

Approved 2-2-88
Date

MINUTES OF THE SENATE COMMITTEE ON PUBLIC HEALTH AND WELFARE

The meeting was called to order by SENATOR ROY M. EHRLICH at
Chairperson

10:00 a.m./~~p.m.~~ on January 28, 1988 in room 526-S of the Capitol.

All members were present except:

Committee staff present:

Emalene Correll, Legislative Research
Bill Wolff, Legislative Research
Clarene Wilms, Committee Secretary

Conferees appearing before the committee:

Dick Kurtenbach, Executive Director, American Civil Liberties Union
Elizabeth Taylor, Kansas Association of Local Health Departments

Dick Kurtenbach, ALCU, presented written testimony and appeared before the committee in opposition to SB-445. Mr. Kurtenbach stated that the heart of his organization's opposition was the concern that this bill does very little to protect the public health and does a great deal to violate the privacy of the individual Kansan. Mr. Kurtenbach quoted the oath medical doctors take saying they pledge that they will "above all do no harm." He stated that in an issue as critical as this one he would like to see a similar pledge by the political leaders. It was felt that had the oath been taken the passage of this bill would violate it. Mr. Kurtenbach further stated that, in his opinion, the most needed was anti-discriminatory legislation. This would protect the rights of an individual, thereby freeing him to obtain necessary tests without fear of reprisal. Attachment 1

Elizabeth Taylor, representing the Kansas Association of Local Health Departments presented written testimony and appeared before the committee concerning SB-445. Ms. Taylor stated that her organization recommends the following: AIDS is a sexually transmitted disease and testing, counseling, education and follow-up are necessary public health components. Testing in prisons and jails would be productive in segregating positive individuals from those who tested negative. Because drug abuse and homosexual activity occurs during incarceration, separation of the prisoners could prevent transmission of the infection and prevent the treatment costs which will fall back on local or State governments operating the prisons and jails. Many of the patients attending family planning and sexually transmitted disease clinics may be in high risk categories and therefore testing should be offered and followed by counseling about the risks of promiscuity. The followup of positive HIV tests will help public health authorities control the spread of this infection. These practices have been successful in syphilis and other communicable diseases. Attachment 2

The chairman announced there would be no committee meeting tomorrow, Friday, January 29, 1988. The committee will meet at 10:00 a m, February 1, 1988.

SENATE
PUBLIC HEALTH AND WELFARE COMMITTEE

DATE January 28, 1988

(PLEASE PRINT)
NAME AND ADDRESS

ORGANIZATION

Mary Slaybaugh	Topeka	SRS
Jan Johnson	Topeka	Budget Division
JOHN TORBERT	"	Assoc. of Counties
KAREN TAPPAN	TOPEKA	Ks DEPT OF HEALTH + ENVIRONMENT
Cynthia PasKorz	"	"
Robt French	"	Ks " " "
Steve Page	"	KDHE
Marilyn Bradt	Lawrence	WINTT CHRISTIAN SCIENCE COMMITTEE ON PUBLICATION FOR KANSAS
KEITH R. LANDIS	TOPEKA	Kans Permitts
Ken Eiko	Topeka	Asso of Local Health Dept
Elizabeth C. Taylor	Topeka	Catholic Health Assn of Ks.
JOHN H. HONMGREN	Topeka	ASSOC. OF CMHCs OF Ks INC.
Paul M. Klotz	Topeka	Ks Medical Society
Chip Wheelen	Topeka	Kansas State Nurses' Assoc.
Torri Roberts	Topeka	Ks Assn OSTEOPATHIC MED.
MARCO RIEHM	TOPEKA	

Testimony on Senate Bill 445
January 27, 1988

Presented by: Dick Kurtenbach, Executive Director
American Civil Liberties Union
of Kansas and Western Missouri

Good morning. My name is Dick Kurtenbach. I am the Executive Director of the ACLU of Kansas and Western Missouri. The ACLU is a private, non-partisan organization devoted to the defense and promotion of the Bill of Rights which, as you know, protects individual liberty in America. We have over 1,600 members in Kansas.

I appreciate the opportunity to appear before your committee. To be sure, the AIDS crisis confronts us with many difficult problems that require your attention.

I appear this morning in opposition to this bill. At the heart of my opposition is my concern that this bill does precious little to protect the public health but does a great deal to violate the privacy of individual Kansans. I have always been impressed with the oath medical doctors take. They pledge that they will "above all do no harm." In an issue as critical as this one, I would like to see a similar pledge by our political leaders. If you had taken that oath, I believe the passage of this bill would violate it.

Under this bill mandatory testing for the presence of the virus will be conducted on Kansans applying for marriage licenses, on prisoners in custody for more than 72 hours, on people involuntarily committed to state institutions, and on people convicted of certain crimes.

The ACLU supports widely available, voluntary testing programs, coupled with adequate counseling and the assurance of anonymity or, if that is not possible, strict protections of confidentiality. The ACLU opposes tests for the AIDS virus, such as those called for in this bill, which are forcibly imposed.

Indeed, for each proposal for forced testing under discussion here, the ACLU believes that the less coercive policy of voluntary testing would work as well or better. In some situations, civil liberties defects aside, mandatory testing seems destined to be counterproductive, irrationally wasteful of public funds, or both.

I am sure you will agree that mandatory testing is invasive to the individual. Because it is so invasive, the groups targeted for it are those that have no choice in the matter...prisoners, involuntarily committed mental patients, people needing a marriage license to be married legally. In fact, there is no more reason to believe that the virus is more present in people applying for marriage licenses than it is in Senators and Representatives in this Legislature. Why not make the test a condition for filing for office.

Such an invasion of privacy is warranted if there is a compelling reason to believe it will significantly protect the public health and there is no less coercive means available to accomplish the same purpose. I submit that readily available voluntary testing will accomplish the same purpose.

There is another problem with mandatory testing and it has to do with the accuracy of the test. The studies are fairly conclusive on this point. They show that in population groups where the level of HIV infection is low, such as people seeking marriage licenses, people in prisons and mental hospitals, and people in legislatures, the false positive rate may be as high as 30%.

Think about it. That means that if you pass this bill for every 28 people you identify as true positives among people seeking marriage licenses, there will be two false negatives and 11 false positives. This information may very well be devastating to those people who are falsely identified as having been exposed to the virus. I direct your attention to the attached recent article looking at a similar testing program in Illinois.

The same problems apply to mandatory testing for the other groups targeted for testing in this bill.

With regard to the reporting and contact tracing aspects of the bill, there are also privacy and public health concerns.

The most effective weapon we have against the spread of the virus and the disease is education to influence behavior. I ask you, is this weapon enhanced when people in high risk groups fear for their own privacy...when some government office has a file on them and a history of their sexual behavior. The risk to privacy caused by reporting people with the virus and contacting their past sexual partners will chase people away from the test and will be counterproductive to the public health concerns.

Finally, there is one measure conspicuously absent from a bill designed to do something about AIDS. I know that there are people in Kansas losing jobs because they test positive. We must protect people who test positive or are perceived to have the virus from such discrimination. If we don't, we simply create another disincentive for people to take the test. I submit that there is a compelling public health reason to pass legislation now to prohibit such discrimination...such legislation will be an important step toward an effective response to the AIDS crisis.

In conclusion, I applaud your concern about this critical public health problem. I urge you to avoid knee jerk responses and rely instead on a careful analysis of the facts. When you do, I believe you will strike the right balance between an effective response to the problem and a legitimate concern for the rights of individual Kansans.

By ISABEL WILKERSON
Special to the New York Times

CHICAGO, Jan. 25 — A new Illinois law requiring tests for the AIDS virus before marriage is sending thousands of couples into a health system all pledged to handle them and has left health officials wondering how to pay for couples who cannot afford the test.

In the weeks since the law took effect, couples seeking marriage licenses have besetted hospitals, clinics and other doctors, anxious to get the test and the required counseling in time for wedding dates and quickly outnumbering those in high risk groups most in need of attention.

Rather than seeing their own physicians for the tests, whose price varies widely but averages about \$70 in Illinois, an unexpected number of couples have sought low-cost tests at public facilities. The sudden rise in these patients has so strained capacity at Cook County Hospital here that after only three weeks officials stopped offering the test to engaged couples, Cook County, the largest public hospital in the state, offered the test without charge.

Even while the public health system copes with this new burden, marriage applications have dropped sharply as

couples wait up to four weeks for test results and to hand reds of others drive to other states to get married without the AIDS on test.

The law, which took effect Jan. 1, was supported by Gov. James R. Thompson last September over the strong protest of the Department of Public

Health, top AIDS specialists, and physicians who are accustomed to performing routine pre-nuptial blood tests for syphilis, but who are unfamiliar with the AIDS procedure and feel ill-equipped to counsel people about the

(Continued on Page 8, Column 1)

Illinois Health System Is Taxed by Law Requiring Pre-Nuptial AIDS Tests

Continued From Page 1

disease. The law requires that a couple provide proof of the test in order to apply for a marriage license. It does not prohibit people who test positive from marrying, but does require that both partners be told the results and be given AIDS counseling.

