Public Health Chronicles

Population-based data provide the foundation of public health research and planning. Yet, historically, such data are collected through untold numbers of individual clinical encounters where the identifying information is carefully controlled. For many conditions, the collection of these data through unlinked anonymous testing (UAT) is unproblematic. This column examines the growing contention over UAT for human immunodeficiency virus (HIV) as effective treatments for the disease are more widely available and as the identification of the HIV-infected person becomes essential for saving lives and stopping the spread of the virus. What were once tools for protecting individuals' rights are increasingly problematic in countries where the population lacks access to basic health services. This column raises important historical and ethical questions: When do the goals of research overwhelm the right of the individual to information? When are the rights to effective care infringed upon by the standard practices of researchers?

David Rosner, PhD
Ronald H. Lauterstein Professor of Sociomedical Sciences and History
Columbia University, Mailman School of Public Health, New York, NY

UNLINKED ANONYMOUS TESTING FOR HIV IN DEVELOPING COUNTRIES: A NEW ETHICAL CONSENSUS

Amy L. Fairchild, PhD, MPH
Ronald Bayer, PhD

June 5, 2011, marked the 30th anniversary of the first report of acquired immunodeficiency syndrome (AIDS) in *Morbidity and Mortality Weekly Reports*.[1] These sentinel cases—the result of careful surveillance on the part of clinicians, local and state epidemiologists, and the Centers for Disease Control and Prevention (CDC)—underscored the centrality of the capacity of public health agencies to identify outbreaks and track the incidence and prevalence of disease. But however important these surveillance methods may be, they have often provoked questions about the ethical foundations of such activities. On occasion—when the disease subject to monitoring raised issues of particular sensitivity, when the population most at risk was especially socially vulnerable, and when the people who spoke on behalf of those with the disease had the capacity to articulate concerns about the importance of effective monitoring or the risks that might follow such efforts—the discussion could be fierce. In the context of the global human immunodeficiency virus (HIV) epidemic, virtually every aspect of surveillance, from name-based case reporting to anonymous serosurveillance, has been marked by dispute. Those questions have been the subject of ongoing discussion and sometimes fierce debate, not only in the United States, but also the global community.

For more than two decades, a core element in the global surveillance of HIV infection has involved unlinked anonymous testing (UAT), which entails the screening of blood specimens taken for purposes other than HIV testing. These samples are permanently stripped of personal identifiers. The process occurs without informed consent. Ethical controversy has haunted this approach to HIV surveillance. How can public health officials best meet their professional obligations to monitor the incidence and prevalence of disease so that preventive interventions can be appropriately targeted? What rights do the subjects of surveillance have to control information about their HIV status? What duties do health officials have to provide vital clinical information to those found to be infected? These questions have persisted, even as the epidemiological, clinical, and social contexts have undergone radical transformations. Both CDC and the World Health Organization (WHO) have engaged these matters with increasing intensity over the past decade, alert to how the solutions proffered in the early days of the epidemic might no longer suffice. At stake is a critical ethical question, often mistaken for a technical one: When are clinical data "good enough" for public health purposes, given the moral unease that surrounds an approach to surveillance that precludes the notification of infected individuals who could benefit from treatment? Although this decades-long controversy is drawing to a close, remarkably, neither the evolution of the debate nor the implicit new consensus that has emerged has been publicly documented.

THE FIRST DECADE OF DEBATE

By the late 1980s, there was widespread agreement in the U.S. that UAT was both essential and ethically unproblematic, despite exceptional attention to the importance of specific informed consent for HIV testing (Unpublished manuscript, CDC [US], Office for the Protection from Research Risks. HIV seroprevalence survey of childbearing women: testing neonatal dried blood specimens on filter paper for HIV antibody, Draft 8. Atlanta, 1988).[2] Only UAT could provide prevalence data unmarred by the selection and participation bias that characterized studies based on volunteers. UAT involved samples of blood, not identifiable individuals. No one's privacy was violated. The social and psychological risks of being identified as infected were precluded by irrevocably unlinking the test results from individuals. Informed consent was hence unnecessary. But what made the studies ethically acceptable also prevented the notification of individuals about their test results. Because little could be done for people with asymptomatic HIV infection at that time, there was consensus that the blinded surveys were ethically permissible given an affirmative public health duty to collect data. Mirroring the U.S. position, WHO's Global Programme on AIDS issued a 1989 report concluding that UAT could be used "without endangering or compromising the broad principles of public health and human rights."[3]

