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TESTIMONY TO THE SUBCOMMITTEE ON NEWBORN SCREENING OF THE NEW YORK STATE AIDS ADVISORY COUNCIL ON NOVEMBER 8, 1993

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In the debate on parturient and newborn testing I believe that we all agree on the pivotal issue: access to care for the mothers and for their newborns. And access to care for the mothers carries with it also our concern for their other children and for future newborns.

The question is, what works? What will bring as many as possible of the infected children into care? Will unblinding the newborn study, or some other form of mandatory testing necessary? Or will voluntary testing, with targeted counselling to pregnant and parturient women, be more effective in achieving this goal? A goal, again, which we all agree is of utmost importance.

I base my recommendations, which are in favor of increased and improved voluntary counselling and against mandatory testing in any guise on the following information and experience.

We know that if testing -- testing with sufficient and appropriate counselling -- is offered, it is accepted by a large number, by most women. There are members of this panel who have developed highly successful counselling and testing programs for pregnant women. We also know that mandatory programs do drive away a certain number of persons -- what proportion in any given situation is not predictable -- drive them away from utilization of services. I am sure you have been given documentation of both these experiences by other speakers.

I will speak from my own particular experience. I am a physician who practices in and develops programs for substance users and former substance users who have <u>never</u> had medical care and who already carry a burden of distrust and suspicion about HIV and the medical system. In focus groups and individual interviews, stigmatization in the health care system is given as the primary reason for not seeking or for refusing HIV care, and distrust in the availability of acceptable HIV care is the reason for not being HIV tested. Many, especially from the African American community, also believe that, understood in the context of the Tuskegee syphilis study, HIV is a racist government plot.

My concern is that the women we would most like to reach will become most inaccessible once they have left the hospital as post-partums. I am also concerned that down the line the job of getting women into prenatal care in the event of future pregnancies will become even more difficult. At the same time, I know from my own experience in working with mothers of HIV infected children that most -- not all, but nearly all -- of these mothers, drug users or otherwise, are fanatical about taking care of their children. I

saw this first at Bellevue when I served as an internist in the pediatric Infectious Disease Clinic trying to draw the mothers into care for themselves. This was a formative experience for me. I see it now every day as I work directly with chemically dependent women.

I believe we must find the means to offer the women the care they really do want for their children. The problems with access to care for newborns, as for women and many others in our quirky health care system, is one of distrust and especially inadequate resources, not one of noncompliance. (A noncompliance which requires credence in a Reagenesque stereotype of a drugged out welfare mother. This is unfortunately a stereotype that our media are sometimes willing to purvey.)

Mandatory testing will simply delay and probably worsen the problems we are already having of providing adequate health care to HIV infected newborns (that is, better access to care than newborns under our current health care system routinely have). Mandatory testing will only push back the problem by one step because it does not get an infant to all his or her appointments nor maintain ongoing health care after that HIV test.

On the other hand, I also know of the extent of the problem from my experiences working with a methadone program. If voluntary counselling and testing is the best strategy, it needs to be where the women are. I had occasion to review the charts of women who were reported pregnant in one methadone clinic in the course of a year. In this particular period, all were cocaine (and polysubstance) users and none had prenatal care. Interviews and chart review in this clinic have told us that crack/polysubstance use, BCW interventions, psychiatric illness and lack of medical care are all far more frequent in HIV infected women. We therefore know from direct experience what our Health Department zip code maps tell us: namely, the confluence of poverty, unplanned pregnancies, HIV infection and chemical dependency in what epidemiologists refer to as a core population for an epidemic.

I can tell you that very little is being done to reach this population prior to the moment of childbirth. Our state and city HIV efforts do not include programs or special measures to identify, educate and offer counselling and testing to pregnant women in drug treatment centers. Why are we not offering HIV counselling and testing to every pregnant woman in drug treatment? Why is this service not funded and mandated, as it is for family planning centers? A large number of the unidentified HIV infected mothers we are discussing could be reached through drug treatment programs.

As much as has been done in this state to promote counselling and testing, including among pregnant women, it has not been nearly enough, and not always as efficient as it should be. Recently

gathered CDC data shows that 43% of HIV infected women receive an AIDS diagnosis only 2 months after being identified as HIV infected. Pure and simple we are not reaching the women in time, in time to help them, in time to help their newborns, in time to help all the children.

In a thoughtful editorial in the New England Journal in August 1992, Dr. Quinn reported the overall experience in Baltimore. Like that in New York State, it reflects increasing success as we have risen on the learning curve. However, their acceptance rates for HIV testing are 96% of hospital and 85% of STD clinic patients (a 20% increase in 2 years). [See attached reprint.] We need to study such experiences closely and learn from them.

