercial enzyme-linked immunosorbent assays (ELISA) (DuPont, Wilmington, Del) confirmed by Western blot. HBV antibodies were assayed with commercial EIAs for total anti-HBc (Corzyme; Abbott Laboratories, Abbott Park, Ill) and HbsAg (Auszyme; Abbott). Anti-HCV was assayed with Ortho HCV version 3.0 ELISA (Ortho-Clinical Diagnostics, Raritan, NY). To ensure that seroconversions were from the same individual, serum protein phenotype analyses were performed.[10] To exclude infections in the seroconversion window at intake, baseline specimens from seroconverters were assayed with polymerase chain reaction (PCR) for all infections (Amplicor HIV-1 monitor test [Roche Diagnostics, Branchburg, NJ] for titers of HIV RNA, Amplicor HBV monitor test quantitative PCR [Roche Diagnostics] for titers of HBV DNA, and Amplicor HCV monitor test [Roche Diagnostics] for titers of HCV RNA).

Analyses

We evaluated whether seasonal variations in prevalence occurred during the 2 years of our study period by calculating HIV, HBV, and HCV prevalence in 3-month intervals. A formal test for trend was performed with logistic regression in which time (by calendar quarters) was a categorical variable or covariate and each infection group (i.e. HIV, HBV, HCV) was analyzed separately as the independent variable (i.e, the outcome). Time in quarters also was included as an indicator variable to test for individual differences compared with the first quarter.

To estimate prevalence, sentenced men were counted only once, regardless of their number of intakes throughout the study period. Racial/ethnic groups were White, Black, Hispanic, and Other (Asian and American Indian). Age at intake was categorized into 4 age groups to minimize reverse identification of inmates. Drug use was subdivided into 3 groups based on drug use history or on evidence of needle marks: injection drug users (IDUs), non–injection drug users, and non–drug users.

Odds ratios (ORs), with each type of infection as the outcome and demographic and medical variables as the exposure, were calculated to determine factors associated with infection. Chi-square tests and 95% confidence intervals (CIs) were used to guide interpretation. Multivariate logistic regression models were constructed with variables found to be significant in univariate analyses to further examine significant predictors of HIV, HBV,

and HCV prevalence, respectively, with control for other variables. Incidence was calculated with person-time techniques (which take into account the sum of each individual's time at risk and the sum of time that each person remained under observation), and time contributed to follow-up was calculated as the interval between intake and the date of the second venipuncture. To confirm that the entire follow-up time was "incarcerated time," we cross-checked with the prison master database to ensure that only inmates with continuous incarceration (i.e., no work release or recidivism) were included.

RESULTS

Of 5390 sequential individual intakes, we obtained residual sera from 5244 (97.3%). The 5244 intakes occurred among 4269 unique individual men. The intake sample obtained and the subset sample for whom drug use was noted were demographically similar to the overall intake population (data not shown).

As shown in Table 1, prevalence was 1.8% (95% CI=1.37, 2.19) for HIV, 20.2% (95% CI=18.95, 21.35) for HBV, and 23.1% (95% CI=21.79, 24.31) for HCV. Prevalence of each infection by calendar quarter of entry showed no significant temporal trend (data not shown).

Univariate Analyses of HIV Seroprevalence

An HIV test result was available for 3932 (92.1%) of the 4269 men in our sample, of whom 98.7% had complete risk behavior information. The demographics of those tested and those not tested were statistically similar, although untested individuals were more likely to be HCV seropositive (OR=1.4; 95% CI=1.09, 1.78) and to have had a prior incarceration (OR=1.5; 95% CI=1.16, 1.96).

Men who were HIV-seropositive at intake were more likely than HIV-uninfected men to be Black or Hispanic, to be older than 40 years, and to be IDUs, but they were less likely to report alcohol use. HIV was not associated with repeat incarcerations.

Univariate Analyses of HBV Seroprevalence

An HBV test result was available for all 4269 inmates. HBV-infected inmates were more likely than uninfected inmates to be of Other (Asian/American Indian) race/ethnicity, to be aged 40–49 years, and to report injection drug use, but they were less likely to report alcohol use, noninjection drug use, and recidivism. HBsAg seropositivity at baseline was 3.1% (134 of 4269).

Univariate Analyses of HCV Seroprevalence

HCV results were available for all but 5 inmates (4264 of 4269). HCV-infected inmates were more likely than uninfected individuals to be White, to be aged 40–49 years, to be IDUs, and to have been previously incarcerated during our study period; however, alcohol use and noninjection drug use were inversely associated with HCV infection.

Adjusted Risk Correlates of Bloodborne Pathogens

In the final multivariate model (Table 2), HIV infection remained significantly associated with Black and Hispanic race/ethnicity, age older than 40 years, and injection drug use. HBV infection was significantly associated with Black, Hispanic, and Other race/ethnicity; age over 30; and injection drug use. HCV infection was significantly associated only with increasing age over 30 and injection drug use.

Intraprison Incidence

Of 4269 men, 1170 were continuously incarcerated for at least 12 months; 583 inmates were unavailable because they were released before they could be approached for participation in the study. Of the 587 inmates available for the incidence study, 446 (76%) consented to venipuncture. Demographic characteristics of those who accepted and those who declined venipuncture were statistically similar. All serial samples were confirmed to be from the same individuals, all of whom were uninfected at baseline. HIV incidence was 0 per 693.7 person-years of follow-up with an upward 95% CI bound of 4 per 1000 person-years.[21] HBV seroincidence was 15 per 564.6 person-years of follow-up, or 2.7 per 100 person-years (95% CI=1.57, 3.58). Of the 5 participants who had sera available for PCR testing, all were found to have an undetectable HBV viral load at baseline. Twelve inmates had excess sera from the second serial sample for immunoglobulin M antibody testing, and 5 tested positive. Three seroconverters overlapped between these 2 groups, thus confirming intraprison transmission for 7 HBV incident cases. HCV seroincidence was 2 per 550.9 person-years, or 0.4 per 100 person-years (95% CI=0.05, 1.44). Table 3 shows the HBV and HCV incidence among men overall and by race/ethnicity and injection drug use. Inmates with incident HBV cases were more likely (although not significantly) to be non-White and to report injection drug use.

DISCUSSION

The major finding of this study was that rates of bloodborne infections among men entering the Rhode Island State prison system indicate cause for continuing public health concern. Although HIV infection was relatively low in this study compared with earlier studies of other eastern seaboard states such as Maryland[2] and New York,[22] the infection rate was similar to what has been previously reported from Rhode Island.[23,24] The prevalence of HBV and HCV at intake was high and was within the same range as findings reported in other US prison settings: 29.5% for HBV prevalence in Tennessee[13] and 37% for HCV prevalence in Maryland.[12] The incidences of HIV and HCV infection were consistent with the earlier literature,[1,12] indicating that although intraprison transmission may occur, it is relatively uncommon in US prisons. By comparison, the incidence rate of 2.7 per 100 person-years for HBV infection was higher than both the incidences reported in 2 earlier studies[13,14] and the national incidence of 2.8 per 100 000 person-years calculated from National Notifiable Disease Surveillance System data.[25] Whether this incidence indicates a high rate of ongoing transmission or represents an isolated outbreak that occurred during the course of the study cannot be determined from our data; however, a recent report in another state prison of an incidence of 3.8% indicates that ongoing transmission of HBV among inmates is a concern.[26] Our data and that of other studies[20,27,28] suggest that activities to prevent transmission of hepatitis in a correctional setting are important for both inmates and correctional staff. Although our data suggest that concerns about prisons

TABLE 1—Intake Characteristics of Male Prisoners, by HIV, Hepatitis B Virus, and Hepatitis C Virus Seroprevalence: Rhode Island, 1998–2000

	HIV			Hepatitis B Virus			Hepatitis C Virus		
	n	% Positive (n)	Odds Ratio (95% Confidence Interval)	n	% Positive (n)	Odds Ratio (95% Confidence Interval)	n	% Positive (n)	Odds Ratio (95% Confidence Interval)
Overall prevalence	3932	1.8 (70)	. . .	4269	20.2 (860)	. . .	4264	23.1 (983)	. . .
Race/ethnicity									
White	2270	0.5 (19)	1.0	2449	19.4 (476)	1.0	2446	26.9 (659)	1.0
Black	987	4.0 (39)	5.2 (2.93, 9.05)	1093	19.2 (210)	1.0 (0.82, 1.18)	1093	16.8 (184)	0.6 (0.46, 0.66)
Hispanic	646	1.9 (12)	2.4 (1.14, 4.95)	693	23.1 (160)	1.3 (1.02, 1.53)	691	19.8 (137)	0.7 (0.55, 0.83)
Other	27	3.7 (1)	4.8 (0.62, 37.43)	32	43.8 (14)	3.2 (1.60, 6.54)	32	9.4 (3)	0.3 (0.09, 0.93)
Age, y									
< 30				2058	9.8 (221)	1.0	2055	7.9 (162)	1.0
30 to < 40[a]	3256	1.3 (42)	1.0	1463	26.2 (383)	3.3 (2.72, 3.95)	1462	33.7 (493)	6.0 (4.90, 7.22)
40 to < 50[a]	676	4.1 (28)	3.3 (2.04, 5.37)	600	38.3 (230)	5.7 (4.61, 7.15)	599	48.3 (289)	10.9 (8.68, 13.67)
≥ 50				148	31.1 (37)	4.2 (2.86, 6.08)	148	26.4 (39)	4.2 (2.80, 6.23)
Alcohol use									
No	2686	2.1 (55)	1.0	3004	21.5 (645)	1.0	3000	24.3 (729)	1.0
Yes	1246	1.2 (15)	0.6 (0.33, 1.04)	1265	17.0 (215)	0.8 (0.63, 0.89)	1264	20.1 (254)	0.8 (0.67, 0.92)
Injection drug use									
No	3439	1.0 (35)	1.0	3481	14.8 (516)	1.0	3478	14.7 (512)	1.0
Yes	443	7.7 (34)	8.1 (4.99, 13.11)	454	59.3 (269)	8.4 (6.78, 10.30)	453	82.8 (375)	27.9 (21.45, 36.17)
Noninjection drug use									
No	3135	2.1 (65)	1.0	3459	21.5 (745)	1.0	3454	25.2 (869)	1.0
Yes	797	0.6 (5)	0.3 (0.12, 0.74)	810	14.2 (115)	0.6 (0.49, 0.75)	810	14.1 (114)	0.5 (0.40, 0.60)
No drug use									
No	1290	3.1 (40)	1.0	1598	28.7 (459)	1.0	1596	36.7 (585)	1.0
Yes	2642	1.1 (30)	0.4 (0.22, 0.58)	2671	15.0 (401)	0.4 (0.38, 0.51)	2668	14.9 (398)	0.3 (0.26, 0.35)
Recidivism									
No	3223	1.8 (57)	1.0	3476	20.5 (714)	1.0	3473	21.5 (746)	1.0
Yes	709	1.8 (13)	1.0 (0.57, 1.91)	793	18.4 (146)	0.9 (0.72, 1.06)	791	30.0 (237)	1.6 (1.32, 1.86)

[a]Age for HIV-infected group was condensed into a binary variable (< 40 or ≥ 40) because of small numbers.

serving as an amplifying reservoir for HIV and HCV might be overstated, these data are indicative of significant ongoing HBV transmission. No other studies published to date have provided such extensive confirmatory data regarding transmission among prison inmates.

Since 1982,[29] the Advisory Committee on Immunization Practices has recommended hepatitis B vaccination for inmates of long-term correctional facilities and IDUs, and the Centers for Disease Control and Prevention in a 2003 report reiterated this suggestion, strongly advising the vaccination of all inmates without proof of vaccination or serological evidence of immunity to infection.[30] At the time of our study, Rhode Island prisons did not offer hepatitis B vaccination to their inmates. However, Rhode Island is not alone among correctional settings in not providing hepatitis B vaccine as standard practice to inmates. A recent survey found that of 36 responding US correctional systems, only 2 provided routine hepatitis B vaccination, 9 offered no vaccination, and the rest offered vaccination to selected inmates.[31] Costs, the challenges of completing vaccination series in a transient population, and an already high prevalence of the disease within known risk groups[13] are the main barriers to routine hepatitis B vaccination within corrections facilities. Vaccination should be initiated even when completion of the series cannot be ensured, however, because protective levels of antibody develop after a single dose of hepatitis B vaccine in 30%–50% of healthy young adults and after 2 doses of vaccine in 75% of healthy young adults.[30]

The argument for vaccinating prison populations is salient because the risk of intraprison HBV transmission among currently incarcerated individuals is not trivial. Thus, the risk of HBV exists both for the already incarcerated population and for those newly incarcerated. Furthermore, 73% of our study sample was released within 12 months of intake. Earlier studies of persons released from prison indicate that incarceration represents a sentinel event and that on release, relapse to risky behaviors occurs rapidly, increasing risk in the general community.[32,33] Thus, the prison

TABLE 2—Adjusted Odds of HIV, Hepatitis B Virus, and Hepatitis C Virus Seroprevalence Among Male Prisoners, by Intake Characteristics: Rhode Island, 1998–2000

Variable	Odds Ratio (95% Confidence Interval)		
	HIV	Hepatitis B Virus	Hepatitis C Virus
Race/ethnicity			
White	1.0	1.0	1.0
Black	8.07 (4.44, 14.70)	1.57 (1.27, 1.95)	0.85 (0.67, 1.08)
Hispanic	3.25 (1.52, 6.95)	2.06 (1.62, 2.61)	1.08 (0.82, 1.42)
Other	5.49 (0.60, 50.17)	6.01 (2.54, 14.24)	0.15 (0.02, 1.22)
Age, y			
< 30	. . .	1.0	1.0
30 to < 40[a]	1.0	3.13 (2.54, 3.85)	6.93 (5.40, 8.88)
40 to < 50[a]	2.84 (1.66, 4.86)	5.62 (4.37, 7.22)	12.50 (9.38, 16.65)
≥ 50	. . .	5.67 (3.73, 8.62)	6.40 (3.98, 10.28)
Injection drug use			
No	1.0	1.0	1.0
Yes	10.06 (5.96, 16.99)	7.86 (6.28, 9.84)	32.44 (24.07, 43.71)

[a]Age for HIV was condensed into a binary variable (< 40 or ≥ 40) because of small numbers.

TABLE 3—Incidence of Hepatitis B Virus and Hepatitis C Virus Infection Among Male Prisoners, Stratified by Intake Characteristics: Rhode Island, 1998–2000

Variable	n	No. Positive	Person-Years	Incidence Rate[a] (95% Confidence Interval)	Rate Ratio (95% Confidence Interval)
Hepatitis B virus infection					
Total	348	15	564.6	2.7 (1.57, 4.45)	. . .
Race/ethnicity					
Non-White	181	9	293.3	3.1 (0.01, 1.67)	1.4 (0.50, 5.16)
White	167	6	271.3	2.2 (0.01, 2.23)	1.0
Injection drug use[b]					
Yes	23	3	36.7	8.2 (1.69, 23.96)	3.1 (0.05, 9.25)
No	213	9	346.3	2.6 (1.19, 4.93)	1.0
Hepatitis C virus infection					
Total	337	2	550.9	0.4 (0.05, 1.44)	. . .
Race/ethnicity					
White	149	1	241.6	0.4 (0.01, 2.23)	1.3 (0.21, 7.91)
Non-White	188	1	309.3	0.3 (0.01, 1.67)	1.0
Injection drug use[b]					
Yes	217	1	18.2	5.5 (0.14, 30.65)	18.3 (3.13, 119.81)
No	11	1	352.7	0.3 (0.01, 1.67)	1.0

[a]Incidence rate per 100 person-years.
[b]Values do not add up to total owing to missing data.

setting is an appropriate venue in which to provide general public health prevention programs. As we have shown, the prison setting is also an ideal venue for access to injection drug users: 35% of our population either self-reported or had visible signs (i.e., track marks) of injection drug use. Few settings offer such efficient access to this otherwise hidden population for the purpose of providing public health services.

Our incidence results cannot be extended to the entire incarcerated population, in particular those with shorter sentences. Jail populations experience shorter sentences than prison populations. HIV prevalence has been reported to be higher in jails than prisons,[24] however, one national study which controlled for geographic location found no significant differences in intake HIV prevalence between jail and prison populations.[34] On the basis of these studies, it is unclear whether shorter sentences pose additional risk and whether further studies are required. Our findings underscore the importance of providing HIV and hepatitis prevention services in the corrections setting, particularly among men. US Census 2000 data show that almost 2 million adult men aged 18–64 years are incarcerated at any given time. Men are 15 times more likely to be incarcerated than are women, relative to their numbers in the overall US population, and in 2001, 10% of Black men aged 25–29 years were incarcerated.[35] The size of the US male population that is incarcerated demands regular monitoring of bloodborne infections both to determine the burden of disease existing within the incarceration setting and to access a population at risk that is not isolated from the community at large. The communities to which inmates return often have problems (mental and chronic illness, poverty, violence) with which to contend,[36] further compounding the consequences of missed prevention opportunity for incarcerated, high-risk groups. Practical challenges associated with administering hepatitis B vaccination in prisons should be considered in relation to the benefits this intervention would afford.

Offering hepatitis B vaccination in prisons must be a public health priority, given the impact of infected individuals on the incarcerated population and, beyond the prison walls, on the transmission of HIV, HBV, and HCV in the communities to which inmates return. ■

About the Authors

Grace E. Macalino, Stephanie Sanford, Sarju Patel, Christopher Salas, and Josiah D. Rich are with Brown University Medical School, Providence, RI. David Vlahov is with New York Academy of Medicine, Center for Urban Epidemiological Studies, New York, NY, and the Johns Hopkins University Bloomberg School of Public Health, Baltimore, Md. Keith Sabin is with the University of Georgia, Athens.

Requests for reprints should be sent to Grace E. Macalino, PhD, MPH, Brown University, 169 Angell St GS-2, Providence, RI 02912 (e-mail: grace_macalino@brown.edu).

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Contributors

G. Macalino conceived the study, supervised all aspects of its implementation, and led the writing. D. Vlahov conceived the study, provided scientific guidance, synthesized analyses, and assisted with writing. S. Sanford led the data management of the study and performed most of the analyses. S. Patel assisted with the analyses, conceptualization, and literature review of the article. K. Sabin provided technical assistance and problem solving in the execution of the study. C. Salas executed all aspects of the study's implementation and oversaw the daily operations of the study. J. Rich established links between the study and the Rhode Island prison and provided guidance in the implementation of the project.

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All procedures and human participant protections related to this study were approved by the local institutional review boards of The Miriam Hospital, the Johns Hopkins University Bloomberg School of Public Health, and the Centers for Disease Control and Prevention.

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Geographic Location of Commercial Plasma Donation Clinics in the United States, 1980–1995

Robert C. James, PhD, and Cameron A. Mustard, ScD

Objective. We examined the location of commercial plasma donation centers in the United States over the period 1980 to 1995 relative to the geographic distribution of risk behaviors associated with transfusion-transmissible infections.

Methods. The census tract locations of commercial source plasma clinics were described by measures of neighborhood social disadvantage and the prevalence of illicit drug use and active local drug economies.

Results. Depending on the measure of social environment used, commercial plasma clinics were 5 to 8 times more likely to be located in census tracts designated high-risk than would be expected by chance.

Conclusions. Commercial source plasma clinics were overrepresented in neighborhoods with very active local drug economies. These patterns persisted after the links between human immunodeficiency virus and hepatitis C virus infections and plasma products had been established and may present risks to blood system safety. (*Am J Public Health.* 2004;94:1224–1229)

The contamination of fractionated plasma products led to an epidemic of infection with human immunodeficiency virus (HIV) and hepatitis C virus (HCV) in the worldwide hemophilia community in the early years of the 1980s.[1,2] The consequences of that epidemic are well known. The World Federation of Hemophilia has reported that nearly half of individuals with hemophilia worldwide are infected with HCV, and 10% are infected with HIV.[3] In North America, approximately 65% of recent mortality among hemophiliacs has been related to HIV.[4,5] The prevalence of HCV, which is associated with hepatocellular carcinoma, nears saturation in older hemophiliacs.[6,7]

The underlying causes and context of this epidemic have been the subject of controversy and civil litigation.[8,9] Responses have ranged from public inquiries in Canada and the United States, to criminal convictions in France, to civil litigation in many countries. There has also been widespread reorganization of many transfusion services over the last 2 decades, including the termination of the Canadian Red Cross Society's role in the provision of blood collection and distribution activities in that country.[10]

The degree to which blood and plasma donors carry, or are at risk for acquiring, transfusion-transmissible infectious agents is an important determinant of the overall safety of blood products. Minimizing the risks associated with blood products is therefore a critical regulatory objective for blood collection and manufacturing agencies. A long-standing criticism of American source plasma collection—where plasma rather than whole blood is procured—is that risk is not minimized. Specifically, it has been suggested that commercial source plasma clinics (which pay donors for plasma) attract high-risk donors,[11–13] and that commercial source plasma clinics are located near areas with a high prevalence of illicit drug use.[14]

Although very limited data are available on infection rates of commercial donors, there is some information indicating higher seropositivity among commercial plasma donors relative to volunteer donors. In a secondary analysis of information submitted by plasma manufacturers in support of viral testing techniques, the US General Accounting Office (GAO) has reported that "test-positive rates for commercial plasma donors were substantially higher than those of volunteer whole blood donors, ranging from 2 to 20 times higher on the different tests."[11(p7)] The GAO proposed that these higher infection rates arise because "monetary incentives such as those offered by commercial plasma-collection centers may be tantalizing to some of those who are known to be at risk for infectious diseases, such as intravenous drug users and prostitutes,"[11(p7)] but offered no evidence to support these arguments. Yet, the GAO statement is consistent with published studies of paid blood/plasma donation in cohorts of injection drug users conducted in South Florida[14] and Baltimore[15] that observed high rates of commercial blood donation in cohorts of street-recruited illicit drug users.