Requiring the tests before issuing a marriage license has been debated all over the country. Only Illinois and Louisiana now require such tests, but other states are considering the idea and some have adopted measures that stop short of mandatory testing.

Supporters say the benefits of pre-nuptial testing outweigh the disadvantages. "If we find just 100 people that could have possibly infected another 100 people it will have been worth it," said State Senator Beverly Fawell, who sponsored the Illinois bill.

Susan Mogerman, a spokesman for Governor Thompson, said today. "It's far too early to make an assessment and know how much of a problem this will be."

Critics See Inefficiency
But critics say that the premarital screening is an inefficient way to identify carriers of the AIDS virus and will divert already overworked AIDS specialists from helping the people most at risk for the disease — drug users and homosexual men.

"This is the most expensive public health program going," said Dr. Ron Sable, who runs an AIDS program here. "It's providing intensive, one-on-one AIDS counseling to the people who need it least."

The test finds blood antibodies that indicate infection with the AIDS virus. People who have been infected can pass the virus to others through sexual intercourse or exchanges of blood, and

infected mothers can pass it to their offspring in the womb or during birth. Mounting evidence indicates that over time a majority of virus carriers will develop AIDS or other disease symptoms.

Researchers say that fewer than 1 percent of the people who are infected with the AIDS virus are likely to be found through pre-nuptial testing. They also note that in a low-risk group like engaged couples, a large proportion of the positive results are false.

Although the Illinois law was not intended to discourage marriage, it appears to be doing so. In Cook County, where nearly half of all Illinois marriages take place, the number of marriage applications in the first three weeks of January dropped from 1,500 last year to 600 now.

"One of the chief ways to limit AIDS is faithful monogamy, and here we have a system that discourages that very thing," said Dr. Renslow Sherer, acting director of the AIDS Prevention Service at Cook County Hospital, who headed a Governor's task force that recommended against the premarital screening requirement.

His hospital has been getting as many as 100 calls a day from anxious couples. "All of them have horror stories," said David Siebert, an AIDS counselor there. "The doctor can't do the test in time or is charging an astronomical fee or the bride is here, but the groom is in North Carolina, and they both have to be tested at the same time. People are wondering how they can do it, and we don't know what to tell them."

Sessions on Sale Sex
About 75 couples were tested at Cook County Hospital in the first three weeks of January and none of them tested positive. Counselors went through peremptory sessions on methods of transmission and safe sexual practices. When the couples return for their test results, Mr. Siebert said, "the follow-up sessions are rather short."

Earlier this week, during the counseling session before their test at Cook County Hospital, Edward Warren, 26 years old, and his fiancée, Alexine Scott, 27, listened with the knowing patience of students hearing the same lecture again. They said they did not think they had been exposed to the virus and figured that if they did test positive they would get married anyway. "If he was positive that would mean I had it, too," Miss Scott said.



Rogelio Cadena, an AIDS counselor at the Cook County Hospital in Chicago, talking with Edward Warren and his fiancée, Alexine Scott, before they were tested for AIDS.

"We think we're going to be negative," Mr. Warren said confidently. Last week county officials announced that the hospital would no longer be able to handle the additional testing. "The purpose of the hospital is to care for the medically indigent," said George Dumme, president of the Cook County Board of Commissioners "and marriage is not a disease."

Worry About the Poor
But officials say they are worried that if public hospitals are unable to provide such a service, the law will discourage poor couples from getting married at all. The cost can range from \$12 to more than \$300, depending on whether a positive result requires a second test. The required counseling involves extra expense. Proponents of the law insist that it will not hurt the poor and say those couples will have to find alternatives to

public hospitals. "That's a very small segment of the population that goes to public hospitals," said Senator Fawell, a Republican who represents a suburban area west of Chicago. "Nobody I know goes to Cook County Hospital." She said that the cost of implementing the law was not a consideration in creating it. "Just like we don't sit down and figure the cost of the syphilis test, we don't know what this will cost," Mrs. Fawell said.

At least 33 other states, including New York, Connecticut and New Jersey, have considered premarital AIDS testing, but only Illinois and Louisiana have approved such a law. In Texas, a new law would require premarital tests only if AIDS infection increase dramatically. Other states have devised alternatives. In California, Hawaii and Virginia, couples must show they have basic

knowledge of the disease by signing for educational material when they get their marriage licenses.

In Louisiana, implementation of the new law appears to be running more smoothly. Aside from public clinics and private physicians, blood banks in Louisiana are offering the tests at reduced rates for engaged couples — \$10 for blood donors and \$15 for those who do not donate blood.

Marriage license bureaus in neighboring states, however, are reporting a higher number of inquiries from Louisiana couples.

The same is true in states surrounding Illinois. "People are looking here out of desperation," said Mark Ryan, deputy county clerk in Milwaukee. "With most of them, it seems to be a planned effort to avoid the AIDS test. They want something in the Midwest, so they come up here in the afternoon and are married by the evening."

New York Times
1/26/88

Public Health and the Law reprint

Legal Control Measures for AIDS: Reporting Requirements, Surveillance, Quarantine, and Regulation of Public Meeting Places

LARRY GOSTIN, JD, AND WILLIAM J. CURRAN, JD, SMHYG

Acquired immune deficiency syndrome (AIDS) currently poses one of the most serious threats to public health of any communicable disease in contemporary times. The effort to reduce its spread has received the highest priority of the federal authorities in the health field.^{1,2}

There have been over 26,000 confirmed AIDS cases since 1981 under the definition adopted by the Centers for Disease Control³ (CDC), with further estimates of up to two million people in the United States infected with the human immunodeficiency virus (HIV).^{4,5} It has been predicted that the disease has the potential for doubling over the next year and perhaps for continuing a geometric growth in both cases and infected population over a period of time.⁴ Others, however, offer more cautious estimates of the increased prevalence of the syndrome and virus suggesting that both will be reduced in rate of growth due to saturation of the primary risk groups in similar fashion to the experience with hepatitis-B.⁶

The widespread publicity given to the potential for continued geometric spread of the disease has charged the atmosphere of health policy debate and injected into it proposals for the application of compulsory legal powers to control the spread of the syndrome and the virus in the population.

Early judicial rulings have shown considerable deference to the exercise of the state's police power to promote the public health. The US Supreme Court in *Jacobson v. Massachusetts*⁶ upheld a Massachusetts law which enabled local health authorities to levy a fine against persons refusing vaccination. As between individual autonomy and the common good of the people, the latter had an overriding interest. The court did require the state to refrain from acting in "an arbitrary, unreasonable manner," or "going so far beyond what was reasonably required for the safety of the public." This concept of public health necessity in the exercise of state powers remains to the present. Yet courts have very rarely

imposed any substantive barriers on the measures which can be taken. The courts have upheld a wide range of public health powers such as immunization,⁷ surveillance and reporting,⁸ compulsory examination and treatment.^{9,10} Quarantine amounts to compulsory deprivation of liberty and should attract the strictest judicial scrutiny. Nevertheless, courts have repeatedly upheld quarantine during periods of epidemics—venereal disease,^{11,12} tuberculosis,¹³ smallpox,¹⁴ scarlet fever,⁸ leprosy¹⁵ and cholera.¹⁶ Judicial subservience to compulsory health powers has occurred even where it was difficult to observe a reasonable relationship between the measure adopted and a preventable harm, for example, a quarantine of an elderly woman with aesthetic leprosy with "hardly any danger of contagion."¹⁵

Despite the traditional deferential posture of the courts, it would be a mistake to assume future judicial complacency in reviewing compulsory powers against persons infected with HIV. Almost all of the relevant cases were decided during a period which preceded the remarkable evolution in constitutional decision-making which has occurred since the civil rights movement of the 1960s. The early public health cases, therefore, are unreliable precedent for determining how modern courts would assess the application of existing statutes and regulations to the AIDS epidemic.¹⁷

More representative of current constitutional analysis is *New York State Association for Retarded Children v. Carey*,¹⁸ concerning hepatitis B, which is transmitted much in the same way as HIV. The Court determined that mentally retarded children who were carriers of serum hepatitis could not be excluded from attending regular public school classes as "the Board was unable to demonstrate that the health hazard . . . was anything more than a remote possibility." This remote possibility did not justify the action taken considering "the detrimental effects of isolating carrier children."

In addition to possible constitutional restraints on state public health departments in the exercise of their powers, there are also statutory provisions at the federal and state level proscribing discrimination against the handicapped. The major provision is section 504 of the federal Rehabilitation Act of 1973. It was this provision which allowed a trial court in *District 27 Community School Board v. the Board of Education of the City of New York*¹⁹ to uphold a city-wide policy of not excluding children with AIDS from school. *Arline v. School Board of Nassau County*²⁰ also supports the view that discrimination against a person with an infectious disease would trigger the protection of section 504, and that public officials must base their decisions on reliable scientific evidence.