Speaking more broadly, we also know that peer counselling and education are extremely effective. In fact, peer education and the media, especially television and radio talk shows, are so far the only demonstrably effective means of reaching into communities that are largely ignorant of the risk of HIV infection to women and children. And they can change that ignorance and the attitudes of distrust and fear that support it. We need to pay much more attention to these strategies before we blame the mothers and declare that unblinding the newborn results is the only or even the better solution to helping their children.

Lastly, but certainly not least, mandatory testing raises serious ethical concerns under any circumstances. Mandatory testing for special populations is untenable. And we can know with certainty that legislation will not settle the issue. Mandatory testing for pregnant women as a selected population will be assailed by women and by advocates everywhere and result in a lengthy and costly battle in the courts.

The role of professionals is to view the available data objectively in order to provide a rational and effective basis for public policy. It is our job to lead the policy makers and legislators away from succumbing to the current fashion of our litigious society in which the health and interests of mothers and children are believed to be adversarial, rather than the welfare of each being intimately bound to the other.

There is much work to be done in the HIV epidemic, and too few of us to do it. We are all exhausted, and I question the wisdom of spending our slender resources to join in a costly legislative and court battle when all of us in this room so clearly agree on the objective, and the evidence is there of how to accomplish it.

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SCREENING FOR HIV INFECTION — BENEFITS AND COSTS

Now in its second decade, the human immunodeficiency virus (HIV) epidemic continues to escalate relentlessly. Approximately 1 million people in the United States are infected with HIV, and nearly a quarter of a million have been given diagnoses of the acquired immunodeficiency syndrome (AIDS).[1] During the first eight years of the epidemic, 100,000 cases of AIDS were reported; another 100,000 were reported within the next two years.[2] AIDS has caused 150,000 deaths in the United States and is now ranked as one of the leading causes of premature death for both men and women in this country,[3] as well as in many others. The epidemic has penetrated many segments of our society. In particular, the incidence of new HIV infection and of AIDS continues to rise rapidly among women and minority groups in our inner cities, where financial resources and access to routine medical care are severely limited.

The early initiation of antiretroviral therapy for asymptomatic persons and of chemoprophylaxis to prevent opportunistic infections can delay the progression of HIV disease and increase survival. Yet there are substantial inequities in access to care for HIV infection. In Maryland[4] and San Francisco,[5] women and minority populations receive zidovudine significantly less often than men and non-Hispanic whites, resulting in marked differences in survival. Since it is likely that future therapeutic advances will involve even earlier treatment interventions, it is imperative that early access to care be provided to all HIV-infected persons to help reduce these differences in survival.

Unfortunately, one of the many tragedies of this disease is that most HIV-infected persons are unaware of their infection. Too often, such people learn of their serologic status only after an opportunistic infection or other serious HIV-related disease has developed. More than half of those with newly diagnosed HIV infection qualify for antiviral therapy at the time of their first serologic test for HIV, and a

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third of these also qualify for *Pneumocystis carinii* prophylaxis.[6] However, from estimates of the number of HIV-infected persons eligible for antiviral therapy[1] and from statistics on the current use of zidovudine, it appears that only 20 percent of eligible persons are receiving therapy. Testing on the basis of clinical suspicion or risky behavior has been insensitive, identifying only 30 to 40 percent of HIV-infected persons. At the Johns Hopkins Hospital, three fourths of the patients found to be HIV-positive on anonymous screening had unrecognized infection.[7] Because HIV infection is so often unrecognized, routine voluntary testing for HIV infection in medical clinics and hospitals, particularly in areas of endemic disease, is a rational approach to ensure that all HIV-infected persons receive adequate medical care and counseling. Routine voluntary testing means specifically offering HIV testing to all patients. This contrasts with routine testing, in which the test is performed unless there is a refusal, and with voluntary testing, in which patients must request the test. The necessary corollary to recommending routine voluntary screening is that financial resources for these activities must be increased. Future policies must reduce barriers impeding the coverage and treatment of all HIV-infected persons, not just those with AIDS.

There have been numerous articles, editorials, and commentaries in the *Journal* over the past five years debating the pros and cons of screening for HIV infection, and no simple recommendation will please everyone. On the one hand, it is in patients' interests to know their serologic status, so as to afford the opportunity for early intervention with antiretroviral therapy and for intensive counseling that might alter behavioral patterns and decrease transmission. On the other hand, HIV testing raises issues of confidentiality and discrimination, individual and social matters that must be addressed in any HIV-testing program. Physicians should work with legislators to forge antidiscriminatory laws that protect HIV-infected persons, and to provide additional funding for indigent populations that require better medical care.