In addition to the risk of commercial donation attracting high-risk donors, concerns have been raised about the location of paid blood donation centers in high-risk areas.[14] Donor recruitment in areas of high prevalence of transfusion-transmissible pathogens presents risks to blood safety arising from false-negative results in donation screening and from the transmission of pathogens for which no screening procedure is available. Although a number of commentaries have suggested that paid blood and plasma clinics are overrepresented in disadvantaged socioeconomic settings, no formal study of the geographic organization of commercial donation sites has been published.[12,16,17]

The objective of this study is to describe the geographic location of commercial source plasma centers in the continental United States over the period 1980 to 1995. We examine evidence for the hypothesis that during the period 1980 to 1989, source plasma clinics were disproportionately located in areas with high rates of risk behaviors that are related to illicit drug use and associated with transfusion-transmissible infections. In addition, we consider whether location practices may have changed in the period 1990 to 1995.

In describing current location practices in the commercial plasma industry, this work is

relevant for evaluating the effectiveness of self-regulation by the plasma industry and also of governmental regulation of source plasma collection in the United States. This work may also have important international implications, as the United States is the chief supplier of source plasma and plasma-derived pharmaceuticals in the world market.

METHODS

Sample

Inclusion criteria. All source plasma clinics regulated by the US Food and Drug Administration (FDA) and operating in the continental United States, Hawaii, or Alaska in the period 1980 to 1990 and in 1995 were eligible for inclusion in this analysis. Addresses were obtained from the trade publication of the American Blood Resources Association,[18–27] which approximately once per year publishes a list of addresses of FDA-licensed source plasma clinics. We obtained addresses from 1980 through 1990, and for 1995 (addresses were not available for 1984, 1985, or 1991 through 1994). Commentary included with these lists suggests that the information was gathered through Freedom of Information Act requests filed by the journal with the FDA, the regulating body for US blood and plasma collection.

Exclusion criteria. Several types of plasma clinics were excluded from our analysis. Clinics operated by the American Red Cross were excluded because these did not offer payment for blood or plasma donations. However, a limited number of community-based blood collection agencies that would not have offered payment remain in our sample as they could not be reliably distinguished from commercial operations.

Plasma clinics operating within penal institutions also were excluded, even though viral hepatitis, drug abuse, and sexual behaviors associated with parenteral disease transmission were recognized to be common in penal institutions.[28–30] Our rationale for excluding these penal clinics was that standard interpretations of census data to characterize neighborhoods would not apply to penal institutions.

We further excluded those plasma clinics for which the reported address was not suitable for geocoding. This exclusion applied to addresses where the mailing address was given as a postal box, or where the address was a building name, a functional description of a building (e.g., "bus depot"), or otherwise not a street address.

Geocoding

Unique addresses were identified by manual comparison of addresses across years, and all nonexcluded addresses were submitted to geocoding. The list of unique plasma clinic addresses was linked with either the 1980 or 1990 US Census tract geography for that address, or both. A census tract is the second smallest areal unit for which census data are publicly reported; it is intended to have a mean population of approximately 4000 individuals and to be socially homogeneous.[31] The census tract is commonly used to operationalize the concepts of neighborhood in US sociology and urban ecology literature.[32]

The 1980s addresses were geocoded by GDT (Lebanon, NH) and used the 1980 census geography. For those addresses with active clinics in the 1990s, Maptitude Geographic Information System Version 4.0 was used (Caliper Corp, Newton, Mass). This package uses US Census Bureau Topologically Integrated Geographic Encoding and Referencing System base maps to determine the 1990 census tract that contains the address.[33]

Once the 1980 and/or 1990 census tract for a given address was known, data from the 1980 and/or 1990 Summary Tape File (STF) 3A census files[33,34] was linked, and the census tract containing the clinic was classified according to 3 neighborhood typologies, described below.

Neighborhood Classification

In this study we applied 3 neighborhood classification schemes (Table 1). All 3 measures were operationalized at the census tract level. Two of the 3 neighborhood classifications were defined by previous work: the US Census Bureau's "extreme poverty areas" designation,[31] and the "underclass areas" designation, proposed by researchers at the Washington, DC–based Urban Institute.[35] The US Census defines extreme poverty areas as those census tracts where the poverty rate is greater than 40%.[31] The "underclass areas" designation does not use poverty as part of the classifying algorithm, but rather identifies high rates of 4 measures of social "deviance." Although neither the associated agencies nor the measures themselves were specifically designed to identify areas with high rates of drug use, extreme poverty areas have been correlated with social problems,[37] and the "underclass areas" definition is specifically designed to find areas with high rates of social problems.[35]

A third classification scheme was developed by the authors to identify areas with high rates of social disorganization and reflected 2 dimensions: economic deprivation and residential instability.[38,39] Neighborhoods with low economic resources and high residential mobility were proposed to be centers of social problems, including illicit drug use. A factor analysis of 14 measures from the US Census, structured to reflect these 2 dimensions, resulted in the definition of 9 neighborhood types.[36] The subset of census tracts with the lowest economic resources and concurrently the highest levels of residential mobility

TABLE 1—Neighborhood Types, by Characteristics

	Characteristics
Extreme Poverty Areas[31]	Household poverty rate greater than 40%.
Underclass Areas[35]	Concurrent high rates for female-headed households, receipt of welfare, high school dropouts, and adult male nonparticipation in the workforce. High rates are defined (for both 1980 and 1990 census years) as greater than the 1980 mean plus one 1980 standard deviation for the measure. All 4 metrics had to be "high" in order to meet the definition.
Socially Disorganized Areas[36]	All US census tracts were stratified into 1 of 9 neighborhood types based on factor analysis of 14 common census variables, independently estimated for 1980 and 1990. Socially disorganized areas had the highest levels of residential mobility and concurrently the highest levels of economic deprivation.

were labeled "socially disorganized" areas. We expected that socially disorganized areas, extreme poverty areas, and underclass areas would show high rates of illicit drug use and active local drug economies.

Neighborhoods and Illicit Drug Activity

To characterize these 3 classes of neighborhoods in terms of their association with illicit drug use, we have elsewhere described the geographic distribution of drug practices and drug choices that have either been linked directly to infectious disease transmission (heroin, crack, PCP, needle use) or that reflect socially proscribed behaviors (selling drugs) suggestive of active local drug economies.[40] That analysis was performed on a special geocoded version of the 1993 National Household Survey on Drug Abuse (NHSDA). The NHSDA is the standard reference survey for population-based studies of drug use in the United States.[36] This survey is a representative sample of household-dwelling adults aged 12 years and older, and uses a multistage sampling design.

Our analyses were restricted to the 1993 survey, with a sample size of 26 489, and focused on neighborhood drug activity, availability of "hard" drugs (i.e. cocaine, heroin, LSD, and PCP), and personal drug use. By special arrangement with the Substance Abuse and Mental Health Services Administration, the 3 neighborhood classification schemes were integrated with the 1993 NHSDA public use file,[36] linking public use file data to specific neighborhoods. This augmentation of the public use file did not compromise the anonymity of respondents.

Selected results from our analysis of the 1993 NHSDA—organized by neighborhood type—are reported in Table 2. As compared with respondents outside of these neighborhood types, residents of extreme poverty areas, underclass areas, and socially disorganized areas all reported rates for drug activity that were higher than the rates reported at the national level. The rate ratios (not shown) varied widely from 2- to 8-fold higher than those reported at the national level (detailed analyses are available from the authors).

Evidence from the NHSDA suggests that these 3 neighborhood types are characterized by very active drug selling and very ready availability of a broad range of "hard" street drugs, as compared with national rates (measures that others have labeled as "drug visibility"). Evidence of substantially higher personal drug use among residents of these neighborhood types was not found in our analysis, a finding that is consistent with recent evidence from an independent survey.[41]

TABLE 2—Respondents' Self-Report of Drug Use and Drug Availability Characteristics, by Neighborhood, and National Rates[40]

Response	National	Underclass Areas	Extreme Poverty Areas	Socially Disorganized Areas
Self-reported use of crack cocaine in the last year	0.5%	1%	0.6%	1.6%
Self-reported use of cocaine in the last year	2.2%	3.4%	1.9%	3.4%
Self-reported use of heroin in the last year	0.1%	0.5%	0.3%	0.4%
"Very frequent" drug sales in neighborhood	5.6%	46.7%	24.9%	32%
"Very frequent" observation of intoxicated individuals in neighborhood	11.5%	49.3%	41.1%	43%
"Very easy" access to cocaine	20%	41.9%	29.2%	40.8%
"Very easy" access to heroin	11.9%	30.1%	17.4%	28.6%
"Very easy" access to LSD	11.4%	24.4%	13.9%	25.2%
"Very easy" access to PCP	9.9%	24.3%	12.8%	25.4%
Lifetime history of injection drug use	1.4%	1.8%	1.3%	1.9%
Self-reported drug selling in last year	0.8%	1.1%	1.5%	1.6%

Note. By special arrangement with the Substance Abuse and Mental Health Services Administration, the 3 neighborhood classification schemes were integrated with the 1993 National Household Survey on Drug Abuse public use file.[36] This augmentation of the public use file did not compromise the anonymity of respondents.

On balance, this analysis provides evidence for a marked concentration of drug sales and some evidence of higher drug use in these populations. On the basis of this evidence, we defined US Census tracts included under any of these 3 designations as high-risk areas for transfusion-transmissible diseases.

Statistical Analysis

Characteristics of census tracts with clinics and of all census tracts in 1980 to 1989 were determined based on the 1980 STF 3A census file, and those of census tracts in 1990 and 1995 were based on the 1990 STF 3A census file. Analyses of the distribution of clinics in the 3 neighborhood types were compared with the national distribution of these neighborhood types from the appropriate census year, and the proportion of clinics in each neighborhood type was compared with the proportion of the total census tracts in that neighborhood type. Statistical testing of the resulting rates was accomplished with Stata Version 6.0 (Stata Corp, College Station, Tex) using exact binomial distribution.

RESULTS

A total of 3962 plasma clinic addresses were reviewed, from which a total of 915 unique addresses were identified. Among the 712 unique addresses from the 1980s, 16 were American Red Cross sites, 16 were penal institutions, and 11 were unsuitable for geocoding. A total of 601 addresses (89.8%) were successfully geocoded, and of these geocoded addresses, 20 failed to link to the 1980 census tract data. A total of 581 unique addresses were available for analysis.

With respect to the 1990-era addresses, a total of 588 unique addresses were identified. Of these, 36 were operated by the American Red Cross, 9 were penal institutions, and 9 were inappropriate for geocoding. The geocoding success rate was 91.9%. All 491 geocoded addresses were linked to a 1990 census tract and associated census data. These geocoding rates are consistent with other studies.[42,43]

Table 3 describes the distribution of commercial source plasma clinics with respect to the 3 classifications of neighborhoods—extreme poverty areas, underclass areas, and socially

TABLE 3—Number of US Commercial Source Plasma Clinics by Neighborhood Type

		Extreme Poverty Areas				Underclass Areas				Socially Disorganized Areas			
Year	Number of Clinics	Proportion of All Census Tracts Defined as EPAs (A)	Number of Clinics in EPAs	Proportion of Clinics in EPAs (B)	Ratio (B/A)*	Proportion of All Census Tracts Defined as UAs (C)	Number of Clinics in UAs	Proportion of Clinics in UAs (D)	Ratio (D/C)*	Proportion of All Census Tracts Defined as SDAs (E)	Number of Clinics in SDAs	Proportion of Clinics in SDAs (F)	Ratio (F/E)*
1980	342	4.36%	77	22.5%	5.16	2.01%	37	10.82%	5.38	3.0%	84	24.56%	8.19
1981	321	4.36%	73	22.7%	5.22	2.01%	33	10.28%	5.11	3.0%	72	22.43%	7.48
1982	299	4.36%	68	22.7%	5.22	2.01%	30	10.03%	4.99	3.0%	64	21.40%	7.13
1983	288	4.36%	68	23.6%	5.42	2.01%	32	11.11%	5.53	3.0%	63	21.88%	7.29
1986	319	4.36%	75	23.5%	5.39	2.01%	33	10.34%	5.15	3.0%	65	20.38%	6.79
1987	335	4.36%	80	23.9%	5.48	2.01%	38	11.34%	5.64	3.0%	69	20.60%	6.87
1988	324	4.36%	77	23.8%	5.45	2.01%	35	10.80%	5.37	3.0%	65	20.06%	6.69
1989	324	4.36%	75	23.1%	5.31	2.01%	34	10.49%	5.22	3.0%	62	19.14%	6.38
1990	392	5.6%	156	39.8%	7.11	1.51%	44	11.22%	7.43	3.9%	114	29.08%	7.46
1995	367	5.6%	136	37.1%	6.62	1.51%	34	9.26%	6.14	3.9%	93	25.34%	6.50

Note. EPA = extreme poverty area; UA = underclass area; SDA = socially disorganized area. Over the period 1980 to 1995, 5% to 10% of clinics could not be associated with a neighborhood type because of missing values for 1 or more of the covariates that set the underlying factor analysis. All rates are estimated with the total number of clinics as the denominator, thereby assuming that none of the clinics not assigned to any of these 3 neighborhood types were at high risk.
*$P < .001$ (exact binomial).

disorganized areas. The degree to which source plasma clinics were disproportionately located in these areas was persistent across all years and all classification schemes, and typically represented at least a 5-fold increased representation over what would have been expected had plasma clinics been allocated randomly across census tracts.

Extreme poverty areas represented 4.36% of all 1980 census tracts and 5.6% of all 1990 census tracts, but represented the location of between 22.6% and 39.8% of all source plasma clinics in the years studied during the period 1980 to 1995. The underclass areas told a similar story: these areas represented approximately 2% of 1980 census tracts and 1.5% of 1990 census tracts, but between 9.3% and 11.3% of all source plasma clinics were located in these areas. Finally, the socially disorganized areas also showed a pattern of overrepresentation of source plasma clinics. Three percent of 1980 tracts and 3.9% of 1990 tracts could be designated as socially disorganized areas, but between 19.1% and 29% of all source plasma clinics were found in these neighborhood types, representing a 6.4- to 8.2-fold excess over what would have been expected by chance alone. All differences between the expected and the observed proportion of clinics in these areas were tested against the binomial distribution, with *P* values consistently less than .001.

The proportion of all census tracts defined as disadvantaged increased between the 1980 and 1990 censuses on the measures of extreme poverty and social disorganization. Additionally, in both 1990 and 1995, the concentration of clinics increased in extreme poverty areas, underclass areas, and socially disorganized areas relative to concentrations observed over the period 1980 to 1989.

DISCUSSION

Our results show that source plasma clinics were disproportionately overrepresented in areas characterized by socioeconomic disadvantage, residential mobility, and active drug sales throughout the period 1980 to 1995. For all 3 measures of neighborhood circumstance, in all years studied, source plasma clinics were more likely to be located in extremely disadvantaged types of neighborhoods.

The number of source plasma clinics operating in extreme poverty areas grew from 77 clinics to 136 clinics during this period, which represented a change from 22.5% of all clinics in 1980 to 37.1% in 1995. For underclass areas, the proportion dropped from 10.8% in 1980 to 9.3% in 1995. With respect to clinics operating in socially disorganized area, the proportion of all clinics was 24.6% in 1980 and 25.3% in 1995. The difference in results between extreme poverty areas and socially disorganized areas (where marked increases in the proportion of clinics are seen) and the results from underclass areas (which decline slightly in the proportion of clinics) suggests some strategic redeployment of clinic resources over this period. Reasons for the marked single-year increase in the overall number of operating clinics in 1990 and why this year should also represent the consistent peak for location of clinics in high-risk areas are unclear and merit further investigation.

There are potential limitations to our study arising from possible errors in classification and measurement. For example, not all clinics were fully geocoded, and those that were not coded may have represented a less-risky pool of clinics. Similarly, some fraction of clinics may have been misallocated to a neighboring census tract. However, because the types of tracts that we have designated as high-risk represent a very small minority of all tracts, the consequence of such an error would be to reduce the proportion of clinics located in high-risk tracts. Overall, potential classification

and measurement errors will have produced a conservative bias in the reported results.

These data clearly suggest that the location of commercial source plasma clinics is markedly nonrepresentative of the spectrum of neighborhood socioeconomic circumstances and social environments in the United States, at least over this 15-year period. The observation that US source plasma clinics were disproportionately located in high-risk areas in the early 1980s is not unexpected, and reflects well-recognized historical strategies for locating these clinics.[15–17]

What is surprising is that such clinics continued to operate in these areas well after the epidemiologies of HIV and HCV and the links between drug use, infection, and blood product infection were established. That these clinics remained in these areas as late as 1995 is inconsistent with epidemiologic evidence that locating commercial source plasma clinics—which provide cash compensation for plasma donation in the midst of active drug markets and poverty—represents a risk to blood system safety.

Regulatory responses to these findings could adopt a multifaceted approach. Clinics could be discouraged from establishing in high-risk areas, but regulation on this point is likely to become embroiled in definitions of high-risk areas. Public accountability mechanisms could also be considered: clinic-specific performance indicators including risk behaviors, third-party drug use surveys of donors, and seroreactivity rates for known pathogens could be required annually on a clinic-specific basis, and this information could be made publicly available by regulatory agencies. Vigorous regulatory oversight could be directed at clinics with poor performance on these indicators.

A potential secondary effect of such clinic-specific performance indicators could be to create a market organized around plasma quality rather than plasma price. Consistently high performance on quality indicators would allow clinics to demand higher return for their plasma. Arrangements should be made to ensure that plasma arising from inferior clinics is not available to non-FDA-regulated international markets.

In our view, the lack of routinely available seroprevalance information for source plasma donors and the absence of monitoring of the geographic location of commercial source plasma clinics together suggest that existing efforts by government agencies lack critical information on which to guide regulation of the safety of domestic and international blood products. Our study documents a systematic and enduring pattern in the location of source plasma centers in nonrepresentative—and high-risk—locations within the United States during the years 1980 to 1995. ■

About the Authors

At the time of the study, Robert James was with the Department of Community Health Sciences, University of Manitoba Faculty of Medicine, Winnipeg. Cameron A. Mustard is with the Department of Community Health Sciences, University of Manitoba Faculty of Medicine; the Department of Public Health Sciences, University of Toronto Faculty of Medicine; the Institute for Work and Health, Toronto; and the Population Health Program, Canadian Institute for Advanced Research, Toronto.

Requests for reprints should be sent to Cameron A. Mustard, ScD, Institute for Work and Health, 481 University Ave, Ste 800, Toronto, ON, Canada, M5G 2E9 (e-mail: cmustard@iwh.on.ca).

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Contributors

R. James conceived of the study and conducted the analysis. R. James and C. Mustard designed the study and participated in the writing of the article.

Human Participant Protection

This protocol was approved by the health research ethics board of the University of Manitoba Faculty of Medicine.

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Adolescent Smoking and Exposure to Tobacco Marketing Under a Tobacco Advertising Ban: Findings From 2 Norwegian National Samples

Marc T. Braverman, PhD, and Leif Edvard Aarø, PhD

Objectives. We examined the extent to which adolescents in Norway have been exposed to tobacco marketing despite an existing ban, and whether exposure is related to their current smoking or expectations they will smoke in the future.

Methods. Questionnaires were administered to nationally representative systematic samples of Norwegian youths aged 13 to 15 years in 1990 (n = 4282) and 1995 (n = 4065).

Results. About half in each cohort reported exposure to marketing. Youths reporting exposure were significantly more likely to be current smokers and to expect to be smokers at 20 years of age, after control for important social influence predictors.

Conclusions. Adolescents' current smoking and future smoking expectations are linked to marketing exposure even in limited settings, suggesting the need for comprehensive controls to eliminate the function of marketing in promoting adolescent smoking. (*Am J Public Health.* 2004;94:1230–1238)

The control of tobacco advertising and promotion is a pivotal policy area in the effort to prevent adolescent smoking.[1,2] Nonsmoking adolescents who are aware of cigarette advertising and can identify specific advertisements are more likely to progress toward smoking over time.[3–7] Exposure to tobacco promotional campaigns and ownership of promotional items such as clothing with cigarette brand logos are associated with greater susceptibility to and actual use of tobacco.[3,8–13] As a result of these findings and other evidence linking tobacco marketing activities to youth smoking initiation,[14–18] there has been widespread support among public health advocates for legislated controls on tobacco advertising and promotion.[19–23]

The 1998 Master Settlement Agreement, under which the tobacco industry agreed to restrict the content of print advertisements, eliminate billboard advertising, and limit certain categories of promotional activities, has changed many aspects of tobacco marketing in the United States but has not resolved fundamental concerns about the overall extent of industry marketing activities and their potential impact.[24–27] There are doubts about the effectiveness of the implementation of the Master Settlement Agreement's restrictions[24,25,27] and, more generally, concerns about the success that can be achieved by limiting some but not all forms of tobacco marketing, given the past record of industry resourcefulness in response to legislative restrictions.[28] In fact, overall cigarette marketing expenditures in the United States rose from $4.9 billion in 1995 to $9.5 billion in 2000, with most of the expenditures being used for promotional allowances, special offers, and gifts.[29] Early investigations of the post–Master Settlement Agreement environment have found that advertising also appears to have increased in magazines, especially those with high youth readership,[30–32] and at point-of-sale displays in stores.[32–34]

The policy environment pertaining to controls on tobacco marketing is in significant transition in the rest of the world as well. Numerous countries have instituted partial or comprehensive marketing bans.[29] In late 2002, the 15-nation European Union approved a ban on tobacco advertising through newspapers, magazines, radio, and the Internet, to take effect in 2005.[35] The ban is not comprehensive, since advertising will still be allowed on posters and billboards, in cinema, and through indirect sources such as clothing. This is a critical consideration, because partial bans result in industry resources being shifted to the remaining venues, and thus partial bans have been found to be far less effective than comprehensive bans in reducing tobacco consumption.[36–39] Most significant, in May 2003, the World Health Assembly adopted the Framework Convention on Tobacco Control, an international treaty that will require participating countries to implement, among other provisions, comprehensive bans on tobacco advertising and promotion.[19,40–44] Currently, the process of achieving treaty ratification by the requisite 40 World Health Organization member nations is underway.

