

**SB 1159 Report:
An Evaluation of Over-the-Counter Sale of
Sterile Syringes in California**



July 2010



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Objectives of this Report

In September 2004, Governor Arnold Schwarzenegger signed Senate Bill (SB) 1159 (Vasconcellos, Chapter 608, Statutes of 2004) in order to “prevent the spread of HIV, hepatitis, and other blood-borne diseases among injection drug users (IDUs), their sexual partners, and their children.” The legislation, enacted on January 1, 2005, allowed cities and counties to authorize and develop local Disease Prevention Demonstration Projects (DPDPs) and legalize over-the-counter (OTC) sale of syringes in DPDP-registered pharmacies. SB 1159 requires that CDPH submit the following report, which addresses key outcomes of the legislation, to the Governor and Legislature by January 15, 2010. The report includes the following:

- An executive summary addressing implementation progress and the six indicators of community effect of the OTC pilot;
- A review of the scientific literature on syringe access and syringe disposal;
- A summary of the SB 1159 legislation and what it entails;
- A description of the research and evaluation methods employed;
- A description of implementation of OTC syringe sales programs;
- A response to the six research questions mandated by the SB 1159 legislation.

Executive Summary

Legislative History and Directive

Expanded access to sterile syringes for IDUs is considered by public health experts to be an integral part of a comprehensive approach to reducing the rates of HIV and hepatitis C virus (HCV) infection in the United States. Forty-six states have syringe exchange programs (SEPs) where IDUs can return used syringes and obtain sterile syringes and access ancillary social and medical services. Additionally, nearly all states in the United States now permit OTC pharmacy sale of syringes without a physician's prescription. California was one of the few remaining states to prohibit OTC sale without required ID until Governor Arnold Schwarzenegger signed SB 1159 (Vasconcellos, Chapter 608, Statutes of 2004) on September 24, 2004. The legislation established a pilot program for OTC sale in which local health departments and pharmacies could participate after securing authorization from their local government. Since 2005, policymakers in a number of local health jurisdictions (LHJs) across the state have authorized local DPDPs, which permit pharmacy sale of up to ten syringes to adults without a prescription.

SB 1159 mandated that CDPH conduct an evaluation of the public health and public safety outcomes of the legislation and related DPDPs, and provide a report to the Governor and Legislature by January 15, 2010. In this report, OA provides a comprehensive description of the implementation and outcomes of this policy change, including documenting decisions of local governments, pharmacy participation, public health department successes and challenges, use of pharmacies by IDUs, safe and unsafe syringe discard practices, outcomes tied to blood-borne disease transmission, and an evaluation of any related negative outcomes as indicated by changes in drug use or crime.

Supporting Evidence

LHJs Adoption: Most Californians Live in LHJs with OTC Syringe Sale, Although Most LHJs have not Authorized OTC Sale

Health departments across California's 61 LHJs were surveyed annually from 2005 to 2007 to monitor the progress of DPDP implementation and assess program coverage, facilitators, and barriers. By 2007, 17 (28.3 percent) LHJs had approved DPDPs, of which 14 had registered 532 (17.8 percent) of the 2,987 pharmacies in these 17 LHJs. The 17 LHJs that implemented DPDPs are among those with the highest HIV/AIDS disease burden, as 70 percent of cumulative HIV/AIDS diagnoses have been reported within these 17 LHJs. The number of registered pharmacies increased 300 percent, from the 133 in 2005 to 532 in 2007. As of 2007, the majority of Californians reside in LHJs with legal access to sterile syringes without prescription requirements. However, the majority of LHJs have not authorized OTC sale, including some counties with high rates of injection drug use-related HIV infection.

More IDUs Report Using Pharmacies as a Source of Syringes

HIV counseling and testing (C&T) data were collected from IDUs who sought testing from State-supported HIV C&T services during 2004 to 2006. Data from 38,420 testing sessions where clients reported drug injection in the previous two years were analyzed.

Reported use of pharmacies as a source of sterile syringes for IDUs increased three-fold in California during this time period, from 5 percent to 16 percent in counties that adopted the legislation, while use of pharmacies in non-adopting LHJs remained static at between 7 and 9 percent.

Early adopting counties (authorized in 2005) experienced substantial increases in the use of pharmacies as a source of sterile syringes among clients at State-supported HIV C&T services: Sonoma (2.9 percent in 2004 versus 28.8 percent in 2006), Los Angeles (LA) (6.5 percent versus 21.3 percent), Contra Costa (1.5 percent versus 16.2 percent), San Francisco (SF) (1.9 percent versus 13.5 percent), and Alameda (1.5 percent versus 5.3 percent) all saw an uptake in the use of pharmacy OTC sale. Additionally, between 40 percent and 45 percent of IDUs in authorizing counties reported never sharing syringes during the past two years. In counties that did not authorize OTC sale, never sharing rates were lower, ranging from 22 percent to 32 percent. Amphetamine injectors and Latino and White IDUs were more likely to report relying on pharmacies as a source of syringes than other groups. In summary, there was an increase in the proportion of IDUs who reported using pharmacies to obtain sterile syringes and pharmacies may be reaching a different subpopulation of IDUs.

In LHJs that Approved OTC Sale, Less than One-half of Pharmacies Registered to Sell Syringes without Prescription

As part of the larger study to evaluate this legislation, factors associated with pharmacy participation in OTC syringe sale were assessed in two cities. Overall, 42 percent of pharmacies reported OTC syringe sale (LA=28 percent, SF=81 percent), although only 33 percent had registered with the county as required by law (17 percent in LA, 76 percent in SF). In addition to important differences in pharmacy participation by city, the odds of OTC sale were significantly higher among pharmacists who thought syringe access was important for preventing HIV among IDUs. The odds of OTC syringe sale were also higher in chain pharmacies compared to independent pharmacies. These results suggest that participation in OTC sale was influenced by community and pharmacists' perceptions. Access to sterile syringes without a prescription might be increased through greater educational efforts directed at pharmacists.

Community Impacts (SB 1159 Mandated Evaluation Indicators)

SB 1159 required that CDPH evaluate six indicators of the effect of the OTC syringe sale pilot. These indicators are highlighted below along with salient evaluation findings.

- 1) "Hypodermic needle or syringe sharing practices among those who inject illegal drugs."

Injection-mediated risks are lower among IDUs in LHJs that have authorized access to sterile syringes through pharmacies.

During 2004 to 2006, between 40 percent and 45 percent of IDUs living in LHJs that authorized OTC sale reported never sharing syringes during the past two years compared to 22 to 32 percent of IDUs in counties that did not authorize OTC sale.

While we cannot attribute reduced syringe sharing practices among IDUs solely to implementation of SB 1159 (other structural and programmatic factors that differ between the authorizing and non-authorizing LHJs could have also played a role), it is favorable from a public health perspective that injection-mediated risks are much lower in LHJs that have expanded pharmacy access to sterile syringes.

- 2) “Rates of disease infection caused by hypodermic needle or syringe sharing.”

More time is required to determine the effect of SB 1159 on HIV incidence rates.

HIV and HCV are the primary infections transmitted by needle sharing. No HIV incidence data was available in California until after SB 1159 was implemented and California does not have an HCV incidence surveillance system. Additionally, because the California names-based HIV case surveillance system only began in 2006, that system will also not permit measurement of infection rates. The only surveillance system addressing this question is for AIDS cases and this system demonstrates decreases in reported AIDS diagnoses from IDUs since 1993 at which point reported AIDS cases reached a peak of 1,410. These declined to 332 reported cases in 2007, a statewide decline which includes the years just prior to and just following SB 1159 authorization and DPDP implementation. However, the long incubation period between HIV infection and AIDS diagnosis makes AIDS surveillance data an unreliable way to measure the impact of recent (those in place less than ten years) prevention measures.