To achieve the objective of identifying HIV-infected persons seeking medical care, Janssen and colleagues in this issue of the *Journal*[8] propose a national strategy for the HIV screening of patients at U.S. hospitals that would provide ready access to appropriate counseling, clinical referral, evaluation, and therapy. In a blinded serologic survey of patients at 20 hospitals in 15 U.S. cities, they found that hospital-specific HIV seroprevalence ranged from 0.2 percent to 14.2 percent and that nearly two thirds of seropositive persons presented with medical conditions other than symptomatic HIV infection or AIDS. Seroprevalence was consistently highest in men and women 25 to 44 years of age, with a rate of 40 percent in one hospital. Whereas infection rates were highest among those presenting with infectious or drug-related conditions, HIV infection was nevertheless widely distributed among those with a variety of presenting symptoms. Like previous investigators,[7,9] Janssen et al. found that nearly two thirds of HIV-positive patients presented with conditions apparently unrelated to HIV infection.

There are several aspects of the study that should be addressed. The hospitals studied were not randomly selected and were more likely than other U.S. hospitals to be in urban areas, to have teaching programs, and to have a large percentage of Medicaid patients. Despite these differences, the authors demonstrated that the AIDS-diagnosis rate was the only variable associated with HIV seroprevalence. The authors suggest that HIV testing of patients 15 to 54 years old in U.S. hospitals with an AIDS-diagnosis rate of 1 or more per 1000 discharges per year would identify 68 percent of all HIV-positive patients admitted with conditions other than AIDS. The authors appropriately caution that the predicted numbers of HIV-positive patients with unsuspected infection may be too high, since it could not be ascertained whether some of the HIV-infected persons were already known by their doctors to be infected. Nevertheless, these figures are remarkably similar to those from studies performed in other selected hospitals.[7,9] Although individual hospitals may wish to validate the association between HIV seroprevalence and the number of AIDS cases per 1000 discharges, the strategy offered by Janssen and colleagues provides a new formula for HIV screening that would be more effective than routine HIV testing of all hospital patients. The latter would entail screening five times as many people (25 million), with only a 20 percent increase in the identification of HIV-positive patients over the strategy suggested by Janssen et al.

Opponents of this strategy will suggest that screening targeted only to people who acknowledge high-risk behavior would be more cost effective. However, as shown in previous studies, many HIV-infected persons report in pretest counseling that they do not engage in high-risk behavior, and more than half of HIV infections may be missed.[10] Other opponents may suggest that the screening of hospitalized patients is designed primarily to prevent transmission of HIV from patients to health care workers.[11] The intent of screening for HIV should only be to identify persons with early HIV infection, so that they can receive appropriate counseling and therapy. Universal precautions remain the only policy for protecting health care workers from HIV transmission. In a recent study at the Johns Hopkins Hospital, my colleagues and I showed that routine screening for HIV alone would fail to identify over 80 percent of patients who pose a risk of transmitting other viruses, such as hepatitis B and hepatitis C viruses, to health care providers.[12]

Public acceptance of this policy will depend largely on how it is presented. Previous polls have demonstrated that 76 percent of those polled are in favor of routine voluntary testing. In a recent study at the Johns Hopkins Hospital, 96 percent of 351 patients admitted to a medical service, excluding the AIDS

inpatient service, agreed to HIV testing, and 15 percent of these were found to be seropositive (Munday L, Janis E: personal communication). Even in sexually transmitted disease clinics in Baltimore, 85 percent of patients now consent to testing, a 20 percent increase over the past two years (Baltimore City Health Department: unpublished data). It is evident that compliance with a screening program can be markedly enhanced with proper education and pretest counseling.

What are the obligations of the hospital? With routine voluntary screening it is the hospital's responsibility to protect confidentiality. There will be a need for additional counselors; facilities for comprehensive HIV evaluation, including appropriate laboratory support; and treatment services and referrals for those found to be infected with HIV. What must be avoided is a laissez-faire attitude toward counseling and testing, or the development of policies in which HIV testing is a requirement for admission or for invasive procedures. If HIV-antibody testing is to be offered routinely, appropriate consent procedures must be followed, and opportunities for education, counseling on risky behavior, and access to care must be provided. Since the assurance of confidentiality is an important factor in any testing policy, this transition would be eased substantially if appropriate federal antidiscrimination legislation were enforced and legal safeguards maintained.[13]

The goal of promoting widespread voluntary HIV testing that is based in the health care system is to inform all persons infected with HIV about their condition. This is a disease of great public health importance, and screening in the hospital setting has clear benefits, particularly in the light of the recent outbreaks of multidrug-resistant tuberculosis among hospitalized HIV-positive persons.[14] Identifying those who are HIV-positive early in their disease affords them the opportunity for reliable tuberculin skin testing and for the provision of antituberculous prophylaxis. This provides benefit to the patient, to the health care provider, and to other patients. With these benefits, however, there will be costs. Many facilities are already under stress, with increasing numbers of HIV-infected persons, a short supply of qualified counselors, and inadequate financial resources. A call for more screening must be accompanied by more resources to meet in full the challenge of caring for newly identified infected patients. Providing access to early treatment means enhancing ambulatory care systems, particularly in the inner cities, where the dearth of resources has limited the availability of high-quality health care.