At present, there is very little research on the patterns of young people's exposure to tobacco advertising and promotion under conditions of a legislated ban. Relevant studies on US adolescent populations over the past decade have of necessity been conducted under conditions of high saturation of advertising content. For example, surveys from the late 1990s show that virtually all US teenagers have been exposed to some form of tobacco advertising,[1,45,46] and adolescents' advertising exposure worldwide tends to be very high as well.[47] Furthermore, the impact of advertising under restricted conditions is unexplored. If health advocates are successful over the coming years in reducing the exposure of adolescents to advertising and other forms of promotion, new research questions will emerge that pertain to the changing social environment. Research is needed on the degree to which relatively limited exposure to tobacco marketing is associated with young people's tobacco use and with psychosocial variables

that usually predict use. If associations are still found between marketing exposure and smoking behavior, the advisability of relying on partial rather than strong comprehensive bans will be called into question as a tobacco control strategy.

The present study addresses these issues by examining the marketing exposure of adolescents in Norway, as well as the relationship of that exposure to their current smoking and future smoking expectations, using data from 1990 and 1995 national surveys conducted by Norway's National Council on Tobacco and Health (now the Department for Tobacco Control). Norway passed legislation banning the advertising and promotion of tobacco in 1975, which included the advertising of all types of tobacco products as well as the use of tobacco products in connection with advertisements for other types of items. Several exceptions to the prohibition were allowed, including newspapers and other printed materials that were imported into Norway as well as indirect publicity in movies and television broadcasts (e.g., sporting events). Thus, despite the relatively comprehensive nature of the ban, the presence of tobacco marketing was not completely eliminated because of some channels not addressed by the legislation and others that proved difficult to control.[48]

The 1975 Norwegian legislation has been considered a strong success.[48–50,51] For example, smoking rates declined steadily among adolescents and young adults through the 1980s (including a decrease among 13- to 15-year-olds from 45.5% in 1975 to 23.6% in 1990[52]), before leveling off during the 1990s. Nevertheless, one goal of Norway's nationwide survey of adolescents was to gauge the degree of penetration of marketing into the country, despite the ban, from the perspective of its youth. Another was to determine whether the tobacco marketing with which the youth came into contact, though limited, was related to their tobacco use. The ban was strengthened by new legislation in 1996, but its conditions were unchanged for the 1990 and 1995 survey cohorts.

The dependent variables we examine include the adolescents' current smoking status and their expectations about whether they will smoke at 20 years of age. Future expectations to smoke or not smoke is a consistent predictor of transitions pertaining to smoking behavior[4,51,53–55] and adds an important dimension to the understanding of adolescents' cognitions regarding smoking. Altogether, 3 primary questions are investigated: (1) To what degree have Norwegian adolescents been exposed to tobacco marketing, despite the ban? (2) Are adolescents' present smoking habits related to their exposure to marketing? (3) Are adolescents' future smoking expectations related to their exposure to marketing? The examination of these questions can help to shed light on the Norwegian experience as a case study of a nation that has instituted a relatively comprehensive advertising ban.

METHODS

Survey Design and Participants

Participants were Norwegian youths in grades 7 through 9 (13–15 years of age) in 1990 and 1995 who took part in a national tobacco use survey conducted by Norway's National Council on Tobacco and Health. This survey has been administered every 5 years since 1975. The questionnaire consists of two pages with closed-ended items. Items on exposure to tobacco advertising were introduced in 1990. Overall results on tobacco use within this age group, including trends between 1975 and 1995, are described elsewhere.[52]

Prior to implementation, all lower-secondary schools in Norway were sent a letter of invitation from the national Ministry of Education. Participation was obtained from over 90% of the country's schools in each survey year. The questionnaires were completed anonymously by students in their regular classrooms, under the supervision of their classroom teachers.

Sampling procedure. More than 125 000 lower-secondary school students completed the surveys in each survey year. To facilitate data management and analysis, the following sampling procedure was implemented: All students born on the 6th of any month were designated for selection, and their questionnaires were forwarded directly to the National Council for data analysis. Results from the other questionnaires were compiled by school personnel and were not included in this data set. The criterion employed for selecting the sample—a single birth date within each month of the year—was judged to be an unbiased systematic sampling procedure that could be implemented by local school personnel with ease and accuracy, compared with more conventional sampling options. Identification of the 6th was a selection made prior to the first survey and repeated in subsequent survey years.

Thus, the sample in the present analysis constitutes approximately 3.3% (i.e., 12/365 days) of all youths attending lower-secondary school in Norway and responding to the survey. There were 4310 respondents in 1990 and 4122 in 1995. According to nationwide school enrollment figures for those years, the estimated survey participation rate for all students in grades 7 through 9 was 80.8% in 1990 and 80.1% in 1995.

Measures

Information was collected on gender; grade; lifetime smoking prevalence; and smoking by mother, father, closest friend, and older siblings (if applicable). The dependent variables in the logistic regressions were current smoking status (daily, occasionally, or never) and future smoking expectations, which was assessed with the question (in translation): "Do you think you will be smoking daily when you are about 20 years old?" (definitely yes, probably yes, probably no, or definitely no).

The independent variable in the regressions was exposure to marketing. Students were asked: "In Norway, all tobacco advertising is forbidden. Despite this, have you recently seen anything that appeared to you to be an ad for cigarettes or other tobacco products?" (yes, no, or don't know). Youths answering "yes" were directed to a checklist of 10 potential venues or locations for tobacco marketing: cinema, television, cafes or restaurants, shops, clothing, ashtrays or matchboxes, toys, carrying bags, magazines or newspapers, and other sources. Youths identified those places where they had seen the marketing. A 4-level count variable was created that reflected the total of locations identified (no locations, 1–2 locations, 3–4 locations, or 5 or more locations).

Procedure

Schools received a packet from the National Council that included instructions to the school administrator and classroom teachers, survey questionnaires for all students, and a school-level reporting form. Teachers administered the survey on a designated day in the fall of the year and, if possible, at the same time in all classes. The questionnaire required about 15 minutes to complete. Students were instructed not to write their names on the questionnaires.

Prior to survey administration, teachers were given a list of students in their class who were born on the 6th day of any month. After the survey had been completed, those students were directed by their teacher to seal their questionnaires in individual envelopes, which were subsequently sent to the National Council for analysis. Thus, during data collection, the experiences of the students in the national sample were identical to those of their classmates. Results from the remaining questionnaires were compiled and used locally by school personnel.

Data Analyses

Data preparation. Prior to data analysis, cases missing information on current smoking status were eliminated from the data set. In addition, cases were identified in which the respondent provided inconsistent information (e.g., reported never having tried smoking but also reported being a daily or occasional smoker). There were only 23 such cases in 1990 and 45 in 1995, and they were eliminated from further analysis. This resulted in a final sample of 4282 youths in 1990 and 4065 youths in 1995.

Summary data and bivariate relationships. For each survey year, data were analyzed to determine the overall level of reported exposure to marketing. Chi-square analyses were used to test the statistical associations between youths' current smoking status and their reported exposure to each marketing venue.

Logistic regressions. To determine whether marketing exposure had an association with current smoking that could be statistically isolated from other potential correlates, we created a dichotomous variable for respondents' current smoking (1=daily or occasional use; 0=no use) and conducted logistic regressions for each survey year, with the 4-level exposure variable as the independent variable of interest. Gender, grade, parental smoking (combined into 1 three-level variable), best friend smoking, and older sibling smoking were included in the model as statistical controls.

We also used logistic regression to examine the relationship between marketing exposure and future expectations to smoke. The 4-level future expectations measure was collapsed into a dichotomous variable (expects vs does not expect to smoke) for use as a dependent variable. The predictor of most interest was the marketing exposure variable. Gender, grade, current smoking status, parental smoking, best friend smoking, and older sibling smoking were included as controls. Once again, separate analyses were conducted for the 2 cohorts.

RESULTS

Descriptive Information and Bivariate Relationships

Table 1 presents descriptive information on the 2 samples and the variables in the analysis. In both 1990 and 1995, slightly more than half the Norwegian youths had tried smoking and about 1 in 4 smoked daily or occasionally. There was an increase in occasional smoking between 1990 and 1995, from 14.5% of the total sample to 17.5%. As the χ^2 analyses show, smoking was significantly more prevalent among girls and older youths, and was strongly associated with parental smoking, sibling smoking, and best friend smoking. Future smoking expectations were similar across the 2 cohorts: in each year, about 11% responded that they expected to smoke (definitely or probably), whereas about 44% believed that they definitely would not. There was a decrease in the percentage of pupils who reported having seen tobacco marketing (from 55.7% to 49.1%). Finally, the bivariate relationships between smoking and exposure to marketing were highly significant in both years. Youths who reported seeing marketing were much more likely to be current smokers than those who did not.

Tobacco Marketing Venues

Table 2 presents the venues in which the youths reported viewing marketing. Overall self-reported exposure is displayed for each venue along with the relationship of that exposure to respondents' smoking status. The widest exposure was reported for tobacco paraphernalia (ashtrays, matchboxes, and lighters), cited by 33.5% of 1990 respondents and 29.3% of 1995 respondents. Not surprisingly, the exposure to these smoking accessories was strongly associated with smoking status, with smokers' exposure being particularly high. However, it is noteworthy that even among nonsmokers these paraphernalia constituted the most widely reported category, with 29.0% (n=947) of nonsmokers in 1990 and 25.0% (n=753) in 1995 reporting exposure. This was followed by the venues of carrying bags; shops and kiosks; clothing; and cafes, snack bars, and restaurants. The venues more closely aligned with mass media—cinema, TV, and magazines—were marked by considerably less exposure in both years.

As the χ^2 analyses demonstrate, smoking status was strongly related to reported exposure within each venue. Almost all the χ^2 tests revealed highly significant associations; only TV, toys, and other places, all in 1990, were nonsignificant.

Logistic Regressions

Table 3 presents the adjusted odds ratios (with 95% confidence intervals) and *P* values resulting from the logistic regressions on smoking status. The analyses show that with the effects of the other social influence variables controlled, smoking status was highly significantly predicted by reported marketing exposure, even for youths who reported only 1 or 2 locations. In both years, the adjusted odds ratios were greater than 2 for those youths who reported 5 or more locations. All of the predictor variables were highly significant, and there was striking consistency across the 2 cohorts. There was only one case where the two years were different: the intermediate level of parental smoking (1 parent smokes) was significant in 1995 but not in 1990.

Table 4 presents the logistic regressions on the youths' future expectations of smoking at

TABLE 1—Characteristics of 1990 and 1995 Samples

Variable	1990 n (%)	1990 % in Demographic Category: Daily Smoker (n = 392)	1990 % in Demographic Category: Occasional Smoker (n = 623)	1990 % in Demographic Category: Nonsmoker (n = 3267)	1995 n (%)	1995 % in Demographic Category: Daily Smoker (n = 334)	1995 % in Demographic Category: Occasional Smoker (n = 713)	1995 % in Demographic Category: Nonsmoker (n = 3018)
Total sample	4282 (100%)	9.2	14.5	76.3	4065 (100%)	8.2	17.5	74.2
Gender[a]								
Male	2221 (51.9%)	8.7	12.8	78.5	2090 (51.5%)	7.5	15.2	77.3
Female	2060 (48.1%)	9.7	16.4	73.9	1969 (48.5%)	9.0	19.9	71.1
χ^2_2		13.69				20.65		
P		.001				<.001		
Grade								
7th	1403 (32.8%)	1.9	9.1	89.1	1347 (33.1%)	2.4	11.7	85.8
8th	1425 (33.3%)	7.2	16.0	76.8	1343 (33.0%)	7.4	18.4	74.2
9th	1453 (33.9%)	18.1	18.4	63.5	1374 (33.8%)	14.6	22.4	63.0
χ^2_4		323.34				217.77		
P		<.001				<.001		
Father smokes								
Yes	1947 (45.8%)	12.7	15.9	71.4	1639 (40.9%)	11.2	19.3	69.4
No	2304 (54.2%)	6.1	13.4	80.5	2373 (59.1%)	6.0	16.2	77.8
χ^2_2		66.08				46.81		
P		<.001				<.001		
Mother smokes								
Yes	1937 (45.4%)	12.4	16.0	71.6	1647 (40.6%)	12.8	19.8	67.5
No	2333 (54.6%)	6.4	13.4	80.2	2412 (59.4%)	5.1	15.9	78.9
χ^2_2		57.24				94.64		
P		<.001				<.001		
Older sibling smokes								
Yes	980 (22.9%)	20.1	21.1	58.8	888 (21.9%)	16.3	23.3	60.4
No	1808 (42.3%)	5.1	13.0	81.9	1733 (42.8%)	5.9	15.5	78.6
No older sibling	1484 (34.7%)	6.8	12.1	81.1	1432 (35.3%)	6.1	16.2	77.7
χ^2_4		258.78				142.51		
P		<.001				<.001		
Best friend smokes								
Yes	893 (20.9%)	37.0	32.0	31.0	959 (23.8%)	31.0	36.6	32.4
No	3370 (79.1%)	1.7	9.9	88.4	3066 (76.2%)	1.0	11.6	87.4
χ^2_2		1506.81				1358.04		
P		<.001				<.001		
Tried smoking								
Yes	2422 (56.6%)	16.2	25.7	58.1	2299 (56.6%)	14.5	31.0	54.5
No	1855 (43.4%)	0.0	0.0	100.0	1760 (43.4%)	0.0	0.0	100.0
χ^2_2		1019.27				1080.15		
P		<.001				<.001		
Expects to smoke at 20 years of age								
Definitely yes	46 (1.1%)	69.6	23.9	6.5	82 (2.0%)	76.8	17.1	6.1
Probably yes	440 (10.3%)	57.0	25.0	18.0	352 (8.7%)	47.4	31.8	20.7
Probably no	1964 (46.0%)	4.9	21.2	73.8	1808 (44.8%)	4.8	24.6	70.6
Definitely no	1824 (42.7%)	0.5	4.7	94.8	1793 (44.4%)	0.8	7.7	91.5
χ^2_6		2003.48				1730.19		
P		<.001				<.001		
Has seen tobacco marketing								
Yes	2383 (55.7%)	11.8	17.2	71.0	1997 (49.1%)	11.4	21.1	67.6
No	1899 (44.3%)	5.8	11.3	82.9	2068 (50.9%)	5.2	14.1	80.7
χ^2_2		85.48				99.17		
P		<.001				<.001		

[a]Sums differ slightly because of missing data on demographic variables.

TABLE 2—Locations of Exposure to Tobacco Marketing

Location	1990 (n = 4282) n (%)	1990 % in Location Category: Daily Smoker (n = 392)	Occasional Smoker (n = 1623)	Nonsmoker (n = 3267)	1995 (n = 4065) n (%)	1995 % in Location Category: Daily Smoker (n = 334)	Occasional Smoker (n = 713)	Nonsmoker (n = 3018)
At the cinema								
Yes	425 (9.9%)	11.5	18.6	69.9	264 (6.5%)	14.0	23.1	62.9
No	3856 (90.1%)	8.9	14.1	77.0	3801 (93.5%)	7.8	17.2	75.0
χ^2_2		10.81				21.45		
P		.004				<.001		
On television								
Yes	623 (14.5%)	10.4	15.7	73.8	427 (10.5%)	13.3	18.5	68.1
No	3659 (85.5%)	8.9	14.3	76.7	3638 (89.5%)	7.6	17.4	75.0
χ^2_2		2.58				17.93		
P		NS				<.001		
At a cafe, snack bar, or restaurant								
Yes	585 (13.7%)	13.5	18.8	67.7	574 (14.1%)	13.4	24.2	62.4
No	3697 (86.3%)	8.5	13.9	77.7	3491 (85.9%)	7.4	16.4	76.2
χ^2_2		29.01				51.66		
P		<.001				<.001		
In shops or kiosks								
Yes	777 (18.1%)	13.9	18.8	67.3	591 (14.5%)	16.4	22.5	61.1
No	3505 (81.9%)	8.1	13.6	78.3	3474 (85.5%)	6.8	16.7	76.5
χ^2_2		45.13				82.39		
P		<.001				<.001		
On clothing								
Yes	722 (16.9%)	13.2	19.8	67.0	626 (15.4%)	12.1	24.0	63.9
No	3560 (83.1%)	8.3	13.5	78.2	3439 (84.6%)	7.5	16.4	76.1
χ^2_2		41.46				41.93		
P		<.001				<.001		
On ashtrays, matchboxes, or cigarette lighters								
Yes	1436 (33.5%)	15.0	19.0	65.9	1190 (29.3%)	13.9	22.8	63.3
No	2846 (66.5%)	6.2	12.3	81.5	2875 (70.7%)	5.8	15.4	78.8
χ^2_2		141.69				120.83		
P		<.001				<.001		
On toys								
Yes	94 (2.2%)	8.5	14.9	76.6	54 (1.3%)	27.8	22.2	50.0
No	4188 (97.8%)	9.2	14.5	76.3	4011 (98.7%)	8.0	17.5	74.6
χ^2_2		.05				30.50		
P		NS				<.001		
On carrying bags								
Yes	902 (21.1%)	13.1	17.7	69.2	823 (20.2%)	11.7	22.2	66.1
No	3380 (78.9%)	8.1	13.7	78.2	3242 (79.8%)	7.3	16.3	76.3
χ^2_2		34.83				37.12		
P		<.001				<.001		
In Norwegian magazines or newspapers								
Yes	414 (9.7%)	10.1	21.3	68.6	318 (7.8%)	13.8	23.3	62.9
No	3868 (90.3%)	9.0	13.8	77.1	3747 (92.2%)	7.7	17.1	75.2
χ^2_2		18.22				25.71		
P		<.001				<.001		
Other places								
Yes	332 (7.8%)	9.9	16.9	73.2	373 (9.2%)	11.5	20.4	68.1
No	3950 (92.2%)	9.1	14.4	76.6	3692 (90.8%)	7.9	17.3	74.9
χ^2_2		2.03				9.45		
P		NS				.009		

Note. NS = not significant.

TABLE 3—Logistic Regression Predicting Adolescents' Current Smoking

Variable	1990 n	1990 OR (95% CI)	1990 P	1995 n	1995 OR (95% CI)	1995 P
Gender						
Male	2184	1.00 ...		2059	1.00 ...	
Female	2027	1.32 (1.10, 1.58)	.002	1931	1.43 (1.20, 1.71)	<.001
Grade						
7th	1381	1.00 ...		1317	1.00 ...	
8th	1402	2.10 (1.65, 2.68)	<.001	1319	1.79 (1.42, 2.26)	<.001
9th	1428	3.29 (2.60, 4.16)	<.001	1354	2.81 (2.24, 3.51)	<.001
Parental smoking						
Neither parent smokes	1608	1.00 ...		1707	1.00 ...	
1 parent smokes	1386	1.21 (0.97, 1.50)	NS	1336	1.38 (1.13, 1.70)	.002
Both parents smoke	1217	1.37 (1.09, 1.70)	.006	947	1.63 (1.31, 2.04)	<.001
Best friend smoking						
No	3335	1.00 ...		3042	1.00 ...	
Yes	876	12.63 (10.46, 15.24)	<.001	948	10.83 (9.05, 12.97)	<.001
Older sibling smoking						
No	1778	1.00 ...		1716	1.00 ...	
Yes	967	2.36 (1.90, 2.93)	<.001	868	1.76 (1.42, 2.19)	<.001
No older sibling	1466	1.08 (0.87, 1.34)	NS	1406	1.01 (0.83, 1.24)	NS
Marketing exposure						
No locations	1866	1.00 ...		2029	1.00 ...	
1–2 locations	1285	1.80 (1.46, 2.23)	<.001	1113	1.44 (1.17, 1.78)	.001
3–4 locations	738	1.87 (1.46, 2.38)	<.001	583	1.96 (1.53, 2.50)	<.001
≥5 locations	322	2.12 (1.53, 2.95)	<.001	265	2.25 (1.62, 3.14)	<.001

Note. OR = odds ratio; CI = confidence interval; NS = not significant. N = 4211 in 1990; N = 3990 in 1995. Dependent variable coding: 0 = current nonsmoker; 1 = daily or occasional smoker.

20 years of age. The analyses show, once again, that marketing exposure has a highly significant effect on this variable, even when effects of the other correlates have been controlled—although in this case, the effect was significant only when 3 or more locations were reported. The highest exposure level—5 or more locations—once again was associated with adjusted odds ratios greater than 2. As in the current smoking analyses, the patterns for 1990 and 1995 were very consistent on almost all predictors.

DISCUSSION

These results indicate that even in the context of a relatively comprehensive ban, about half of Norway's adolescents reported exposure to marketing. Although this level of exposure is far less than levels in other countries, according to 1999–2001 data from the Global Youth Tobacco Survey,[47] it must nevertheless be considered a high proportion in light of the legislation's intent, and reflects the challenges faced by individual nations that attempt to eliminate marketing in its numerous forms.