- 3) “Needle-stick injuries to law enforcement officers and waste management employees.”

Reported needle-stick injuries among law enforcement officers remain rare.

In 1993, OA began documenting voluntarily reported accidental needle-stick injuries among California law enforcement personnel. Between 1993 and 2009, a total of 186 accidental needle-stick injuries were reported to OA’s HIV/AIDS Registry, 101 in LHJs that had not authorized DPDPs and 85 in LHJs that had, but the differences were not statistically significant. Between 2005 and 2009, post-authorization of DPDPs, 19 accidental needle-stick injuries were reported among law enforcement in LHJs that had authorized DPDPs and 15 accidental needle-stick injuries were reported among law enforcement in LHJs that had not authorized DPDPs, and the differences were not statistically significant.

- 4) “Drug crime or other crime in the vicinity of pharmacies.”

Drug-related crime remained stable in LHJs that authorized DPDPs.

After an extensive analysis of available data on crime and local clustering of crime, there was no evidence of elevated crime rates in counties that authorized a local

DPDP. The highest levels of clustering of crime were in counties that have not authorized DPDP.

- 5) "Safe or unsafe discard of used hypodermic needles or syringes."

Low levels of unsafe discard of used hypodermic needles or syringes were observed around DPDPs.

Systematic neighborhood observations and surveys conducted in LA and SF during 2007 and 2008 to assess levels of unsafe syringe discard in the vicinity of pharmacies and in high-risk neighborhoods, respectively, found a very low rate of unsafe discard of syringes near pharmacies or in communities where OTC sale of syringes is allowed. There is no evidence that DPDPs resulted in an increase or decrease in unsafe discard of syringes.

- 6) "Rates of injection of illegal drugs."

Levels of injection of illegal drugs decreased among publicly funded HIV testing clients since implementation of SB 1159.

During 2004 to 2007, more than 436,000 HIV C&T sessions were conducted in publicly funded test sites. During the HIV C&T sessions, clients were asked about their sexual and injection-mediated HIV risk behaviors. The proportion of HIV C&T clients who reported injecting illicit substances during the two years prior to their testing visit decreased from 12.37 percent during the first half of 2004 (pre-SB 1159) to 9.67 percent during the second half of 2007 (post-SB 1159).

OA is unaware of any evidence of change in rates of drug injection found in any state criminal databases or other sources in the period following authorization of SB 1159.

Findings and Conclusions

SB 1159 appears to be having the desired effect of augmenting access to sterile syringes to prevent transmission of HIV and other blood-borne viral infections among IDUs. While some parts of the state with high HIV prevalence now allow OTC sale as a result of SB 1159, there are regions that lack legal access to sterile syringes that have not engaged in the political process necessary to authorize a DPDP. To date, just 17 of the 61 eligible LHJs have implemented local programs, and just four of the hundreds of California cities have taken action to participate in the pilot (Figure 1). Although the number of new LHJs adopting SB 1159 has diminished each year since 2005, those that have adopted it (n=17) account for 70 percent of currently living HIV/AIDS diagnoses in the state.

Our evaluation suggests that counties authorizing OTC sale of syringes without a prescription possess lower syringe sharing levels among IDUs than counties that have not authorized OTC sale. It is possible that the availability of OTC syringe sales

contributed to a reduction in syringe sharing levels but no consistent causal trends have been observed thus far.

Comparing time periods prior to and following SB 1159 authorization, our evaluation found no evidence of an increase in drug use or crime in the state of California as a whole or in areas that authorized sale of syringes without a prescription. This suggests the authorization of OTC syringe sales did not promote increased drug-related crime as some had feared.

Since implementation of SB 1159, fewer clients presenting for testing for HIV at state-funded testing sites report injecting illegal drugs. This suggests that authorization of OTC syringe sales did not have the negative impact of increased injection drug activity, a concern expressed by some prior to authorization.

Our evaluation found that, following implementation of SB 1159, accidental needle-stick injury to law enforcement officers remained rare in California. Between 2005 and 2009, post-authorization of DPDPs, 19 accidental needle-stick injuries were reported among law enforcement in LHJs that had authorized DPDPs and 15 accidental needle-stick injuries were reported among law enforcement in LHJs that had not authorized DPDPs. The variation in recent years is not great enough to suggest a statistically significant relationship to the authorization of DPDP.

Furthermore, our evaluation finds no increase in unsafe discard of syringes since implementation of SB 1159. Syringe discard rates have remained static and no associations between unsafe syringe disposal and OTC syringe sales have been found.

Our overall findings are consistent with those of other states that have transitioned, as California has, from a complete prohibition on sale and possession of syringes, to allowing a limited number to be sold to adults.



Figure 1: Cities and Counties that have Approved Implementation of SB 1159 and DPDPs in California, April 2009

SECTION 1: BACKGROUND AND SIGNIFICANCE

This section provides context for the evaluation of SB 1159 by presenting a review of the scientific literature on the topic of OTC syringe sales and an overview of the legislation that permits OTC sales of sterile syringes in California. The section includes the following subtopics:

- HIV/AIDS data, definitions, and data sources;
- Syringe access;
- Syringe disposal;
- OTC syringe sales experiences in other states; and
- Legislative Overview: What does SB 1159 do?

HIV, AIDS, and HIV/AIDS: Data, Definitions, and Data Sources

California has traditionally relied on several data sources to monitor the HIV/AIDS epidemic. For the current report, OA relies primarily on HIV/AIDS case reporting, HIV C&T data, and findings from research conducted with collaborators in several agencies in Northern and Southern California. This approach allows for a closer investigation of the effects of HIV/AIDS on specific population groups in California.

AIDS has been a reportable condition in California since 1983. AIDS data provides a good indicator of the overall burden of the epidemic in California. HIV infection has been reportable in California since 2002, upon the implementation of HIV reporting by non-name code. HIV surveillance data is generally recognized as a good indicator of disease risk. While it is not a direct measure of HIV incidence, it is more reflective of recent infections and recent risk behaviors. In April 2006, the code-based HIV reporting system was replaced by a name-based HIV reporting system. As this report primarily focuses on syringe access policy and on HIV/AIDS risk behaviors during the years just prior to and the years immediately following name-based reporting (2004 to 2007), it is challenging to compare HIV surveillance data that rely on code-based and name-based reporting systems. As a result, most of the surveillance data that we report focuses on AIDS diagnoses, since AIDS case reporting protocols have remained consistent during this time frame. Where possible (i.e., when we focus on time frames with consistent reporting methods), we attempt to reflect the full burden of the epidemic by combining HIV/AIDS reporting data. Findings from collaborative research conducted with colleagues across California are used to fill gaps in surveillance data.

Syringe Access

Expanded syringe access has led to decreases in injection-mediated HIV risk behaviors and decreases in HIV transmission among IDUs internationally (Hurley, Jolley, and Kaldor, 1997; MacDonald et al., 2003; Bluthenthal et al., 2000; Gibson, 2002). In the United States, SEPs and OTC syringe sales are the primary legal sources of sterile syringes.

Since the early 1990s, in response to the AIDS epidemic, 46 states throughout the United States introduced legislation to permit OTC sale of pharmacy syringes (Fuller et

al., 2007; Deibert et al., 2006; Valleroy et al., 1995; Burris, et al., 2002; Singer et al., 1998; Junge et al., 1999; Compton et al., 2004; Stopka et al., 2002; Fuller et al., 2002). Pharmacy syringe sales have been associated with reduced rates of syringe sharing (Pouget et al., 2005; Wodak and Cooney, 2006) and reduced rates of HIV infection among IDUs (Friedman et al., 2001; Holmberg et al., 1996). OTC sales offer the potential for enhancing syringe availability due to the broad distribution of pharmacies throughout most regions of the United States and extended hours of operation (Stopka et al., 2002; Wodak and Cooney, 2006; Jones and Coffin, 2002). IDUs in many locations perceive pharmacies as stable, safe, and affordable sources of sterile syringes (Reich et al., 2002; Junge et al., 1999). In states as far reaching as Connecticut, Kentucky, Missouri, and Colorado, where legislation has permitted the statewide sale of OTC syringes, a large percentage of pharmacists have agreed to sell syringes (Compton et al., 2004; Valleroy et al., 1995; Groseclose et al., 1995; Singer et al., 1997) and in Maryland, have run SEPs in their stores (Riley et al., 2000).