Weiss and Thier[15] stated that the question "Why test?" must be fully addressed in any policy of HIV screening. Access to early therapy and prophylactic regimens, as well as repeated counseling to reduce further transmission, clearly benefits the patient and society. Increased voluntary testing in health care facilities appears to be the most rational approach to achieve these objectives. With all the improvements in survival and quality of life for HIV-infected persons, it is imperative that patients be given the opportunity to be routinely counseled and tested for HIV. In the end, the patient benefits, the medical profession benefits, and society benefits, but it must be recognized that this benefit is not without certain costs. More financial resources at the local, state, and national levels will be needed and must be made more readily available if we are to meet this obligation.

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HEPATITIS A VACCINE

THE first effective control measures for the prevention of enterically transmitted viral hepatitis resulted from research conducted during World War II. In 1945, Neefe et al.[1] demonstrated that infectious virus could be transmitted by contaminated drinking water, that treatment of the water by filtration and chlorination made it safe to drink, and that gamma globulin derived from convalescent-phase serum from patients with hepatitis could protect adults from clinical hepatitis.[2] Except for refinements in methods of preparing food and water and the establishment of standards for the preparation and use of immune globulin, there

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AIDS ADVISORY COUNCIL
SUBCOMMITTEE ON NEWBORN SCREENING

TESTIMONY OF
DEBRA FRASER-HOWZE
EXECUTIVE DIRECTOR/CEO
BLACK LEADERSHIP COMMISSION ON AIDS

NOVEMBER 8, 1993

My name is Debra Fraser-Howze and I am the Executive Director & Chief Executive Officer of the Black Leadership Commission on AIDS--the oldest and longest surviving public policy, advocacy, research and community development agency focused solely on communities of African descent. The agency's chief mission is to organize Black leadership across this city, state and nation on HIV/AIDS related issues.

The 65 members of the Commission consist of clergy, politicians, social policy, business and medical experts who have a daily outreach capacity to 2.5 million people of African descent across the state of New York. On behalf of this organization that has singlehandedly brought more than 750 Black churches to the HIV/AIDS epidemic from disparate philosophical issues to providers of service and has helped to access upward of $11 million for Black organizations working in AIDS, I am here today to discuss the "unblinding" of the HIV status of newborns and the effects this will have on us as a people and the current health care system. In all its good intentions, this system remains the most racist and benignly neglectful system in the universe.

In 1987, when it was formed, the Black Leadership Commission on AIDS {BLCA} began to ask questions regarding policies that were established in the early 1980s--to service a very different infected population. The primary question was: Do these policies and programs established for the White, gay male majority still stand to service the growing number of people of color who are increasing in numbers among those infected with HIV? Today, six years later, when AIDS has become the first disease to kill multiple generations of the same race of people, SIMULTANEOUSLY, across two continents, we can no longer passively examine AIDS policies. We must dissect them; turn them inside out; use our real experiences as the litmus test, and where we see the need for change and the allocation of dollars to effect this change, we **must** demand it!

The policies now in affect around newborns and their mothers must change, but they must change for the betterment of all and **not simply for the egos of some.** And it is in these days that common sensitivity, rationalized and illustrational behavior are most needed and the days I miss Dr. Nick Rango the most.

You are having discussions today about an issue that has two sides.

(1) Is it critically important to the health of the mother and child to know if a baby and mother are both HIV+?

(2) Is it not critical in standards of care for this information to be revealed?

But this, as most AIDS issues, is once again being fought out by the " AIDS community"

and its various factions that have little to do with this mother and child. Some are members of a Gay white male structure that has institutionalized an epidemic and must keep their financial and moral obligations to the groups for which they advocate--be damned the public health impact on people of color, particularly women and children. Some are white lesbians who never got a chance to play a meaningful role in the AIDS epidemic, so their white woman maternalism/paternalism says, "this is it!"

And then there are others of us--those that I hope are in this hearing now--who want to be rational, good thinking, caring, and professional providers of every sex, race or sexual orientation. These are those who care so much for the people this policy will affect that we will fight tooth and nail to get the right thing done.

The point here is no matter how good-natured, we are all still doing the wrong thing. We are here debating with each other, and little has been heard from the women and children who will really be impacted. So I share with you two perspectives.

