cination should not be placed on immunization of infants. All age groups must participate. In this era of diminishing resources for health care, the regular visits recommended during pregnancy provide an opportunity for interventions that should not be squandered. □

W. Paul Glezen, MD
Department of Microbiology and Immunology
Baylor College of Medicine
Houston, Tex

References

1. Centers for Disease Control and Prevention. Progress toward the global elimination of neonatal tetanus, 1989–1993. *MMWR Morb Mortal Wkly Rep.* 1994;43:885–894.
2. Koenig MA, Roy NC, McElrath T, Shahidullah MD, Wojtyniak B. Duration of protective immunity conferred by maternal tetanus toxoid immunization: further evidence from Matlab, Bangladesh. *Am J Public Health.* 1998;88:903–907.
3. McCarroll JR, Abrahams I, Skudder PA. Antibody response to tetanus toxoid 15 years after initial immunization. *Am J Public Health.* 1962;52:1669–1675.
4. Edsall G, Elliott MW, Peebles TC, Levine L, Eldred MC. Excessive use of tetanus toxoid boosters. *JAMA.* 1967;202:111–113.
5. Mulholland K, Suara RO, Siber G, et al. Maternal immunization with *Haemophilus influenzae* type b polysaccharide-tetanus protein conjugate vaccine in The Gambia. *JAMA.* 1996;275:1182–1188.
6. Englund JA, Glezen WP. Maternal immunization for the prevention of infection in early infancy. *Semin Pediatr Infect Dis.* 1991;2:225–231.
7. Stanfield JP, Gall D, Bracken PM. Single-dose antenatal tetanus immunisation. *Lancet.* 1973;1:215–219.
8. Englund JA, Glezen WP, Thompson C, et al. *Haemophilus influenzae* type b-specific antibody in infants after maternal immunization. *Pediatr Infect Dis J.* 1997;16:1122–1130.
9. Gill TJ, Repetti CF, Metlay LA, et al. Transplacental immunization of the human fetus to tetanus by immunization of the mother. *J Clin Invest.* 1983;72:987–996.
10. Vanderbeeken Y, Sarfati M, Bose R, Delespesse G. In utero immunization of the fetus to tetanus by maternal vaccination during pregnancy. *Am J Reprod Immunol.* 1985;8:39–42.
11. Englund JA, Mbawuike IN, Hammill H, et al. Maternal immunization with influenza or tetanus toxoid vaccine for passive antibody protection in young infants. *J Infect Dis.* 1993;168:647–656.
12. Amstey MS, Insel R, Munoz J, Pichichero M. Fetal-neonatal passive immunization against *Hemophilus influenzae,* type b. *Am J Obstet Gynecol.* 1985;153:607–611.
13. McCormick JB, Gussmao HH, Nakamura S, et al. Antibody response to serogroup A and C meningococcal polysaccharide vaccines in infants born of mothers vaccinated during pregnancy. *J Clin Invest.* 1980;65:1141–1144.
14. Advisory Committee on Immunization Practices. Prevention and control of influenza. *MMWR Morb Mortal Wkly Rep.* 1997;46(RR-9):5–6.
15. Monto AS, Iacuzio DA, LaMontagne JR. Pandemic influenza—confronting a reemergent threat. *J Infect Dis.* 1997;176(suppl):S1–S3.

Annotation: Prevention of HIV, Other Sexually Transmitted Diseases, and Unwanted Pregnancy—Testing Physical Barriers Available to Women

In this annotation, we carry forward our thinking on methods women could use for protection in sexual encounters. Unlike vaccines and the new microbicides, for which we await proof of safety before they are released for public use, several barriers that women might adopt for protection in sexual encounters are now freely available: the male condom, the female condom, the vaginal diaphragm, and the cervical cap. Although all are approved for contraception, none have been tested fully for protection against sexually transmitted diseases (STDs). It is time to repair this gap.

We set out 3 issues relevant to the evaluation of these physical devices in protecting against sexually transmitted diseases. As we see these issues, they can be resolved or bypassed without further testing. To do so, one must give proper weight to prior work and strict logic.

The first issue is the current requirement for testing the prophylactic efficacy (or "method effectiveness") of all types of barriers, excepting solely the male condom.[1] Efficacy requires a specific test of whether a method, properly applied, achieves what it is supposed to achieve under ideal conditions. Standard procedures for efficacy tests involve double-blind, randomized, controlled trials at the level of the individual.

With respect to testing physical barriers, we believe that official agencies involved in funding or regulation should part company with a narrow interpretation of efficacy testing procedures. Instead, we need to move directly to tests of effectiveness (or "use effectiveness"). Effectiveness requires a more generalizable test of whether a method achieves what it is supposed to achieve under routine field conditions. Such a test necessarily includes the behavior of participants in relation to such matters as acceptability, adherence to advice, and implementation.