In addition, the findings establish that adolescents' current smoking status and their expectations about smoking in early adulthood can be linked to marketing exposure even in a context where most forms of advertising are banned and exposure is much lower than will be found in the great majority of countries. In both cohorts, youths who reported seeing marketing in 5 or more types of locations were roughly twice as likely to be current smokers and to expect to smoke at 20 years of age. Furthermore, their current smoking status was significantly associated with even the lowest level of exposure (only 1–2 locations). The results for 1990 and 1995 were highly comparable, and thus these samples provide independent replications for the analyses and serve as evidence for the stability of the relationships.

Interpreting the Findings

The logistic regressions controlled for social influence variables that are powerful and consistent predictors of adolescent smoking. To the extent that marketing exposure might be correlated with these social influence factors, our model probably represents a conservative test of marketing's contribution to predicting the 2 dependent variables. For example, since one effect of tobacco advertising is to increase favorable images of smoking within peer networks,[56] the predictive power of friends' tobacco use may reflect, in part, one effect of advertising. Thus, inclusion of best friend smoking as a control in the regression model masks some of advertising's indirect effect and may result in an underestimation of its overall relationship to smoking.

It is noteworthy that marketing exposure was found to be predictive of future smoking expectations even when controlling for the respondents' own current smoking, which was, not surprisingly, an extremely powerful predictor of future expectations. This suggests that the adolescents were responding on the basis of an active self-definition process that went beyond a straightforward assumption that they would continue their present behavior patterns into the future. For example, more than one fourth of daily smokers (27.5% in 1990 and 30.5% in 1995) and the great majority of occasional smokers (80.5% in 1990 and 82.2% in 1995) believed they would not be smoking at 20 years of age, although a small proportion of current nonsmokers (2.5% in 1990 and 2.6% in 1995) believed that they would. Our results indicate that marketing exposure may contribute to the variability in this self-definition process. Investigations of the intraindividual factors that affect the accuracy of young people's expectations are clearly warranted.

Although these links are strong, the data do not demonstrate that a causal relationship exists between marketing exposure and either current smoking status or future expectations.

TABLE 4—Logistic Regression Predicting Adolescents' Future Smoking Expectations

Variable	1990 n	1990 OR (95% CI)	1990 P	1995 n	1995 OR (95% CI)	1995 P
Gender						
Male	2180	1.00 ...		2045	1.00 ...	
Female	2025	1.53 (1.17, 1.99)	.002	1916	0.82 (0.63, 1.07)	NS
Grade						
7th	1379	1.00 ...		1303	1.00 ...	
8th	1400	0.65 (0.46, 0.92)	.014	1310	0.51 (0.36, 0.72)	<.001
9th	1426	0.48 (0.34, 0.69)	<.001	1348	0.35 (0.25, 0.50)	<.001
Current smoking						
Never	3215	1.00 ...		2949	1.00 ...	
Occasionally	609	7.08 (5.02, 10.00)	<.001	687	6.32 (4.50, 8.87)	<.001
Daily	381	82.50 (53.48, 127.28)	<.001	325	59.43 (38.63, 91.41)	<.001
Parental smoking						
Neither parent smokes	1607	1.00 ...		1700	1.00 ...	
1 parent smokes	1384	2.78 (1.94, 3.98)	<.001	1320	1.98 (1.41, 2.77)	<.001
Both parents smoke	1214	4.26 (3.00, 6.06)	<.001	941	2.81 (2.01, 3.94)	<.001
Best friend smoking						
No	3330	1.00 ...		3020	1.00 ...	
Yes	875	1.49 (1.09, 2.04)	.013	941	1.94 (1.41, 2.65)	<.001
Older sibling smoking						
No	1776	1.00 ...		1701	1.00 ...	
Yes	967	1.62 (1.18, 2.21)	.003	859	1.57 (1.15, 2.14)	.004
No older sibling	1462	0.96 (0.69, 1.34)	NS	1401	0.82 (0.59, 1.14)	NS
Marketing exposure						
No locations	1864	1.00 ...		2010	1.00 ...	
1–2 locations	1284	1.31 (0.95, 1.81)	NS	1107	1.01 (0.72, 1.40)	NS
3–4 locations	736	1.45 (1.01, 2.06)	.043	579	1.85 (1.30, 2.63)	.001
≥5 locations	321	2.42 (1.56, 3.76)	<.001	265	2.08 (1.33, 3.23)	.001

Note. OR = odds ratio; CI = confidence interval; NS = not significant. N = 4205 in 1990; N = 3961 in 1995. Dependent variable coding: 0 = expects not to smoke; 1 = expects to smoke.

In addition to differences in actual exposure to marketing, respondents' reports on these variables might reflect differences in selective attention, perception, interpretation, and memory for tobacco marketing,[57,58] and smoking susceptibility might precede differences in these underlying cognitive processes. Thus, youths who are at higher risk for starting smoking—and who predict they will smoke in adulthood—might attend more closely to tobacco advertisements or be more likely to remember them. Nevertheless, even the mechanisms that do not imply a direct causal link provide serious cause for concern. Tobacco advertising and promotion can serve to reassure adolescents and reinforce their developing notions about the extent of smoking in society, its acceptability, its social value, and its relationship to their own identities.[1,59–61] Advertising has also been found to reduce adolescents' perceptions of the risks associated with smoking.[56] These normative and attitudinal processes can occur for adolescents at any phase of progression, including neversmokers, experimenters, and experienced smokers. Therefore, even if differences in reported exposure are the result of selective attention by youths who are already favorable toward smoking, such exposure can increase the likelihood of future experimentation or regular smoking or can decrease the likelihood of quitting.

Finally, the analysis did not include psychosocial variables such as perceptions of smoking prevalence or perceptions of the social benefits of smoking, many of which are strongly implicated in tobacco initiation.[2,51] It is likely that marketing exposure interacts with these variables through a variety of mediating mechanisms to influence smoking susceptibility, and the exploration of these relationships is another important avenue for further research.

Implications for Policy

What can be learned from these findings relating to advertising bans? These data demonstrate that there can be significant marketing penetration despite a ban, and that the relationship between marketing and youth smoking persists even in this specialized context of limited exposure. Our finding that most of the frequently cited marketing venues involved promotional items—ashtrays, clothing, and carrying bags—rather than mass communication media suggests that the industry's use of promotional activities presents a particular challenge for legislative efforts to restrict tobacco marketing. The response must be stricter enforcement of existing laws, the introduction of broader legislation, and international cooperation to reduce tobacco advertising and the distribution of tobacco promotional items. Norway has continued its tradition of strong legislative activity in all areas of tobacco control—including a smoking ban in all restaurants and bars that took effect in June 2004—and now has a fully comprehensive ban on all forms of tobacco advertising, promotion, and sponsorship.

In the United States, the combined effects of local ordinances and legal settlements are resulting in wider constraints on tobacco advertising and promotion. In past years, the exposure of youths to marketing has been nearly universal,[1,45,46] but this situation may change over the coming years. Although more research is needed, the present results suggest that even very limited levels of advertising and promotion are cause for concern. Thus, the Norwegian experience can serve as a model that other countries can use to examine the interaction patterns of smoking risk factors under highly constrained marketing conditions. ■

About the Authors

Marc T. Braverman is with the University of California, Davis. Leif Edvard Aarø is with the University of Bergen in Norway.

Requests for reprints should be sent to Marc T. Braverman, PhD, Department of Human and Community Development, University of California, One Shields Avenue, Davis, CA 95616 (email: mtbraverman@ucdavis.edu).

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Contributors

Both authors developed the research questions, designed the data analyses, and interpreted the results. M.T. Braverman conducted the data analyses and drafted the article. L.E. Aarø was an investigator on the original survey project, participated in designing the survey and data collection procedures, participated in the data analyses, and reviewed and revised the article.

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Do Favorite Movie Stars Influence Adolescent Smoking Initiation?

Janet M. Distefan, PhD, John P. Pierce, PhD, and Elizabeth A. Gilpin, MS

Objectives. We sought to determine whether adolescents whose favorite movie stars smoke on-screen are at increased risk of tobacco use.

Methods. During interviews, adolescent never smokers taking part in the California Tobacco Survey nominated their favorite stars. We reviewed popular films released during 1994 through 1996 to determine whether stars smoked on-screen in at least 2 films.

Results. One third of never smokers nominated a star who smoked on-screen, which independently predicted later smoking risk (odds ratio [OR] = 1.36; 95% confidence interval [CI] = 1.02, 1.82). The effect was strong among girls (OR = 1.86; 95% CI = 1.26, 2.73). Among boys, there was no independent effect after control for receptivity to tobacco industry promotions.

Conclusions. Public health efforts to reduce adolescent smoking must confront smoking in films as a tobacco marketing strategy. (*Am J Public Health.* 2004;94:1239–1244)

Adolescents watch an average of 3 movies per week,[1] and cigarette smoking among actors in movies has increased in frequency over the past decade.[2] Several recent observational studies suggest that the apparent product placement of smoking in movies might encourage young people to start smoking.[3–6] Public health advocates are calling for the removal of smoking from movies targeted at children and young adolescents.[7]

Evidence exists that adolescent smoking is partially attributable to aggressive tobacco marketing strategies aimed at youths via popular culture.[8–11] One such strategy is to ensure that stars smoke in popular movies.[12–14] Placing products or brand identifiers in movies is recognized as a standard marketing option to advertise and promote product use.[15] Previously unreleased tobacco industry documents emphasize the value of marketing strong positive images for cigarettes in movies,[12] and, in the 1980s, the chairman-elect of Phillip Morris focused on the need to find more opportunities to portray cigarettes on-screen.[12]

The advertising literature notes that movie product placements are effective if the viewer interprets the brand image according to who the character is and how the brand is used by the character.[16] The perceived optimal (i.e., most expensive) placements are in scenes in which the brand is used by the movie's stars.[17] Examples cited in the literature include the 65% increase in sales of Hershey's Reese's Pieces candy after its use by the main character in the movie *E.T.*[18] and dramatic increases in demand for the BMW Z3 automobile, evident by long waiting lists and the withdrawal of discounts for purchase, following the James Bond character's use of the car in the movie *Goldeneye.*[16,19,20] If on-screen smoking by a main character is associated with initiation of smoking among adolescents, this would indicate credible evidence that placement of cigarettes in movies is a successful marketing strategy to encourage minors to smoke.

We report results from a longitudinal study, conducted between 1996 and 1999, involving a representative sample of California adolescents who were initially aged 12 to 15 years. At baseline, adolescents who reported that they had never smoked were asked to nominate their 2 favorite male and female movie stars. The most popular stars' movies in the 3 years before baseline were reviewed, and whether or not the star smoked on-screen was recorded. Adolescent smoking status was reassessed 3 years later in a follow-up interview.

METHODS

The baseline sample for this study included 3104 never smokers aged 12 to 15 years who were interviewed as part of the 1996 California Tobacco Survey (CTS), a random-digit-dialing telephone survey of households in California. Versions of the CTS have been conducted approximately every 3 years since 1990. After separate funding was obtained in 1999, a letter was sent to each adolescent's original address introducing the follow-up survey. Verbal parental consent was obtained, and a telephone interview was scheduled for the adolescent. Completed follow-up interviews were available for 2084 adolescents (77% of the homes located), or 67% of the original sample.

All surveys were offered in either English or Spanish. Nonrespondents were more likely to be members of non-White ethnic groups (rates of nonresponse were 52.2% among African Americans and 21.6% among non-Hispanic Whites), to report average or below-average performance at school (rates of nonresponse were 49.8% among those who reported average or below-average school performance and 27.2% among those who reported performing better or much better than average), and to have family members who were smokers (rates of nonresponse were 37.2% among those exposed to familial smoking and 29.0% among those not exposed to familial smoking).

The adolescent surveys conducted at baseline and follow-up included questions (described previously[11]) focusing on demographic characteristics, exposure to smoking among family and friends, self-reported school performance, and receptivity to tobacco advertising and promotions. Other measures are described in the sections to follow.

Smoking

At baseline and follow-up, we asked respondents "Have you ever smoked a ciga-

rette?" and "Have you ever tried or experimented with cigarette smoking, even a few puffs?" A negative response to both questions at baseline classified an adolescent as a never smoker and as eligible for this analysis. The outcome in our analysis was any smoking by the follow-up survey, as indicated by a positive response to either of these 2 questions.

Smoking Status of Favorite Star

At baseline, adolescents were asked to name their 2 favorite female and 2 favorite male actors. Using each response as a separate observation, we ranked top 10 favorite male and female actors separately for male and female adolescents.[6] J.M. Distefan viewed all films (n=50) that featured these stars in the 3 years (1994–1996) before the baseline survey and classified each film according to whether or not the star smoked on-screen. As in a previous study of smoking in movies,[5] we conservatively required a star to smoke a cigarette in at least 2 of these movies before we labeled him or her as smoking on-screen.

Parental Disapproval of Smoking

At baseline, adolescents were asked "If you lit up a cigarette tomorrow in front of your parents, how do you think they would react?" Possible responses were as follows: (1) tell you to stop and be very upset, (2) tell you to stop and not be upset, (3) not tell you to stop but disapprove, and (4) have no reaction. Adolescents were also asked to either agree or disagree with the statement "When I'm older my parents won't mind if I smoke." Parental disapproval of adolescent smoking was categorized as adolescents (1) reporting that their parents would tell them to stop and be very upset in response to the first question and (2) disagreeing with the second statement.

Statistical Analysis

The various versions of the CTS involve complex designs that provide population estimates of behaviors and attitudes. Statistical weights account for design constraints and adjust for nonresponse. The 1996 weights were ratio adjusted (so that the group followed would be representative of the full sample and of the population) to the computed totals for all 1996 adolescent respondents (i.e., both followed and not followed) according to gender, age, ethnicity, school performance, and smoking status (any tobacco use in the previous 30 days). Next, these weights were further ratio adjusted to population totals for adolescent gender, age, ethnicity, state region, educational status of head of household, and whether head of household was a father or someone else. Information on population totals was derived from the 1996 Current Population Survey (demographic characteristics), the 1996 US census (county/region estimates), and the 1996 CTS household screener (head-of-household status). The weighted analyses we report allow our results to be generalized to the California adolescent population.

We computed variance estimates and 95% confidence intervals (CIs) using the jackknife procedure.[21] To evaluate demographic differences, we performed modified 2-tailed χ^2 tests.[22] We conducted logistic regression analyses to identify independent predictors of smoking by the time of the follow-up interview among adolescents who, at baseline, reported that they had never smoked. Interactions tested included a 3-way interaction of gender, receptivity to tobacco advertising and promotion, and smoking by a favorite star; 2-way interactions between receptivity and smoking by a favorite star; and interactions of the independent variables with adolescent age and gender. All analyses were conducted with the WesVar PC program,[23] which incorporates the jackknife technique.

RESULTS

On-Screen Smoking Status of Favorite Stars

Table 1 lists the names and movies of the favorite stars of male and female adolescent never smokers (baseline) who smoked on-screen during the period covered by the study. Brad Pitt was the most popular star among girls (nominated by 15%), and 9 of the 16 movies in which girls' favorite stars played a main character were rated PG-13. In the case of boys, only 4 of their favorite stars smoked on-screen; all were female actors, and all were starring in R-rated movies.

Respondents whose favorite stars smoked on-screen (34.6%) were more likely to be girls (39.2% vs 29.9%) and to be in their middle adolescent years (40.7% among those aged 14–15 years at baseline vs 29.5% among those aged 12–13 years at baseline). African American adolescents were less likely (10.5%) to name a star who smoked on-screen than were members of other groups (rates of 35.0% to 40.1%).

Favorite nominated stars who were classified as not smoking on-screen were Julia Roberts (named by 6% of girls and 2% of boys), Michelle Pfieffer (6% of girls and 5% of boys), Tom Cruise (12% of girls and 6% of boys), Tom Hanks (4% of girls and 3% of boys), Arnold Schwarzenegger (0% of girls and 12% of boys), Jim Carrey (3% of girls and 12% of boys), and Mel Gibson (4% of girls and 3% of boys).

Receptivity to Tobacco Advertising and Promotions

Since movie product placement is a tobacco marketing strategy, we compared receptivity to tobacco industry advertising and promotions with smoking on-screen on the part of adolescents' favorite actors (Table 2). In general, boys were much more likely than girls to be highly receptive to tobacco industry advertising and promotions. In the case of both genders, those who were minimally receptive to tobacco industry advertising and promotions were less likely to have favorite stars who smoked on-screen. Boys (but not girls) who were highly receptive to tobacco industry advertising and promotions were more likely to have a favorite star who smoked on-screen (36.5% vs 23.3%). The differences in adolescents' responses to the different marketing strategies according to gender suggested that interactions of influences on smoking initiation should be examined in the multivariate analysis.

Predicting Smoking at Follow-Up

Table 3 presents the results of the logistic regression analysis designed to identify predictors of smoking by the time of the follow-up interview among adolescents who were never smokers at baseline. Never smokers who had friends who smoked were approximately twice as likely to have smoked by the follow-up interview as those who reported no smoking among family or friends. Adolescents who were highly receptive to tobacco adver-

TABLE 1—Top 10 Favorite Film Stars and Titles of 1994–1996 Movies in Which They Smoked, by Popularity Among 12- to 15-Year-Old Adolescents: California, 1996

	Sample, No. (%)	Movie(s) in Which Actor Smoked (MPAA Rating)
Adolescent girls (n = 1040)		
Brad Pitt	159 (15.1)	*Legends of the Fall* (R)
		Sleepers (R)
Sandra Bullock	140 (12.2)	*In Love and War* (PG-13)
		The Net (PG-13)
		Speed (R)
		A Time to Kill (R)
Leonardo DiCaprio	100 (9.0)	*The Basketball Diaries* (R)
		Marvin's Room (PG-13)
		Romeo and Juliet (PG-13)
Winona Ryder	54 (4.7)	*How to Make an American Quilt* (PG-13)
		Reality Bites (PG-13)
Demi Moore	49 (4.3)	*The Juror* (R)
		Now and Then (PG-13)
Drew Barrymore	27 (2.3)	*Bad Girls* (R)
		Batman Forever (PG-13)
		Boys on the Side (PG-13)
		Mad Love (PG-13)
Adolescent boys (n = 1044)		
Pamela Anderson	121 (13.1)	*Barb Wire* (R)
		Best of Pamela Anderson (not rated)
Sandra Bullock	101 (8.9)	*In Love and War* (PG-13)
		The Net (PG-13)
		Speed (R)
		A Time to Kill (R)
Demi Moore	57 (4.7)	*The Juror* (R)
		Now and Then (PG-13)
Sharon Stone	38 (3.6)	*Casino* (R)
		Diabolique (R)
		Intersection (R)
		The Quick and the Dead (R)
		The Specialist (R)

Note. MPAA = Motion Picture Association of America. All percentages are weighted and adjusted for sampling design and nonresponse. Percentages do not sum to 100% because only stars who were classified as having smoked on-screen are listed.

tising and promotions were twice as likely as those who were minimally receptive to have smoked by the follow-up interview. Susceptibility to smoking demonstrated its usual independent and significant effect on future smoking (odds ratio [OR]=1.88; 95% CI=1.45, 2.43). Adolescents with a favorite star who smoked on-screen were also significantly more likely to have smoked by the follow-up interview (OR=1.36; 95% CI=1.02, 1.82). A significant interaction was observed between gender and favorite stars' on-screen smoking status (P=.01).

When the multivariate analysis was restricted to girls, having a favorite star who smoked on-screen increased the risk of smoking almost twofold (OR=1.86; 95% CI=1.26, 2.73). Figure 1 (top) displays the effects of favorite star smoking and receptivity to tobacco advertising among girls. Only 20% of adolescent girls initiated smoking if, at baseline, they were minimally receptive to tobacco advertising and their favorite movie star did not smoke on-screen. Conversely, more than 50% of girls who were highly receptive to advertising and promotions and had a favorite star who smoked on-screen initiated smoking. The results for boys, presented in the bottom panel of Figure 1, revealed few differences according to stars' smoking status. When the multivariate analysis was restricted to boys, smoking by the time of the follow-up interview was related to receptivity to tobacco industry advertising and promotions but not to having a favorite star who smoked on-screen.

DISCUSSION

The results of this longitudinal study indicate that smoking by stars in movies significantly increases the risk of future smoking among adolescent girls who have never smoked, independent of effects arising from other tobacco advertising and promotional practices. Adolescent girls who had a favorite star who smoked in movies released between 1994 and 1996, before the baseline survey, had more than 80% increased odds of smoking by the time of the follow-up interview relative to those whose favorite star did not smoke on-screen. The lack of effect among boys (as described subsequently) may, in part, be due to a stronger influence of their receptivity to other tobacco advertising and promotional practices.

There is a considerable literature suggesting that product placement in film is an effective way to promote behavior.[15–17] Substantial increases in sales have accompanied a number of product placements in movies.[15,24,25] The practice of product placement grew rapidly throughout the 1990s and is now common in virtually every big-budget Hollywood film.[26,27] The rapid diffusion of this practice has been attributed to the money that product placements offer movie studios, producers, and directors.[28] While it is compulsory that the tobacco industry comply with demands of the Federal Trade Commission (as per the Federal Cigarette Labeling and Advertising Act) for information on expenditures for product placement in movies, records suggest that no money was spent on these activities throughout the 1990s.[29] However, previously unreleased documents exposed in litigation

TABLE 2—On-Screen Smoking Status of Favorite Stars and Receptivity to Tobacco Advertising and Promotions, by Adolescent Gender (n = 2084)

Level of Receptivity in 1996	Girls, %		Boys, %	
	Favorite Actor Smoked (n = 423)	Favorite Actor Did Not Smoke (n = 617)	Favorite Actor Smoked (n = 308)	Favorite Actor Did Not Smoke (n = 736)
Minimal	6.2	15.2	2.0	8.3
Low	28.1	27.7	15.4	31.7
Moderate	49.3	41.0	46.1	36.8
High	16.5	16.1	36.5	23.3
P	<.01		<.01	

Note. Percentages are weighted and adjusted for sampling design and nonresponse.