In one of our more recent focus groups, a women named Sally sat in our board room and listened to us describe for her why, if she went to bed with a man who was HIV+ and the public health system knew she was at high risk by coming in contact with the virus, they would not tell her. It all boiled down to an issue of privacy and the avoidance of discrimination.

She looked at me and said, "Debra you mean if I am at risk for AIDS because somebody

I gave some to had it, you would not tell me so that I could get tested and if I am going to die, find someone to care for my five children because of privacy? When I go down to the welfare every six months with my life in a paper bag to get recertified for a check, I have no privacy! **If you do this to me what rights do you have to keep information from me that could help my babies."**

And Sally is right. So a system has to be designed in some way for Sally to get the information she wants, because she has a right to it, plain and simple!

But in the same vain Sally--a Black, single, welfare mother of 5--also knows the "the rush of white folks" to chew us up and spit us out because ***they are all in the Kool Aid and don't even know the flavor.***

That's what mandatory testing is for Sally - being all in the Kool Aid and not even knowing the flavor. If you want to be in the Kool Aid and know the flavor, then you should know that Sally cares as much for her babies as you care for yours.

If you have no babies, you can still be in the Kool Aid but not as a child advocate who does not take into account the importance of this mother to the survival of this child. And the most important thing to consider is the survival of this mother for the other children in the household and the survival of this mother for the communities I represent.

You will and must think about her, respect her and give her care within the context of the hippocratic oath that says: First do no harm! If you do not, we promise to organize a movement of the sisterhood in this state, like New Yorkers have never seen before, in opposition to the cruel and inhuman circumstances of telling a woman she has a fatal disease and that her child tested positive for the same virus that she has and may not make it. All of this will be happening while she is lying in the hospital trying to figure out how she will survive with this new life she created under great emotional and financial stress. She's resting her head on a pillow with no case, lying on sheets long ago stained, sharing a toilet with six profusely, bleeding women in a health care facility that won't even provide her paper slippers for the cold floor.

This is not a <u>real</u> health care system. This is torture, and if you seek to add torture to this clearly painful condition, which spells out that we are already at the bottom of the belly of the beast, then you have **no compassion**; you care not about the hippocratic oath, and you should get out of health care. We cannot fix hospitals with this issue, but this should provide an opportunity to start.

Washington Post 5/26/95, A.27.

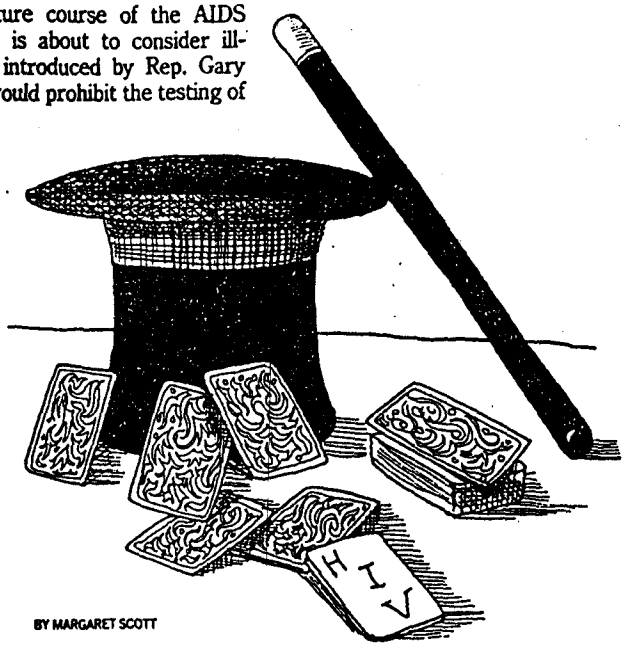
Ronald Bayer

It's Not 'Tuskegee' Revisited

The false furor over HIV testing and newborn babies.

For seven years state health departments across the nation, with support from the federal Centers for Disease Control and Prevention, have conducted epidemiological surveillance of HIV infection in the population by testing blood samples drawn from hospital, clinic and emergency room patients after the samples have been permanently stripped of all personal identifiers.

Those efforts have been crucial to our understanding of the geographic and demographic pattern of HIV infection in the United States and to our understanding of the future course of the AIDS epidemic. Now Congress is about to consider ill-advised legislation to be introduced by Rep. Gary Ackerman (D-N.Y.) that would prohibit the testing of blood samples, drawn from newborns, that have been rendered anonymous. Faced with that legislative effort, the CDC precipitously announced that it would suspend newborn surveillance pending review. In so doing, it has interrupted the efforts of 45 states that have tracked the number of babies being born to HIV-infected mothers.



