



# EXPANDED SYRINGE ACCESS DEMONSTRATION PROGRAM IN NEW YORK STATE: AN INTERVENTION TO PREVENT HIV/AIDS TRANSMISSION

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## BACKGROUND

The contributions of injection drug use to the domestic human immunodeficiency virus (HIV) epidemic have been well documented. In 1996, the Centers for Disease Control and Prevention concluded that half of all new HIV infections in the US occurred among injection drug users (IDUs).<sup>1</sup> The intersection of HIV and injection drug use has raised unprecedented challenges to urban health. The estimated number of IDUs in New York City alone exceeds 200,000.<sup>2</sup>

In New York State, injection drug use has been a driving force of the HIV epidemic since the mid-1980s. In 1987, the percentage of reported acquired immunodeficiency syndrome (AIDS) cases in New York State as reported to the New York State AIDS Case Registry attributable to injection drug use was 40%. An additional 4.8% of cases occurred among men reporting male homosexual/bisexual contact and injection drug use. Together, these two risk categories— injection drug use and male homosexual/bisexual contact with an IDU—surpassed those with the reported risk of the male homosexual/bisexual contact (43.5%).<sup>3</sup> In 1988, more cases were attributed to injection drug use (44.8%) alone than to male homosexual/bisexual contact (38.5%).<sup>3,4</sup> Although the proportional contribution of injection drug use to the New York State epidemic began to decline in 1992,

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in 1999 this risk category alone still accounted for almost one-third of new AIDS cases in New York State.<sup>3</sup>

Similarly, cumulative data on New York State AIDS cases through March 31, 2000, show that, of almost 140,000 AIDS cases reported, IDUs account for 44% of reported AIDS cases. An additional 3% of AIDS cases are among men reporting both injection drug use and sex with other men as risk factors. The female sexual partners of male IDUs who do not themselves use injectable drugs make up the largest group of AIDS cases attributed to heterosexual transmission in New York State. The cumulative percentage of adult women for whom the associated risk is heterosexual contact is 7%. Of the over 2,100 AIDS cases in New York State reported through March 31, 2000, among children under the age of 13 years, 64% acquired their infections through maternal HIV transmission from mothers primarily infected through personal injection drug use or through sexual contact with an injection drug user.<sup>5</sup>

Because of the devastating toll of HIV/AIDS on individuals, families, and communities, especially communities of color, and the heavy impact of injection drug use, the New York State AIDS Advisory Council in 1996 unanimously adopted recommendations made by its Subcommittee on Harm Reduction. Those recommendations included the revision of the Public Health Law to permit adults 18 and older to obtain syringes without a prescription from pharmacies, health care facilities, and health care practitioners. The council's report referenced broad-based support for expanded syringe access, including that coming from the American Medical Association, the American Psychiatric Association, the American Public Health Association, the American Society of Addiction Medicine, the American Association of Social Workers, the National Association of Substance Abuse Trainers and Educators, the National Commission on AIDS, and the National Academy of Sciences.<sup>6</sup>

#### **HISTORY OF SYRINGE ACCESS IN NEW YORK STATE**

In New York State, public health programs to increase access to sterile hypodermic needles and syringes as a measure to address HIV and other blood-borne diseases (including hepatitis B and C) among IDUs began in 1992. Since then, the New York State Commissioner of Health has had regulatory authority to grant renewable 2-year waivers to community-based not-for-profit organizations and governmental entities to conduct syringe-exchange programs within the context of a comprehensive harm reduction model of HIV prevention.<sup>7</sup> There are currently 12 of these programs: 9 in New York City and 1 each in Buffalo, Rochester, and Mount Vernon. As of June 30, 1999, cumulatively, 80,103 persons had enrolled in these

programs. Most of the authorized programs are operating currently at capacity and are serving a relatively small percentage of the state's estimated drug injectors.

To promote safe disposal of hypodermic needles and syringes, hospitals and nursing homes in New York State were required by Chapter 438 of the Laws of 1993, which amended the Public Health Law, to accept used hypodermic needles and syringes, commonly known as "household sharps."<sup>8</sup> For the first time, hospitals and nursing homes in urban, suburban, and rural locations statewide provided safe disposal options to communities they served.