One compelling circumstance in this recommendation to bypass efficacy is the virtual impossibility, in a randomized controlled trial, of rendering subjects blind to the nature of any available physical barrier. Therefore, the social and behavioral responses in experimental and control groups cannot be assumed to have been made equivalent by randomization. When groups are exposed to perceptibly different devices, no design can ensure that randomization will neutralize the effects on the responses of the groups. Such potentially disparate social and psychological responses vitiate supposed efficacy tests, and such trials do not meet the ideal conditions demanded for a test of efficacy. They are converted at best into tests of effectiveness. Thus, in any randomized controlled trial of physical methods, it is fair to say that effectiveness, and not efficacy, is at stake.

The second issue in trials of barriers concerns the appropriate interventions to be offered to the experimental groups. In this respect, individual-level randomized trials of these barrier devices must overcome another major obstacle. This obstacle resides in the primacy accorded the male condom in terms of efficacy. After long-standing use, the male condom has gained wide acceptance,[2] bolstered only recently by a number of relevant observational studies (e.g., studies of sero-discordant couples).[3]

The ethical consequence of this primacy is that any design for testing an intervention other than the male condom must demonstrate its equivalence or better against the male condom. In line with this position, a prevailing view is that all participants in a trial, whether experimental or control, must be offered the male condom. From this position it follows that, in the experimental group, another method is deemed permissible only as a supplement to the male condom.

In our view, this is not always a tenable position. Under conditions requiring male condoms as a first choice, even tests of chemical barriers as supplements have proved arduous to evaluate.[4] Because of the considerable efficacy of the male condom, even in long and expensive studies of microbicides with very large samples,[5] the numbers have yet proved insufficient and the results too often inconclusive.[6]

Tests of physical barriers, under the same conditions, are at least equally arduous and, in most conceivable circumstances, even more daunting. In particular, we contest any universal requirement for providing the male condom to all subjects in connection with the female condom. This device is the most likely of all physical barriers to match or surpass the efficacy of the male condom.[7] The female condom, in practice, cannot be used as a supplement together with the male condom. Does this make the female condom untestable, since it can obviously be used only as an alternative to the male condom? With the vaginal diaphragm and the cervical cap, both very attractive to women because they are essentially clandestine,[8] supplemental use might perhaps be feasible. Yet, even with these devices, the practical odds are surely against adherence to such dual methods. Thus, diaphragm and cap, in any trial and also in practice, are bound to become alternative rather than supplementary methods. In these 3 cases, the necessity for permitting experimental alternatives to the male condom rather than supplements to it is, to us, self-evident.

Given this complicated situation, in any test of effectiveness we must allow that the male condom will be the standard method of intervention in the control group. In the experimental group, however, we can accept primacy, but not monopoly, for the male condom, permitting use of alternatives and not merely supplements. In many circumstances, a choice of alternate methods rather than only a single method is likely to produce the best results.[9–11] The problems to be overcome are those of acceptability, of relations and negotiations between sexual partner and so-called gender scripts, of cultural norms, of self-protection for women in the face of coercion, and, not least, of feasibility and practicability.[12,13] Our own and other studies indicate that to make a hierarchy of methods[14] available to women—taking into account their needs for contraception or fertility, for overt or clandestine protection, for dry or lubricated sex—enables them to select with understanding those methods most suitable to each occasion.[15]

The provision of alternatives to the male condom gains scientific legitimacy for lack of any better approach. Similarly, trials of alternative barrier methods gain ethical legitimacy, since there will always be women who will need them. Indeed, to embargo the trial of such alternatives is to render many women unable to protect themselves from a raging human immunodefiency virus (HIV) epidemic and is therefore, in our view, unethical.

The third issue we wish to argue is the decision as to the level of intervention, as between individual or group. In our view, the most efficient, economical, and even the most ethical approach is to execute tests for defined populations or communities at the group level.[16] The investigator will inter alia collect such individual-level data as will serve to buttress group analysis against confounding by covariates. In these circumstances, the effectiveness of different programs, rather than of single specific methods for individuals in isolation, would be under trial.

We and others have considered some of the technical and analytic problems at length elsewhere.[17,18] Informed epidemiologists recognize that epidemics are invariably group phenomena that ultimately must be dealt with at the group level.