BY MARGARET SCOTT

Rep. Ackerman's proposal would permit only screening that would make possible the notification of the mothers of babies who test positive. Republicans and Democrats, liberals and conservatives have signed on to the Ackerman proposal, demonstrating the appeal of legislation that, on its face, only seeks to protect mothers and their children. The specter of the Tuskegee syphilis study—the notorious federal experiment that traced the course of syphilis in African American men who were deprived of the knowledge that they had a treatable sexually transmitted disease—hovers over the debate.

Public health officials, on the other hand, are appalled at the prospect that the Ackerman proposal will be enacted, depriving them of the capacity to obtain knowledge crucial in the struggle against AIDS. They have a right to be concerned. A serious misunderstanding of the public health and ethical issues involved has permitted an unusual alliance to join hands in what may represent a serious blow to the nation's effort to understand and combat AIDS.

The CDC's proposals for HIV surveillance were subject to searching ethical and legal scrutiny. Did they violate the right of privacy? The right of patients to be informed about their medical conditions? The Office for the Protection from Research Risks at the National Institutes of Health found blinded surveillance both ethical and legal. When a task force made up of ethicists, lawyers, civil liberties advocates, gay rights proponents and public health officials met at the Hastings Center—a bioethics think tank—to consider the issue, there was not a single objection to such studies. A 1988 review of the issue by a Canadian working group gave its stamp of approval to blinded seroprevalence surveys. So too did the World Health Organization's Global Program on AIDS.

Now that early clinical intervention for people with HIV infection has become the standard of care, however, some people have begun to assert that ethical considerations render blinded surveillance unacceptable. Infected individuals need to know their status so that they can commence treatment. This, it is claimed, is especially the case with regard to babies and their mothers. Is it morally defensible to continue studies that by their very nature preclude the possibility of notifying mothers that their babies carry the antibody to HIV—and which also indicate that the mothers themselves are infected? Don't both baby and mother have a right to that information? Is not the continuation of blinded HIV surveillance studies analogous to the continuation of the Tuskegee study, begun before the advent of penicillin, but which extended for years after the treatment of syphilis became easy and effective?

analogue

If the Ackerman proposal is enacted, or if the CDC does not reverse its decision, babies and their mothers will not necessarily be better off, but the plug will have been pulled on the radar that tracks the progress of HIV infection among childbearing women and their babies.

To understand the controversy, it is necessary to go back to the mid-1980s, when the practice of testing blood samples after they had been stripped of personal identifiers—so called blinded seroprevalence studies—was begun.

Soon after the licensure of the HIV antibody test in 1985, officials at the CDC began to plan for large-scale HIV seroprevalence studies because they understood that tracking cases of full-blown AIDS alone could not provide an adequate picture of the epidemic's dimensions. AIDS cases were but the tip of the iceberg: They told us about infections that had occurred up to 10 years earlier.

However, mandatory testing of identifiable individuals was deemed neither ethical nor politically acceptable. Studies that would rely on volunteers were thought to be unrepresentative—after all, there was no way of knowing whether those who would agree to participate were more or less likely to be infected.

Therefore, the CDC elected to use, as the basis for its studies, blinded seroprevalence studies based on blood samples already drawn for other clinical purposes. Because such samples would be unlinked to individuals, no person could be placed at risk of the kind of stigma and discrimination that surrounded AIDS. No one's privacy would be violated. And thus it was unnecessary to obtain informed consent before testing occurred.

The very process of eliminating identifiers, however, precluded the possibility of notifying persons who were infected. Since there was little that could be done for people with asymptomatic HIV infection, this was thought to pose no problem. Moreover, none of this would prevent people who wanted to be tested from seeking to learn their HIV status in settings that provided confidential results.

The answer in each case is no. In the case of Tuskegee, individuals who were known to be afflicted with syphilis were willfully deprived of that knowledge. Indeed, every effort was made to prevent those impoverished African American men from knowing about their situation or about the availability of therapy. The situation is very different in the case of HIV.

What the enhanced prospects of therapeutic intervention for both babies and their mothers require is not that we abandon critical surveillance studies but rather that we undertake vigorous efforts to encourage voluntary HIV testing. What blinded seroprevalence studies can do is help guide the necessary public health efforts to identify the women and babies in need of care. They can tell us about where we should expend the greatest efforts in developing the capacity to provide voluntary testing and counseling.

Now that it appears that the risk of transmission of HIV from infected pregnant women to their fetuses can be radically reduced by treatment with AZT during pregnancy, such studies can tell us where to focus resources so that women are encouraged to undergo testing before they give birth. Here there is a chance for real HIV prevention.

Most important, it is crucial that we make certain that women and babies who are identified through voluntary testing programs be provided with access to needed clinical and social services.