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Research for this paper was supported in part by the U.S. Department of Health and Human Services, contract no. 282-86-0032. W. Curran, L. Gostin and M. Clark: Acquired Immunodeficiency Syndrome: Legal and Regulatory Analysis (1986). The full report is available from the National Technical Information Service, US Department of Commerce, 5285 Port Royal Road, Springfield, VA 22161. The views expressed herein are solely those of the authors and do not reflect the position of any official of the federal government. This is the first of two columns on AIDS. The next column, to appear in the March issue of the Journal, will be on proposals for compulsory screening. This paper was accepted for publication by George J. Annas, JD, MPH, Editor of the Public Health & the Law section of the Journal.

The *Arline* case, which involves the dismissal of a school teacher with tuberculosis, is currently before the US Supreme Court. The United States Justice Department has argued that the Supreme Court should construe Section 504 narrowly. In a memorandum to the US Department of Health and Human Services it concluded that "an individual's (real or perceived) ability to transmit the disease to others is not a handicap. . . . and, therefore, discrimination on this basis does not fall within section 504."²¹ This opinion is not supportable by legal analysis or scientific fact. Clearly people with AIDS or ARC (aids-related complex) have a disability limiting their major life functions; and those with HIV infection may be perceived by others as having a handicap. This brings HIV disease well within the definition of "handicap" in the Act. The Justice Department memorandum takes the position that discrimination because of the fear of transmission is not based upon a handicap but upon a health risk to others. Yet, the scientific community has empirically demonstrated the absence of any material risk of transmission of HIV from casual association.²² In our view, any discrimination against persons with an infectious condition, which has no reasonable scientific public health justification, should come within the remit of section 504.

Reporting

Reporting of individuals who harbor a communicable agent to the public health department is a necessary first step in effective infection control programs. State reporting requirements in relation to AIDS can be classified into three kinds: CDC-defined AIDS is reportable in every state; specific requirements to report positive HIV antibody tests are found in Colorado, Montana, Arizona, Idaho, South Carolina, and Wisconsin; and general provisions, which do not specify HIV infection as notifiable, but which require the reporting of any "case", "condition", or "carrier state" relating to listed diseases including AIDS are found in states such as Minnesota.

These requirements to report AIDS or HIV infection would be regarded as constitutional under the doctrine enunciated by the US Supreme Court in *Whalen v. Roe*²³ if: 1) the information were reasonably related to a valid public health purpose; 2) the information were limited to public health departments; and 3) there were adequate statutory confidentiality protections in place. The *Whalen* court said that "limited reporting requirements in the medical field are familiar and generally are not regarded as an invasion of privacy."

The state has a valid public health purpose in collecting information about the epidemiologic distribution of CDC-defined AIDS within the population. The CDC surveillance definition was developed for precision, consistency in interpretation, and specificity in order to provide useful data on disease trends. This helps public health departments to plan and to deliver health and counseling services.

Does a similarly valid government purpose exist in collecting information as to HIV antibody status? A reporting requirement of the carrier state has superficial advantages as it enables public health officials to keep records of all those who are infectious and, therefore, capable of transmitting the AIDS-related virus. Infected individuals are, or more, likely to engage in behavior leading to the spread of the virus; an asymptomatic carrier is often physically better able to enter sexual relationships than a person who is actively exhibiting AIDS-related symptoms.

A more thoughtful consideration, however, militates against reporting the carrier status. Current programs for HIV antibody testing cover only quite limited groups in the population. Serologic testing is effectively a self-selecting process which is probably underrepresentative of the total infected population. Statutory requirements to report every positive test result might also be a disincentive voluntarily to seek testing which could further limit the sample of infected individuals. These factors could result in a skewed epidemiologic impression of the total infected population.

The total infected population can be extrapolated from the CDC definition. It is estimated that the infection-to-AIDS ratio is between 50:1 and 100:1.⁴ Accordingly, valid epidemiologic objectives can be achieved by reporting the full blown disease state. Since the disease reporting requirement affects the privacy of much fewer people, and since it adequately accomplishes the public health objective, it is to be preferred as a policy alternative. As there is no proven preventive or therapeutic intervention available, systematic collection of antibody status by the public health department at this time would be premature.

The "carrier" reporting requirement, while logically flawed, would probably be found constitutional under the deferential *Whalen* doctrine provided there was no evidence in the record indicating an invalid state purpose based upon prejudice or irrational fear. Given the major health impact of HIV infection, the courts could well leave the states wide leeway in their infection control strategies. In sum, there are probably no insurmountable constitutional barriers to statutory requirements to report HIV infection, but there are strong practical public health arguments against such a course of action.

Surveillance and Contact Tracing

Contact tracing is a program where public health officials keep a register of infected individuals and then investigate their contacts in order to prevent spread of the infection. Successful programs for contact tracing require the cooperation of the index case who will be asked to disclose the names and addresses of his/her sexual and drug sharing partners; this involves the state in investigating the location of contacts and interviewing them. The information required could disclose the commission of a criminal offense; sodomy is a crime in half the states and the use of dangerous drugs is proscribed throughout the United States. The index case, therefore, is being asked to incriminate close associates. Current laws for contact tracing do not give specific authority to compel infected persons to provide personal information. There is, for example, no power to cite the patient for contempt.

Contact tracing represents a deep invasion into privacy which is justified only by a clear public health benefit. Contact tracing within large, infected risk groups would not produce sufficient public health benefits to justify this deep intrusion into privacy. First, concern of the confidentiality of individual contacts would undermine the cooperation of high-risk groups with vital public health programs. Attendance at sexually transmitted disease (STD) and drug dependency treatment clinics or counseling sessions would be hindered if clinics implemented aggressive programs in contact investigation.

Second, contact tracing among high-risk groups would not be feasible in areas with a high reservoir of infection. In many major cities in the United States, such as New York or

San Francisco, high-risk groups have been virtually saturated with HIV infection. Contact tracing in such circumstances is futile, because it would lead the investigator to virtually every member of the high-risk group. The alternative of providing major resources into public education, testing, counseling, and treatment on a voluntary basis, targeted at the risk group as a whole, would be both more effective and economical.

Thirdly, a systematic program of contact tracing in areas of high infection would drain limited public health resources and be exceedingly difficult to plan and enforce. It would require a substantial investment in health care and laboratory resources: to carry out the ELISA (enzyme-linked immunosorbent assay) test and to confirm positive results with the Western Blot; to investigate the location of contacts; and to provide professional treatment and counseling services. Public health officials would also have to determine what frequency of testing is required, because the ELISA will not register positive on a person recently infected, and some individuals who are not currently infected may contract the infection in the future. A voluntary system of testing and counseling infected individuals to inform their own contacts provides the best opportunity of impeding the spread of HIV.

The case for contact tracing is strongest in cities and states with a low incidence of HIV infection or where the suspected mode of transmission is heterosexual. In such cases, the contact may be unaware that he or she has been exposed to the virus—such as the wife of an infected IV (intravenous) drug user. Contact tracing would allow the contact to modify his or her behavior based upon the test result as explained by a trained health counselor. For example, the wife of an IV drug user could take precautions not to bear children if she has a positive serologic status.

Personal Control Measures

The traditional public health response to infectious disease is to identify those harboring the live virus through screening, surveillance, and reporting requirements. Public health officials must then develop a strategy for limiting the spread of the virus. Because AIDS is a blood-borne disease usually requiring some conscious behavior for viral transmission, public health officials focus on altering behavioral patterns rather than on isolating carriers. We endorse the approach of the federal authorities which relies upon public education and counseling to encourage behavioral change.²⁴ Experience with hepatitis B has demonstrated that voluntary compliance can reduce the spread of a virus with an analogous pattern of transmission;^{25,26} and emerging evidence on AIDS already shows significant alteration of behavior necessary to reduce spread within significant risk groups.^{27,28} Further, experience with the use of highly coercive measures in venereal disease control shows that they can be ineffective, discriminatory, and invidious.^{29,30} Absent evidence that personal control measures change behavior more effectively than voluntary education and counseling programs, public health officials cannot justify their use.

The power to isolate infected individuals is the most commonly recognized personal control measure to be identified in public health statutes. Isolation of HIV carriers is claimed to be favored by 42 per cent of the public,³¹ and at least one state has amended its quarantine law with the effect that it would provide a statutory basis for the detention of recalcitrant AIDS patients.³² Isolation is a uniquely serious form of deprivation of liberty as it can be utilized against a

competent and unwilling person; it is based upon what a person *might* do in future rather than what he or she has done; there is no clear temporal limitation; and it is not subject to the same vigorous due process procedures as in crime.