In 1993, after new legislation lead to increased syringe access through pharmacies, 83 percent of pharmacies were found to sell OTC syringes within the five largest cities of Connecticut and more IDUs reported purchasing syringes from a pharmacy after the new laws (19 percent before versus 78 percent after) (Groseclose et al., 1995). In other locations, however, relatively low proportions of IDUs relied on pharmacies for syringes directly after pharmacy access legislation changed (Fuller et al., 2002); yet, over time, more IDUs have begun to rely on pharmacies as a primary source of sterile syringes (Pouget et al., 2005). Pharmacists' attitudes and beliefs, however, vary considerably and are, at times, detrimental to adequate provision of sterile syringes (Compton et al., 2004; Stopka et al., 2002; Farley et al., 1999; Gleghorn et al., 1998; Reich et al., 2002) and can lead to decreases in OTC sales (Singer and Stopka, 2000). In a number of states, some with high prevalence of HIV among IDUs, OTC sales have been restricted by law or pharmacy regulation until recent years (Taussig et al., 2000). The following table, developed by Burris and colleagues, provides a summary of OTC syringe sale deregulation in the United States since the late 1980s.

Table III: Syringe Deregulation in the United States

State	Year	Prior Law(s)	Change
OR	1987	Paraphernalia law	Syringes explicitly excluded from paraphernalia law
WI	1989	Paraphernalia law	Syringes explicitly excluded from paraphernalia law
CT	1992	Prescription law	Allowed purchase of 10 or fewer syringes without prescription
	2005 2006	Paraphernalia law	Allowed possession of 10 or fewer syringes without a prescription (raised to 30 or fewer in 1999 amendment) Redefined paraphernalia to exclude syringes.
		Paraphernalia law	Redefined paraphernalia to exclude syringes.
ME	1993	Prescription law	Allowed the sale of 10 or fewer syringes without a prescription
	1997	Paraphernalia law	Allowed possession of 10 or fewer syringes
MN	1997	Paraphernalia law	Allowed pharmacy sale of up to 10 syringes without a prescription and the possession of up to 10 unused syringes at
NY	2000	Prescription law	Allowed the sale of 10 or fewer syringes without a prescription (during two-year experiment)
		Paraphernalia law	Allowed the possession of legally obtained syringes (during two-year experiment)
NH	2000	Prescription law	Allowed the purchase of 10 or fewer needles in a pharmacy without a prescription
		Paraphernalia law	Syringes excluded from paraphernalia law
RI	2000	Prescription law	Repealed
		Paraphernalia law	Syringes excluded from paraphernalia law
NM	2001	Paraphernalia law	Allowed the sale of syringes by licensed pharmacists
HI	2001	Paraphernalia law	Exempts sale by medical professionals to IDU for disease control purposes; exempts possession by IDU
WA	2002	Paraphernalia law	Allows pharmacy sale and IDU possession “for the purpose of reducing the transmission of blood-borne diseases”
IL	2003	Prescription law	Allowed pharmacy purchase and subsequent possession of up to 20 syringes without a prescription
		Paraphernalia law	Allowed the possession of legally obtained syringes
CA	2004	Prescription law	Authorized local governments to permit pharmacy sales
		Paraphernalia law	Allowed the possession of legally obtained syringes
MA	2006	Prescription law	Allowed non-prescription pharmacy purchase by purchasers >18
		Paraphernalia law	Syringe sales explicitly excluded from the paraphernalia law

Available at: www.temple.edu/lawschool/phrhcs/otc.htm.

Syringe-Mediated Disease Risk

In California, injection drug use is associated with 19 percent of the 190,000 reported HIV/AIDS cases (OA) and it has been estimated that approximately 750 new HIV infections are attributed to injection drug use annually (revised estimates to Facer et al., 2001). In addition, an estimated 475,000 Californians are currently living with chronic HCV in California; however, these estimates do not include people who are incarcerated, homeless or in the military (Armstrong et al., 2006). It has been estimated that at least 60 percent of prevalent cases and nearly all incident HCV cases are attributed to injection drug use (Williams, 2001) and approximately 5,000 incident cases occur annually in California (CDPH, 2001). In Sacramento, 87 percent of patients of a methadone clinic were found to have HCV antibody (McCarthy and Flynn, 2001). In SF, nearly one-half (45 percent) of IDUs under 30 years of age have HCV antibody (Hahn et al., 2001) and, among IDUs who have injected more than six years, 71.3 percent have HCV antibody (Tseng et al., 2007). Thus to prevent both HIV and HCV infections, interventions to decrease the use of non-sterile syringes among IDUs are essential.

There is consistent indication that increased use of pharmacies is associated with lower syringe sharing rates among IDUs, as was recently seen in New York (Pouget et al., 2005; Fuller et al., 2007). Further, HIV infection levels were found to be twice as high among IDUs in cities across the United States that do not permit sales of syringes in pharmacies compared to IDUs in cities that do permit OTC sales (Holmberg, 1996; Friedman, Perlis, and Des Jarlais, 2001). In a cross-sectional analysis, Friedman et al., found that metropolitan areas in the United States with anti-OTC laws had a higher average HIV prevalence (13.8 percent versus 6.7 percent) than other U.S. metropolitan areas while the population proportions of IDUs did not vary by presence of anti-OTC laws.

Syringe Disposal

In the United States, an estimated 8 million individuals self-inject legal and illegal substances outside the health care setting using between 2 to 3 billion syringes annually (Macalino et al., 1998). IDUs dispose of approximately one-third of these syringes (Macalino et al., 1998). Involving IDUs in safe community sharps disposal programs is an important public health goal, which can reduce disease transmission risks, but may be frustrated by legal barriers (Burriss et al., 2002). A 16 state study found that laws, regulations, and guidelines relating to community syringe collection and disposal were somewhat inconsistent and confusing and presented potential barriers to safe disposal (Turnberg and Jones, 2002). Several states and cities, however, have established supportive regulations, policies (Turnberg et al., 2002), community-based programs (Drda et al., 2002; Caranci et al., 2002), local initiatives and public education programs (Derflinger and Druckenmiller, 2002) that assisted in the development of community needle disposal programs. In August 2002, several national organizations, including the American Medical Association and the American Pharmaceutical Association, called for renewed attention to safe syringe disposal outside of health care facilities (Elliot, 2002; Coalition for Safe Community Needle Disposal, 2002). Promoting safe syringe disposal has gone hand-in-hand with expanded syringe access through pharmacy sales in some states (Klein et al., 2002). In other locations, community

discard boxes have been utilized in high drug use areas to collect syringes that have been obtained from various sources (Riley et al., 1998; Caranci et al., 2002). While there is no one-size fits all approach to syringe disposal, many of the programs that have been implemented to date show promise. Syringe discard boxes and so-called syringe discard kiosks have proven to be popular among injectors in Baltimore, Maryland (Riley et al., 1998), New York State (Klein et al., 2002) and in Seattle and Kings County, Washington (Marks, Hanrahan et al., 2002), where nearly 24,000 syringes were collected for processing in local waste management systems during one year (Deibert et al., 2006).