To compare blinded surveillance for HIV infection to Tuskegee is to threaten the interest of the mothers and babies who could benefit from carefully targeted efforts to identify those in need of care. Clever political slogans about the right of mothers to know about their babies' lethal infections should not serve to justify an attack on studies that have proved so invaluable in the past and that remain crucial today.

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Annotation

The Ethics of Blinded HIV Surveillance Testing

Soon after the licensure of the test to detect antibody to human immunodeficiency virus (HIV), officials at the US Centers for Disease Control began to plan for large-scale seroprevalence studies because it was understood that recording cases of full-blown acquired immunodeficiency syndrome (AIDS) alone could not provide an adequate picture of the dimensions of the American epidemic. Only by fully understanding the prevalence of HIV infection in the population would it be possible to plan for and provide targeted prevention programs and needed social and medical services. However, mandatory testing of *identifiable individuals* was deemed neither ethical nor politically acceptable, and studies that would rely on volunteers were deemed unreliable owing to selection and participation bias. Therefore, the Centers for Disease Control elected to use unlinked or blinded seroprevalence surveillance, in which blood drawn for one purpose in selected settings would be stripped of all personal identifiers before testing. Because such screening would involve samples and not people, no individual could be placed at risk. Thus privacy rights were not thought to be implicated, and consent was not necessary. But the very process of eliminating identifiers that would render consent unnecessary would preclude the possibility of notifying persons who were infected.

Since the mid- and late 1980s, blinded seroprevalence studies have provided a massive array of data, most importantly on the prevalence of infection among childbearing women, because 44 states perform HIV blinded testing on all newborns (who carry maternal antibody). Even more than do the incident cases of AIDS, these data reveal how much of a catastrophe HIV infection will be among poor minority women in East Coast cities.

Such testing is legal, but is it ethical? And if ethical, does it represent wise social policy? In a letter in this issue, Isaacman[1] raises this question and, in blunt language, denounces the program of blinded seroprevalence screening. Calling them "deceitful if not unlawful," an affront to human dignity and to the principle of equity, Isaacman compares these studies to the infamous Tuskegee syphilis experiment undertaken by the US government between 1932 and the early 1970s.

Such charges are not new; they have been at the heart of the objections to blinded seroprevalence studies by thoughtful lawyers and ethicists in Europe, most prominently in Great Britain and the Netherlands. These critics have argued that, no matter how important the data produced by blinded studies are, it is unethical to obtain such information from the unconsented testing of blood.[2] Furthermore, European critics have argued that the clinician's responsibility to inform patients about conditions critical to their own well-being is violated by such screening. Such arguments have been strong enough to inhibit the initiation of blinded surveillance in the Netherlands and in Denmark,[3] for example.

But in North America, the picture has been very different. The Office for the Protection from Research Risks has reviewed the ethics of blinded testing and found such surveillance both ethical and legal.[4] That determination was not ad hoc but reflected a long-standing policy that explicitly exempted from the requirements of informed consent

> research involving the collection or study of existing data, documents, records, pathological specimens or diag-

Editor's Note. See related Letter to the Editor by Isaacman (p 597) in this issue.

> nostic specimens, if these sources are publicly available, or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.[5]

When a working group comprised of ethicists, lawyers, civil liberties advocates, gay rights proponents, and public health officials met at the Hastings Center, a research institute devoted to the study of ethical questions in medicine, there was not a single objection to such studies.[6] In both California[7] and New York,[8] whose confidentiality and consent requirements for HIV testing are among the most stringent, blinded seroprevalence studies have been explicitly excluded from the requirement of informed consent. Review of the issue by a Canadian task force that included ethicists also found blinded HIV surveillance acceptable.[9] Finally, a special consultative group convened by the World Health Organization Global Programme on AIDS at a time when it was especially sensitive to human rights issues found no threat in blinded studies.[10]

In each of these instances, those committed to protecting the rights of research subjects and vulnerable minorities carefully considered the kinds of objections Isaacman raises. In each case they found that, on balance and given both the public health benefits of population-based surveillance for HIV and the fact that no individual could be identified by such testing, blinded seroprevalence studies were ethically acceptable.

Much of the initial discussion of unlinked surveillance for HIV infection took place before the importance of early clinical intervention became clear. It might then be argued that, even if surveillance had been ethical in the period of therapeutic impotence, that is no longer the case. By their very design, such studies preclude the identification of *individuals* in need of prophylactic therapy. Such a claim, which echoes the challenge posed by Isaacman, is founded upon a fundamental confusion between the ethics of surveillance and the ethics of case finding.

What the enhanced prospects of therapeutic intervention require is not that we abandon critical surveillance efforts; rather, they require that we undertake vigorous efforts to encourage voluntary HIV testing in those locales where the prevalence of HIV infection is high, and that we make certain that those who are identified with HIV infection are provided with access to needed clinical and social services. Failure to provide those services will not only inhibit the willingness of individuals to come forward for testing but also represent a profound betrayal of the moral responsibility of the state to meet the health care needs of its most vulnerable citizens.