UAT still provoked controversy in some economically developed nations, including the U.K. and the Netherlands. Critics included leading medical ethicists Raanan Gillon and Ian Kennedy.[4,5] Summarizing the objections, one U.S. expert on the ethics of human subjects research stated, "The fundamental issue for these critics is that such programs conscript research subjects to efforts that they may not want to be part of."[6]

At the same time, CDC sought to provide a conceptual frame that would distinguish surveillance activities (public health practice) from research. Only in the case of the latter was Institutional Review Board oversight required. Only for studies that were defined as research, because they sought to produce "generalizable knowledge," was informed consent a necessity.[7] For CDC, UAT was a form of public health practice and, hence, required neither informed consent nor ethical review.

As the therapeutic prospects changed in the 1990s, so too did an immediate interest in knowing one's clinical status. In 1994, when a clinical trial revealed that zidovudine could reduce the risk of vertical transmission from mother to fetus by two-thirds, pressure mounted in the U.S. to unblind the newborn screening serosurveys to assure the notification of all women who might benefit. UAT was subject to sustained criticism across the political spectrum in the U.S. Congress. Indicating the racially charged nature of the conflict, CDC was accused of repeating the ignominious Tuskegee syphilis study, this time neglecting HIV-infected women in the U.S., most of whom were black and Latina.[7] CDC responded by ending the use of UAT altogether in 1995.[8] In Europe, UAT subsequently fell out of favor in all but a few countries.[9]

UAT continued in antenatal clinics (ANCs) in developing countries where neither testing nor antiretroviral therapy was widely available. For U.S. officials, this globally bifurcated situation would make it necessary to confront troubling ethical and political questions: If UAT among childbearing women domestically had ceased because of ethical concerns and controversy, was it permissible for CDC to fund such efforts abroad? Alternatively, would a cessation of funding for such efforts represent a kind of "ethical imperialism"—i.e., imposing U.S. norms on other nations? More than a decade ago, at a 1998 CDC ethics consultation, an indisputable consensus emerged that, given the public health benefits, UAT remained vital to the global response to the HIV pandemic. As long as voluntary counseling and testing was provided in contexts where surveillance occurred or was available and accessible in the community, no violation of ethical norms existed. This was a standard that was rarely obtained in the most HIV-burdened settings (Unpublished manuscript, CDC [US]. Summary of ethical review of CDC anonymous HIV surveys, final version. Atlanta, 1998).

SHIFTING CONCERNS: UAT IN THE DEVELOPING WORLD

Reflecting a growing sense of discomfort, international consultations regarding the ethics and conduct of UAT sponsored by WHO and CDC occurred virtually every year over the course of the next decade. Central to those discussions were issues of consent and the right to know. Despite its importance, this is a controversy that has gone virtually unreported, a void in the literature that is lamentable because of the critical issues at stake.

In 2001, the WHO Regional Office for Africa (AFRO) Technical Network on HIV/AIDS and STI Surveillance met in Pretoria, South Africa, to discuss the continuing usefulness of UAT in response to what one participant called "misdirected" attacks against the practice. In the face of such criticism, WHO/AFRO's Nicholas Meda articulated the moral calculus of those concerned about the duty to conduct surveillance activities: the goal of UAT was not the identification of infected individuals, but rather the acquisition of population data needed "for advocacy, resource

allocation, and targeting interventions."[10] The fundamental ethical problem, he argued, was not UAT, but a lack of services and access to treatment. Clearly, UAT was still necessary, but only because ANCs provided data inadequate for public health "advocacy, resource allocation, and targeting interventions."[10] In 2004, Kevin DeCock argued at a CDC-sponsored meeting in Ethiopia that the question was not whether to continue UAT but rather "how high participation in Prevention of Mother to Child Transmission (PMTCT) programs needed to be for the data to be" able to meet surveillance needs.[11]

Discussions moved to Zimbabwe in 2006. Thailand—where more than 90% of births occurred in hospitals, and the uptake of HIV testing in ANCs exceeded 95%—provided an example of how it was possible to use clinical data to replace UAT. It suggested to some that clinical data could "provide greater coverage and representation than UAT" and demonstrated that the benefits of surveillance need not come at the expense of a woman's right to know her HIV status. The consultation consensus was that, with rapid expansion and increased availability of PMTCT and treatment services, "it is ethically difficult to justify UAT unless all UAT sites are providing PMTCT services" (Unpublished manuscript, CDC [US]. Concept paper: consultation to review the ethical issues surrounding unlinked anonymous HIV testing surveillance and survey activities supported by the President's Emergency Plan for AIDS Relief, Attachment 7. Atlanta, 2009).