A general isolation which reaches all those who test positive for HIV antibodies or all those with the disease would in our judgment be unconstitutionally overbroad: not all those who test positive harbor the live virus; and even the majority of true positives (particularly those in a debilitating disease state) would be unlikely to intentionally engage in behavior leading to viral transmission. Given the inability to predict with any reasonable certainty who would or would not communicate the virus, deprivation of liberty of entire population groups would not be upheld by the courts.

Moreover, there are numerous public policy reasons against a general isolation which flow from the unique combination of scientific findings relating to HIV: the sheer number of people capable of transmitting the virus which is estimated to be between one to two million,⁴ making a general isolation wholly unmanageable; there is no finite period of infectiousness, and consequently the isolation would be without limit of time; there is no prevention or curative treatment,³³ so that those whose liberty is infringed would have no way to restore themselves back to a normal condition in order to re-join the community; and the virus is not spread through casual contact^{34,35} making segregation from society unnecessary and overly restrictive. These factors set AIDS apart from other communicable diseases which have been the subject of traditional personal control measures.

More limited isolation suffers from many of the same public policy objections, but might not attract judicial censure. Constitutionally allowable isolation would not focus on a person's *status* as having an infection or a disease, but upon his or her *behavior* leading to transmission. An isolation statute could require a due process determination that a viral carrier is unwilling or unable to refrain from engaging in conduct likely to spread the disease. The most obvious illustrations are the recalcitrant individual who intentionally and continuously refuses to comply with reasonable public health directions; or the patient with AIDS-related dementia³⁶⁻³⁸ who is incapable of complying with public health directions. It is difficult to envisage a court striking down a narrowly conceived measure when there was clear evidence available to a public health official that an individual was likely to engage in behavior leading to transmission of a potentially lethal virus. The courts have consistently upheld civil confinement of persons shown to be dangerous in the public health¹¹⁻¹⁶ and mental health³⁹ context.

Even if the courts were to uphold limited isolation, there are distinct public policy reasons that make them weak candidates for implementation. First, coercive measures would discourage members of risk groups from seeking testing or treatment, or speaking honestly to counselors concerning their future behavioral intentions. Second, objective statutory criteria and psychological parameters could not be framed to accurately determine who was "recalcitrant" or to predict future dangerous behavior;⁴⁰ for example, individuals who declared an intention to engage in such behavior could not be reliably distinguished from those who foreswore unsafe conduct. Third, those who come to the attention of public health officials as candidates for isolation are likely to be the poorest, least articulate of those harboring the virus; the vast majority of instances of transmission would continue to go unnoticed. This makes a limited quarantine a lottery affecting primarily the most vulnerable

and having a negligible impact on the epidemiology of the disease. Finally, a limited isolation based upon preventing intimate personal behavior has unimaginable monitoring and enforcement difficulties; it could be viewed as a license for public health and law enforcement officials to intrude into the most private parts of the lives of people in risk groups.

Whenever the state interferes with personal liberty, it must first explore less restrictive alternatives to achieve the public health objective.⁴¹ Thus voluntary efforts or a sliding scale of less coercive measures such as fines, supervision or attendance orders, guardianship orders or civil commitment for incompetent persons, and narrowly conceived public health statutes of a corrective nature could be used if *clearly necessary* to seek behavioral change. Any measure which could achieve the public health objective with less intrusion on individual freedom would take precedence over the more restrictive.

Even where courts accede to the power of state legislatures to protect public health they should require procedural due process safeguards prior to or immediately after the exercise of control measures. Strict due process standards for quarantines are necessary because of the deprivation of individual liberty; the risk of erroneous fact finding; and the importance of avoiding the confinement of non-dangerous individuals. One state appellate court has held that the same procedural safeguards required in civil commitment of mental patients are applicable to the quarantine of infectious patients.¹³ These procedures include written notice, counsel, presenting evidence and cross examination, a clear and convincing standard of proof, and a verbatim transcript for appeal. But the state need not go so far as providing procedural safeguards of a criminal trial.⁴²

Regulation of Public Meeting Places

As intimate sexual behavior is the most frequent method of transmission of HIV, public meeting places which condone such behavior have been a favorite target for government regulation. The New York State Public Health Council passed a regulation defining anal intercourse and fellatio as "high-risk sexual activity," and said that no establishments shall make facilities available where such activity takes place. The regulation resulted in the forced closure of a gay bar, Mine Shaft, and a gay bathhouse, New St. Mark's, as well as other voluntary closures in New York City; the order against St. Mark's has been upheld on statutory and constitutional grounds by a trial court in New York County.⁴³ Other meeting places such as clubs, bookstores, and hotel rooms have been discussed.⁴⁴ An attempt to close bathhouses and other establishments where unsafe sexual activity take place in San Francisco was invalidated by a California Superior Court, which allowed the facilities to remain open subject to restrictions intended to decrease the spread of AIDS.⁴⁵

Constitutional review of decisions to close bathhouses hinges on whether the closure would burden constitutionally protected interests in privacy and association, and, if so, whether the state could demonstrate a compelling public health interest. The courts have protected intimate relations and freedom of association under the highest level of judicial scrutiny;⁴⁶ implicit in the Constitution is the right to join with others as a form of collective expression.⁴⁷ In *Bowers v. Hardwick*,⁴⁸ however, the US Supreme Court decided that private homosexual activity between consenting adults in their own homes is not constitutionally protected. If the state constitutionally can make sodomy a crime, it clearly can

regulate that activity in bathhouses. Even if some narrow right to privacy were recognized by the courts in the future, it would be unlikely to extend to encounters in places to which the public has access such as commercial clubs and bathhouses;⁴⁷ here, there is no reasonable expectation of private intimacy. The state has no constitutional mandate to countenance the operation of premises existing for the express power of sex between members of the public where that activity poses a demonstrable risk to health. It is true that some proportion of the unsafe activity which takes place in bathhouses would simply shift to private forums over which the state has no direct control. But that does not obviate the right of the state to proscribe or regulate unsafe sexual activity in establishments it licenses or otherwise controls.

Sexual intercourse with anonymous multiple partners is a prime high-risk factor in the spread of HIV,⁴ and the state has a compelling public health interest to reduce this conduct. The more difficult question is whether closure of selected meeting places is the most effective means of reducing irresponsible sexual activity, or whether it is potentially counterproductive in terms of disease prevention. The major concern of health authorities is human behavior, not where it takes place. Closure of a single type of public facility is unlikely to result in significant change of personal behavior patterns in other locations such as private homes and public restrooms.

A further question is whether closure is the least restrictive public health option. Where a significant aspect of the business to be closed is the exchange of beliefs and ideas such as a bookstore or cinema, or the association with peers such as a gay club or bar, any state regulation should minimize the burden on collective expression. An alternative approach to selective closure of meeting places would be to use them as a focus for public education, including distribution of health warnings, other literature and information on referrals for assessment, counseling, and other services. Also, regulation could require adequate supervision of the premises by employees, bright lighting of all areas, removal of partitions and doors, and regular inspection of premises by public health authorities.

Conclusion

Public policy makers can be virtually assured of judicial and political support for compulsory public health measures to control the spread of AIDS which are carefully based upon the current state of scientific understanding. Such measures would not be required "to resort to close distinctions or to maintain a precise scientific uniformity,"⁴⁹ no matter how much this is desirable. What policy makers may *not* do—even under the judiciary's "minimum rationality" review—is to base their measures on "vague, undifferentiated fears . . . of some portion of the community" or on "irrational prejudice."⁵⁰ Worse, public health regulators may not succumb to "a bare . . . desire to harm a politically unpopular group."⁵¹ Even stricter scrutiny will be applied to public health measures which affect liberty, autonomy, or privacy of human beings. These measures should not be promulgated without searching examination as to public health need, specificity of the targeted population, and adherence to the principle of the least restrictive alternative.

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Table 1.—Number of Persons Married in 1982*

Age Range, y	Women	Men
14-17	84 943	12 818
18-19	255 254	119 652
20-24	685 773	632 089
25-29	395 910	477 761
30-34	201 921	258 802
35-44	171 884	228 931
45-64	98 706	148 767
≥65	18 293	33 864
Total, ≥14	1 912 684	1 912 684

*Data from US Dept of Health and Human Services *Vital Statistics of the United States: 1982, vol 3: Marriage and Divorce.*

Table 3.—Accuracy of EIA Tests for HIV Infection*

Test†	%	
	Sensitivity	Specificity
Abbott Laboratories, North Chicago, Ill	98.3	99.8
Du Pont Pharmaceuticals, Wilmington, Del	99.3	99.7
Electro-Nucleonics Inc, Columbia, Md	99.6	99.2
Litton Bionetics Inc, Charleston, SC‡	98.9	99.6
Travenol Laboratories Inc, Deerfield, Ill, and Genentech Inc, South San Francisco	100.0	99.2

*Adapted from Dodd.¹⁰ EIA indicates enzyme immunoassay; HIV, human immunodeficiency virus.

†Test manufacturer and location are given.

‡Now Organon Teknica, Oklahoma City.