TABLE 3—Logistic Regression Analysis Predicting Smoking by the 1999 Follow-Up Interview Among Adolescent Never Smokers at Baseline (n = 2084)

Independent Variable in 1996	No. (%)	Smoking by 1999, OR (95% CI)
Gender		
Female	1040 (29.5)	1.00
Male	1044 (33.7)	1.18 (0.90, 1.56)
Exposure to smokers		
Not exposed to friends or family who smoke	918 (21.7)	1.00
Exposed to family who smoke, but not friends	322 (29.1)	1.34 (0.93, 1.97)
Exposed to friends who smoke, but not family	513 (40.7)	1.99 (1.50, 2.64)
Exposed to both friends and family who smoke	331 (45.8)	2.25 (1.54, 3.28)
Susceptibility to smoking		
Committed never smoker	951 (21.9)	1.00
Susceptible to smoking	1133 (39.2)	1.88 (1.45, 2.43)
Parental disapproval of smoking		
Disapprove	1798 (30.7)	1.00
Do not disapprove	286 (36.1)	0.99 (0.68, 1.44)
Receptivity to tobacco advertising and promotions		
Minimal	177 (19.6)	1.00
Low	563 (24.7)	1.17 (0.69, 2.00)
Moderate	931 (38.9)	1.34 (0.76, 2.35)
High	413 (45.1)	1.99 (1.07, 3.72)
Favorite star on-screen smoking status		
Favorite star does not smoke	1353 (27.6)	1.00
Favorite star smokes	731 (39.2)	1.36 (1.02, 1.82)

Note. CI = confidence interval. Percentages are weighted and adjusted for sampling design and nonresponse. Odds ratios (ORs) are weighted and adjusted for age, ethnicity, school performance, and all of the other variables shown.

against the tobacco industry clearly indicate that the practice occurred.[12]

We classified 41% of girls and 30% of boys in California who had never smoked in 1996 as having a favorite movie star who smoked on-screen. This is a very conservative estimate in that we considered the films of only the most nominated stars; we also required at least one of an adolescent's favorite stars to smoke in at least 2 film releases in the 3 years before the baseline survey before we classified the adolescent as having a favorite star who smoked on-screen. These criteria would be expected to significantly underestimate exposure levels and to bias the analysis toward finding no effect of on-screen smoking among movie stars.

There are several possible explanations for the lack of effect among boys. Although genre was not coded in this study, the lack of effect for boys may reflect gender differences in film genre preferences. Previous research has shown that female adolescents prefer movies characterized as romances/dramas,[30,31] which tend to contain high levels of star smoking,[32] and male adolescents prefer action/adventure films,[30,31] which tend to involve lower levels of star smoking.[32] This effect was also seen in our study. Brad Pitt smoked repeatedly in dramatic films and was nominated by female adolescents, and Pamela Anderson smoked less frequently in an action film and was nominated by male adolescents.

Boys nominated female actors who smoked in R-rated films. Leading female actors are more likely to smoke in films aimed at young audiences (i.e., films rated PG and PG-13) than in R-rated movies.[33] Indeed, some public health advocates have voiced their concern about the high prevalence of smoking in PG-13 movies as a reason for adding smoking to the criteria for rating movies.[34]

The lack of effect seen among boys may also be related to the time period covered by this study. In 1996, the tobacco industry's use of promotional items to promote smoking peaked, before being limited by the Master Settlement Agreement reached between the tobacco industry and the states' attorneys general in 1998. Without the high receptivity to promotional items seen among adolescent boys in 1996, smoking by actors might have been more strongly associated with increased smoking initiation on the part of boys. Conversely, if girls were more receptive to industry promotional activities, the effect of product placement in movies may have been diminished.

At baseline, African American adolescents were less likely than other adolescents to nominate a star who smoked on-screen during the study period, and notably our review did not identify any favorite African American actor who smoked on-screen. This suggests that the tobacco industry was not trying to associate cigarettes with favorite African American actors (Whitney Houston, Wesley Snipes, and Will Smith) during the study pe-

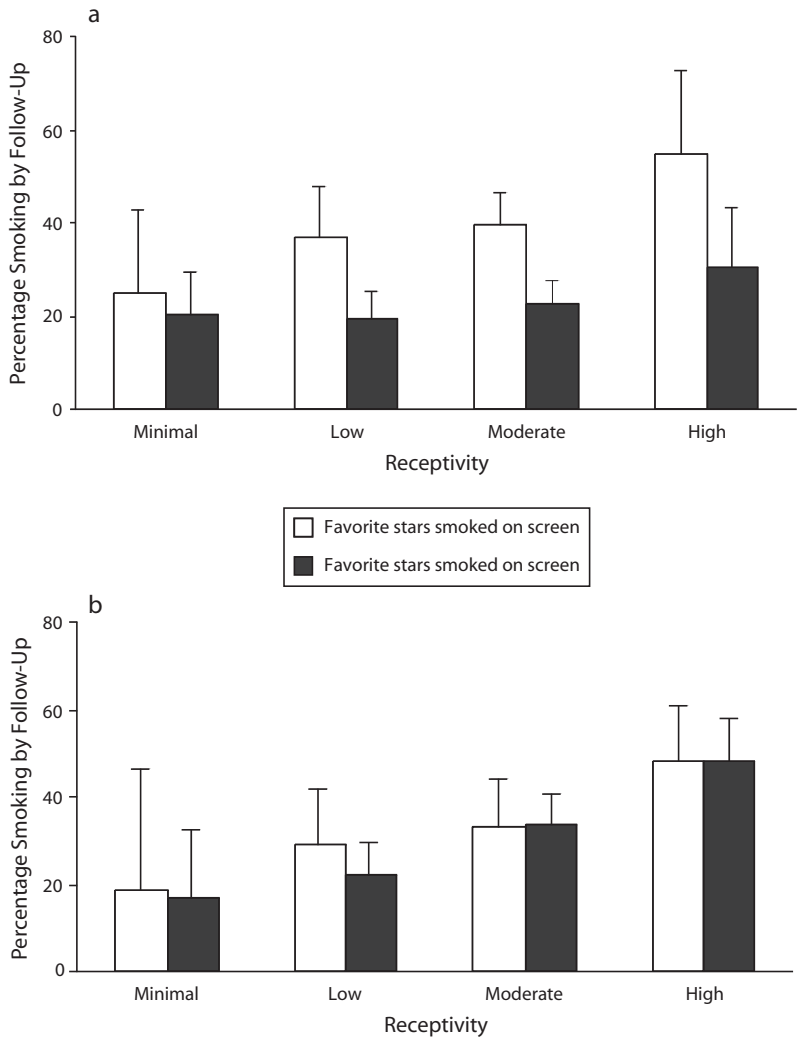

FIGURE 1—Rates of smoking by the 1999 follow-up survey, by baseline (1996) receptivity to tobacco advertising and promotions and favorite stars' on-screen smoking status: California (a) adolescent female (n = 1040) and (b) adolescent male (n = 1044) never smokers.

riod, although soon after this period Will Smith smoked cigars repeatedly in the film *Independence Day*. The study period occurred at the end of more than a decade of declining trends in smoking among African American adolescents.[35]

Limitations

The findings of this study are limited by its response rate. At baseline, we did not seek a commitment to the follow-up study or collect contact information to aid in tracing. Rather, at the time of the second survey, we sought to locate the original respondents and once again obtain parental consent. The vast majority of the nonrespondents did not reside at the same address, and we were unable to locate some of these adolescents. This group differed from respondents at baseline in that they exhibited a higher number of risk factors for later smoking, which would have reduced our study's power to detect associations with smoking onset rather than invalidating positive findings. We examined the effects of on-screen smoking by popular movie stars. It is important that future studies code how actors use cigarettes and that more than one reviewer undertake coding.

Conclusions

This study provides evidence that smoking by movie stars can play an important role in encouraging female adolescents to start smoking. The gender difference in impact of on-screen smoking by favorite actors suggests that more research is needed to identify whether the effect on adolescent initiation is linked to how smoking is portrayed in movies. However, our data strongly suggest that levels of smoking in movies may undermine other public health tobacco control efforts and need to be monitored carefully. Interventions designed to discourage actors from smoking in movies and to limit adolescent exposure to smoking in movies should have a high public health priority. ■

About the Authors

At the time the research for this article was completed, Janet M. Distefan was with the Cancer Prevention and Control Program, Cancer Center, University of California, San Diego. John P. Pierce and Elizabeth A. Gilpin are with the Cancer Prevention and Control Program, Cancer Center, University of California, San Diego.

Requests for reprints should be sent to John P. Pierce, PhD, Cancer Prevention and Control Program, Cancer Center, University of California, San Diego, La Jolla, CA 92093-0645 (e-mail: jppierce@ucsd.edu).

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Contributors

J.M. Distefan performed the analysis for this study, J.P. Pierce created the analysis plan, and E.A. Gilpin reviewed the analysis plan. All of the authors were involved in writing the article.

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Human Participant Protection

This research was approved by the institutional review board of the University of California, San Diego. Also,

informed consent was obtained for the surveys in accordance with the guidelines of that board.

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Evaluating the Effectiveness of Public Health Leadership Training: The NEPHLI Experience

Shadi S. Saleh, PhD, MPH, Dwight Williams, MSW, and Modinat Balougan, MPH

Objectives. We assessed the effect of public health leadership training on the capacity of public health leaders to perform competencies derived from the list of "Ten Essential Public Health Services" presented in 1994 by the steering committee of the Public Health Functions Project.

Methods. Graduating scholars of the Northeast Public Health Leadership Institute were surveyed to determine differences in skill level in 15 competency areas before and after training. Surveys were completed after program completion.

Results. The training program improved the skill levels of participants in all 15 competency areas. A relation also was detected between the frequency of use of the competency and the improvement experienced.

Conclusions. Public health leadership training programs are effective in improving the skills of public health workers. (*Am J Public Health.* 2004;94: 1245–1249)

The aftermath of the September 11, 2001, terrorist attacks and the threat of further attacks by biological means have taken public health out of the shadows and cast it in a more visible role in protecting the nation.[1] However, these threats have only compounded the need for an effective public health infrastructure, of which a competent leadership is an important element. Major changes, including managed care approaches to health care and changing demographics, are also affecting public health and require attention. Moreover, because public health agencies provide population-focused services to entire communities rather than individualized care,[2] an increased need exists for public health personnel capable of leading efforts to ensure the effectiveness and quality of these services.

These existing and emerging responsibilities are presenting a challenge to the public health field to reevaluate and improve the competencies of its workforce. The need for competency building has been expressed by many who think that ongoing training in specific skill areas would better prepare public health practitioners and leaders to be more effective in responding to ever-changing public health challenges.[3] Among these specific skill areas frequently mentioned are management and leadership competencies. Findings from a 1997 study showed that 78% of local public health leaders lacked public health graduate education, and many reported limited opportunities for continuing education.[4] Porter et al.[5] noted that the Institute of Medicine's 1988 report, *The Future of Public Health,* alluded to the need for managerial and leadership training.[6] Other studies cited a similar need and recommended that public health professionals be trained in several management and leadership competency areas.[7,8]

As a direct result of this obvious need for training, the public health field is witnessing a major effort by public health leaders to understand their roles and develop the knowledge and skills necessary to perform much-needed services.[8] However, the multidisciplinary nature of public health requires training in a multitude of competency areas.[2] For example, studies have shown that successful efforts that were aimed at improving management skills of public health administrators have included a wide array of management-related topics.[5] This notion of multidisciplinary training has been enforced by the list of "Ten Essential Public Health Services" presented in 1994 by the steering committee of the Public Health Functions Project in a consensus statement titled *Public Health in America.*[9] The list included community-oriented services that require an able public health workforce, as an infrastructure, with basic public health science, analytic, communication, and program planning and policy development skills and knowledge.

The Northeast Public Health Leadership Institute (NEPHLI) provides such comprehensive leadership training. Affiliated with the University at Albany School of Public Health and the New York State Health Department, NEPHLI fulfills the need for closer ties between schools of public health and health departments outlined in the report presented by the Pew Health Professions Commission.[10,11] NEPHLI is part of a network of public health leadership institutes developed across the United States. It provides training that consists of a year-long experiential program aimed at building and improving the leadership skills of current and future public health practitioners. Participating scholars gain practical experience from experts in a variety of fields. Topics covered include influencing others, measuring and improving public health performance, developing collaborative relationships and partnerships, risk communication, team building, group problem solving, responding to the needs for cultural diversity and competence, and emergency preparedness training. The primary aim of NEPHLI is to train emerging leaders from state and local public health departments and allied public and private organizations to broaden their vision of public health policy, practice, and collaboration and to foster improved decision-making within their organizations. NEPHLI provides training to practitioners from Maine, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, and Vermont.

The purpose of this study was to assess the effect of leadership training on a set of competencies derived from the "Ten Essential Public Health Services" outlined in the *Public Health in America* consensus statement.

METHODS

Survey and Study Participants

The survey was designed to assess the effect of NEPHLI on the scholars' competencies related to the "Ten Essential Public Health Services" outlined in the *Public Health in America* consensus statement.[9] The competency areas examined in the study were tailored to reflect the mission and goals of NEPHLI. Fifteen competency areas were developed with an emphasis on leadership and administrative skills and knowledge. Each of the 15 items asked respondents to rate their competency level before and after receiving NEPHLI training, as well as the frequency of their use of each of the competencies. Responses were rated on an ordinal scale (1=low, 5=high).

The study population included all 114 NEPHLI scholars who graduated from the program in the years 1998 through 2001. A list containing contact information for all NEPHLI scholars (1998–2001) was developed. Follow-up contacts were made via telephone, e-mail, and regular mail. Some scholars were not contacted because current contact information was not available.

Analysis

The change in the level of each of the 15 competency areas before and after participating in the leadership training program was used to measure improvement (or decline). Student *t* tests were used to examine the statistical significance of these changes.

Another comparison was aimed at examining changes in the competency levels by frequency of use. Because of the relatively small sample size, the frequency of use of each of the competency areas was recoded into "high" (fairly often, very often) or "low" (sometimes, once in a while, never) use. The associations were tested for significance with *t* tests. Also examined was the relation between the scholar's occupational position and the change in competency level. Positions were classified as "director/assistant director" or "other."

To further analyze changes in competency levels, the study examined the change in the percentage of respondents who considered their skill level as "high" before and after the training program. Chi-square tests were used to assess whether the proportions were significantly different. The association between frequency of use of the competency and the proportion of scholars with "high" skill levels also was tested with χ^2, as was the job position of the scholars.

RESULTS

The 114 study participants represented NEPHLI scholars from the classes of 1998, 1999, 2000, and 2001. There were 32 scholars from the class of 1998, 30 from the class of 1999, 30 from the class of 2000, and 24 from the class of 2001. Two scholars did not complete their year-long training and were not part of the evaluation. Women constituted more than half of the study cohort (69.3%). Sixty percent of the respondents had a master's degree, of which one fifth possessed MPH degrees. A combined total of 15% had doctoral degrees in public health, medicine, philosophy, education, or nursing. Six percent of this group had MPH and doctoral degrees. Ninety-nine percent of the scholars were at least middle managers, identified for study purposes as directors or assistant directors. This cohort also included assistant commissioners and county health officers. Of the 114 scholars who completed training during the period 1998 through 2001, 81 (71.1%) responded.

Change in Competency Levels

Descriptive statistics on the skill level before and after the training program are presented in Table 1. As mentioned earlier, the responses ranged from high (5) to low (1). The results showed that scholars reported a significant improvement in their skill levels in all 15 competency areas examined.

The greatest improvements were reported in the scholars' ability to "cope with and lead changes in public health practice" (an improvement in the mean score from 3.0 to 4.0) ($P<.001$) and "use the media and other forums to inform, educate, and empower people about health issues" (an improvement in the mean score from 2.7 to 3.7) ($P<.001$). Smaller improvements were detected in the scholars' ability to "communicate clearly and effectively public health laws and regulations" (2.9 to 3.5) ($P<.001$), "accurately and effectively communicate information to a professional and a lay audience" (3.4 to 4.0) ($P<.001$), and "use visual representations of data to identify public health problems" (3.1 to 3.7) ($P<.001$).

Change in Competency Levels by Frequency of Use and Position

The association between the change in competency level and its frequency of use is presented in Table 2. Respondents who had a low frequency of use of "dealing with cultural and ethnic diversity in the context of access to health services" had a greater improvement in their skill level than did those who used it more frequently (1.0 vs 0.5) ($P<.05$). On the contrary, those who used the ability to "understand the administrative, social, and political implications of alternative policy options" more frequently achieved a greater improvement in that skill level (1.0 vs 0.5) ($P<.01$).

No association between the position of the scholar and changes in competency levels was evident (Table 3). A marginally significant relation was detected that showed that respondents who were not directors or assistant directors had a greater improvement in their ability to "understand the administrative, social, and political implications of alternative policy options" (1.0 vs 0.7) ($P=.05$). It is worth noting that the analysis of the association between position and frequency of use of competencies found a strong association between both in several competency areas examined. Directors were more likely to use these competencies than were "nondirectors."

Change in the Proportion of High-Skill Scholars

Analysis was also done to examine the proportion of scholars reporting a high skill level before and after NEPHLI training. The results showed a significant increase in the proportion of respondents with high skill levels in all 15 competency areas examined (Figure 1).

Further analysis of the relation between frequency of use and change in the proportion of high-skill-level scholars showed a significant increase in the latter who more frequently used the skills to "communicate clearly and effectively public health laws and

TABLE 1—Change in Competency Levels Among the Study Respondents

Competency	Competency Level, Mean (SD)	
	Before Training	After Training
Cope with and lead changes in public health practice*	3.0 (0.9)	4.0 (0.6)
Match the skills and knowledge of public health workers with appropriate tasks*	3.0 (0.8)	3.7 (0.8)
Deal with cultural and ethnic diversity in the context of access to health services*	3.1 (1.0)	3.8 (0.7)
Mobilize resources in the community needed to increase access to public health services*	2.8 (0.9)	3.5 (0.7)
Communicate clearly and effectively public health laws and regulations*	2.9 (0.9)	3.5 (1.0)
Advocate for the enforcement of laws and regulations pertaining to public health*	2.9 (1.0)	3.6 (0.9)
Understand the administrative, social, and political implications of alternative policy options*	2.9 (0.9)	3.8 (0.9)
Work with, coordinate, and/or lead community efforts to address public health problems*	3.1 (0.8)	3.9 (0.7)
Build strong and ongoing relationships with the community*	3.3 (0.9)	4.0 (0.8)
Interact, inform, and educate individuals from diverse cultural, socioeconomic, educational, and professional backgrounds*	3.3 (0.9)	4.0 (0.8)
Use the media and other forums to inform, educate, and empower people about health issues*	2.7 (0.8)	3.7 (0.8)
Collaborate with colleagues and the community to manage and investigate public health problems*	3.3 (0.9)	4.2 (0.6)
Accurately and effectively communicate information to a professional and a lay audience*	3.4 (0.8)	4.0 (0.6)
Lead and participate in groups to identify public health problems*	3.1 (0.8)	4.0 (0.6)
Use visual representations of data to identify public health problems*	3.1 (0.9)	3.7 (0.7)

*$P < .001$.