OTC Syringe Sales Experience in Other States and Countries

Impact on Risk Behavior

Individuals' safe syringe disposal increased over time following a 2001 New York demonstration program that allowed legal pharmacy sales of syringes without prescriptions (Cleland et al., 2007). On the other hand, a study regarding pharmacy sales in Minnesota found no changes in syringe disposal practices during the one year following legal non-prescription pharmacy sales (Cotten-Oldenburg et al., 2001). Whether differences in these studies are due to geographic differences (e.g., attitudes or culture that are location-specific) are unclear.

Impact on Discarded Syringes

In New York State, where pharmacy access to OTC syringes was legalized in 2000, researchers employed systematic observation techniques and found that syringe and paraphernalia discard rates remained unchanged when comparing rates before and after the implementation of the Expanded Syringe Access Program (Klein et al., 2002). Additionally, needle sightings and on-the-job needle-stick injuries among New York City Department of Sanitation workers decreased substantially subsequent to changes in OTC legislation (Klein et al., 2002).

Accidental Needle Sticks

OTC and SEPs have been legally permitted in the state of Connecticut since 1993. Syringe possession laws also changed during the early 1990s, reducing the fear among IDUs of being arrested for carrying syringes. Concurrent with these changes in legislations, accidental needle sticks among law enforcement officers decreased significantly, indicating that enhanced syringe access legislation that also permits legal possession of syringes, may also decrease risk to law enforcement (Groseclose et al., 1995).

Physician Prescription of Syringes and Syringe Discard Kiosks

In Rhode Island, a comprehensive disease prevention approach includes enhanced sterile syringe access through pharmacies (Rich et al., 2002) and physician prescriptions. In Rhode Island, many physicians have participated in public health policy that allows them to reduce HIV transmission risks by providing prescriptions to injection drug using patients for sterile syringes, as well as medical services and referrals that are not often accessed by IDUs (Rich et al., 2004). Further, concurrent with enhanced syringe access initiatives, syringe discard kiosks have proven effective in

increasing safe syringe disposal among IDUs in the United States (Caranci et al., 2002) and in Canada (de Montigny et al., 2009).

Drug-Related Crime

Analyses that assess drug-related crime potentially associated with sterile syringe programs have been limited. In Baltimore, Maryland (Marx et al.) found no significant changes in drug-related crime rates in the vicinity of syringe exchange programs (Marx et al., 2000). OA was not aware of any studies focused on drug-related crime that have found this crime to be associated with OTC syringe sales.

Legislative Overview: What Does SB 1159 Do?

In 2005, California became the 45th U.S. State to permit OTC in an effort to prevent HIV transmission (Stopka et al., 2007). However, California law requires each LHJ to formally register with the State (i.e., “opt-in”) to authorize OTC pharmacy syringe sales. As of 2007, 17 (28.3 percent) LHJs have authorized OTC programs and 532 (17.8 percent) of the pharmacies in these 17 LHJs have registered to participate, while 2,457 pharmacies (82.2 percent) have not (Garfein et al., 2008). General and specific components of the legislation follow.

General Components

SB 1159, subject to authorization by a County Board of Supervisors or City Council, creates DPDP, a collaboration between pharmacies and local and state health officials, and authorizes pharmacists in licensed pharmacies who have registered with their local health department, to sell ten or fewer hypodermic needles or syringes for human use without a prescription. The aim of the legislation is to prevent the spread of blood-borne pathogens, including HIV and HCV. This provision became effective January 1, 2005, and is schedule to sunset on December 31, 2010.

Pharmacy Components

- The legislation authorizes a licensed pharmacist to sell or furnish ten or fewer hypodermic needles or syringes to a person 18 years or older for human use without a prescription if the pharmacist works for a pharmacy that is registered with the local health department for a DPDP.
- SB 1159 requires participating pharmacies to:
 - 1) register with their local health department and certify that they will provide the purchaser with written information or verbal counseling on all of the following: how to access drug treatment; how to access testing and treatment for HIV and HCV; and how to safely dispose of sharps waste;
 - 2) store hypodermic needles and syringes so that they are available only to authorized personnel; and
 - 3) provide for the safe disposal of hypodermic needles and syringes through one or more of the following options: providing an on-site safe hypodermic needle and

syringe collection and disposal program; furnishing or making available for purchase mail-back sharps disposal containers that meet state and federal standards; and furnishing or making available for purchase personal sharps disposal containers.

- The legislation deletes the prior requirement that a pharmacist keep detailed records of OTC sale of hypodermic needles and syringes and deletes the requirement that a signature and address be obtained from the person to whom the needle or syringe was furnished.

Customer Components

- SB 1159 allows a person who is 18 years or older to purchase ten or fewer hypodermic needles or syringes without a prescription at pharmacies that registered with a local DPDP.
- Authorizes a person to possess ten or fewer hypodermic needles or syringes if acquired through an authorized source.
- Makes it unlawful to discard or dispose a hypodermic needle or syringe upon the grounds of a playground, beach, park, or any public or private elementary, vocational, junior high, or high school. SB 1159 would make a knowing violation of this prohibition a crime, punishable by a fine (\$200-\$2,000), imprisonment (up to six months), or both.
- Exempts syringes that have been appropriately containerized for safe disposal from paraphernalia statutes (i.e., those syringes cannot be used as evidence of possession of drug paraphernalia). (This is a permanent change in law and does not sunset in 2010.)

CDPH Components

- The legislation required CDPH to convene an uncompensated advisory panel comprised of specialists, representatives, and stakeholders from the State, health, pharmacy, law enforcement, and waste management communities.
- Required CDPH, in conjunction with the advisory panel, to evaluate the effects of allowing licensed pharmacists to furnish or sell a limited number of hypodermic needles or syringes without prescription, and provide a report to the Governor and the Legislature on or before January 15, 2010. The report shall include, but need not be limited to, the effect of OTC hypodermic needle or syringe sale on all of the following: 1) hypodermic needle or syringe sharing practices among those who inject illegal drugs; 2) rates of disease infection caused by hypodermic needle or syringe sharing; 3) needle-stick injuries to law enforcement officers and waste management employees; 4) drug crime or other crime in the vicinity of pharmacies; 5) safe or unsafe discard of used hypodermic needles or syringes; and 6) rates of injection of illegal drugs.

- SB 1159 encouraged CDPH to seek funding from private and federal sources to pay for the evaluation.

Local Health Department Components

SB 1159 requires local health departments to:

- 1) maintain a list of all pharmacies that have registered under DPDP; and
- 2) make available to pharmacies written information to be provided in writing or orally by the pharmacy to the customer at the time of furnishing or sale of OTC hypodermic needles or syringes. This information will include: how to access drug treatment; how to access testing and treatment for HIV and HCV; and how to safely dispose of sharps waste.

SECTION 2: IMPLEMENTATION OF DPDP

Since SB 1159 was signed into law, numerous activities have occurred on the local, county, and state level that have set strategic planning, infectious disease prevention, and research and evaluation activities in motion. The following subjects will be discussed in this section:

- Timeline for SB 1159 implementation and evaluation activities;
- SB 1159 technical assistance (TA) provided by OA; and
- Case study on the two-step implementation process.

Stakeholders on the local, county, and state levels have been involved with a wide variety of authorization, implementation, and evaluation activities since the advent of SB 1159 and related DPDPs. The following timeline provides a brief overview of the primary SB 1159-related activities from 2004 to 2010.