Emblematic of the politics of these unfolding discussions was a WHO/AFRO recommendation to obtain informed consent in "situations where UAT is not acceptable for surveillance."[10] While this accommodation addressed the real-world context within which surveillance occurred, it undercut the central methodological premise of UAT, which sought to avoid the threats of participation and selection bias by testing all samples—a condition that could only be met if informed consent were not required.

Recommendations to test with informed consent highlighted discomfort over UAT in the context of ANCs. An official with CDC's Global AIDS Program (GAP) in Ethiopia noted that his program staff considered UAT at ANCs to be research warranting informed consent, a confusion reflecting international uncertainty. More stunning, he noted that, in some parts of Ethiopia, UAT results actually remained linked to individuals. U.S. Public Health Service regulations require that personally identifiable HIV test results be provided to those who were tested. Keeping UAT results linked to individuals but not providing them with their test results was a clear violation of those regulations. On the one hand, this report raised a red flag that staff had failed to understand the principle of UAT and that further training was warranted. On the other, and more seriously, UAT seemed discordant with the international effort to provide ethical oversight for research.[11]

A NEW CONSENSUS AND THE DEATH THROES OF UAT

Years of dispute appeared to reach an important turning point as the first decade of the 21st century drew to a close. In 2008 and 2009, leading ethicists convened to clarify the issues at stake. In addressing the CDC-sponsored session held at Columbia University in New York on the long-debated question of UAT in ANCs, they concluded that periodic review was necessary "to determine whether [circumstances] warrant testing without providing results to the individual tested"—a conclusion no different from that which had been asserted for years (Unpublished manuscript, CDC [US]. Draft summary of ethical consultations held in New York [2008] and Geneva [2009]: HIV testing in surveillance and survey protocols. Atlanta, July 14, 2009). No effort was made to define the threshold beyond which UAT would no longer be acceptable, leaving unresolved the issue at the heart of debate.

A year later, with the 2008 CDC consultation setting the stage, discussion once again shifted to Geneva. Some used the occasion to assert that the time had come to abandon UAT—the needs of surveillance could not outweigh the individual's right to the test result; testing without consent had never been ethically justified, and the failure to inform women of their HIV status compounded the failure (Unpublished manuscript, UNAIDS/WHO. Ethics in HIV surveillance consultation, meeting I: proceedings and recommendations. Geneva, Switzerland, February 23–24, 2009). The consultation struck a more modest stance in endorsing the proposition that, to the extent possible, PMTCT data should replace UAT.

The massive U.S. global commitment to provide treatment funds via the President's Emergency Plan for AIDS Relief (PEPFAR) created an impetus to provide clear guidance for surveillance efforts. In mid-2009, relevant U.S. agencies reviewed the implications of the consultations that had addressed the ethics of UAT in the prior year. There were no surprises. But now a degree of specificity was provided. Where PMTCT programs or stand-alone testing services were available in less than 75% of ANC sites, and where uptake of testing in these clinics was less than 90%, "a waiver should be submitted to conduct UAT surveillance."

The default position was non-UAT-based surveillance (Unpublished manuscript, CDC [US]. Draft summary of ethical consultations held in New York [2008] and Geneva [2009]: HIV testing in surveillance and survey protocols. Atlanta, July 14, 2009). It is worth noting that, on occasion, CDC GAP efforts to move away from UAT have encountered resistance from local-level officials in PEPFAR countries. In seeking to address claims that UAT still provided critically important surveillance data, CDC has required documentation of the nature of the deliberations that resulted in such conclusions, including the range of participants who were consulted. Made clear in these encounters were the unexpected, and sometimes paradoxical, ways in which ethical and empirical questions have played out in the context of HIV surveillance.