100 000 persons tested, and among women, the rate was about seven per 100 000. Also, persons between the ages of about 18 and 45 years appear to be at highest risk. As a first approximation of the age- and gender-specific rates of infection among a premarital population, we assume that men between the ages of 18 and 45 years have a prevalence of HIV infection of 70 per 100 000 and that all others have a rate of seven per 100 000. These rates were applied to the premarital population (Table 1) to produce an estimate of the number of infected individuals who would be screened (Table 2).

Test Performance

The HIV is currently difficult to culture, and the most commonly used strategy of testing for HIV infection is to test blood for HIV antibodies using a commercially distributed enzyme immunoassay (EIA). If repeated tests are positive, a separate confirmatory test is conducted, usually a Western blot assay for antibody to specific HIV proteins.¹¹

The absence of antibodies does not necessarily mean that a person is free of infection with HIV. For example, infected individuals may not yet have developed detectable levels of antibody, especially in the first few weeks to months after exposure to the virus.^{12,13} Infrequently, asymptomatic individuals may not develop antibodies for more than a year, or not at all.^{14,15} Individuals ill with AIDS may be immunologically compromised and incapable of produc-

Table 2.—Number in Each Age and Gender Group Assumed to Be Infected

Age Range, y	Female Infected	Male Infected
14-17	6	1
18-19	18	84
20-24	48	442
25-29	28	334
30-34	14	181
35-44	12	160
45-64	7	10
≥65	1	2
Total	134	1214

ing antibodies.¹⁴ Alternatively, a person who is not infected may have HIV antibodies in his or her blood, such as from injection of hyperimmune gamma globulin,¹⁷ although such cases are thought to be rare.

Screening tests may not accurately indicate whether antibody is present because of an inability to detect low levels of IgG antibodies below the "cutoff" for a particular test,¹⁸ or a variety of other biologic or technical sources of error. Some individuals have repeatedly false-positive test results for biologic reasons, such as interfering antibodies to human antigens contaminating the viral antigens in the test kits.^{19,20} Technical sources of error include testing samples that have been heat-treated to protect laboratory personnel,²¹ mislabeling of samples, or errors in the testing and interpretation process. As an illustration of the variability of test results, only 17% of one series of persons with positive initial EIA tests had consistently positive EIA test results.⁷

A standard way to describe the performance of screening tests is to calculate the proportion of affected individuals who test positive (sensitivity) and the proportion of unaffected individuals who test negative (specificity).²² However, for HIV infection, there is no independent, unequivocal way of identifying a group of individuals who are all assuredly infected or uninfected. Cultures for HIV are not an ideal way of defining a standard infected population because many infected individuals do

not have positive cultures,²³ and the antibody tests may perform differently among infected individuals with and without positive cultures.²³ It is even more difficult to select a population in which assuredly no one is infected. Furthermore, sensitivity and specificity may vary in different groups that are tested.²⁴ Thus, current estimates of test sensitivity and specificity are based on numerous assumptions.

The manufacturers of EIA test kits must provide sensitivity and specificity data for licensure. Some manufacturers subsequently modified their tests to improve performance. Claims for test sensitivity and specificity for some EIA test kits available in 1986 are given in Table 3.¹⁰ For the purpose of the analyses presented here, we assume that the sensitivity and specificity of the EIA test would be 98.3% and 99.8%, respectively (values from Table 3 for the test most widely used). These estimates are based on the proportion of positive test results among patients with AIDS and the proportion of negative test results among low-risk blood donors and are subject to the limitations outlined above.

The Western blot is currently used only for testing blood samples that test positive with an EIA test. Therefore, for our analyses, it is necessary to estimate how it performs when used among infected and uninfected individuals with positive EIA results. The Western blot, although considered more accurate than the EIA, also has an error rate. An Atlanta area study of consecutive EIA-positive blood donors collected data on Western blot and culture results that can be used to estimate the sensitivity of the Western blot.²⁵ In that study, the Western blot assay results were considered positive if both the p24 and gp41 precipitation bands were identified, or if one of these bands was consistently identified on repeated tests. If one assumes that all of the donors who had a positive culture were truly infected, then the sensitivity of the Western blot among EIA true-positive donors was 23/25, or 92%.

Some of the factors that result in false-positive EIA results may also lead to false-positive Western blot. To calculate the minimum specificity of the Western blot among those with EIA false-positive tests, one could assume that only individuals in the Atlanta study who had positive cultures were infected. However, it is difficult to culture virus from infected individuals, and many of the individuals with a positive Western blot and negative culture probably represent false-negative cultures rather than

Compulsory Premarital Screening for the Human Immunodeficiency Virus

Technical and Public Health Considerations

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The effectiveness of a mandatory premarital screening program was examined as a means of curtailing the spread of the human immunodeficiency virus (HIV) infection in the United States. The epidemiology of the HIV, the technical characteristics of tests for antibodies to HIV, and the logistic, economic, and legal implications of such a program were considered. In one year, universal premarital screening in the United States currently would detect fewer than one tenth of 1% of HIV-infected individuals at a cost of substantially more than \$100 million. More than 100 infected individuals would be told that they were probably not infected, and there would likely be more than 350 false-positive results. Public education, counseling of individuals, and discretionary testing can be important tools in reducing the spread of HIV infection, but mandatory premarital screening in a population with a low prevalence of infection is a relatively ineffective and inefficient use of resources.

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IN 1991, as many as 54 000 Americans are expected to die of acquired immunodeficiency syndrome (AIDS).¹ However, perhaps 10 000 of these infections could be prevented.^{1,2} One policy currently being considered by many state legislatures as a measure to reduce the spread of the virus is mandatory premarital screening. As of July 31, 1987, seventy-nine bills on the subject had been introduced in 35 states.³ An ultimate goal of such a human immunodeficiency virus (HIV) screening program is to reduce

the number of new infections, and we examined whether mandatory premarital screening would be an effective way to attain this goal. We also considered some of the legal, economic, and policy implications of such a program.

METHODS

In this article, we estimate the number of people who would need to be tested, the number of infected individuals who would be detected, and the number of individuals with false-positive and false-negative test results. We also estimate the number of cases of HIV infection that might be prevented by a compulsory premarital screening policy and predict the financial costs of such a program.

In the following sections, we review data relevant to each of these estimates

and use those data to project the overall impact of a mandatory, premarital screening program. In each situation where data are sparse or nonexistent, we make conservative assumptions. As conditions change or new data become available, the analytic framework will allow for updated projections.

Description of Population

The numbers of men and women who were married in the United States in 1982 are listed by age group in Table 1. To our knowledge, there are no broad-based seroprevalence studies that document the prevalence of HIV infection in persons planning marriage, so estimates must be based on data from other populations. The most frequently tested group of low-risk individuals is blood donors. Blood collection facilities actively discourage individuals at high risk of infection from donating blood. Age- and gender-specific rates of infection among blood donors currently are a reasonable baseline for estimating the rate of infection among persons about to be married.

Studies of blood donors report rates of Western blot-confirmed seropositive results of about 40 per 100 000 persons screened, with considerable regional variation.^{4,5} Men have higher rates of confirmed seropositive results than women. For example, in the American Red Cross data reported by Schorr et al,⁷ the rate of seropositivity among male donors was approximately 66 per

This paper is a summary of work conducted by a subgroup of the Study Group on Acquired Immunodeficiency Syndrome and Public Policy in the Division of Health Policy Research and Education at Harvard University, Boston.

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	HIV Infection†	No HIV Infection	Total
	Enzyme Immunoassay		
Positive	1325	7648	8973
Negative	23	3816372	3816395
Total	1348	3824020	3825368
	Western Blot		
EIA-positive, positive Western blot	1219	382	1601
EIA-positive, negative Western blot	106	7266	7372
Not tested (EIA-negative)	23	3816372	3816395
Total	1348	3824020	3825368

*EIA indicates enzyme immunoassay; HIV, human immunodeficiency virus.
†Based on Table 2.

Given the large proportion of false results among EIA positive tests, and the devastating consequences of incorrectly telling individuals they test positive, it would be imperative to conduct confirmatory Western blot tests on all persons who test repeatedly positive on the EIA test. Using our assumptions, the results of such confirmatory testing are presented in the lower half of Table 4. The proportion of persons in our example with positive EIA and Western blot tests who are truly infected is 76% (1219/1601). Approximately 100 infected individuals with positive EIA results might be falsely reassured by negative Western blot results, in addition to about 20 infected individuals who are falsely reassured with a negative EIA test. The data in Table 4 are also useful for evaluating the advisability of informing persons with a positive EIA test and a negative Western blot of those findings—the chance of infection among such persons is about 1% (106/7372).