Timeline for SB 1159 Implementation and Evaluation Activities

- **September 2004:** Governor Schwarzenegger signs SB 1159 (Vasconcellos).
- **December 2004:** Contra Costa Board of Supervisors authorizes the first California DPDP.
- **January 2005:** SB 1159 becomes law and local DPDPs can now be implemented; Contra Costa and Yuba Counties implement DPDPs.
- **March 2005:** SB 1159 Evaluation Advisory Panel (EAP) meets for the first time in Sacramento, California, to discuss implementation, research, and evaluation activities.
- **May 2005:** Researchers from OA and University of California (UC), San Diego submit SB 1159 grant proposal to the National Institutes of Health (NIH); proposal is not funded.
- **July 2005:** OA research staff completes first SB 1159 LHJ survey with public health staff across California.
- **September 2005:** Researchers submit revised application to NIH for research funding; proposal is not funded.
- **October 2005:** SB 1159 EAP holds its third meeting in Los Angeles, California, to revise suggestions for research and evaluation activities.
- **December 2005:** One year after SB 1159 was enacted, 13 counties have authorized SB 1159; OA IDUs program specialist and research staff provide TA to implementing and interested LHJs.
- **March 2006:** Fourth EAP meeting held.
- **April 2006:** OA sends out request for applications to IDUs researchers in California to conduct comprehensive evaluation of SB 1159 outcomes.
- **April 2006:** Internal baseline evaluation of the SF Department of Public Health DPDP to examine practices, experiences, and perspectives of pharmacies one year after SB 1159 was enacted.

- **July 2006:** Newly funded research and evaluation team initiates research activities; investigators include researchers from California State University (CSU)/Dominguez Hills, UC San Diego, UCSF, RTI International, and OA.
- **September 2006:** Wave II of the LHJ survey completed.
- **November 2006:** Data collection begins in LA and SF.
- **December 2006:** As of December 2008, 17 LHJs have authorized DPDPs across California (see Figure 1).
- **December 2007:** Wave III LHJ survey complete; 525 pharmacies in 17 LHJs across California are registered to sell OTC sterile syringes.
- **January-March 2008:** Pharmacist and IDUs surveys are completed in LA and SF to learn about local experiences with SB 1159.
- **April-June 2008:** Street observations conducted in LA and SF to assess syringe disposal practices.
- **March-December 2008:** Pharmacist and IDUs surveys are completed in Humboldt, San Mateo, Santa Cruz, and San Luis Obispo Counties to examine willingness to participate in pharmacy sales in four counties that approved local legislation yet had not implemented a DPDP under SB 1159 as of March 2008.
- **June 30, 2009:** OA-funded research and evaluation funding cycle ends; data collection complete and data analyses finalized.
- **January 15, 2010:** SB 1159 Evaluation Report submitted to Governor and Legislature.
- **December 31, 2010:** SB 1159 scheduled to sunset.

SB 1159 TA Provided by OA

Since the inception of the legislation that permits OTC sale in California, OA staff and agencies that were contracted by OA have provided TA to LHJs and pharmacy staff to facilitate DPDP implementation. In most locales which chose to pursue authorization of the provisions of SB 1159, the decision to move forward was made by the county local health officer (LHO) who was responsible for educating the county Board of Supervisors or City Council and persuading them of the merits of authorization. The work of developing an implementation plan, building a coalition in support of the plan, negotiating with law enforcement, registering pharmacies, and developing educational materials was usually led by the local HIV education and prevention (E&P) coordinator.

OA developed several mechanisms to assist LHOs in navigating the political complexities of authorization, and to provide HIV E&P coordinators with help in educating themselves, their LHOs and their local stakeholders. TA provided by OA staff working on the project included phone consultations, e-mail correspondence, presentations at meetings and testimony at hearings, development and dissemination of educational materials and linkages to both local stakeholders and to other health departments in the state working on the issue. TA included information on the legal requirements of DPDP, mandated roles of participating pharmacies and local health departments, syringe disposal options, scientific literature on syringe access, and HIV/AIDS trends among IDUs. Similar material was developed by the local health departments themselves, and shared with colleagues in other LHJs.

OA also developed a TA Web site which provided fact sheets, research articles, and templates that could be adapted for local use, which ranged from PowerPoint presentations to enrollment forms to letters aimed at recruiting pharmacy participation. OA also developed and distributed a short educational DVD for pharmacists addressing questions about the program.

Among the 57 LHJs surveyed in 2005, 26 (46 percent) reported that they had received some form of TA related to the implementation of DPDP. Among those, 65 percent reported that they had received TA from other LHJs, 58 percent had received information from OA, and 35 percent had received information from the TA Web site (Stopka et al., 2007).

SB 1159 TA provided by LHJs

Educating local stakeholders was a critical part of the project for local health department staff. In the 2005 survey, 37 LHJs (65 percent) reported that they had provided education to stakeholders and decision-makers, including pharmacists, law enforcement, waste management officials, and SEP staff and participants (Stopka et al., 2007). Both receiving and giving such education was time-consuming for local public health departments, as was seeking project approval from local elected officials.

The most significant challenges with DPDPs for the 17 implementing LHJs in 2007 were: “time management” (24 percent), “securing DPDP approval” (24 percent), and “enlisting pharmacy participation” (24 percent). Among the 35 LHJs without plans to seek approval of DPDPs in 2007, 40 percent listed “competing priorities–limited time” as a reason for not seeking to implement the program (Garfein et al., 2008).

Case Study on the SB 1159 Two-Step Implementation Process

In many counties, especially those with long-standing SEPs, there was no controversy surrounding the proposal of OTC syringe sale; public records indicate that local elected officials in these counties accepted the recommendation of the LHO with little or no debate or discussion. The Boards of Supervisors of four counties (Riverside, Fresno, Shasta, and Sacramento) held votes which resulted in rejection of a DPDP. Media reports followed the political process connected to the discussions in Sacramento County. Prior to the Board of Supervisors meeting on the issue, Sacramento Health Officer, Dr. Glennah Trochet, worked with her staff to assemble a group of experts to present on the science surrounding enhanced syringe access and disease prevention. Over 200 physicians signed a letter endorsing the proposal which was presented to the Board of Supervisors. Among the many people who testified in support at the two-hour hearing were public health experts, physicians, pharmacists, epidemiologists, harm reduction specialists, drug and alcohol treatment professionals, people living with HIV and HCV, and the Dean of the School of Medicine of UC Davis. These experts cited the scientific literature as well as their own clinical and personal experiences to demonstrate that expanded access to sterile syringes results in decreased risk of disease transmission. In addition to those who testified in favor of DPDP, three individuals testified against the proposal, including a representative of local law enforcement.

During the discussion by the Board of Supervisors, one supervisor suggested that local City Council members should also have the opportunity to discuss and vote on DPDP authorization. Two other supervisors agreed, and the Board of Supervisors asked the LHO to present information on DPDP to all of the local governing bodies within Sacramento County. Over the following months, Dr. Trochet, public health experts, and community members testified at seven local City Council meetings. Six of seven City Councils voted against implementation of a DPDP. When the County Board of Supervisors again considered the proposal, they voted three to two not to authorize a DPDP.

Despite the outcome on the county level, the City Council of Sacramento decided to pursue the project. In August 2006, the Sacramento City Council voted seven to two in favor of establishing a DPDP. Additionally, in a separate vote, the City Council for the first time permitted SEPs to operate within the city's jurisdiction.

This illustrates one example of the challenges presented by the two-level approval process required by SB 1159. Much time, energy, and fiscal support was required of the LHO, county and state public health staff, and members of the Board of Supervisors and local City Councils in order to authorize a DPDP on the local level. The process experienced here, however, also illustrates how some local authorities valued and utilized the local control component of SB 1159.

SECTION 3: SB 1159 RESEARCH AND EVALUATION

Several evaluation mandates are outlined in the SB 1159 legislation. With limited resources and staff, OA endeavored, with colleagues from across the state, to address each of these mandates. In this section, we highlight various phases and outcomes of SB 1159 research and evaluation efforts in California between 2005 and 2009. This section includes information on:

- SB 1159 EAP: Activities and Guidance;
- OA Request for Applications for SB 1159 evaluation;
- Specific aims and research questions;
- Study design and data sources;
- Study populations and study sites;
- Research methods and study instrumentation; and
- Research and evaluation findings.

