

Testimony Prepared for Presentation  
Senate Public Health and Welfare Committee

Presented by

Margaret Trexler Hessen, MD,  
FACP Infectious Disease Physician  
Pennsylvania Medical Society  
Commission on Public Health

Wednesday, May 14, 2008

The intent of the Bill 1261 is to facilitate expanded testing for HIV infection by removing some of the procedural barriers to testing, and to normalize or “routinize” HIV testing, bringing it into the fold of everyday medical screening. These changes reflect new recommendations by the CDC.

In order to lay the groundwork for a discussion of the medical and social implications of the bill, I think it is useful to recount some of the history of HIV/AIDS and of Act 148 (which was passed in 1990), and to present the experiences and the new data that bring us to Bill 1261 eighteen years later.

In 1981, physicians in San Francisco noted a pattern of highly unusual infections and malignancies in young gay men. Similar illnesses were soon observed in the homosexual population of New York City, and then in IV heroin users, hemophiliacs and Haitians, making up the four H’s identifying the early patients. The occurrence of disease in these groups suggested that the condition was caused by an infective agent transmitted through blood and other body fluids, either by injection, transfusion, or sexual relations. This agent, in turn, destroyed the body’s immune system, rendering it susceptible to infections and malignancy.

I saw my first AIDS patient in 1985, when I was in Infectious Disease specialty training. There was no effective treatment at the time, and he died several months after diagnosis. He and his family suffered terribly. Fast forward a few years and much research later. Many of the patients that I saw in the early 1990s are still alive and well, working and going about their normal activities.

Other things have changed as well. The profile of those diagnosed with HIV is different, as sexual contact has spread the disease from the original four Hs to their sexual partners, and to those partners’ other partners, and so forth. Perinatal infection of newborns has also been a tragic consequence of unrecognized infection.

This brings us to today’s discussion. Thus far, about 500,000 Americans have died from AIDS. In the United States today there are about **one million** known persons **living with HIV/AIDS**. An estimated **250-300,000** cases are **undiagnosed**. There are **40,000 new cases every year** in the United States, **more than half** of which are thought to have been **infected by a person unaware of his or her HIV infection**.

**Pennsylvania ranks eighth** in the nation in the frequency of HIV/AIDS. We’ve had close to 40,000 cases of AIDS since the start of the epidemic. An additional 11,000 Pennsylvanians are HIV+ but have not yet developed AIDS. We see 1000-1500 new cases per year in Pennsylvania. Extrapolating from national data, there may be several thousand more who don’t know they are HIV+.

How can we break this epidemic cycle? In controlling any epidemic, the key factor is to **diagnose** those who have the disease, and to follow diagnosis with measures to **treat** the condition and to **prevent spread**. For example, even before effective medicines were available, widespread screening and appropriate medical care controlled tuberculosis, which had killed on a massive scale. More recently, universal screening of donors has eradicated HIV from the blood supply.

A diagnosis of HIV can be made through a blood test which is positive long before symptoms declare its presence. **Early diagnosis is beneficial** in several ways. **Patients diagnosed early benefit much more from medical care—they live longer, more productive, better quality lives than those diagnosed late.** Cost-benefit studies support early diagnosis from an economic standpoint. **Transmissibility is also reduced.** Treatment with antiviral medication reduces the concentration of viral particles in blood and other body fluids, making transmission less likely. Studies show that people who know they are HIV positive reduce behaviors that put others at risk by 50-70%. Taking all these factors into account, the transmission rate is about 2% for those who know they are HIV+ compared to 10% for those who don't.

With these issues in mind, the CDC recently issued new testing guidelines. These advocate routine screening of all people between the ages of 13 and 64 in addition to the previous recommendation to test those known to have risk factors for HIV (or “targeted testing”). This measure would uncover a greater number of unsuspected cases and would destigmatize testing by its all-inclusiveness.

In order to implement screening of large numbers of people, often in crowded emergency room situations and public health clinics, the CDC has re-evaluated some of the processes earlier recommended in conjunction with HIV testing.