This approach to the urgent and overwhelming problem of the HIV/STD epidemic (now most pressing especially in Sub-Saharan Africa) circumvents and renders moot some obdurate and divisive ethical issues, for instance, those noted earlier that bear on what forms of protection are permissible. In a single project that tests group programs against each other, we can at once move 2 steps forward, beyond efficacy and also beyond effectiveness at the individual level, to address the epidemic itself. Here we note also that undue delay in arriving at results has become an ethical issue in prophylactic and therapeutic trials. At the same time as our suggested approach tests programs to stem the epidemic in real-life circumstances, it does not preclude the collection of usable data about the acceptability and practicability of a variety of available prophylactic methods and about women's requirements for family planning.[19] Some light may be shed also on the effectiveness of specific devices.

In summary, consideration of the 3 issues argued briefly here yields guidelines for research into barrier methods that women might adopt. We conclude, at this point in time, that trials might best test program effect rather than efficacy; that the experimental intervention, to be measured against male condoms in the control group, should offer a choice between a hierarchy of methods; and that the design should encompass the group level rather than solely the individual level. □

Zena Stein
Associate Editor

Mervyn Susser
Editor

References

1. International Working Group on Vaginal Microbicides. Recommendations for the development of vaginal microbicides. *AIDS.* 1996;10:UNAIDS1–UNAIDS6.
2. Roper WL, Peterson HB, Curran J. Commentary: Condoms and HIV/STD prevention—clarifying the message. *Am J Public Health.* 1993:83:501–503.
3. DeVicenzi I, European Study Group on Heterosexual Transmission of HIV. A longitudinal study of human immunodeficiency virus transmission by heterosexual partners. *N Engl J Med.* 1994;331:341–346.
4. de Zoysa I, Elias CJ, Bentley ME. Ethical challenges in efficacy trials of vaginal microbicides for HIV prevention. *Am J Public Health.* 1998;88:571–575.
5. Roddy RE, Zekeng L, Ryan KA, et al. A randomized controlled trial on the effect of nonoxynol-9 film use on male-to-female transmission of HIV-1. Presented at the National Conference on Women and HIV, May 1997, Pasadena, Calif.
6. Wittkowski KM, Susser E, Dietz K. The protective effect of condoms and nonoxynol-9 against HIV infection. *Am J Public Health.* 1998;88:590–596.
7. Gollub E. The female condom: STD protection in the hands of women. *Am J Gynecol Health.* 1993;7:91–92.
8. Stein ZA. HIV prevention: the need for methods women can use. *Am J Public Health.* 1990;80:460–462.
9. Steiner MJ, Glover LH, Bou-Saada I, Piedrahita C. Increasing barrier method use among oral contraceptive users at risk of STDs: what approach is best? *Sex Transm Dis.* 1998;25:139–143.
10. Musaba E, Morrison CS, Sunkutu MR, et al. Long-term use and acceptability of the female condom among couples at high risk of HIV in Zambia. Presented at the XI International Conference on AIDS, July 1996, Vancouver, British Columbia, Canada.
11. Fontaner AL, Saba J, Chandeyeng V, et al. Increased protection against sexually transmitted diseases by granting sex workers in Thailand the choice of using the male or female condom: a randomized controlled trial. Submitted for publication.
12. Ehrhardt A. Behavioral intervention with women. In: *National Institutes of Health Consensus Development Conference Statement. Interventions to Prevent HIV Risk Behavior.* Bethesda, Md: National Institutes of Health; 1997.
13. Gupta GR, Weiss E. Women's lives and sex: implications for AIDS prevention. *Cult Med Psychiatry.* 1993;17:399–412.
14. Cleary J, Winters S. *Female Condom: Efficacy, Acceptability and Relationship to Women's Hierarchy of Risk Reduction.* Albany, NY: Division of HIV Prevention, New York State Department of Health AIDS Institute; 1994.
15. Gollub E, French P, Latka M, et al. The women's safer sex hierarchy: initial responses to counseling on women's methods of STD/HIV prevention at an STD clinic. In: *11th International Conference on AIDS, July 1996; Vancouver, Canada.* Abstract MoD583.

16. Hayes R, Wawer M, Gray R, et al. Randomized trials of STD treatments for HIV prevention: report of an international workshop. *Genitourin Med.* 1997;73:432–443.
17. Susser M. The logic of ecologic, I: the logic of analysis. *Am J Public Health.* 1994:84;824–829.
18. Susser M. The logic of ecologic, II: the logic of design. *Am J Public Health.* 1994;84:830–835.
19. Stein Z. Family planning, sexually transmitted diseases, and the prevention of AIDS—divided we fail? *Am J Public Heath. Am J Public Heath.* 1996;86:783–784.