SB 1159 EAP

SB 1159 stipulated that CDPH must convene an uncompensated Evaluation Advisory Board (EAP). In coordination with this panel, CDPH was required to design and implement a comprehensive evaluation that would assess the impact that SB 1159 had on HIV and hepatitis risk behaviors as well as the health and well-being of surrounding communities and stakeholders. The legislation highlighted specific fields of expertise that needed to be present on EAP. The panel was to be comprised of:

- Infectious disease control specialists;
- California Board of Pharmacy representative(s);
- Representative(s) of independent pharmacies;
- Representative(s) of chain pharmacies;
- Law enforcement representatives:
 - Executives, such as police chiefs and sheriffs; and
 - Rank and file officers.
- Specialist(s) in hazardous waste management from CDPH;
- Waste management industry representative(s); and
- LHOs.

Soon after authorization and implementation of local DPDPs began in early 2005, and following the mandate of the legislation, OA developed the SB 1159 EAP. During recruitment and formation of the panel, members were informed of the intricacies of SB 1159 as well as the instrumental role that the panel would play in providing guidance and technical support related to implementation and evaluation of local DPDPs and SB 1159 broadly. The first meeting of the EAP took place in Sacramento, California, during March 2005. Per the legislative language in SB 1159, EAP was comprised of individuals from numerous fields of expertise across the state, including specialists from:

- The California Board of Pharmacy;
- The California Department of Waste Management;
- CDPH Environmental Waste Management;
- UC Davis, School of Medicine and Graduate Group in Epidemiology;
- Sonoma County HIV Prevention;
- SF Department of Public Health;
- Stericycle;
- Sheriff of Mendocino County;
- LA County Department of Public Health;
- The Drug Policy Alliance;
- Walgreens Regional Office (Sacramento);
- San Jose Police Department;
- CDPH, OA;
- UC San Diego;
- UCSF;
- RAND Corporation;
- Charles Drew University; and
- CSU/Dominguez Hills.

During the initial meeting, panel members discussed a number of issues in plenary and breakout sessions, addressing questions such as the following:

- What current information/data can be used for preliminary findings or serve as baseline data for the evaluation?
- Who is preparing to or is already collecting data that can be used in the evaluation?
- Where are the gaps in the information/data that will be needed to address the evaluation protocol set forth in the legislation?
- Who can play a more active role in the implementation and evaluation of SB 1159? Who else should attend advisory panel meetings?
- What sub-committees are needed and which would you participate in at the next advisory panel meeting?
- What other suggestions do you have for DPDP evaluation and implementation?

Subsequent EAP meetings were held in LA and Sacramento, California, during June and October 2005 and March 2006. The SB 1159 EAP provided CDPH with the opportunity to fine tune plans for impending SB 1159 research and evaluation activities and to learn about experiences and suggestions from local HIV prevention coordinators, law enforcement, pharmacies, and researchers.

Suggestions from local public health experts with regard to DPDP implementation included the following:

- 1) Alert pharmacies to how the program would be evaluated;
- 2) Have pharmacies play a more active role in the implementation process and paperwork;

- 3) Engage pharmacists in peer education;
- 4) Foster referrals from SEPs to pharmacies;
- 5) Provide local outreach to pharmacies and IDUs to make sure that things go well initially;
- 6) Consider social marketing initiatives;
- 7) Develop community collaboratives with other stakeholders;
- 8) Develop and share standard health education materials;
- 9) Provide outreach to physicians informing them about local DPDPs;
- 10) Provide a list of participating pharmacies; and
- 11) Develop a consistent and uniform project logo/sign for participating pharmacies.

Many of the suggestions that evolved from the early SB 1159 EAP meetings guided subsequent TA efforts provided by OA staff members.

SB 1159 EAP: Research and Evaluation Guidance

SB 1159 EAP members provided essential information that informed decisions for research hypotheses, research and evaluation methods, and data analysis plans that were integrated into federal research grant proposals that were submitted to NIH in 2005 and 2006 (see Appendix 1 for specific aims). While these grant proposals were not funded by NIH, they provided a key framework for research and evaluation aims, research methods and implementation plans that ultimately lead to development of an OA Request for Applications.

OA Request for Applications

During early 2006, OA developed a Request for Applications focused on evaluation of SB 1159 and DPDPs. Researchers in California with experience in injection drug use-focused research subsequently submitted research and evaluation applications that aimed to address the research mandates set forth in the legislation. Ultimately, a collaboration of academic researchers with more than 40 years of combined injection drug use research experience was funded to conduct the SB 1159 evaluation. The funded application (Ricky Bluthenthal, Principle Investigator [PI], CSU/Dominguez Hills and RAND; Richard Garfein, Co-Investigator, UC San Diego; Elise Riley, Co-Investigator, UCSF) included a comprehensive study design which, together with complementary research and evaluation activities conducted by OA, would provide salient findings for the mandated evaluation outcomes highlighted in the SB 1159 legislation. The study was funded for \$150,000 per year for three years, which provided support for the investigators to address most but not all of the research mandates set forth in the legislation. Another study funded for \$107,994 by CHRP (Valerie Rose, PI, Public Health Foundation Enterprises, Inc.) examined the willingness of pharmacists to sell OTC syringes in four LHJs that approved local legislation yet had not implemented a DPDP under SB 1159. Collaboration with additional researchers in California was pursued in an effort to gain additional insights from studies that were already in progress.

Specific Aims and Research Questions (RQs) (Funded by OA)

SB 1159 research activities funded by OA began in 2006. The following specific aims and RQs guided research efforts:

- Specific Aim 1: To determine the knowledge, attitudes, beliefs, and preferences (KABPs) of pharmacists, IDUs, and community members regarding syringe access and syringe disposal options.

RQs: What syringe access and disposal options are preferred by pharmacists, IDUs, and community members? Do KABPs for syringe access and disposal mechanisms change over time?

Connection to legislative requirement: This specific aim was intended to assist collection of self-report data that would help us assess syringe access and syringe sharing practices as well as levels of injection of illegal drugs (SB 1159 evaluation mandates No. 1 and No. 6).

- Specific Aim 2: To document the uptake of pharmacy-based syringe access and disposal options by IDUs.

RQs: What proportion of IDUs access and dispose of syringes through pharmacies? Does the proportion of IDUs who use pharmacy disposal differ by syringe disposal mechanism offered by the pharmacy?

Connection to legislative requirement: This specific aim was intended to yield collection and analysis of data that would help us assess safe or unsafe discard of syringes (SB 1159 evaluation mandate No. 5).

- Specific Aim 3: To determine if self-reports of unsafe syringe disposal amongst IDUs differ by modality of pharmacy-based syringe disposal.

RQs: Does unsafe syringe disposal among IDUs differ by pharmacy-based syringe disposal option? Do IDUs with any pharmacy-based syringe disposal option report lower unsafe syringe disposal as compared to IDUs with no pharmacy-based syringe disposal options? Does pharmacy purchase of syringes result in increased disposal of syringes at SEPs?

Connection to legislative requirement: Specific Aim 3 also facilitated collection and analysis of self-report data that would help us assess safe or unsafe discard of needles and syringes (SB 1159 evaluation mandate No. 5).

- Specific Aim 4: To determine whether the number of publicly discarded syringes in areas with SB 1159 registered pharmacies differ as compared to similar areas without registered pharmacies and by syringe disposal options at the pharmacies.

RQs: Does publicly discarded syringes in areas near pharmacies registered to sell OTC syringes differ as compared to areas where pharmacies do not sell syringes or provide syringe disposal? Do publicly discarded syringes in areas near SB 1159 pharmacies differ by syringe disposal options?