Early guidelines encouraged “pre-test prevention counseling” through which persons undergoing HIV testing be educated about modes of transmission and means of prevention. This is time-consuming and not practical for mass screening. Further, some studies suggest that it is only marginally effective when compared to more thorough post-test counseling of those with positive tests. The new CDC guidelines therefore suggest eliminating requirements for pre-test prevention counseling. Prevention counseling should be provided for HIV+ persons and for those known to be at high risk, but it need not be a pre-requisite for testing.

Early in the AIDS era, confidentiality became a significant and legitimate concern. As I mentioned before, HIV/AIDS was originally a disease of gay men, IV drug users, hemophiliacs and Haitians. If you were diagnosed with HIV and you weren't a bleeder or from Haiti, then you must belong to group seen by some as social outcasts. Because of discrimination and economic burdens on employers and insurers, many people with AIDS lost their jobs, insurance and housing. For these reasons, laws such as Act 148 were enacted to safeguard the privacy of those tested for HIV. Also, in order to guarantee that appropriate information about the test and the significance of potential

results be provided prior to testing, Act 148 required signed informed consent specifically for HIV testing.

The need for a separate signed consent for HIV testing has proven to be a logistical barrier. Also, treating HIV testing in a manner separate and different from routine blood testing reinforces the fear and stigma associated with HIV and discourages patients from undergoing the test.

In an effort to reconcile all these issues, the CDC and others have devised a compromise strategy described as “opt-out” testing. **“Opt-out” testing** entails the provision of information about HIV testing to the patient and the opportunity to ask questions. However, instead of signing a separate informed consent pertaining only to HIV testing, the patient is asked to sign a declination if he or she does not wish to undergo HIV testing. Consent for HIV testing is included in the consent for treatment unless the patient thus “opts out.” “Opt-out” testing has been shown to improve acceptance dramatically. In the Health and Hospitals Corporation in New York City, for example, “opt-out” testing resulted in a 57% increase in the number of tests done and a doubling in the number of HIV diagnoses made. “Opt-out” screening of pregnant women has resulted in significant increase in testing, coupled with a reduction in perinatal transmission of HIV infection.

**To summarize, current CDC guidelines** advocate the following new strategies:

1. **HIV screening** should be offered to all those aged 13-64 who enter medical care for any reason.
2. Informed consent must be obtained, but need not be in the form of a separate, signed document. Rather, an **“opt-out”** approach is recommended.
3. **Pre-test prevention counseling** should **not** be required.

**The goals of these recommendations are two-fold: to increase the number of HIV infections diagnosed, improving the care of those infected and reducing transmission; and to work toward removing the fear and stigma associated with HIV testing by incorporating it into routine healthcare.**

**Senate Bill 1261** would permit Pennsylvania health care providers to practice in accordance with the CDC guidelines. It **removes** the previous **requirement for pre-test prevention counseling, eliminating a practical and psychological barrier** to testing large numbers of people. It **preserves** the requirement for **documented informed consent**, but allows this to be incorporated in an **“opt-out” format**. As written, it does not alter the requirement for post-test counseling, for strict confidentiality (which is also safe-guarded by federal HIPAA law), or any of the other provisions of Act 148.

Most of the issues raised in debate about opening Act 148 center on concerns that the individual rights of those tested will be compromised. Clearly, given the history that we've reviewed, this has been a valid apprehension. However, I would reiterate that most of those concerns are addressed in the HIPAA law and other regulations. Furthermore, I would submit that we should also respect—and protect-- the individual rights of those who might be unwittingly infected by a person who does not know that he or she is HIV+, and who might have taken steps to reduce or eliminate infectivity had he or she known. Bill 1261 is all about discovering more cases early, getting them to counseling and treatment while they can be helped most effectively, and preventing transmission. It's about responsible, sensible public health policy that keeps pace with current science.

Thank you. I will be happy to answer questions.