CONCLUSION: AN ELEGY FOR UAT

Reflecting the ways in which clinical, epidemiological, and political change alter ethical norms, there is now clear consensus that both the principle of consent and the right of individuals to have access to information critical to their well-being and to their capacity to access treatment that might not be locally available render UAT—an approach to surveillance that makes neither possible—all but moribund. This remarkable transformation is little known and entirely undocumented. The English language literature is only just beginning to reflect this transition in thinking regarding an approach to surveillance that precludes the direct communication of HIV test results, calling it "not ethically justifiable."[12,13] Ongoing discussion must now take account of a context in which it is important to provide antiretroviral therapy to the infected for purposes of preventing progression to AIDS and drastically reducing the risk of HIV transmission.[14]

Only the current limits of clinical data for public health surveillance purposes sustain UAT. But continuing to hold out for a technical solution is a mistake. While there are certainly technical dimensions to the issues at stake, the question of UAT has, at base, always been ethical. Resolution requires widely acknowledging the new consensus. In situations where there appears to be no alternative to UAT, because clinical data provides neither the reliability nor validity required, officials must consider whether resources devoted to UAT might be better used to enhance PMTCT programs. The burden should now fall to those who conduct surveillance to spell out explicitly how they will move beyond an approach whose ethical underpinnings have collapsed.

As the new consensus takes hold, it would be a mistake to conclude that those who supported UAT at an earlier moment, when clinical services for individuals with HIV were unavailable, had adopted an ethically unacceptable position. In fact, it is the very ethical principles that undergirded the earlier defense of UAT that make such an approach to surveillance at this juncture difficult to defend. New facts require moral recalculation.

Amy L. Fairchild and Ronald Bayer are Professors of Sociomedical Sciences in the Center for the History and Ethics of Public Health at the Columbia University Mailman School of Public Health in New York, New York.

Address correspondence to: Amy L. Fairchild, PhD, MPH, Columbia University, Mailman School of Public Health, 722 W. 168th St., New York, NY 10032; tel. 212-305-1724; fax 212-842-1986; e-mail <alf4@mail.cumc.columbia.edu>.

REFERENCES

1. Pneumocystis pneumonia—Los Angeles. MMWR Morb Mortal Wkly Rep 1981;30(21):250-2.
2. Bayer R, Levine C, Wolf SM. HIV antibody screening. An ethical framework for evaluating proposed programs. JAMA 1986;256:1768-74.
3. World Health Organization, Global Programme on AIDS. Unlinked anonymous screening for the public health surveillance of HIV infections. Proposed international guidelines. Geneva: WHO; 1989.
4. Gillon R. Testing for HIV without permission. Br Med J (Clin Res Ed) 1987;294:821-3.
5. House of Commons (UK), Social Services Committee. Problems associated with AIDS, vol. 2. London: Her Majesty's Stationery Office; 1987.
6. Brody BA. The ethics of biomedical research: an international perspective. New York: University Press; 1998.
7. Fairchild AL, Bayer R. The uses and abuses of Tuskegee. Science 1999;284:919-21.
8. EuroHIV. Report on the EuroHIV 2006 survey on HIV and AIDS surveillance in the WHO European Region. Saint Maurice (France): Institut de veille sanitaire; 2007.
9. Fairchild AL. Dealing with Humpty Dumpty: research, practice, and the ethics of public health surveillance. J Law Med Ethics 2003;31:615-23.
10. World Health Organization, Regional Office for Africa. Report: meeting of WHO AFRO Technical Network on HIV/AIDS and STI Surveillance. 2001 [cited 2011 Aug 24]. Available from: URL: http://www.who.int/hiv/strategic/surveillance/en/afr_pret_01.pdf
11. World Health Organization. New strategies for HIV/AIDS surveillance in resource-constrained countries. 2004 [cited 2011 Aug 24]. Available from: URL: http://www.who.int/hiv/pub/epidemiology/en/Addisconference_part1.pdf
12. Krishnan S, Jesani A. Unlinked anonymous HIV testing in population-based surveys in India. Indian J Med Ethics 2009;6:182-4.
13. Rennie S, Turner AN, Mupenda B, Behets F. Conducting unlinked anonymous HIV surveillance in developing countries: ethical, epidemiological, and public health concerns. PLoS Med 2009;6:e4.
14. Cohen MS, Chen YQ, McCauley M, Gamble T, Hosseinipour MC, Kumarasamy N, et al. Prevention of HIV-1 infection with early antiretroviral therapy. N Engl J Med 2011;365:493-505.