Connection to legislative requirement: This Aim would provide data that would help assess actual safe and unsafe syringe discard in the area around DPDP and non-DPDP pharmacies (SB 1159 evaluation mandate No. 5).

- Specific Aim 5: To determine whether accidental needle-stick injuries among law enforcement, waste management staff, and community members differ by syringe disposal options at pharmacies and to determine whether needle-stick injuries differ among these personnel in areas with any pharmacy-based syringe disposal as compared to areas without pharmacy-based syringe disposal.

RQs: Do counties without pharmacy purchase or pharmacy-based syringe disposal options report more per capita needle-stick injuries among law enforcement and waste management personnel than counties with pharmacy syringe purchase and disposal options? Does the per capita rate of needle-stick injury among law enforcement officials and waste management workers differ between areas with different pharmacy-based syringe disposal options?

Connection to legislative requirement: Aim 5 provided evaluation results that would allow us to assess needle-stick injuries among law enforcement officers in California (SB 1159 evaluation mandate No. 3).

- Specific Aim 6: To characterize all 61 LHJs in California regarding: 1) local authorization to establish a DPDP; 2) implementation of DPDP; 3) level of participation among pharmacists in each DPDP; 4) characteristics of DPDP (i.e., community involvement, syringe discard methods, customer education methods, advertising); and 5) characteristics of LHJs (e.g., population size, drug-related crime, HIV/AIDS prevalence).

Connection to legislative requirement: This Aim yielded data that would allow us to assess authorization and implementation levels of local DPDPs as well as drug-related crime and HIV/AIDS prevalence on the LHJ level (SB 1159 evaluation mandates No. 2 and No. 4).

- Specific Aim 7: To identify implementation factors that are associated with DPDP success (i.e., decrease in syringe sharing controlling for syringe acquisition source).

Connection to legislative requirement: Specific Aim 7 lead to collection and analysis of data that would allow us to assess factors associated with HIV and hepatitis risk behaviors, comparing DPDP authorizing and non-authorizing LHJs (SB 1159 evaluation mandate No. 1).

Study Design and Research Methods

To accomplish these aims, we developed a multi-pronged, multi-site approach using mixed methods. The study design, data source, study population, study site, research methods, and study instrumentation used to address each specific aim are highlighted below:

Specific Aims 1-3

Study Design and Data Source:

To accomplish **Specific Aims 1-3**, OA used data from a pharmacy survey, an IDU, and a community forum survey, to document and compare KABPs among these populations. OA also conducted secondary analysis of HIV C&T and HIV/AIDS surveillance data to assess trends in HIV risk behaviors as well as HIV/AIDS infection in DPDP authorizing and non-authorizing LHJs. Additionally, OA used the HIV C&T data to characterize IDUs who were more likely to use pharmacies as a source for sterile syringes.

Study Sites and Study Populations:

The study sites for **Aims 1-3** included LA and SF Counties for primary data collection. Study populations for these aims included pharmacists and pharmacy staff in LA and SF, street-recruited IDUs in LA and SF, community members who participated in SB 1159 informational forums in LA, and all SEP clients in LA. Data from publicly funded HIV C&T sites and HIV/AIDS surveillance sites across all California LHJs were analyzed to assess risk behaviors, HIV/AIDS infections, and IDUs use of pharmacies as a source of sterile syringes over time.

Research Methods/Study Instrumentation:

Pharmacy Survey: OA conducted phone surveys and in-person (LA only) surveys with pharmacists in LA and SF. The pharmacy survey included items on KABPs regarding SB 1159, syringe sales, and syringe disposal. In addition, for those pharmacists who registered with a local DPDP for sale of syringes without prescription OA asked items on syringe disposal modalities, their experiences with and issues related to pharmacy syringe sales, syringe disposal, and potential negative consequences of syringe sales and disposal. In LA and SF Counties, OA recruited from all retail pharmacies in high-need areas including those who did not register for syringe sales. High-need was defined by higher than average per capita IDUs in a ZIP Code based on California alcohol and drug program treatment information. Participating pharmacies included both those registered and not registered to sell OTC syringes. OA planned to interview roughly 300 pharmacists annually (100 in SF and 200 in LA). The pharmacy survey was to be conducted during the first and second years of the study. Similar pharmacy surveys were conducted by colleagues funded by CHRP in other California LHJs.

IDU Survey: OA recruited annual cross-sections of IDUs using street outreach efforts and chain referrals among IDUs. Our goal was to recruit 200 IDUs annually. The IDUs survey included items on KABPs regarding SB 1159, utilization of pharmacy as a source of syringes, use of pharmacy-based syringe disposal options, use of other syringe disposal options, and other issues related to syringe disposal practices such as

socioeconomic status, demographic, health status, and drug use patterns and practices. These interviews occurred in private or semi-private locations using hand-held computer assisted personal interviewing software. Participants received five dollars for completing the interview. OA planned to conduct 200 interviews with IDUs annually in LA and SF Counties over three years (total n=600).

LA SEP Client Encounter Forms: OA used data from all LA City-funded SEPs to assess uptake of pharmacy purchase and calculate the contribution of syringes purchased from pharmacies to SEP disposal. Two items were added to the existing encounter form that is filled out at each SEP visit. All clients were asked if they had purchased syringes at a pharmacy in the last seven days and how many of the syringes that they were exchanging were purchased from a pharmacy. This would provide us with information from over 11,000 IDUs in LA City on both pharmacy purchase of syringes and the magnitude of diversion of purchased syringes into SEPs. The encounter form also includes information on age, drug preference, housing status, and residential ZIP Code thus permitting examination of neighborhood differences in uptake of pharmacy purchase.

Community Survey: OA used an anonymous self-administered survey to collect KABPs about SB 1159 at community forums in LA County. KABPs data was collected at these forums from business owners, residents, and pharmacists. Domains included in this survey were SB 1159 knowledge items, acceptability, and preferences for syringe disposal mechanisms, beliefs about syringe access, and recent observations of injection trash among other items.

AIDS CASE REPORTING 1983-2005

AIDS has been a reportable condition in California since 1983. HIV infection has been reportable in California since 2002, upon the implementation of HIV reporting by non-name code. In April 2006, the code-based HIV reporting system was replaced by a name-based HIV reporting system. As this report primarily focuses on HIV/AIDS during the 2001-2005 period, HIV case counts and statistics provided in this profile represent the code-based HIV cases diagnosed through December 31, 2005, and reported to OA between July 2002 and March 2006. The implementation of code-based HIV reporting in 2002 coincided with an increase in the reporting of prevalent AIDS cases. Therefore, statistical adjustment of HIV/AIDS cases to account for reporting delay, which assumes stability of case reporting, was not applied to HIV or AIDS case counts.

HIV/AIDS Reporting System (HARS)

HIV and AIDS are reportable diseases in all U.S. states and territories. HIV/AIDS surveillance in clinical settings that involves the reporting of confidential HIV tests and AIDS diagnoses is sometimes called “core” or “case” surveillance. HARS is a public health surveillance system through which HIV and AIDS cases are reported from local health care providers and laboratories. HIV infections and AIDS diagnoses are reported to local health departments through a combination of passive and active surveillance. Passive surveillance is conducted through State-required reporting of HIV and AIDS cases by health care providers and reporting of HIV-positive test results from

laboratories to local health departments. Active surveillance is accomplished through routine visits to hospitals, physician offices, laboratories, HIV C&T sites, and outpatient clinics to ensure completeness, timeliness, and accuracy of reported data. In California, HIV/AIDS surveillance has traditionally relied upon active case surveillance, through onsite chart reviews and case report completion by local surveillance staff at the health care provider's office.