TABLE 2—Change in Competency Level, by Frequency of Use, Mean (SD)

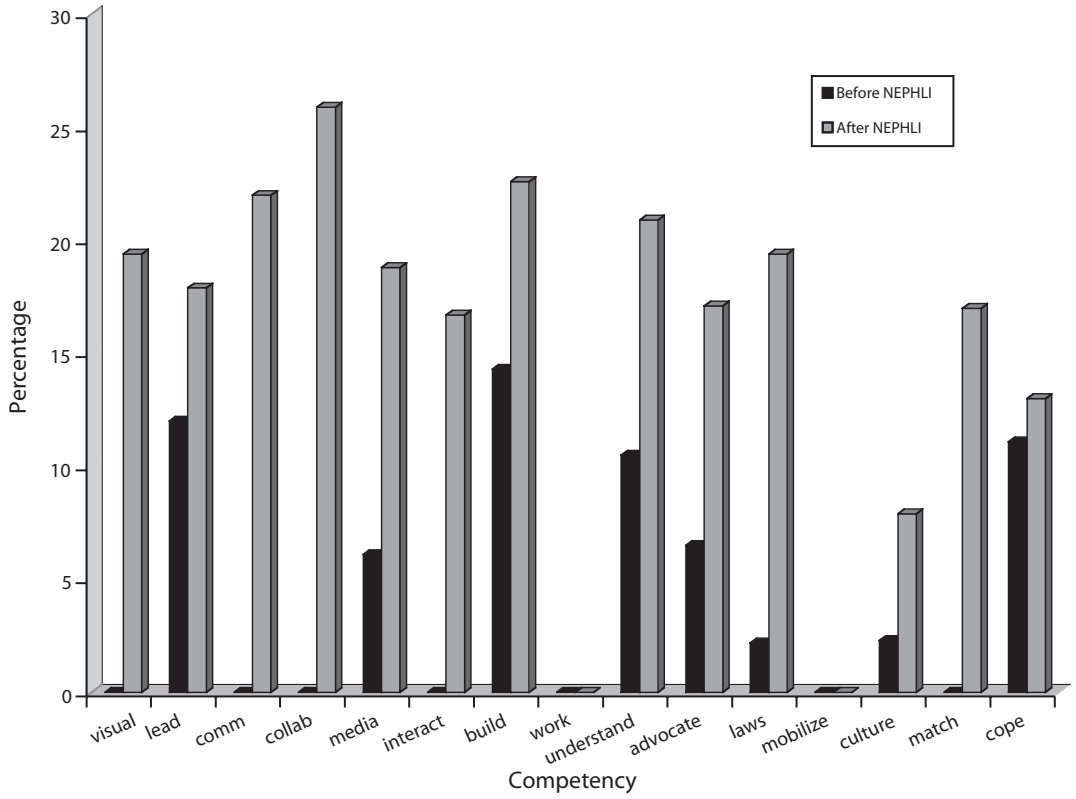
Competency	Low Frequency	n	High Frequency	n
Cope with and lead changes in public health practice*	1.2 (1.1)	13	0.9 (0.6)	68
Match the skills and knowledge of public health workers with appropriate tasks	0.7 (0.7)	18	0.7 (0.7)	63
Deal with cultural and ethnic diversity in the context of access to health services*	1.0 (0.9)	17	0.5 (0.7)	64
Mobilize resources in the community needed to increase access to public health services	0.7 (0.8)	23	0.7 (0.7)	56
Communicate clearly and effectively public health laws and regulations	0.5 (0.8)	19	0.7 (0.7)	61
Advocate for the enforcement of laws and regulations pertaining to public health	0.9 (0.9)	24	0.7 (0.7)	55
Understand the administrative, social, and political implications of alternative policy options**	0.5 (0.5)	16	1.0 (0.6)	65
Work with, coordinate, and/or lead community efforts to address public health problems	0.8 (0.7)	17	0.8 (0.7)	64
Build strong and ongoing relationships with the community	0.9 (0.7)	15	0.6 (0.6)	66
Interact, inform, and educate individuals from diverse cultural, socioeconomic, educational, and professional backgrounds	0.4 (0.5)	11	0.6 (0.7)	70
Use the media and other forums to inform, educate, and empower people about health issues	1.1 (0.9)	24	1.0 (0.7)	56
Collaborate with colleagues and the community to manage and investigate public health problems	0.9 (0.6)	8	0.9 (0.8)	71
Accurately and effectively communicate information to a professional and a lay audience	0.7 (0.7)	9	0.6 (0.6)	70
Lead and participate in groups to identify public health problems	1.2 (0.8)	6	0.9 (0.6)	75
Use visual representations of data to identify public health problems*	0.4 (0.6)	20	0.8 (0.8)	61

*$P < .05$; **$P < .01$.

regulations"; "use visual representations of data to identify public health problems"; "collaborate with colleagues and the community to manage and investigate health problems"; "interact, inform, and educate individuals from diverse cultural, socioeconomic, educational, and professional backgrounds"; "accurately and effectively communicate information to a professional and a lay audience"; and "match the skills and knowledge of public health workers with appropriate tasks." However, the analysis showed no association between the type of position and the change in the proportion of high-skill-level participants.

DISCUSSION

Until recently, the public health field has been quietly playing its role in addressing public health problems. However, recent events added to that role and placed public health at the center of the nation's efforts to



Note. visual = use visual representations; lead = lead and participate; comm = communicate; collab = collaborate; NEPHLI = Northeast Public Health Leadership Institute.

FIGURE 1—Percentage of scholars reporting high skill level before and after leadership training.

TABLE 3—Change in Competency Levels by Position

Competency	Position	
	Director or Assistant Director (n = 40)	Others (n = 41)
Cope with and lead changes in public health practice	0.9 (0.7)	1.0 (0.8)
Match the skills and knowledge of public health workers with appropriate tasks	0.7 (0.6)	0.7 (0.7)
Deal with cultural and ethnic diversity in the context of access to health services	0.5 (0.7)	0.7 (0.8)
Mobilize resources in the community needed to increase access to public health services	0.8 (0.7)	0.6 (0.7)
Communicate clearly and effectively public health laws and regulations	0.6 (0.7)	0.6 (0.7)
Advocate for the enforcement of laws and regulations pertaining to public health	0.8 (0.7)	0.7 (0.8)
Understand the administrative, social, and political implications of alternative policy options	0.7 (0.5)	1.0 (0.7)
Work with, coordinate, and/or lead community efforts to address public health problems	0.9 (0.6)	0.8 (0.8)
Build strong and ongoing relationships with the community	0.6 (0.6)	0.7 (0.7)
Interact, inform, and educate individuals from diverse cultural, socioeconomic, educational, and professional backgrounds	0.5 (0.6)	0.6 (0.7)
Use the media and other forums to inform, educate, and empower people about health issues	1.0 (0.8)	1.0 (0.8)
Collaborate with colleagues and the community to manage and investigate public health problems	0.9 (0.7)	0.9 (0.8)
Accurately and effectively communicate information to a professional and a lay audience	0.6 (0.5)	0.7 (0.7)
Lead and participate in groups to identify public health problems	0.9 (0.6)	0.9 (0.7)
Use visual representations of data to identify public health problems	0.6 (0.7)	0.7 (0.8)

improve its readiness. Such a responsibility enhanced the need to upgrade the public health infrastructure. Developing qualified and able public health leaders is a critical step in building the infrastructure needed to address public health challenges.

In 1988, the Institute of Medicine report, *The Future of Public Health,* noted the importance of public health leadership development. This culminated in the Centers for Disease Control and Prevention establishing the National Public Health Leadership Institute and subsequently funding state and regional leadership institutes.

This study examined the effectiveness of a leadership training program in improving the skills of its graduates. Results showed that the program improved the skill levels of the scholars in all of the 15 competencies examined, which were derived from the "Ten Essential Public Health Services" outlined in the *Public Health in America* consensus statement. The greatest improvements were observed in the ability to cope and lead changes in public health practice and to use the media and other forums to inform, educate, and empower people about health issues. These 2 skills are relevant more than ever given the challenges that confront the public health workforce.

The results also found an association between the frequency of use and improvement in the skill levels for certain competencies. Such a relation highlights the importance of tailoring leadership programs to participants' interests and needs. Individual leadership institutes will have to tailor the curriculum to respond to the needs of its constituents. For example, leadership training for public health workers located in areas with a high representation of minorities should highlight cultural and ethnic sensitivity topics. Leadership training in areas with a higher risk of terror attacks may consider concentrating training on mobilizing resources and collaboration with other public health and non–public health agencies and groups.

In conclusion, leadership development is an essential element in the nation's efforts to improve the public health infrastructure. Training of public health professionals must incorporate leadership skills and knowledge to augment the overall competency of the workforce. ■

About the Authors

The authors are with the School of Public Health, State University of New York at Albany. Dwight Williams is also with the Northeast Public Health Leadership Institute, School of Public Health, State University of New York at Albany.

Requests for reprints should be sent to Shadi S. Saleh, PhD, MPH, School of Public Health, SUNYA, One University Pl, Rensselaer, NY 12144 (e-mail: ssaleh@albany.edu).

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Contributors

S.S. Saleh and D. Williams planned and directed the study and wrote the article. M. Balougan conducted the literature review, helped in the data analysis, and contributed to the writing of the article.

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Geographic Clustering of Adult Asthma Hospitalization and Residential Exposure to Pollution at a United States–Canada Border Crossing

Tonny J. Oyana, PhD, Peter Rogerson, PhD, and Jamson S. Lwebuga-Mukasa, MD, PhD

Objectives. We conducted a case–control study of adulthood asthma and point-source respirable particulate air pollution with asthma-diagnosed case patients (n = 3717) and gastroenteritis-diagnosed control patients (n = 4129) to determine effects of particulate air pollution on public health.

Methods. We used hospitalization data from Buffalo, NY, neighborhoods for a 5-year period (1996 through 2000), geographic information systems techniques, the Diggle method, and statistical analysis to compare the locations of case patients and control patients in terms of proximity to different known pollution sources in the study area.

Results. We found a clustering of asthma cases in close proximity to the Peace Bridge Complex and the freeways and a dose–response relationship indicating a decreased risk of asthma prevalence the farther an individual resides from the source of exposure.

Conclusions. These findings provide a basis for the development of new hypotheses relating to the spatial distribution of asthma prevalence and morbidity in this community. (*Am J Public Health*. 2004;94:1250–1257)

Buffalo's West Side contains the Peace Bridge Complex (PBC), the busiest US–Canada crossing point for commercial traffic in the eastern United States. Over the past decade, there has been a steady increase in commercial traffic primarily owing to the increased trade resulting from the North American Free Trade Agreement (NAFTA).[1] Increased asthma prevalence and health care use resulting from traffic-related pollution around the US–Canada border crossing point has been a major focus of previous studies.[2–7] These studies have provided evidence supporting the hypothesis that there is a high respiratory burden among residents living in close proximity to the NAFTA corridor.

The PBC is located in a densely populated, urban, and predominantly minority community. Although the increased traffic through the PBC has brought economic prosperity to the United States, Canada, and Mexico, the health effects of NAFTA trade associated with traffic pollution in the communities along the US–Canada border have not been extensively studied. A recent report on health effects in NAFTA corridors[8] concluded that commercial traffic contributes significantly to air pollution in all NAFTA corridors, particularly to nitrogen dioxide and particulate matter, but the report did not include the PBC. Diesel exhaust particles have been shown to worsen respiratory symptoms and to lead to deterioration in lung function, especially among individuals with preexisting chronic conditions such as asthma.[9–12]

Previous studies, such as those by Schwartz and Dockery,[9,10] Dockery et al.,[13] Schwartz,[14,15] Schwartz and Morris,[16] Styer et al.,[17] Norris et al.,[18] Wong et al.,[19] Samet et al.,[20] and Peters et al.,[21] have reported an association between cardiopulmonary morbidity and mortality and exposure to respirable particulate matter. In a groundbreaking study, the United States Environmental Protection Agency (EPA) concluded that long-term inhalation exposure to diesel exhaust particles is likely to pose a lung damage threat, including a risk for cancer, to humans.[22] The study further noted that short-term exposures can cause irritation and inflammatory symptoms of a transient nature.[22]

In previous studies, we reported an increased risk of asthma among residents living along the US–Canada border crossing and the major roadways feeding it. An association between increases in commercial traffic across the PBC and increases in health care use for asthma was reported in Lwebuga-Mukasa et al.[23] A sharp decrease in traffic after the September 11, 2001, World Trade Center terrorist attacks was associated with a decline in health care use for respiratory illnesses, which rebounded when traffic recovered.[7] A house-to-house survey of 214 homes in the area (from 1996–1997) and another of 1644 homes (in 2002) found households in close proximity to the PBC to have asthma prevalence rates that were double those of households located on Buffalo's East Side (J.S. Lwebuga-Mukasa, MD, PhD, unpublished data).[6] These observations indicate that increased traffic on Buffalo's West Side may be associated not only with asthma exacerbations but also with increased prevalence in the community.

Cumulative evidence is also emerging from studies reviewed in Peterson and Saxon,[24] Kane et al.,[25] Lwebuga-Mukasa and Dunn-Georgiou,[2,3,26] Lwebuga-Mukasa and Pszonak,[4] and Lin et al.[5] showing a higher respiratory burden on the communities residing in Buffalo's West Side than on the surrounding communities. However, there is little focus on the spatial relationships between increased risk of asthma and environmental exposure. In this study, we investigate the hypothesis that proximity to the major commercial routes; the PBC; and EPA-designated toxic air release sites and multiple-emission sites are associated with increased asthma risk. Characterization of environmental and human characteristics of clusters would provide a basis for identification of factors contributing to an increased asthma burden in the community and to the development of mitigation measures.

FIGURE 1—Resident locations of case patients and control patients, network of major roads, and focus sites in the study area.

METHODS

Study Area and Population

The study area covered 156 census tracts with an estimated population of 529 846 people in Erie County, according to the 2000 population data obtained from the US Census Bureau.[27] About 40% of the study population was between 18 and 64 years of age. The study area includes inner-city areas characterized by low socioeconomic status, poor housing conditions, low education levels, high unemployment, and high percentages of minority population.[27] Figure 1 shows resident locations of case patients and control patients, the network of major roads, and focus sites in the study area.

Study Design

A cross-sectional study based on case–control data for adulthood asthma (case patients) and nonrespiratory disease (control patients) for a 5-year period (1996–2000) was conducted using hospitalization data. Case subjects (n=3717) and control subjects (n=4129) consisted of asthma patients (*International Classification of Diseases, 9th Revision* [*ICD-9*] code 493)[28] and gastroenteritis patients (*ICD-9* code 558), respectively, residing in Buffalo neighborhoods during the same period. The study was based on a database that was obtained from Kaleida Health Systems, a major provider of health care in western New York. The data were available at individual and zip code levels. Data with residential addresses was separated, processed, and geocoded for use in spatial analysis and a geographic information systems (GIS). At the census tract level, we analyzed cases patients per population and identified local asthma clusters. At the zip code level, a comparison of case patients and control patients was conducted to identify which zip codes had an elevated risk of asthma. We also conducted a field assessment of the previously identified focus sites.

Data Categories

The 3 data categories analyzed in this study are as follows: hospitalization and outpatient visits for asthma, 1996 through 2000; hospitalization and outpatient visits for gastroenteritis, 1996 through 2000; and focus sites. The data categories are described in detail in the following sections.

Hospitalization and outpatient visits for asthma, 1996 through 2000. The hospitalization and outpatient visits data were based on the patient records of kept by Millard Fillmore Health Hospitals, which are divisions of the Kaleida Health System, and covered admissions from January 1996 to August 2000. Some of these data have been published in Lwebuga-Mukasa et al.[6] and in Oyana and Lwebuga-Mukasa.[30] The records contained the residential addresses of patients and their insurance status. The data were vital for the identification of spatial relationships between case address locations and polluting sources.

Hospitalization and outpatient visits for gastroenteritis, 1996 through 2000. Data on hospitalization and outpatient visits for gastroenteritis were obtained from the same source for the same time period. The database contained information on the case patients, including the patient's address and insurance status. The case patients were also categorized into 2 groups: clinical and emergency department cases. Gastroenteritis was used as the control disease. Only cases detected from 1996 through 2000 among residents of the study area were included in the case–control study.

Focus sites. Focus sites were previously obtained from the EPA Web site (http://www/epa.gov/enviro/index.html) and mapped as point data, as shown in Figure 1. Three focus sites identified in Oyana and Lwebuga-Mukasa[29] were of primary interest, given their statistically significant association with increased risk for asthma, and 10 additional sites were also included. Six of these additional sites were test sites used in the validation of the model. The test sites were chosen randomly, outside of the statistically significant distance bands. However, the 13 focus sites used in this study do not constitute an exhaustive list of possible exposure sites in the study area.

We conducted a preliminary field assessment of the 3 sites (Birge Company, Ogrady Winnifred Silver, and Marnap Industries) to further our understanding of their surroundings in the study area. A working assumption was developed after finding out that 2 of the 3 focus

sites had gone out of business, thereby attracting new business opportunities and developments in their original locations. We agreed that the focus sites represented air pollution in the preceding decade, when exposures might have occurred. This assumption seems reasonable for air pollution sources that have been in operation since the 1980s and whose dispersal is mediated by transport mechanisms (e.g., prevailing winds) that have not changed a great deal in the past 10 to 20 years.

Three additional sites (Miken Company, Nabisco Company, and Harrison Radiator) that are currently in operation and that have active licenses were obtained from the Department of Environmental Conservation, Buffalo. We also conducted a preliminary field assessment of these 3 sites that confirmed that the sites were functional.

Analytical Techniques

Rigorous analytical methods were applied to the case–control data to study whether there is an association between increased risk of asthma and pollution sources. The Diggle method was applied to test disease clustering of asthma around the focus sites.[30,31]

The Diggle method is a focused cluster-detection approach appropriate for handling spatial data at the individual level.[31,32] The method compares the spatial pattern of case locations with the spatial pattern of control locations; for instance, using a more common control disease. The control acts as a null model of no clustering and normally reflects the spatial pattern of the population-at-risk. The test is based on maximizing the likelihood of the sample of case patients and control patients, which in turn is based on an exponential decline in risk as the squared distance from the source increases.

GIS techniques combined with statistical analysis were used to compare odds ratios (ORs) for the location of case patients and control patients in relation to proximity to different pollution sources in the study area. The choice of these analytical techniques was based on their wide applications in studying patterns of disease, prevalence, health care use, and incidence. These techniques have also been widely popularized by the development of the ClusterSeer[32] (TerraSeer, Inc, Ann Arbor, Mich) and ARCGIS[33] (Environmental Systems Research Institute [ESRI], Inc, Redlands, Calif) software packages, which handle large volumes of geographical data.

ClusterSeer Version 1.1.4 (TerraSeer); ArcStreet USA, ARCGIS 8.1.2, and ARCVIEW 8.1 (ESRI); and Microsoft Excel (Microsoft, Inc, Redmond, Wash) software packages were used in spatial analysis, GIS mapping, and data analysis. All of the data were compiled and analyzed at the Center for Asthma and Environmental Exposure, Kaleida Health Buffalo General Division, University at Buffalo School of Medicine and Biomedical Sciences.

The data were also loaded into ARCStreet USA to match the physical addresses with geographical latitudes and longitudes. ARCStreet USA contains the most up-to-date street addresses in the United States. Address matching was based on the Dynamap/Zip+4 Centroids and Correspondences Files (Geographic Data Technology, Inc, Lebanon, NH). Geographic Data Technology provided this comprehensive street database to ESRI. Case patients' and control patients' addresses were mapped as point data. We had 2340 and 2571 case and control patients, respectively, with matched addresses. We obtained an accuracy level of over 90% during the address-matching exercise. The geocoded data were processed in ARCGIS 8.1.2 for further spatial analysis.

It was assumed that those who lived within 1 km of the emission sites and busily traveled roadways were exposed to vehicle exhaust fumes and pollutants from suspected sources of pollution, and that those living farther away (>2 km) were assumed to be unexposed. Rijnders et al.[34] recommended that variables such as degree of urbanization, traffic density, and distance to a nearby highway or any potential pollution source can be used to estimate exposure to traffic-related air pollution. Milligan et al.[35] also used a distance of more than 2 km in their study to estimate exposure resulting from traffic-related air pollution.

Epidemiological methods based on ORs and 95% confidence intervals were used to compute the spatial risk relationships between case patients and control patients (using a significance level of $P \leq .05$). A 2×2 table analysis was conducted to demonstrate the relationship between 2 dichotomous or binary variables (exposed and unexposed groups).

RESULTS

Case–Control Demographics

In the Kaleida database, there were 3717 patients hospitalized because of asthma. There were 6265 hospital discharges for asthma during the period between 1996 and 2000. The majority (80%) of the patients were adults (aged 17–64 years). Thirty-two percent were from the city of Buffalo, 3.2% were from the town of Amherst, 3.1% were from Williamsville, and 61.7% were from other places. There was a notable increase in hospital admission between 1996 and 2000, especially in zip codes 14201 and 14213.

In the Kaleida database, there were 4129 patients hospitalized because of a nonrespiratory disease—gastroenteritis. Inpatients constituted 3.9% of the patients, and the remaining 96.1% were outpatients. Emergency department and clinic patients constituted 36.4% and 40.3% of the total, respectively. The number of patients admitted with gastroenteritis remained constant over this period. Annual admissions ranged from 800 to 829, with an average of 826 patients admitted annually from 1996 to 2000. Zip codes 14201, 14213, and 14221 contributed 44% of the patients during this period.

Table 1 lists the odds ratios from the case–control study at the zip code level between 1996 and 2000. A comparison of odds ratios by zip codes shows certain zip codes with statistically significant increased odds of having asthma, relative to nonrespiratory disease. We observed a positive association between possible exposure and outcome at the 5% significance level in zip codes 14201, 14213, 14207, and 14204. All of these zip codes that were statistically significant with odds ratios greater than the value 1 are located on Buffalo's West Side. In zip codes 14221, 14214, 14217, 14150, and 14227, we observed a negative association between possible exposure and outcome at the 5% significance. Zip codes that were statistically significant with odds ratios less than the value 1 are located further away from the West Side of Buffalo. The remaining zip codes had statistically nonsignificant results.

TABLE 1—Exposure Based on Geographic Locations Identified at the Zip Code Level: Odds Ratios From a Case–Control Study, 1996–2000

	Case Patients (n = 3717)		Control Patients (n = 4129)		
Zip Code	% Diagnosed Asthma	Asthma Hospitalization Rates (per 10 000)	% Diagnosed Gastroenteritis	Gastroenteritis Hospitalization Rates (per 10 000)	Odds Ratio (95% Confidence Interval)
14228	3.82	767	4.53	1010	0.84 (0.67, 1.05)
14201	15.77	349	11.04	271	1.51 (1.32, 1.72[a])
14213	24.19	275	18.16	229	1.44 (1.29, 1.61[a])
14203	0.43	129	0.34	113	1.27 (0.61, 2.61)
14068	1.67	114	1.99	150	0.84 (0.60, 1.17)
14026	0.08	109	0.15	218	0.53 (0.14, 2.08)
14222	3.55	105	2.88	95	1.24 (0.96, 1.60)
14207	6.54	101	5.01	86	1.33 (1.10, 1.61[a])
14209	2.18	89	2.49	113	0.87 (0.65, 1.17)
14216	4.20	63	4.94	82	0.84 (0.68, 1.04)
14204	1.75	58	0.97	35	1.82 (1.22, 2.72[a])
14226	4.95	57	5.55	71	0.89 (0.73, 1.08)
14202	0.43	56	0.53	78	0.81 (0.43, 1.54)
14221	8.18	55	14.48	109	0.53 (0.46, 0.61[a])
14208	1.32	34	1.19	34	1.11 (0.75, 1.66)
14212	1.53	29	1.11	23	1.38 (0.93, 2.05)
14214	1.61	28	2.25	43	0.71 (0.51, 0.98[b])
14217	1.88	27	3.39	55	0.55 (0.41, 0.73[b])
14215	3.44	27	3.92	35	0.87 (0.69, 1.11)
14223	1.91	27	2.47	39	0.77 (0.57, 1.04)
14211	2.64	25	2.16	23	1.23 (0.92, 1.64)
14150	3.63	25	5.74	44	0.62 (0.50, 0.77[b])
14210	0.78	16	0.75	17	1.04 (0.63, 1.73)
14227	0.91	13	1.72	28	0.52 (0.35, 0.79[b])
14206	0.89	13	1.07	17	0.83 (0.53, 1.30)
14220	0.78	10	0.58	8	1.35 (0.78, 2.33)
14218	0.59	10	0.44	8	1.34 (0.72, 2.52)
14219	0.35	10	0.15	4	2.34 (0.88, 6.22)

Note. Denominators derived from population data from the 1990 US Census; case patients and control patients derived from hospitalization and outpatient visits for asthma (*ICD-9* code 493) and gastroenteritis (*ICD-9* code 558) from Kaleida database, 1996–2000.
[a]Positive association between exposure and outcome at the 5% significance level.
[b]Negative association between exposure and outcome at the 5% significance level.