Topics for Our Times: Managed Care and Public Health Opportunities

It is widely recognized that health and longevity are substantially affected by environmental, behavioral, and socioeconomic factors that pose direct threats to health or that affect exposure to risk, coping capacities, or access to health interventions. Health promotion and disease prevention depend on a population perspective that allows for the identification of risks and the mobilization of protective and remedial interventions for both the individual and the community. This has been the vision of public health for more than a century, but this mission has been limited by the fact that public interventions are often in conflict with political, social, religious, and commercial interests. Not least among them has been the long-standing resistance of private physicians to public health efforts that in any way interfered with the flow of paying patients. It is inevitable that public health will continue to face ideological conflict because of political, commercial, and religious differences. The growth of managed care, however, may remove one major historical obstacle to many public health initiatives, and it offers new opportunities to invigorate many community efforts.

An influential report published by the Institute of Medicine in 1988 described our public health system as a "shattered vision" and as a system in disarray. It noted that public health in the United States "has been taken for granted, many public health issues have become inappropriately politicized, and public health responsibilities have become so fragmented that deliberate action is often difficult if not impossible."[1p17] Little has changed since then. Public health remains underfinanced and underappreciated and still has little priority relative to biomedical bench science and curative medicine. Indeed, despite a robust economy, the health care market has become more fragmented, the number of uninsured persons has grown, and social inequalities that contribute to poor health have increased.

The development of bacteriology was seen as heralding a golden age of public health, but it also contributed to separating public health from broader social and moral concerns.[2] Narrowing the emphasis brought greater social acceptability but moved the focus from social and environmental amelioration to individual interventions. At the individual level, it accentuated the competition between public health and fee-for-service medicine and relegated public health to a secondary role. Public health efforts addressed to individual interventions added to the already large fragmentation of health care services.

Some observers argued that public health required the centrality and influence of curative medicine, but it was difficult to see how the "public" aspects of broad public health responsibilities could reasonably be launched from the individualized perspective of medicine and medical education. Medicine's new interest in population perspectives and outcomes makes possible a more powerful collaboration based on a shared epidemiological conception, but the roles of medical care and public health remain different. The movement from fee-for-service medicine to capitation and other forms of prospective reimbursement aligns the interests of these two endeavors and potentially allows more unity in addressing major social and environmental risks. Perhaps public health and medicine together can be a stronger voice for protective and preventive efforts that face ideological resistance, ranging from needle exchange programs to sex education.

Until recently, physicians and health plans often perceived many public health programs, from school-based services to disease screening, as competitive, and these programs have often been irrationally restricted. As medical care providers increasingly are paid by capitation and are more often evaluated according to their success in improving outcomes, public health efforts at the individual as well as the community level are in their interest. At the very least, any services offered by public health reduce demand on medical providers and support their responsibilities. To the extent that public health successfully improves health behavior, reduces risk, and promotes function, it contributes to the newly defined goals of medical care. Managed care provides an opportunity for an effective public-private interface.

Defining the boundaries for this interface is an important challenge. Many health departments seeking to fill the gap in serving the growing uninsured population see their resources dissipated in responsibilities that are appropriately those of medical care, leaving few resources to address protection, promotion, and prevention responsibilities at the community level. In the presence of immediate need, the goals of public health may seem more distant and less compelling. In the light of community and moral pressures to back up the failures of the private sector, it is unlikely that public health can achieve its full potential outside a system of universal insurance coverage. Health departments cannot and should not avoid the compelling pressures to provide service to individuals who fall through the cracks, but they must not neglect their broader obligations: to organize community efforts to prevent disease and promote health through epidemiologic intelligence, strategic community planning, and appropriate regulation, research, and education, and to act as a catalyst for community action by private organizations and the public sector.

This potential for collaboration between the private and public sectors faces significant barriers. Competing health care plans continue to benefit more by selecting healthy enrollees whose care is inexpensive than by taking positive measures to promote health and reduce morbidity. Until we have good ways to adjust capitation to take account of illness and needs, health care plans will have strong incentives to avoid individuals with the most serious and costly conditions. Adjusted capitation is now an area of intensive research, but we still lack reliable predictors of future resource use.

For-profit firms, more accountable to their stockholders than to the public health, are especially motivated to seek short-term advantages, eliminating preventive measures to cut costs and increase profits, knowing that their enrollees may shift plans in the future and not remain their financial responsibility if and when they develop preventable illness. Not-for-profit plans are converting to for-profit status at an alarming rate, and we require much tougher accountability to ensure that

David Mechanic is René Dubos Professor of Behavioral Science at Rutgers University, New Brunswick, NJ.

Requests for reprints should be sent to David Mechanic, PhD, Institute for Health Policy, Rutgers University, 30 College Avenue, New Brunswick, NJ 08903.