What blinded seroprevalence studies can do at this moment of changing clinical prospects is provide us with a unique tool in following the pattern of HIV infection. These studies will permit us to raise questions about why so many of those who are infected still fear to come forward for diagnosis. On both counts, not only are blinded seroprevalence studies ethically permissible, but their conduct is an ethical responsibility of those responsible for the public health. □

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Nat Hentoff

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Another 'Tuskegee'?

After winning a Pulitzer Prize for commentary this year, Jim Dwyer of Newsday was being interviewed on the New York affiliate of National Public Radio. The host, Brian Lehrer, was puzzled—indeed disturbed—that part of Dwyer's prize was due to a series of columns exposing the fact that although New York State—like 44 others—has been testing all newborns for various conditions, it does not disclose an infant's HIV status to either the mother or her doctor. It is a "blind" test.

Dwyer considers this failure to inform—with subsequent illnesses and early death for thousands of children who could have been treated—outrageous. The interviewer, however, said to Dwyer: "You're considered a liberal columnist, but on the HIV-testing of infants, you took the conservative position."

Such presumably liberal organizations as the ACLU, the National Organization for Women and the Gay Men's Health Crisis do indignantly oppose the withholding of the test as an invasion of the privacy of the mother whose own infection will be revealed if the child's is. Therefore, all privacy is somehow endangered. [illegible]

Yet Rep. Gary Ackerman (D-N.Y.)—with a 100 percent ACLU rating—introduced a bill, "The Newborn Infant HIV Notification Act," that compels every state requiring infants' HIV tests to disclose the results to the mother. The bill would apply to the anonymous tests that have been funded and conducted in 45 states by the Centers for Disease Control since 1988, for epidemiological reasons.

Ackerman already had 220 co-sponsors—more than half the House—and the ideological range is extraordinary. Ardent liberal Pat Schroeder (D-Colo.) is allied with Robert Dornan (R-Calif.) who

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makes Pat Buchanan sound like a lyrical moderate. Also on board is Nita Lowey (D-N.Y.), a leader of pro-choice issues in the House, and Bill McCollum (R-Fla.) whose ACLU rating has been zero.

As the bill began to gather momentum, Ackerman was visited, he told me, by Dr. David Satcher, head of the CDC, and Patricia Fleming, the White Ackerman to abandon his bill. One of their arguments was that if mothers are told they and their children are infected, they will panic and leave the health care system. There is abundant evidence, however, that black and Latina mothers—who tend to be often, but hardly exclusively, at risk—care as much about their children as do white mothers and would not remove them from treatment.

Indeed, a recent poll by New York's Hispanic Federation—an umbrella organization of many Latino groups—revealed that two-thirds of those polled support mandatory HIV testing and disclosure for everyone, not only infants.

Gary Ackerman refused to withdraw his bill. He told me that the head of the CDC said he might then consider withdrawing the "blind" tests altogether rather than disclose the results.

Earlier, when the conversation was focusing on increasing criticism—from various quarters—of the CDC's "blind tests," Ackerman felt that the man from the CDC appeared to be most troubled by the analogy between its study and the Tuskegee experiment. [illegible]

From 1932 to 1972, some 400 illiterate black men with syphilis were observed—but not treated—by Public Health Service physicians as they deteriorated and eventually died, having been told only that they had "bad blood." [illegible]

The Tuskegee reference entered the HIV-testing debate through Dr. Arthur Ammann, a distinguished professor of pediatrics at the University of California. In Jim Dwyer's column, Ammann, referring to the CDC's anonymous testing of infants for HIV, said: "The maintenance of anonymous test results at a time when treatment and prevention are readily available will be recorded in history as analogous to the Tuskegee 'experiment.'"

Suddenly, on May 10, the CDC announced it was immediately suspending its HIV testing for newborns throughout the country. Instead it would focus on encouraging women to engage in voluntary HIV-testing during and before pregnancy. (CDC was silent on the fate of the sizable number of women who do not appear for any prenatal treatment or counseling.)

Rep. Ackerman intends to get a majority of Congress to mandate that the CDC resume the tests—and from now on disclose the results as well as arrange for counseling. Meanwhile, the American Academy of Pediatrics is "shocked and dismayed" at CDC's total abandonment of its epidemiological tracking tests. Those were the first to show the extent of AIDS among women.

The CDC could have continued the tracking, added disclosure of results, and been free of the taint of the Tuskegee "experiment." But instead the politicized CDC has chosen to fold—extricating itself from accountability.