Effects on Transmission of HIV

The benefit of detecting the 1200 cases in Table 4 is reduced by previous transmission of the virus. Among couples who have had previous sexual relations, the virus would already have been transmitted in approximately 70 cases. Therefore, the test results could potentially prevent infection of the partner only among about 660 people who had not already transmitted the virus and about 490 persons who had not had sexual contact, or about 1150 individuals. These calculations are based on optimistic assumptions about the potential impact on couples. It is highly probable that the risk status of partners would be more similar than expected by chance.²⁷ Therefore, the number of couples with true-positive results is likely to be lower than the number of individuals with true-positive results.

Our calculations indicate that approximately 500 infected infants would be conceived by infected mothers in their lifetime if their fertility rates were com-

parable with uninfected individuals. This number of infected births would be prevented only if no infected couple detected by the screening program conceived any children subsequent to learning of their infection as a result of the screening test results. However, some persons who develop AIDS or AIDS-related complex would likely limit the number of children they have even if they had been unaware of their serologic status at marriage. Also, many couples may be less likely to have subsequent children if an infected child was born and developed AIDS or AIDS-related complex. Conversely, many couples who learn of their infection continue to bear children.^{28,29} It is not possible to predict accurately how many infected births would be prevented by a screening program, but we suspect that the number would be less than half the number of potential births, or about 250.

The annual cost of approximately 3.8 million EIA test series and almost 10 000 confirmatory Western blot tests each year would be about \$23 million. The costs of counseling would increase costs to more than \$100 million.

Sensitivity Analysis

Key assumptions about the prevalence of infection and accuracy of tests could change markedly in the future. To estimate how sensitive our analyses were to the assumptions made, we recalculated the figures shown in Table 4 assuming that (1) the prevalence of infection was twice what we assumed, (2) the sensitivity and specificity of the EIA tests used were 99% and 99.9%, respectively, and (3) the conditional sensitivity and specificity of the Western blot were 99%. Under such conditions, a premarital screening program would detect about 2600 cases, would result in about 40 "confirmed" false-positive tests, and would not detect about 50 infected persons. As discussed above, the number of cases of transmission that could be prevented would be fewer than

this number. Such results are partially better than our original estimates. However, in our opinion, it is arguable whether they represent the type of results that would be sufficient to justify such an expensive program with a small yield relative to the size of the problem, when more effective uses of resources are available.

COMMENT

In our analysis, approximately 1200 infected persons who had not already transmitted the virus to their partner would be detected each year. Many of those persons might alter their behavior to prevent or reduce the spread of the virus to others,^{30,31} but this is the best result achievable in a program that screens more than 3.5 million people. As many as 380 people with confirmed positive results would be told incorrectly that they were almost certainly infected (Table 4), and many of these people probably would experience severe psychosocial morbidity. More than 100 infected persons would be told that they were probably not infected, and this false reassurance could increase high-risk behaviors.

There would be other logistic difficulties in implementing a mass testing and notification program in a premarital setting. It currently takes up to four weeks for some testing sites to complete a series of EIA and Western blot tests on a sample. It would be necessary to develop protocols about what information, if any, should be given to patients with EIA-positive tests, pending Western blot results. Also, if test results were needed before marriage, the test sequence would have to be initiated about a month ahead of the planned marriage date.

Our analysis indicates that perhaps 250, but probably fewer, infected births might be prevented by screening, and it is arguable whether premarital screening is the most efficacious approach to this problem. Of the 1 445 000 first births in 1980, only 63% were conceived within marriage.³² In New York City, 75% of the children with nonparenterally acquired AIDS were born to unmarried women (Pauline Thomas, MD, oral communication, 1987).

The financial and opportunity costs of a national screening program would be enormous, probably exceeding \$100 million annually. Such an expenditure might be justified if the program could sufficiently reduce the spread of HIV and if other, more cost-effective, efforts were already being taken. Considering that there are probably between 1 and 2 million infected individuals in the United States³³ and that \$100 million

false-positive Western blot.

In a study of blood samples collected from intravenous drug users in 1971 and 1972, before the virus is thought by many to have entered the United States, 4% of the samples were repeatedly positive on an EIA test. Among these reactive samples, there were also positive Western blot results. If only the gp41 band was required to consider the Western blot positive, seven of the 45 samples were Western blot positive; three of the 45 had both p24 and gp41 bands.²⁴ If one accepts the premise that none of these persons was infected as early as 1972, then all the EIA-positive results were false-positives and the probability of a falsely positive Western blot result among these persons was between 7% and 16%. Although this study was conducted among intravenous drug users, the biologic reasons for "double false-positives" may be similar, though much less prevalent, in low-risk populations.

The Food and Drug Administration has recently approved a Western blot kit from Du Pont Pharmaceuticals, Wilmington, Del, for which standards have been established, but standardized, commercial Western blot tests are not yet universally used and test results may vary among laboratories. When a panel of 15 serum samples was sent to five commercial laboratories to assess standardization, six (8%) of the 75 samples from low-risk individuals with a negative test on an EIA were reported to have positive Western blot results.²⁷ In addition, there is not universal agreement about the pattern of antibody bands that satisfy criteria for a positive result. For example, in the US Army testing program, in the absence of an antibody band corresponding to the transmembrane glycoprotein gp41, the presence of bands corresponding to the major core protein p24 and its precursor p55 is considered positive.²⁷ However, there have been several reports of Western blot-positive results in persons with this latter pattern who were apparently not infected.^{23,28}

For the purpose of the analyses presented here, we assume that the sensitivity and specificity of the Western blot among persons with EIA-positive tests are 92% and 95%, respectively.

Attributable Prevention

Many persons who marry will have had sexual intercourse before marriage. Data from the National Longitudinal Survey of Youth in 1983 indicate that by the age of 19 years, 77.6% of boys and 62.9% of girls have experienced coitus at least once; yet, in 1984, 96.8% of boys aged 18 or 19 years and 87.1% of girls of

the same age had not yet married.³⁰ In the analyses presented here, we assume that 60% of the couples planning marriage already will have had sexual intercourse before screening.

The number of couples in which the virus already has been transmitted to the partner will depend on the frequency of sexual relations, the specific sexual acts performed, and whether condoms or spermicides are used regularly. One study found that 58% of spouses of infected individuals tested positive for antibodies to HIV,³¹ but this study could not differentiate heterosexual transmission within couples from other sources of infection, such as shared needles. Another recent study found that 23% of women who were sexual partners of infected men during the preceding year tested positive for antibody to HIV.³² We use an estimate of 10% for transmission between sexually active partners before marriage.

One possible beneficial outcome of a premarital screening program would be reducing the number of infected infants. In recent years, the average number of lifetime births expected per married woman has been about 2.0,^{33,34} but this number is higher than the number of infected births that could be prevented in each infected couple. Only 68.6% of the marriages in 1982 of women under the age of 44 years were first marriages, and many persons starting a second or subsequent marriage will already have had children. In addition, 16.4% of all first births to once-married mothers in 1980 were conceived before marriage.³⁵

To estimate the maximum number of potential infected births, we assume that women entering their first marriage will have, on average, two children. We then subtract from this figure the number of first births to these women that are expected to be conceived before marriage.³⁵ For women entering a second or subsequent marriage, we used age-specific expectations for future births³⁷ as an estimate of the number of potentially preventable infected births. We assume that all women would marry a man with a risk of infection of 70 per 100 000, that all infected men would marry uninfected women, and that 50% of the infected men would transmit the virus to their spouse before childbirth. The information about transmission of infection to the fetus by mothers is limited,³⁸ but some data indicate that as many as 50% of infants born to infected mothers will also be infected. We use this figure to calculate the number of infected infants who might have been born in the absence of a screening program.

Costs

The US Conference of Local Health Officers has estimated that the costs of HIV antibody counseling and testing would range from \$22 to \$75, although several health departments estimated costs for people with a positive test at more than \$100 each (unpublished National Institutes of Mental Health memorandum, 1987). The Massachusetts Department of Health has examined the possibility of a premarital screening program and estimated the cost of conducting an EIA series to be \$6, a Western blot to cost \$50, and counseling costs at \$65 per person married (L. Kunches, RN, MPH, oral communication, 1987). The range of current charges for HIV antibody tests is quite large. For example, the Massachusetts Red Cross charges \$15 for an HIV antibody screening panel (EIA followed, when positive, by Western blot), and a commercial laboratory charges patients \$47.50 for EIA and \$121 for Western blot (Damon Laboratories, Needham, Mass, oral communication, 1987). For these analyses, we assume that the resource cost of an EIA series is \$6, that a Western blot would cost \$50, and that additional counseling costs for each person tested would be \$25 on average. These figures represent only part of the economic costs of a large-scale program. For example, more resources would probably have to be allocated to maintain the quality of testing programs as the volume of tests increased.

RESULTS

Based on our assumptions, the numbers of persons planning marriage who would test positive and negative on an EIA test in a given year are shown in Table 4. Data from screening of donated blood indicate that the proportion of blood samples from a low-risk population that are repeatedly positive on an EIA test is between 170 and 337 per 100 000.³⁴ Using these rates, the number of persons in the premarital population described in Table 1 who would have repeatedly positive results on the EIA test would be between about 6500 and 12 900. These numbers are consistent with our estimate of approximately 9000 individuals with positive EIA results (Table 4).