Spatial Analysis of Case–Control Study

The Diggle method, as used within ClusterSeer, was applied to test the null hypothesis of no clustering of case patients in comparison with a common control disease around a focal point, at $\alpha = 0.05$. GIS was used to determine whether spatial associations were between emission sites, major roadways, and residential locations of case patients and control patients. Sites were defined to include the PBC, air, toxic, and multiple releases, as shown in Figure 1. The busily traveled roadways were defined according to the type and volume of traffic on the basis of data from the Department of Transportation, as well as on information obtained from the residences, to include Main Street, Bailey Avenue, Niagara Street, Seneca Street, Delaware Avenue, Interstate 198, Interstate 190, and Route 33 (Figure 1).

Figure 1 shows the increased odds of having asthma among the residences living in close proximity to the sites or interstate roadways. Overall, there was a lower risk of asthma diagnosis for adults living farther away from sites and busily traveled roadways.

We analyzed exposed and unexposed case patients and control patients living within 1 km or farther away from sites and roadways. Table 2 shows increased odds of having asthma among the residences living in close proximity to the sites or roadways—there was a higher risk of asthma diagnosis for adults who lived in close proximity to those areas.

Case–control data showed that patients living along Main Street, Bailey Avenue, Niagara Street, Seneca Street, and Interstate 190 all had increased odds of having asthma. Most of the case patients at sites had statistically significant increased odds of asthma within 0.5 km versus more than 2 km away from the roadways, but the control patients did not. Apart from Interstate 190, which had statistically significant increased odds of asthma both at 0.5 versus 2.0 km and 1 versus 2 km, 4 roadways (Main Street, Bailey Avenue, Niagara Street, and Seneca Street) were also statistically significant at 1 versus 2 km. Three roadways (Delaware Avenue, Interstate 198, and Route 33) that carry mostly automobile traffic did not seem to have much effect when case patients and control patients were compared at 0.5 or 2 km farther away (within 500 m or more than 2 km).

The highest odds ratios were observed at air release sites (stationary sources of air pollution), with OR = 15.77 at 0.5 versus 2 km. Residents living at 0.5 km from air release sites have 15 times the odds of having asthma among all emission sites compared with those living more than 2 km away. The PBC had OR = 4.41 at 0.5 versus 2.0 km, toxic sites had OR = 0.70 at 0.5 versus 2.0 km, and multiple release sites had OR = 1.93 at 0.5 versus 2.0 km.

The evaluation of increased risk of diagnosed asthma near the focus sites that were identified in Oyana and Lwebuga-Mukasa[29] was carried out using the Diggle method and the individual-level data. Figure 2 both shows asthma clusters identified by 2 methods using group-level data[36,37] and shows the distribution of asthma cases per 1000 people. For this analysis, we have increased the scope of the investigation to include test and alterna-

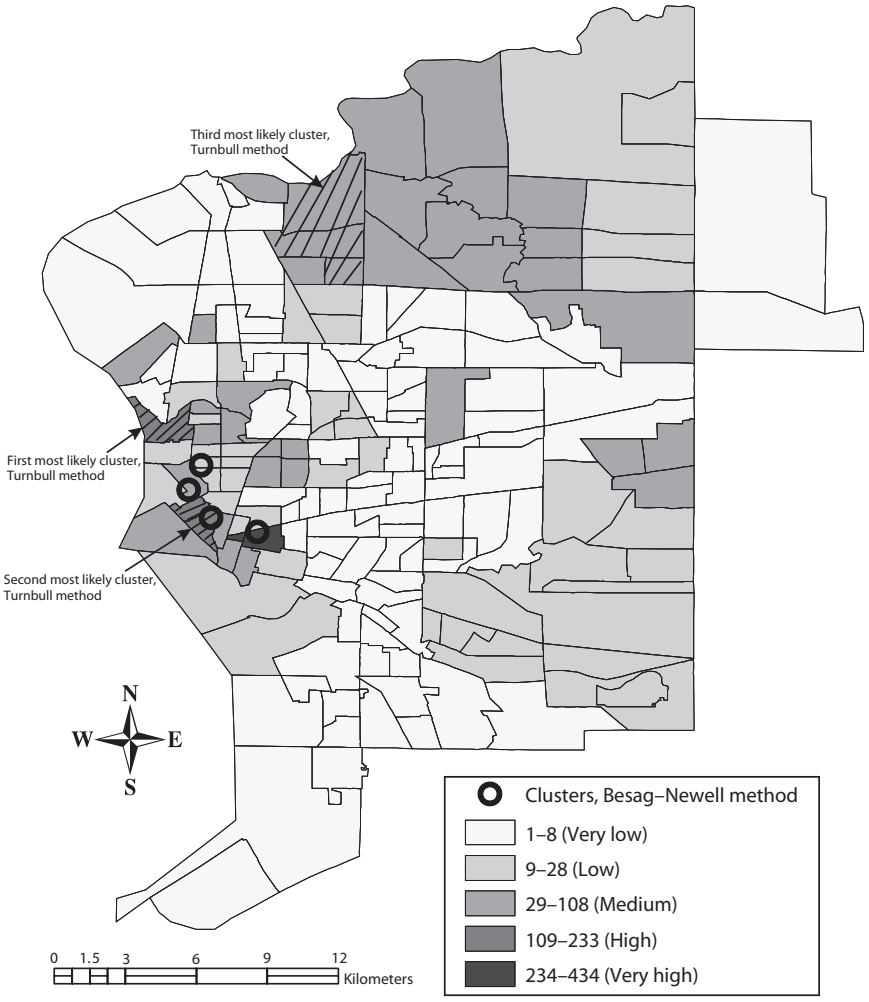

FIGURE 2—Asthma clusters identified by 2 methods and the distribution of asthma cases per 1000 people.

TABLE 2—Spatial Analysis of Case–Control Study Showing Odds Ratios

Sites	Odds Ratios		95% Confidence Interval	
	0.5 vs 2 km	1 vs 2 km	0.5 vs 2 km	1 vs 2 km
Peace Bridge Complex	4.41[a]	0.52	3.26, 5.97	0.39, 0.70
Air release	15.77[a]	0.91	9.93, 25.04	0.67, 1.22
Toxic release	0.70	0.42[b]	0.40, 1.22	0.29, 0.60
Multiple release	1.93[a]	0.56[b]	1.60, 2.32	0.46, 0.69
Interstate 190	1.30[a]	3.26[a]	1.02, 1.66	2.67, 3.97
Interstate 198 and Route 33	0.67[b]	0.49[b]	0.51, 0.87	0.39, 0.63
Main St, Bailey Ave, Niagara St, and Seneca St	1.11	1.36[b]	0.95, 1.30	1.15, 1.61
Delaware Ave	0.65[a]	0.96	0.51, 0.83	0.76, 1.21

Note. Case patients and control patients derived from hospitalization and outpatient visits for asthma (*ICD-9* code 493) and gastroenteritis (*ICD-9* code 558) from Kaleida database, 1996–2000.
[a]Positive association between exposure and outcome at the 5% significance level.
[b]Negative association between exposure and outcome at the 5% significance level.

tive sites (geographic coordinates) around the focus sites to evaluate how the *P* value changed. Our null hypothesis was that the case and control occurrences have the same underlying spatial distribution. The alternative hypothesis was based on case subject locations having different spatial patterns in comparison with the control locations and on the fact that the density of the case locations was higher than that of the control near the focus sites.

Model results for the 13 focus sites showed that certain geographical areas were significantly more affected by asthma than others. For instance, our study shows that the chance of achieving more extreme outcomes (if the null hypothesis was true) for the model parameters for 4 focus sites (Birge Company, PBC, Ogrady Winnifred Silver, and Miken Company) located in Buffalo's West Side had $P \leq .0001$. We further observed that focus sites located in Buffalo's West Side have associations that are very highly significant, and the effects appear to extend over a large area. However, there were also modest associations for 2 focus sites (Marnap Industries, $P \leq .053$; and Nabisco Company, $P \leq .045$) located on Buffalo's East Side, and the effects appear to extend over a small area. There was no evidence of association for Harrison Radiator, also located on Buffalo's East Side, as well as the other 6 test sites. Overall, the analysis of case–control data establishes further evidence of an association between diagnosed asthma and 4 focus sites located on Buffalo's West Side. Our study also finds modest associations for locations within Buffalo's East Side, especially the Nabisco Company, which manufactures Milk-Bone bakery products and releases respirable air-borne dust particles. These associations warrant further investigation.

Comparability of Case Patients and Control Patients

Insurance status as a possible confounder was evaluated during the study period. A comparison of insurance status for case patients and control patients was conducted to evaluate whether a significant difference existed between asthma and gastroenteritis patients in 34 subcategories of insurance status reported in the databases, which were identified following these 5 tallies: total number of

case patients, inpatients, outpatients, emergency room use, and clinical case patients. Overall, based on a *t* test, there was no statistical difference in insurance status between asthma and gastroenteritis patients in the subcategories described above. However, there were some slight differences that were observed in 3 subcategories: outpatients ($t_{observed}$=1.669, *df*=66, $t_{critical}$=1.668, $P \leq .049$), clinical ($t_{observed}$=2.562, $P \leq .006$), and case patients diagnosed in 2000 ($t_{observed}$=1.694, $P \leq .047$).

Additional analysis was conducted on the basis of the 4 categories of benefits (private benefit programs, public-sponsored benefit programs, self-sponsored benefits, and others) that were identified with insurance status data. In this particular analysis, it was assumed that those patients who were most likely to have access to private preventive care belonged to the private benefit programs category. Insurance status data for patients seeking emergency and urgent care in the hospital showed that 34.85% and 30.28% of the patients with asthma and gastroenteritis diagnoses, respectively, were most likely to have private preventive care as well. The remaining subcategories showed that public-sponsored benefits were used by 26.99% and 28.41% of the asthma and gastroenteritis patients, self-sponsored benefits constituted 20.62% and 22.15% of the asthma and gastroenteritis patients, and others constituted 17.5% and 18.9% of patients with asthma and gastroenteritis diagnoses, respectively. Overall, the comparison of insurance status for patients seeking care in the emergency room during the study period shows a comparable ratio of 1:1 in all 4 subcategories. The insurance status of case patients with asthma diagnosis and diagnosed gastroenteritis was therefore comparable, lending support for gastroenteritis as an appropriate candidate for the case–control study.

DISCUSSION

There are 4 major findings from this study: first, the distribution of asthma, after accounting for spatial variation in the population at risk, is nonhomogenous; second, areas in which case patients have high rates of asthma appear clustered in proximity to air-polluting sites, including the PBC and the busily traveled roadways supplying it, in addition to EPA-designated toxic air release sites; third, the decrease in asthma prevalence as a function of distance from sites indicates that pollutants from the sites are not only associated with the worsening of asthma symptoms but may also play a role in the etiology of asthma; and fourth, further analysis of common features of pollutants may help elucidate mechanisms relating exposures to the genesis of asthma. To date, studies have focused on high-level exposures and have paid relatively little attention to local multiple exposures. Identification of clusters associated with different sources may provide insights into how mixtures of pollutants may interact and lead to development of asthma in susceptible individuals. The study findings support and expand our earlier observations in Lwebuga-Mukasa and Dunn-Georgiou,[2,3] Lwebuga-Mukasa and Pszonak,[4] Oyana and Lwebuga-Mukasa,[29] and Lwebuga-Mukasa et al.[6] These findings are also consistent with previous findings that have been reported in Peterson and Saxon,[24] Kane et al.,[25] Briggs et al.,[38] Donaldson et al.,[12] Dockery,[39] Loh et al.,[40] Lin et al.,[5] and Lin et al.[41] The findings confirm earlier reports that indicated that increases in NAFTA traffic across the PBC were related to increases in prevalence and health care use for asthma.[23] This study, together with the previous studies, provides a basis for systematic investigation of environmental exposures in communities and their effect on residents.

Levels of Geographic Resoloution

This study has benefited from the use of more than 1 level of geographic resolution. Our spatial analysis has been conducted here at 2 different levels. At the individual level, we analyzed and compared spatial locations of case patients and control patients at varying distances from sites. At the zip code level, we computed odds ratios to evaluate which zip codes were heavily burdened by respiratory illnesses. In a previous study,[29] we analyzed census tract (group)–level data to obtain case patients per population size and to identify local asthma clusters. These different levels of geographic resolution enabled us to gain more insight into the problem of respiratory illnesses faced by communities living in close proximity to the PBC, major roadways, and pollution sites.

Proximity to Sites

This study pinpoints proximity to air release sites including the PBC as a significant contributor to increased asthma exacerbations in the study area. For the residents living within 0.5 km from air release sites, the odds of having asthma were 15 times greater compared with those of patients living more than 2 km away. We also observed a 4-fold increase in the odds of having asthma among residents living in close proximity to the PBC compared with those living in nonexposed areas farther away. It is probable that these sites significantly affect the quality of inhalable air, which in turn could trigger episodes of airway inflammation among individuals with asthma. It is therefore reasonable to suspect that communities living in close proximity to these sites are exposed to high levels of particulate emissions[42] that contribute to increased asthma exacerbations. In addition, this particular finding might explain the high rates of hospitalization and emergency room use already reported in previous studies.[4,23] Overall, the extreme increase in asthma risk associated with toxic air release sites points to the need to minimize toxic releases because of their potential health risk to residents nearby.

Significant Associations

Six statistically significant associations of diagnosed asthma near the focus sites, in comparison with the geographical distribution of gastroenteritis, were found using the Diggle method. Although 1 focus site located on Buffalo's East Side did not reach statistical significance, there was modest evidence of increased diagnosed asthma in 2 focus sites located in this area. Of the 13 sites for which we fitted models, we observed a higher increased density of case locations in comparison with control locations on Buffalo's West Side than in other areas. These associations are consistent with those identified using *K*-means and nearest-neighborhood hierarchical clustering techniques, the score test of Lawson and Waller, the Bithell score risk test, and Besag and Newell's methods. The PBC site was not statistically significant by 1

method—the score test of Lawson and Waller,[29] but all the other methods, including the Diggle model, found that particular site very highly significant.

The analysis of case–control data establishes further evidence of associations between diagnoses of asthma and the 4 focus sites located on Buffalo's West Side. However, we cannot necessarily attribute all of the effects to these 4 focus sites, because statistically significant *P* values extend over a large area. Other possible explanations are explored below. This study also found modest associations for 2 focus sites located on Buffalo's East Side, especially for the Nabisco Company, which produces grain and flour, and these associations warrant further investigation. Current data do not permit determination of whether the increase in diagnosed asthma is related to residents working at the factory or whether exposure was secondary to air pollution.

Our study had 3 limitations. First, because the hospital data we used were from a single hospital system, we could not examine other hospital admissions in the same area. Second, it was not possible to determine why patients were admitted to the hospitals (i.e., the patient's original complaint). Third, the data set did not contain information pertaining to the living conditions of the patients; this information could explain other exposures to asthma risk factors.

Although there is mounting cumulative evidence associating increased risk of asthma to traffic-related pollution, it is reasonable to suspect the existence of a number of other prime risk factors, such as possible mixtures of pollutants and the interaction of local ecological factors that might better explain spatial variations of asthma in the study area. We suspect that these risk factors are key contributors of asthma on Buffalo's West Side, given that previous studies[6] have absolved possible confounders such as exposure to environmental tobacco smoke, race, and income.

Interpretations

These interpretations were arrived at on the basis of the following factors. First, there is a significant release of diesel exhaust particles[42] from a busily traveled state highway in which the bulk of commercial traffic serving the NAFTA trade corridor flows through this community. In the summer of 2002, a preliminary chemical analysis of respirable particles collected from the PBC by Baier, one of the research scientists studying traffic-related pollution, revealed high ammonium carbonates, nitrates, and sulfates in the study area (R. E. Baier, oral communication, August 23, 2002). His analysis further revealed a net addition of silicates and iron-bearing particles to the respirable fraction, which was independent of wind direction. Baier suggested that the net increase of respirable silicate-rich and iron-rich matter was attributable to truck emissions, based on further comparisons to spectra of impacted aerosol samples from a Cheektowaga truck stop, where numerous idling trucks were present. These unusually high levels of silicate-rich and iron-rich matter are residues of burning diesel that may combine with local factors and contribute to chronic airway and lung inflammation[44–49] and set the stage for airway hyperresponsiveness, a characteristic of asthma, and worsening of asthma symptoms among individuals who already have the disease. Second, there is a significant number of manufacturing industries located on Buffalo's West Side that might be emitting respirable particulates. The evidence of clusters of asthma about the focus sites we studied illustrates this point. Third, local ecological factors may be important, including the urban heat island phenomenon,[49,50] residential overcrowding, and most important, meteorological conditions influenced by the presence of Lake Erie and the Niagara River, which have an effect on the dispersion of particulate pollutants. There is a low density of vegetation on Buffalo's West Side compared with other areas in the study area, which causes the area to be warmer than normal. Finally, the age of the housing units is a potential confounder that warrants further investigation.

CONCLUSIONS

There are 2 implications of the study findings: first, current traffic levels not only contribute to asthma and other respiratory disease exacerbations but may also contribute to high asthma prevalence on Buffalo's West Side in comparison with other Buffalo communities; and second, identification of asthma clusters along busily traveled roadways and the PBC, in addition to other sites, indicates an etiological link between pollutants and high asthma prevalence rates. These implications are important for the development of new hypotheses relating to the spatial distribution of asthma prevalence and morbidity in this community. Although our study does not provide specific information pertaining to the chemical compositions of the focus sites, it provides evidence about the locations at which exposures may affect susceptible individuals. ■

About the Authors

Tonny J. Oyana and Peter Rogerson are with the Department of Geography, University of Buffalo, Buffalo, NY. Tonny J. Oyana and Jamson S. Lwebuga-Mukasa are with the Center for Asthma and Environmental Exposure, Lung Biology Research Program, Pulmonary and Critical Division, Department of Internal Medicine, University of Buffalo School of Medicine and Biomedical Sciences, Kaleida Health Buffalo General, Buffalo, NY.

Requests for reprints should be sent to Jamson S. Lwebuga-Mukasa, MD, PhD, Center for Asthma and Environmental Exposure, Lung Biology Research Program, Department of Internal Medicine, UB School of Medicine and Biomedical Sciences, Kaleida Health Buffalo General Division, 100 High St, Buffalo, NY 14203 (e-mail: jlwebuga@acsu.buffalo.edu).

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Contributors

Tonny J. Oyana participated in data processing, geocoding, data analysis, and geographic information systems (GIS) modeling and wrote the article. Peter Rogerson advised on data analysis and also contributed to editing the article. Jamson S. Lwebuga-Mukasa provided the data sets for disease analysis and guidance on medical issues and also participated in editing the article. The spatial and GIS approach used in this study was developed by Tonny J. Oyana in consultation with Peter Rogerson and Jameson S. Lwebuga-Mukasa.

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Human Participant Protection

All research reported in this article was approved by the University of Buffalo human sciences investigation review board.

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Marshfield Clinic Research Foundation
Director of Medical Research

Marshfield Clinic Research Foundation (MCRF) announces a search for a Director of Medical Research.

Marshfield Clinic is a premier health care network of over 740 physicians in 40 locations throughout central, northern and western Wisconsin. Its mission is to serve patients through accessible, high quality health care, research and education. The Marshfield Clinic Research Foundation is the largest private medical research facility in Wisconsin, with areas of focus in clinical research, rural health and safety, epidemiology, human genetics, personalized medicine, and health services research.

The position of Director of Medical Research provides an outstanding opportunity for an individual who will be a leader and mentor for the physicians, scientists and staff. The Director should be a competent manager, with excellent people skills and an ability to execute a growth-oriented research strategy. The candidate must possess a MD, DO and/or Ph.D. degree and have a record of achievements in medical research and administration.

Marshfield Clinic is an Equal Opportunity/ Affirmative Action employer

Interested candidates should send their CV, in confidence, to:

Cindy Schuster
Physician Recruitment Manager,
Search Committee for Director of Medical Research
Marshfield Clinic
1000 N. Oak Avenue
Marshfield,
Wisconsin 54449

800-782-8581, ext. 19777
Fax: 715-221-9779

E-mail:
schuster.cindy@marshfieldclinic.org

Website:
www.marshfieldclinic.org

MARSHFIELD CLINIC
Where the future of medicine lives

IDAHO STATE UNIVERSITY

Institute of Rural Health
Pocatello, Idaho

Research Associate/Assistant Professor or Post-Doctoral Fellowship

Up to four grant funded, 1-3 year positions (future employment contingent on funding) in beautiful Idaho. Under the direction of the PI, assist with grants; research administration, clinical and evaluation activities; write grants, reports, and articles. Current projects are varied including the National Child Traumatic Stress Network, telehealth, aging, substance abuse, and disabilities (see **www.isu. edu/irh**). The long-term goals for these positions include developing independent or collaborative extramurally funded research programs. Requires earned doctoral degree (ABD considered) in a health profession (medicine, nursing, psychology, public health, etc.), education, technology, or related field. The specific field is open, but scientific writing, technology interest, and research training/experience are mandatory. Clinical training, experience with external funding, and health policy desirable. Projects are varied and workload typically includes 60-80% research and 20% service with 20% teaching possible. For a complete announcement, please visit www.isku. edu/humanr. Applications should include letter of application, statement of professional goals/interests, curriculum vitae with funding and publication history, writing sample, and names of three professional references with their contact information. **Submit to Idaho State University, Office of Human Resources, Campus Box 8107, Pocatello, ID 83209**. Rank and salary commensurate with education and experience; competitive benefits package. **Address questions to Phone (208) 282-4828, Fax 282-4976**. Program inquiries only to Dr. Beth Hudnall Stamm at **irh@isu.edu.** Minority candidates strongly encouraged to apply.