New York State has been one of only eight states requiring prescriptions for the purchase of hypodermic needles and syringes.<sup>9</sup> In 2000, New York State enacted temporary legislation to promote access to sterile hypodermic needles and syringes without a prescription to reduce the exposure to and transmission of HIV and other blood-borne infections (most notably hepatitis B and C) among IDUs.<sup>10,11</sup> This followed similar actions by Connecticut (1992), Maine (1993), and Minnesota (1997).<sup>12-15</sup>

#### **EXPANDED SYRINGE ACCESS DEMONSTRATION PROGRAM IN NEW YORK STATE**

In 2000, New York's Public Health Law was amended to allow the sale or furnishing of up to 10 hypodermic needles and syringes without a prescription to persons age 18 years or older by licensed pharmacies and health care facilities and certain health care practitioners, subject to a number of conditions. This program, dubbed the Expanded Syringe Access Demonstration Program (ESAP), is authorized for the period January 1, 2001, until March 31, 2003.

Key features of the law include

- Licensed pharmacies, health care facilities, and health care practitioners otherwise authorized to prescribe use of hypodermic needles or syringes may register with the Department of Health to sell or furnish 10 or fewer hypodermic needles or syringes to persons 18 years of age or older.
- Persons 18 years of age or older may obtain and possess hypodermic needles and syringes legally without a prescription.
- Hypodermic needles and syringes provided to consumers are accompanied by a safety insert, attached to or included with the hypodermic needles and syringes, that discusses proper use, risk of blood-borne diseases, methods for prevention of blood-borne diseases, proper disposal practices, dangers of injection drug use, and how to access drug treatment, toll-free telephone number regarding HIV/AIDS, and information on safe disposal.

- Participating pharmacies, health care facilities, and health care practitioners are required to cooperate in a program to ensure safe disposal of used hypodermic needles or syringes. Pharmacies may not advertise availability by retail sale or furnishing of hypodermic needles or syringes without a prescription. Hypodermic needles or syringes must be kept in a manner that makes them available only to authorized pharmacy personnel (i.e., not openly available to customers).
- The Department of Health must submit an independent evaluation, developed in consultation with the AIDS Advisory Council, to the governor and the legislature on or before January 15, 2003. The report will assess the impact of the law on needle and syringe sharing; substance abuse; pharmacy practice; criminal activity; accidental needle sticks among law enforcement, sanitation, and other personnel; syringe disposal; and various methods of education on safe use and proper disposal.

The Department of Health will promulgate rules and regulations to implement the provisions of this law prior to the January 1, 2001, effective date.

The statute uses the existing health care delivery system to incorporate expanded access to individuals who are at risk of HIV exposure and transmission through injection drug use. Often, contact with a health care professional with regard to drug use is the initial step for an individual to enter substance abuse treatment. A multiprong approach to care provided by pharmacies, health care facilities, and practitioners provides several avenues of opportunity for IDUs not only to obtain sterile syringes, but also to enter into medical and mental health care to address issues related to drug use. And, the new program will build on already-existing safe disposal options—through hospitals, nursing homes, and approved syringe-exchange programs. New York State law does not prohibit safe disposal of sharps in household waste. Public and provider education on safe disposal options will be key features of the new program.

#### **IMPLEMENTATION AND EVALUATION CHALLENGES**

Successful implementation will require communication and coordination of diverse public, private, and voluntary agencies and organizations. Outreach and education to pharmacies, health care facilities, health care practitioners, law enforcement, consumers, health and human service providers, local governments, researchers, and many others is necessary. Development and promulgation of regulations in time for a January 1, 2001, effective date is required.

Evaluation findings will play a critical role in the public policy debate as the effective dates of the temporary amendments to the Public Health Law draw to

a close. In little more than 2 years time, the program must be implemented and a meaningful evaluation report prepared. Data collection strategies must be designed not to be burdensome. For example, collection of necessary information from pharmacies without discouraging their participation in ensuring access to sterile syringes requires a balancing of needs for essential information and respect for operational considerations. Consistency of data across sites and synthesis of quantitative and qualitative findings into useful, user-friendly formats in sufficient time to inform the public policy discussion around continuation of the program will be critical. Finally, rapid dissemination of intermediate/interim results has the potential to improve practice during the timeframe of the demonstration project.

The two reports from the New York Academy of Medicine, elsewhere in this issue, provide baseline information that may be useful to advance pharmacy practice.<sup>16,17</sup> They reflect a proactive effort on the part of the New York Academy of Medicine to gather preimplementation baseline information to guide program development and to measure the impact of the law on pharmacy practice. Pharmacies are expected to be a vitally important access point for individuals seeking to obtain sterile hypodermic needles and syringes under the ESAP. Such studies will be particularly important to ensure that the impact of the ESAP is evaluated objectively as a basis for sound public health policy in New York State and beyond.

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