There are several striking results in Table 4. First, only 15% (1325/8973) of individuals with positive EIA tests are infected. Also, the absolute number of true-positive tests is small; a screening program involving more than 3.8 million people would detect only slightly more than 1300 infected persons. At the same time, a small number of infected individuals would test negative.

represents more than the federal government will spend on AIDS education in 1987, a compulsory premarital screening program does not appear to be a sensible allocation of resources.

This analysis has some bearing on the legality of proposed legislation related to mandatory premarital HIV testing. As of July 31, 1987, three states (Illinois, Louisiana, and Texas) have enacted statutes concerning premarital screening. The legislation in each state differs, but none restricts the right to marry among individuals with seropositive results.⁴³ The courts traditionally have given deference to public health officials when attempting to slow the spread of infectious disease and do not require the states to institute the most effective policies. Since current statutes for premarital screening will achieve some marginal public health purpose and do not impact on any fundamental right, as defined by the Supreme Court, they would be likely to be held constitutional.⁴⁴

The Supreme Court has repeatedly decided that marriage is a fundamental right.⁴⁵ If a screening statute were to restrict significantly or bar marriage, it likely would be held constitutional only if it were the least restrictive policy to achieve a compelling public health purpose. In *Zablocki v. Redhail*,⁴⁶ the Supreme Court stated that:

[I]f a statutory classification significantly interferes with the exercise of a fundamental right, it cannot be upheld unless it is supported by sufficiently important state interests and is closely tailored to effectuate those interests.

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Our data show that premarital screening would not be a well-focused policy likely to achieve a substantial public health interest. Statutes that infringe on the fundamental right to marry, therefore, are unlikely to be held as constitutional. One example is the recent Utah statute,⁴⁷ which does not set up a screening program, but which bans all marriage of persons with Centers for Disease Control-defined AIDS.

It may be instructive to consider syphilis screening programs as an example of universal screening policies that have been abandoned primarily because they have not effectively served the public good. Screening blood for evidence of syphilis was first required in the mid-1930s, and by the late 1940s, virtually every state had mandated premarital and prenatal syphilis serologies.⁴⁸ Initially, the rationale for blood screening programs seemed compelling: if every individual in the United States were tested at the time of marriage and all infected individuals treated, families would be protected from the consequences of syphilitic infection. Despite the conceptual appeal of these programs, over the years it became apparent that mass premarital screening seldom identified previously undetected cases, and because the prevalence of infection was low, there were more false-positive than true-positive results with high costs per detected case.⁴⁹ In 1978, premarital screening accounted for only about 1% of all positive syphilis tests. The cost of conducting the premarital screening tests is estimated at \$80 million.⁴⁸ In light of such data, several states enacted legis-

lation ending premarital screening to detect syphilis.⁵⁰ Thus, the program that is often cited as a precedent for HIV screening has itself been judged to be ineffective and unnecessary.

Many people believe that compulsory screening is a way to stop the spread of HIV, but such attitudes reflect a misunderstanding of the epidemiology of HIV infection and the performance of diagnostic tests. The more resources that we devote to such marginally effective ventures, the fewer resources we will have to develop truly effective public health programs. A comprehensive public health education program, in which premarital counseling and voluntary testing is one component, has the greatest potential for reducing the spread of infection. Screening tests are most useful in populations with a moderately high prevalence of infection in which it is possible to prevent the spread of HIV.^{51,52} Such programs should be motivated by an analysis of the epidemiologic facts rather than a response to political pressures, and such policies should be part of a multifaceted, nationwide program to reduce the transmission of HIV.

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Sloppy Faults Labs' Accuracy In Testing for AIDS Infection

By Susan Okie
Washington Post Staff Writer

Laboratories testing blood for evidence of AIDS have such a high error rate that in some low-risk groups, nine out of 10 positive findings would probably be wrong, a new government analysis has found.

Such a high rate of these so-called "false positives"—in which people without the AIDS virus wrongly appear to have it—would cast grave doubts on the reliability of massive screenings.

The analysis was done by the congressional Office of Technology Assessment and presented last week at a hearing of the subcommittee on regulation and business opportunities of the House Small Business Committee. It was based on recent results of proficiency testing of approximately 700 U.S. laboratories by the College of American Pathologists (CAP).

Rep. Ron Wyden (D-Ore.), chairman of the subcommittee, said in an interview that he found the labs' error rates "mind boggling."

In addition to the false positives, the data suggest that labs may be reporting falsely negative blood test results on as many as 10 percent of individuals who are really infected with the virus.

"Both the false positives and the false negatives have frightening social implications," Wyden said. "False negatives are people who think they're well and spread the virus. False positives have the potential of just causing social chaos," because uninfected individuals might base decisions about marriage, childbearing and careers on an erroneously positive test result.

The standard blood tests currently available to detect infection with the AIDS virus are the enzyme immunoassay (EIA or ELISA) and the Western blot. The EIA, performed initially as a screening test, detects protein antibodies produced by an infected individual's immune system against particles of the virus, known as human immunodeficiency virus, or HIV.

The more accurate and expensive Western blot is done as a confirmatory test if the EIA is positive. Poor-quality Western blots are the main reason for the laboratories' high false-positive and false-negative rates.

Because donated blood is discarded even if positive only on the initial EIA test, these findings do not suggest that infected blood is any more likely than previously believed—1 in 10,000—to pass through undetected.

When they are perfectly performed, both the EIA and the Western blot are highly sensitive, providing positive results in infected individuals in 99.6 percent of cases. They are also highly specific, giving negative results in uninfected persons in at least 99 percent of cases. But the pathologists'

ERRORS IN AIDS TESTING

PERCENT OF POSITIVE TEST RESULTS LIKELY TO BE 'FALSE-POSITIVE'

GROUP	IDEAL TESTING QUALITY	ACTUAL TESTING QUALITY
HIGH-RISK (Urban gays, Iv. drug users)	0.04%	0.79%
TEXAS MARRIAGE LICENCE APPLICANTS	0.6	9.6
MALES IN MILITARY	3.0	34.5
FEMALES IN MILITARY	7.6	59.3
U.S. BLOOD DONORS	11.1	69.0
PEORIA, ILL., BLOOD DONORS	33.3	89.9

NOTE: The likelihood of a false positive test result is greatest in groups with a low incidence of AIDS infection.

SOURCE: Office of Technology Assessment

proficiency testing program, in which laboratories were sent a series of "unknown" blood samples to test, showed that the error rates in laboratories around the nation are considerably higher than these ideal figures, especially for the technically more complicated Western blot.

The CAP's proficiency testing of laboratories during the period from July 1986 through June 1987 showed that the overall false-positive rate for the Western blot was 4.7 percent. The theoretical false-positive rate, if the test is properly performed, is 0.5 percent. The laboratories' overall false-negative rate was 9.3 percent, compared with a theoretical false-negative rate, if the test is properly performed, of only 0.4

Some laboratories achieve performance standards close to the ideal rates, while others have even higher error rates than the averages cited in the CAP data. But consumers having the blood tests, and doctors ordering them, often have no way of judging an individual laboratory's performance, the subcommittee was told.

In large-scale AIDS testing programs, false-positive results make up a greater proportion of all positive results when the group being tested is at low risk of infection with the virus. In contrast, false-negative results assume greater importance when a high-risk group is tested. The OTA analysis used the laboratories' performance record to predict the outcome of testing in six different populations for whom some estimate of infection with the AIDS virus was available.

For example, in a program to test 100,000 high-risk patients at a sexually transmitted disease clinic, the OTA predicted that 984 of an estimated 10,000 infected individuals would be missed because of a falsely negative blood test, while 72 uninfected people would test falsely positive.

On the other hand, if 100,000 blood donors were tested in Peoria, Ill., a group with a very low frequency of infection, 80 of the 89 positive blood tests, or 90 percent, would be false positives, the OTA analysis predicted.

Other experts testifying before the subcommittee echoed the concerns raised by the OTA report. Different laboratories use different criteria to identify a positive Western blot, and national standards have not been established for the test's performance, interpretation or quality, said James R. Carlson, director of the AIDS Virus Diagnostic Laboratory at the University of California at Davis.

Of 19 commercial laboratories sent "blind" samples by the U.S. Army to test their performance of the Western blot, 10 failed the test, some of them repeatedly, said Col. Donald S. Burke, who directs the Army's HIV screening program.

Most doctors who order AIDS blood tests assume they are accurate and know little about variations in laboratory performance, said Patricia Watson Martin, director of product development at Epitope Inc., a clinical laboratory and diagnostics firm based in Portland, Ore. "Because the opportunities for making profit from HIV antibody testing are so vast . . . we must act quickly to put controls into place to insure the quality of testing," she told the subcommittee.