Idaho State University is an AA/EEO Employer.

ASSISTANT PROFESSORS/OBESITY PREVENTION
UNIVERSITY OF MINNESOTA

Division of Epidemiology, School of Public Health, University of Minnesota, seeks two 100%-time non-tenure-track Assistant Professors for academic research faculty positions in obesity prevention. Primary content areas of expertise sought are in 1) physical activity behavior or 2) environmental variables related to food and physical activity behaviors.

Requirements include: 1) earned doctoral degree in epidemiology, nutrition, psychology, kinesiology, or other related area; 2) relevant publication record in peer-reviewed journals, 3) relevant research experience; 4) experience in grant writing or history of externally-funded research; and 5) evidence of strong quantitative skills.

Research responsibilities include developing an independent program of research in an area of behavioral obesity prevention that dovetails with and expands upon current faculty expertise. The faculty person will be expected to both lead his or her own research efforts and collaborate with other faculty as co-investigator on new grant initiatives. Teaching responsibilities will be limited.

Positions available as early as Summer 2004. Positions are open until filled. Applicants should submit a statement of scientific interests, curriculum vitae, publication list and names of at least 3 references to **Dr. Simone French c/o Kathy Ramel, Div. of Epidemiology, School of Public Health, University of Minnesota, 1300 S. 2nd St., #300, Minneapolis, MN 55454-1015. Please reference job #124810.**

The University of Minnesota is an equal opportunity educator and employer.

UNIVERSITY of VIRGINIA
FAMILY MEDICINE

The University of Virginia Department of Family Medicine is seeking a full-time assistant, associate, or professor of family medicine, Ph.D. or equivalent degree required. This person will join our Center for Family and Community Health Research in a tenure track position. Candidates should have a nationally recognized program of research and scholarship, as well as a demonstrated ability to secure external support for independent research from federal agencies and/or national foundations. Capacity for collaborative, interdisciplinary work in a team-oriented setting across clinical and academic disciplines is highly desirable. We are seeking a candidate with expertise in epidemiology, health disparities, maternal and child health, health promotion, nutrition, medical informatics, or related fields. The successful candidate will be expected to establish independent, externally funded research projects, collaborate with other researchers, assist in mentoring junior faculty in their research endeavors, and participate in teaching programs within the department.

The UVa Department of Family Medicine is developing a burgeoning national record of scholarship, including research and educational grant funding. We seek to expand our current research emphases in health disparities, technological innovation at the point of care, and preventive services. Located within one hour of the Blue Ridge Parkway and Appalachian Trail, the Charlottesville area is highly regarded for its beauty, recreational opportunities, excellent schools, and quality of life.

Candidates should send the following via email or regular mail: A statement of research interests, a CV, two published manuscripts, and the names of three references (with complete contact information, including address, telephone number and email address) to: **Fern R. Hauck, MD, MS, Director, CFCHR, Department of Family Medicine, University of Virginia Health System, P.O. Box 800729, Charlottesville, VA 22908-0729. Email: lps5ps@virginia.edu; phone: (434) 924-1835**

The University of Virginia is an Equal Opportunity/Affirmative Action Employer. We strongly encourage applications from qualified women and minority group members.

NATIONAL CANCER INSTITUTE

NATIONAL INSTITUTES OF HEALTH

Be an NCI Cancer Prevention Fellow

The Department of Health and Human Services, National Institutes of Health, National Cancer Institute, Division of Cancer Prevention, sponsors the Cancer Prevention Fellowship Program (CPFP). Its purpose is to train individuals from a multiplicity of health professions and biomedical science disciplines to become leaders in the field of cancer prevention and control.

What will I get out of the program?
- Master of Public Health degree
- NCI Summer Curriculum in Cancer Prevention
- Mentored research opportunities at the NCI
- Professional development and leadership training

What areas of cancer prevention research are available?
- Clinical cancer prevention research
- Epidemiology
- Ethics and evidence-based decision making
- Laboratory-based research
- Social and behavioral research
- Statistical methodology

Am I eligible?
You must have a doctoral degree (M.D., Ph.D., J.D., or equivalent). Foreign education must be comparable to that received in the United States.

You must also be a citizen or permanent resident of the United States at the time of application (September 1).

How long is the program?
The typical duration is 3 years (year 1: M.P.H.; years 2-3: NCI Summer Curriculum in Cancer Prevention and mentored research).

How do I apply?
Beginning May 1, the on-line application will be available on our web site: **http://cancer.gov/prevention/pob**

How do I obtain more information?
Visit our web site: **http://cancer.gov/prevention/pob/**

To receive a catalog, contact:*
Douglas L. Weed, M.D., M.P.H., Ph.D.
Director, Cancer Prevention Fellowship Program
National Cancer Institute
6130 Executive Boulevard (EPN)
Suite 3109, MSC 7361
Bethesda, MD 20892-7361

* Please provide home address, telephone, e-mail, and where you heard about the program.

When are applications due?
Applications are due September 1, 2004, for entry into the program the last full week of June 2005.

Further inquiries:
Mrs. Barbara Redding
Program Coordinator
Phone (301) 496-8640
Fax (301) 402-4863
E-mail br24v@nih.gov

DHHS, NIH, AND NCI ARE EQUAL OPPORTUNITY EMPLOYERS

Selection for these positions will be based solely on merit, with no discrimination for non-merit reasons, such as race, color, gender, national origin, age, religion, sexual orientation, or physical or mental disability. NIH provides reasonable accommodations to applicants with disabilities. If you need reasonable accommodation during any part of the application and hiring process, please notify us. The decision on granting reasonable accommodation will be handled on a case-by-case basis.

Kuwait University Faculty of Medicine

Applications are invited by the Department of Community Medicine and Behavioral Sciences for the position of Assistant. Associate or Full Professors in the following areas:

1. Medical Sociologist (One Position)
The responsibilities of this position include: teaching pre-clinical and clinical medical students, graduate students and Ministry of Health students in a multidisciplinary environment as well as conducting individual and collaborative research. Applicants should hold a PhD degree in Sociology with a minimum of five years experience in a medical setting. Experience in international settings will be preferred. Knowledge of Arabic is an advantage.

2. Health Planning and Administration Specialist and Health Economist (Two Positions)
Applications are invited from scholars holding a doctoral degree in Health Administration with Specialization in Health Services Planning, Management, Evaluation, or in Health Economics or related fields. The responsibilities of this position include: teaching pre-clinical and clinical medical students, graduate students and Ministry of Health students in a multidisciplinary environment as well as conducting individual and collaborative research. Special areas of instruction will include a critical evaluation of the health care delivery system in Kuwait and the Gulf, identifying weaknesses and suggesting solutions. Assessing costs of health care and devising mechanisms for cost containment and sharing, as well as continuous quality improvement. Candidates must have strong quantitative, analytical and computer skills. Applicants with teaching and research experience in a medical institution, and those who have experience in international and developing country settings will be preferred. The applicant should also have a demonstrated interest in the areas identified above supported by publications and teaching experience. Knowledge of Arabic is an advantage.

3. Environmental / Occupational Health Specialist (One Position)
The responsibilities of these positions include: teaching pre-clinical and clinical medical students, graduate students and Ministry of Health students in a multidisciplinary environment as well as conducting individual and collaborative research. Applicants should hold a MD and a PhD or Dr. PH degree in Occupational / Environmental Health or Occupational / Environmental Epidemiology. A minimum of two years of teaching as well as research experience is required. Knowledge of Arabic is an advantage.

4. Epidemiologists (One Position)
The responsibilities of this position include: teaching pre-clinical and clinical medical students, graduate students and Ministry of Health students in a multidisciplinary environment as well as conducting individual and collaborative research. Applicants should hold a MD and a PhD or equivalent in Epidemiology or in Public Health, or MD and MPH degrees plus Board Certification in Epidemiology, Preventive Medicine or Public Health. Knowledge of Arabic is an advantage.

5. Biostatistician (One Position)
The responsibilities include teaching biostatistics to undergraduates and graduate students of the Health Sciences Centre. Duties also include collaboration with clinical and biomedical investigators, biostatistical and methodological research, thesis supervision in graduate programs in biostatistics and epidemiology. Offering biostatistical consultations to different categories of students, researchers and faculties are among the required duties. Applicants should hold a PhD degree in Biostatistics. A minimum of 2 years teaching experience is required.

Teaching at the Faculty of Medicine is in English.

Salaries and Benefits

Rank	Salary Range	
	In Kuwait Dinars	In US dollars
Professor	KD 1670-1830	US$ 5511-6039
Associate Professor	KD 1320-1480	US$ 4356-4884
Assistant Professor	KD 1030-1190	US$ 3399-3927

In addition a social allowance of KD 65-87 per month is given. There is no income tax in Kuwait and currency is transferable without restriction. (1 KD = approx. US$ 3.30)

Other benefits:
- Baggage and freight allowance.
- Partial education allowances for up to 3 children attending Schools in Kuwait.
- Free furnished accommodations or housing allowance (KD 350 or 450) and a one-time furniture allowance (KD 3500 or 4500) depending on marital status.
- 60 days (2 months) paid summer leave and two weeks mid-year break.
- Annual round-trip air tickets for staff member and dependents.
- End-of service gratuity (one month's basic salary for each year of service).
- Health Insurance.
- Attendance at one approved conference per year.

Applications accompanied by complete curriculum vitae and the names, addresses, fax numbers and email addresses (if available) of three references should be sent to:

The Dean (Recruitment office), Faculty of Medicine
P.O. Box 24923
Safat 13110
Kuwait

EOE

Department of Health and Human Services
Recruitment in Social and Behavioral Research
National Human Genome Research Institute • National Institutes of Health

The Social and Behavioral Research Branch (SBRB) is a newly-formed Branch of the National Human Genome Research Institute whose mission is to conduct innovative research in:

- applying genetic discoveries to improve interventions for disease prevention and health promotion,
- evaluating genetic risk communications,
- developing for communicating genetic risk to affected individuals, families, communities, and populations,
- understanding how social factors influence genetic discoveries and research, and
- investigating the ethical and public policy implications of genetic research and the use of genetics in clinical practice.

The SBRB currently consists of seven investigators whose research is at the intersection of genomics and social and behavioral science, including clinical genetic counseling, risk communication, health behavior change, bioethics and social policy, health disparities, community research, and public health.

We are seeking dynamic investigators at various levels (staff scientists, tenure track and tenured) to join us in meeting our goal of becoming one of the premier programs in this area. New SBRB investigators will be expected to develop an independent research program in keeping with the Branch's broad research mission. Candidates should have expertise or interest in conducting innovative research on behavioral and social aspects of human genome discoveries. Prior genomic research experience is desired but not required. General areas of interest being targeted for recruitment include but are not limited to:

- **Risk communications**
- **Behavior change interventions**
- **Decision assistance interventions**
- **Health services research**
- **Community involvement research**
- **Health economics**
- **Mass communications**
- **Bioethics**
- **Public policy and regulation**
- **Research protections**
- **Health Disparities**

Candidates must have a Ph.D., M.D. or equivalent degree. Rank will be commensurate with qualifications.
The positions include an ongoing commitment of research support and space, support personnel, and post-doctoral positions.
Interested applicants should send a curriculum vitae, a three-page description of research interest and vision, and three letters of recommendation through our online application system at http://research.nhgri.nih.gov/apply
Applicants who cannot submit their materials electronically should submit their applications to:

Charlene Patrick
SBRB Search Committee
National Human Genome Research Institute
50 South Drive
Building 50, Room 5349
Bethesda, MD 20892-8000
cp55h@nih.gov

Applications will be reviewed beginning July 15, 2004 and continue until positions are filled or September 30, 2004.
For more information on SBRB and NHGRI's Intramural Program, http://www.genome.gov

DHHS and NIH are Equal Opportunity Employers

JOHNS HOPKINS BLOOMBERG SCHOOL of PUBLIC HEALTH

ASSISTANT/ASSOCIATE PROFESSOR
Centers for Public Health Preparedness and Leadership
Bloomberg School of Public Health
The Johns Hopkins University

The Johns Hopkins Bloomberg School of Public Health is seeking to appoint one or two full-time, Assistant/Associate Professor(s) to join the Centers for Public Health Preparedness and Leadership. The Centers are an expanded initiative to increase the School's focus for workforce development and training of the public health community for all the School's students, and to meet the specific ongoing educational needs of the Mid-Atlantic (Maryland, Delaware, and DC) region. Qualified individuals will have formal training in public health or a related area as well as experience in an applied and/or academic area within public health. The incumbent(s) will collaborate in the activities of the Centers for Public Health Preparedness and Leadership in efforts such as assessment of training needs, training public health practitioners in core public health competencies, preparedness training, student internships in health departments, engaging public health practitioners in educational programs, collaborative research between Hopkins and public health agencies, and preparation of public health professionals for leadership positions. Teaching responsibilities include collaboration with faculty on programs in public health practice and preparedness. The position(s) include(s) opportunities for pursuit of research and evaluation activities as well. The incumbent(s) will participate in the leadership of relevant local, state, and national initiatives. Candidates with past involvement in public health preparedness or related areas (e.g., surveillance and outbreak investigations), public health workforce development and training, and/or executive leadership development are highly desirable.

The position(s) will be filled at the Assistant/Associate Professor or Public Health Assistant/Associate Professor rank, depending on the qualifications, interests, and experience of the individual selected. Academic appointment(s) will be made in a department that is appropriate to the interests and skills of the incumbent.

Nominations, applications, and inquiries should be received by July 1, 2004 at the address below:

Dr. Lynn Goldman, Chair
Public Health Preparedness and Leadership Search Committee
c/o Ms. Barbara Diehl
Johns Hopkins Bloomberg School of Public Health
615 North Wolfe Street, Baltimore MD 21205, Rm. W1504
bdiehl@jhsph.edu • **www.jhsph.edu**

The Johns Hopkins University actively encourages interest from women and minorities and is an affirmative action/equal opportunity employer.

FACULTY POSITIONS
CENTER FOR BIOBEHAVIORAL HEALTH

The CENTER FOR BIOBEHAVIORAL HEALTH in The Ohio State University Department of Pediatrics at Columbus Children's Research Institute and Children's Hospital is seeking PhD, MD, or MD/PhD candidates for tenure-track positions to develop and conduct independent research programs within the broad domain of biobehavioral health. Candidates with a record of accomplishment in research regarding the relationships between neurobiological and psychosocial processes in childhood illnesses are particularly encouraged to apply. Existing lines of research include neurobehavioral outcomes of traumatic brain injury, child and family adjustment to chronic illness, and access to and costs of mental health services. Desired areas of interest for new faculty include obesity, sleep disorders, autism, and the neurosciences, although the quality of the candidate is more important than the specific research focus. Research space is available within the Columbus Children's Hospital. The recruitments are part of a larger 5 year planned expansion of research initiatives by the institution and include the recruitment of 35-40 new investigators in both basic and clinical research. The institution is especially committed to building its clinical research program, and has attractive startup packages available for qualified applicants. Joint appointments within graduate departments of The Ohio State University are available. The positions are most likely to be filled at the Assistant or Associate Professor level, although outstanding candidates at the Professor level will also be considered.

For more information, please visit our website at **www.ccri.net**

The Ohio State University is an Equal Opportunity, Affirmative Action Employer. Women, minorities, veterans, and individuals with disabilities are encouraged to apply.

Address correspondence with three references and curriculum vitae to:

Keith Owen Yeates, PhD
Director, Center for Biobehavioral Health
Columbus Children's Hospital
700 Children's Drive, Columbus, OH 43205
Phone: (614) 722-4700 • FAX: (614) 722-4718
E-mail: yeatesk@chi.osu.edu

DIRECTOR OF ENVIRONMENTAL HEALTH

County of Sonoma

Sonoma County, California is a special place. It's environments range from the surf-pounded cliffs of the coast to the golden Mayacamas Mountains, from the cool stillness of redwood forests to the marshes that feed San Francisco Bay. Santa Rosa, home of the County Offices, was just named one of "America's Most Livable" medium-sized cities by Partners for Livable Communities, a nonprofit group based in Washington D.C.

The County of Sonoma Department of Health Services is seeking a Director of Environmental Health to provide progressive leadership and direction for our comprehensive environmental health program. The Director of Environmental Health is the delegated authority to enforce environmental health laws, regulations and ordinances and is expected to exercise a considerable amount of independent judgment and initiative to achieve policy objectives. This position reports to the Director of Health Services. The individual we are seeking will possess excellent written and verbal communication skills and possess a collaborative management style to create a positive and innovative partnership with the community.

The ideal candidate will have the ability to provide fiscal analysis of state and county budgets and their impacts on revenues, expenditures, staffing levels and types of services. The ideal experience profile will include three years of progressively responsible experience as an Environmental Health Specialist, which includes at least one year in a supervisory or administrative capacity. Possession of a valid California certificate of registration as an Environmental Health Specialist is required. Salary: $80,206 - $97,509 + excellent benefit package including 3% at 60 retirement plan. **For more information or to apply on line, visit: www.sonoma-county.org or call Lynn Vender, County of Sonoma Human Resources (707) 565-2923. Final filing date is: July 30, 2004**.

EOE

Simon Fraser University
Faculty of Health Sciences

Simon Fraser University is internationally recognized for research and teaching excellence in the liberal arts and sciences, and for innovative interdisciplinary and professional programs. The new Faculty of Health Sciences will extend and enhance this reputation. In conjunction with a new innovative Masters program in Population and Public Health, beginning in September 2005, we are seeking seven new faculty positions. A major emphasis of the program is to enhance skills in collaborative community health research, advance the ability to prevent disease, and increase understanding of the complex inter-play among types and levels of societal investment in health and social systems, the resulting trade-offs and implications for public policy-making. We invite applications for the following tenure-track positions in these areas:

- Health Economics
- Epidemiology (three positions)
- Qualitative Research Methods in Health
- Biostatistics
- Public Health/Community Medicine

Successful applicants will have demonstrated teaching and research excellence. All academic ranks will be considered. Detailed information about these positions and the Faculty of Health Sciences can be found at **http://fhs.sfu.ca/facultyopenings. php** or **http://www2.sfu.ca/vpacademic/Faculty_ Openings**.

Simon Fraser University is committed to employment equity and encourages applications from all qualified women and men, including visible minorities, aboriginal people, and persons with disabilities. All qualified applicants are encouraged to apply, however Canadian citizens and permanent residents will be given priority. Positions are subject to final budgetary approval.

Applications will be reviewed commencing September 30, 2004; however, positions will remain open until filled. Please send a full C.V., a descriptive statement on research plans and teaching activities, and the names of three referees to:

Dr. David MacLean
Chair, Faculty Search Committee
Faculty of Health Sciences
WMC 2812 Simon Fraser University
8888 University Drive
Burnaby, BC, Canada V5A 1S6

EOE

Simon Fraser University
Faculty of Health Sciences

Tier II Canada Research Chairs in Health Sciences

Simon Fraser University is internationally recognized for research and teaching excellence in the liberal arts and sciences, and for innovative interdisciplinary and professional programs. The new Faculty of Health Sciences will extend and enhance this reputation. In conjunction with a new innovative Masters program in Population and Public Health, beginning in September 2005, we are seeking two Tier II Canada Research Chairs. A major emphasis of the new program is to enhance skills in collaborative community health research, advance the ability to prevent disease, and increase understanding of the complex inter-play among types and levels of societal investment in health and social systems, the resulting trade-offs and implications for public policy-making.

The Canada Research Chair Program is supported by the Government of Canada and was established to enable Canadian Universities to achieve the highest levels of research excellence. Information about the program may be found at http://www.chairs.gc.ca.

Candidates should have the potential to become acknowledged international leaders in their discipline. Appointments will be made in accordance with the university's strategic research plan. (See website http://www.sfu.ca/vpresearch/). The salary and rank will be based on qualifications and experience. The appointments will be made at the Assistant or Associate Professor level, depending on the qualifications and experience of successful candidates. The start date is expected to be September 1st, 2005. Additional information about these positions and the Faculty of Health Sciences may be found at **http://fhs.sfu.ca/faculty_openings.php** or **http://www2.sfu.ca/vpacademic/Faculty_ Openings**.

Simon Fraser University is committed to employment equity and encourages applications from all qualified women and men, including visible minorities, aboriginal people, and persons with disabilities. All qualified applicants are encouraged to apply, however Canadians and permanent residents will be given priority. These appointments will be contingent on the candidates being approved for CRC Chairs by the CRC Secretariat. These positions are also subject to budgetary approval by the University.

Applications will be reviewed commencing October 31st, 2004; however, positions will remain open until filled. Please send a full C.V., a descriptive statement on research plans and teaching activities and the names of six referees should be sent to:

Dr. David MacLean
Chair, CRC Search Committee
Faculty of Health Sciences
WMC 2812 Simon Fraser University
8888 University Drive, Burnaby, BC, Canada V5A 1S6

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