Wyden said he plans to press for stronger federal oversight of the rapidly growing HIV-testing industry. "You can be pro or con testing, but as a prerequisite to a national testing policy, we're going to have to deal with this accuracy issue," he said.

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Sunday, May 17, 1987.

When to Test for AIDS

Why not compel everyone to be tested for AIDS as the basis for halting further spread of the virus? That's a natural first thought to anyone who ponders the deadly epidemic. But it's only a first thought. That some senior Administration officials argue for mandatory AIDS testing shows how late in the day they have arrived at step one.

William Bennett, the Secretary of Education, wants AIDS tests to be given to everyone admitted to the hospital or applying for a marriage license. Gary Bauer, a senior White House aide, says opponents of such tests are promoting "a bizarre type of enforced ignorance." The Public Health Service now says that all immigrants will be screened for AIDS virus.

There are at least six reasons for believing that advocates of general forced testing are opinionated, hasty or poorly informed.

Lesson One: Don't drive victims underground. Homosexuals and intravenous drug abusers, the principal victims, are not mainstream America. Living at the edge of social tolerance in many states, they face plenty of discrimination already. Their cooperation in changing their own behavior is crucial in slowing the disease's spread to other groups. Mandatory testing is the surest way to discourage them from contact with health authorities.

Lesson Two: A consensus is not a conspiracy. No one should lightly deny public health officials the tools they need to combat AIDS, including use of the AIDS antibody tests. What public officials want — for the reason cited above — is more voluntary testing, not mandatory testing. Mr. Bennett seems to believe that the Federal public health agency has fallen under the influence of homosexuals who oppose mandatory testing for self-interested reasons. But the reason for agreement is not conspiracy. Both groups believe voluntary testing is the better way of halting AIDS.

Lesson Three: Why in hospitals? Hospital patients are predominantly the elderly and the very young, two categories least likely to have AIDS. Why does Mr. Bennett propose to look there for the virus instead of among high-risk groups? Because hospitals are where testing is easiest. So too argued the drunkard who lost his keys in the dark and explained he was searching for them under the lamp-post because the light was better.

Lesson Four: Like it or not, morals have changed. Many states require a syphilis test for those seeking a marriage license. Mr. Bennett can't understand why an AIDS test isn't given too. The

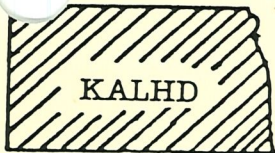
reason is that a minute proportion of known syphilis cases are detected this way. New York recently dropped the syphilis test because the results were not worth the cost, and because of suspicion that some couples nowadays have sex before marriage. The same logic applies to AIDS, but there's another, far more cogent reason.

Lesson Five: False alarms have grim consequences. The two present tests for AIDS virus are highly specific but even in conjunction are not totally accurate. The danger of "false positives" — diagnosing individuals as exposed to AIDS when they are not — is probably minuscule with high-risk populations. But the danger grows rapidly when screening large populations at low risk.

According to a paper to be published shortly by Michael J. Barry and colleagues at the Harvard School of Public Health, the two standard AIDS tests would identify 28 true positives, 2 false negatives and 11 false positives when applied to a low-risk population, defined as 30 AIDS cases per 100,000 people. What those figures say is that, for every 28 cases correctly diagnosed, the tests risk falsely informing 11 individuals that they carry the virus of a deadly disease and should never have children. Without guarantees of confidentiality, the insurers, employers, landlords and classmates of these 11 individuals may also learn, and act, on the false information. What a burden for mandatory testers to bear.

Lesson Six: AIDS makes a poor political football. Mr. Bauer believes that public health officials have few qualms in urging explicit sex education for young children, offensive as that may be to conservatives. But when it comes to testing, "the left's political agenda takes over." He says, "Either this is potentially the Black Death or it isn't." In fact, no one knows how widely AIDS will spread, but it's prudent to take precautions. Teaching teen-agers safe sex is an effective precaution — and mandatory testing is not.

AIDS is a medical issue. Those who politicize it, or see political motives where none exist, are seriously delaying national policy on AIDS and measures to save lives. The only known way to curb AIDS is to persuade people to change behavior. The Administration still has not mounted a massive public education program of the sort already under way in several European countries. The Secretary of Education should be leading the charge for education about AIDS and voluntary testing. Mandatory testing should be his last thought, not his first.



KANSAS ASSOCIATION OF LOCAL HEALTH DEPARTMENTS

"... Public Health in Action"

FY 1989

AIDS PREVENTION AND CONTROL

I. Issue Definition

The public health aspects of acquired immunodeficiency syndrome (AIDS) should be handled as other communicable diseases in that positive blood tests should be reported to health departments and contact follow-up should take place. Mandatory blood tests should be required under some circumstances and all medical information should be kept confidential as it is with other communicable diseases.

II. Background

AIDS is a fatal disease caused by a virus that is transmitted by sexual intercourse and blood, the latter usually is through sharing of contaminated needles by intravenous drug abuse. Since AIDS was first reported in the United States in mid 1981, public health services has received reports of about 36,058 cases with a case fatality ratio of 58%. Approximately 70% of the cases has occurred in homosexual/bisexual men and 17% have occurred in intravenous drug abusers. While the percent of cases in these groups has remained constant, there has been a significant increase in heterosexual cases. AIDS is a public health problem that merits serious concern and is a major priority of the U.S. Public Health Service. The AIDS virus is spread by sexual contact and needle sharing and may be transmitted from infected mother to infant during pregnancy or birth, or shortly after birth (probably through breast milk). The risk of infection with the virus is increased by having multiple sexual partners, either homosexual or heterosexual. Through June 18, 1987 there have been 74 AIDS cases in Kansas with a case fatality ratio of 64%.

The current recommendations for the prevention and control of AIDS is through education in schools, the workplace and the general public and through anonymous testing of individuals in high risk groups. There is no contact follow-up. Positive blood tests are not reported to local or State health officials and no contact follow-up is made. The number of people estimated to be infected with the AIDS virus in the

United States is about 1.5 million. All of these individuals are assumed to be capable of spreading the virus sexually (heterosexually or homosexually) or by sharing needles and syringes or other implements for intravenous drug use. Scientists predict that 20%-30% of those infected with the AIDS virus will develop AIDS within five years. Traditionally the control of communicable diseases has been to report known cases to official public health agencies, so their contacts can be investigated. Also, individuals who are infected and capable of transmitting the infection are reported to public health officials so their contacts can be investigated.

III. Options

- A. Continue with education and anonymous testing and hope that it diminishes further spread of the AIDS virus.
- B. Continue education and voluntary anonymous testing of high risk individuals and mandate testing of immigrants and prisoners in local jails and State prisons.
- C. Supply increased funding for AIDS with the following priorities.
 - 1. Support the continued testing, counseling, and education of individuals with high-risk behaviors.
 - 2. Support public health departments in their effort to do contact follow-up of cases and those with positive HIV test results.
 - 3. Offer voluntary testing in clinics for family planning and sexually transmitted diseases and for anyone thought to be at risk.
 - 4. Mandate testing in prisons and jails.
 - 5. Provide voluntary testing for individuals not in high-risk groups.
 - 6. Continue with education about AIDS in schools, workplaces, and for the general public.

IV. Recommendation

The Kansas Association of Local Health Departments recommends option C. AIDS is a sexually transmitted disease and testing, counseling, education and follow-up are necessary public health components. Testing in prisons and jails would be productive in segregating positive individuals from those who tested negative. Because drug abuse and homosexual activity occurs during incarceration, separation of the prisoners could prevent transmission of the infection and prevent the

treatment costs which will fall back on local or State governments operating the prisons and jails.

Many of the patients attending family planning and sexually transmitted disease clinics may be in high risk categories and therefore testing should be offered and followed by counseling about the risks of promiscuity. The follow-up of positive HIV tests will help public health authorities control the spread of this infection. These practices have been successful in syphilis and other communicable diseases.

V. Fiscal Impact

The cost of performing the procedures under option C would be high but case treatment costs are extremely high. The cost to draw the blood for the test and provide counseling is estimated at \$15.00 per person. The number of positive tests will probably be small and the number of contacts to be followed should not be overwhelming.

VI. Legislative Implications

Legislation would be needed to mandate testing in prisons and jails. There may be the need to strengthen the anti-discrimination laws to protect individuals who are found to be positive on mandated and voluntary testing.

VII. Impact on Other Agencies

Option C and accompanying legislation would have an impact on the KDHE laboratory and epidemiology unit, local health departments that would test and counsel individuals, State Prisons and County jails, and private physicians that would do voluntary testing.

VIII. Supporting Documents

Surgeon General's report on Acquired Immune Deficiency Syndrome. Facts about AIDS-winter 1987-U.S. Public Health Service. Public Health and the Law-AIDS Screening, Confidentiality, and the Duty to Warn. Larry Gostin, J.D. and William J. Curran, J.D., LLM, SMHYG. APHA 77;361-365, 1987.