- **Key Strengths:** HARS is the only source of population-based AIDS information available in all U.S. states. Standardized reporting of demographic, risk, clinical, and laboratory information for AIDS cases has provided uniform trend and distribution data since 1983. In California, laboratory-based reporting of HIV fosters timely access to information necessary to measure the burden of disease and support prevention planning efforts. With the implementation of HIV reporting, California has data that is representative of more recent HIV infections, which can be used to identify emerging patterns of disease.
- **Key Limitations:** Not all persons infected with HIV are tested and people test at different stages of infection. Information from a health care provider is necessary to complete all HIV and AIDS case reports. Therefore, HARS cases are only representative of persons who have sought or received care in a clinical or other confidential diagnostic setting. HARS data are not representative of individuals testing at anonymous testing sites. While AIDS has been reportable in California since 1983, HIV infection has only been reportable since 2002. In 2002, California implemented HIV reporting by non-name code. The HIV name-based reporting system was established in April 2006. HIV case counts and statistics provided in this profile represent the code-based HIV cases reported through March 2006. Implementation of HIV reporting in 2002 resulted in an increase in prevalent AIDS reporting. Therefore, California AIDS data do not meet the stability of reporting assumption required for statistical adjustment for reporting delay; estimated HIV/AIDS incidence and prevalence estimates in this report are based on actual case counts. As a result, AIDS data presented in this report may not include persons diagnosed, but not yet reported to the HIV/AIDS Case Registry and AIDS incidence for more recent years may be underestimated. These numbers, therefore, represent a minimum estimate of persons diagnosed and living with HIV/AIDS in California. Further, changes in race/ethnicity reporting implemented in 2003 in response to Office of Management and Budget Guidelines make trend analysis difficult due to the need compare data collected under more than one racial/ethnic classification system. Moreover, the expansion of Hispanic ethnicity to include persons of any race and the addition of the multiple race category limit the ability to compare data from differing time periods.
- **For more information:** Centers for Disease Control and Prevention (CDC). "HIV/AIDS Statistics and Surveillance." Available at: www.cdc.gov/hiv/topics/surveillance/index.htm.

HIV C&T Data

The HIV C&T Program provides HIV testing to clients, often with integrated prevention counseling. All states, territories, and selected cities receive funding to support HIV counseling, testing, and referral programs as part of HIV prevention cooperative agreements with CDC. Standardized data on clients who are tested for HIV are available at the local level and data may offer insights into HIV infection rates for a high-risk population in that area. In California, HIV C&T services are provided by 59 of 61 LHJs and their subcontractors at both anonymous and confidential HIV C&T sites. Data from HIV counseling, testing, and referral programs include information on client demographics as well as HIV C&T data (e.g., self-reported testing history and test result). Examples of behavioral data collected by HIV C&T sites include:

- Male-to-male sexual contact;
 - Heterosexual relations with a male who has sex with other males;
 - Injection drug use; and
 - Sex industry work.
- **Key Strengths:** HIV C&T programs provide standardized data on clients who seek free HIV testing in sites throughout the state. At sites where client-based estimates are used, HIV positivity offers one estimate of HIV prevalence within certain high-risk populations. HIV C&T Program data also provides information on risk behaviors, such as sex industry work, not routinely collected in HARS.
 - **Key Limitations:** HIV C&T collects information only from clients who seek HIV C&T services at an OA-funded site. Therefore, HIV C&T data only represents persons who consider themselves at risk for HIV and persons willing to take an HIV test and do so at a publicly funded site; thus they are not representative of the general population. Another limitation of HIV C&T data is that it is not possible to distinguish persons who have been tested multiple times. Estimates of new HIV-positive tests are derived from self-reporting of a previous HIV-positive test result, which could introduce response bias in the testing history data. Population estimation of HIV seroprevalence is not possible at sites where HIV C&T data are test based. Because HIV C&T gathers data on prevention activities, changes should be interpreted with caution as they may reflect changes in program priorities rather than testing patterns of individuals.
 - **For more information:** OA's HIV C&T Program. Local Evaluation Online (LEO) – HIV C&T Guidance Documents. Available at: www.cdph.ca.gov/programs/AIDS/Pages/OALEOCTDocs.aspx.

Specific Aim 4

Study Design and Data Source:

For **Specific Aim 4**, OA used systematic observation data to compare prevalence of injection trash near pharmacies.

Study Sites:

The study sites to address **Aim 4** included the one-block area surrounding pharmacies DPDP-registered and non-registered pharmacies that had been previously surveyed. Systematic observations were conducted in LA and SF Counties.

Research Methods/Study Instrumentation:

Systematic Street Observations: OA selected and systematically observed one-block areas around pharmacies with and without syringe disposal options and areas with different syringe disposal options to determine the incidence of publicly discarded drug injection trash (defined as syringes or syringe parts [caps, plunger, barrel], drug vials/balloons, and cookers). Using methods developed and previously used by investigative team members, OA conducted annual street observations to document changes in publicly discarded injection-related trash (defined as syringes, syringe caps, cookers, bag/baggies/foil wrap, cotton, and ties). Observations were conducted on the block where pharmacies were located and one block in every direction surrounding the pharmacies. Block observations consisted of two raters walking along the periphery of one block and counting visible injection-related trash at baseline then as annual follow ups. Only trash that could be viewed from the sidewalk was counted; no potentially obstructive objects were removed. If there were questions regarding whether objects constituted “injection trash,” a consensus approach was used to make the final determination. To control for temporal changes in amount of garbage discarded in general, OA included a potential confounding variable, the number of whole glass bottles. Whole glass bottles were counted regardless of size and whether they came bundled together in bags or other containers. At least 24 pharmacy locations were scheduled to be observed during each year of the study, one for each disposal condition including no disposal options. This would provide OA with at least 72 time-place observations which would provide sufficient observations to permit statistical analyses. These activities occurred around pharmacies that had previously participated in our pharmacist survey in LA and SF Counties. Colleagues from RTI International (Alex Kral, PI) also conducted widespread systematic street observations in SF as part of an independent study while conducting comprehensive syringe disposal surveys with a targeted sample of IDUs in the city.

Specific Aim 5

Study Design and Data Source:

To address **Aim 5**, trends in accidental needle-stick injuries among law enforcement personnel were tracked before and after implementation of SB 1159 at the county level.

Study Sites and Study Population:

All California counties are eligible to report accidental needle sticks among law enforcement personnel.

Research Methods/Study Instrumentation:

Occupational needle-stick injuries among law enforcement: Occupational needle-stick injuries among law enforcement personnel have been voluntarily reported to the OA HIV/AIDS Case Registry since 1993. Needle-stick injury reports are completed by law enforcement agencies in LHJs across the state. Analysis of needle-stick data included

data reported from 1993 to 2009. Annual comparisons of needle-stick injuries by LHJs with and without DPDPs were conducted. Needle stick frequencies were also compared across pre- and post-DPDP authorization timeframes.

Specific Aims 6 and 7

Study Design and Data Source:

For **Specific Aims 6 and 7**, serial cross-sectional surveys were conducted annually, from 2005 to 2007, with public health personnel in LHJs across the state to determine barriers and facilitators of DPDP authorization and implementation, as well as lessons learned.

Study Sites and Study Population:

California is divided into 61 LHJs served by 58 county and three city (Pasadena, Berkeley, and Long Beach) health departments. Between 2005 and 2007, personnel from public health departments in each of these 61 California LHJs were recruited to complete the survey.

Research Methods/Study Instrumentation:

LHJ Survey: Support for completion of the survey was garnered during meetings of the California Conference of Local Health Officers, the California Conference of Local AIDS Directors, and the County Health Executives Association of California. Questionnaires were initially sent to LHOs in each LHJ. Alternate respondents were requested when someone other than the LHO was primarily responsible for DPDP activities. Questionnaires also requested contact information for the person who would be most appropriate for future surveys. Through this process, OA was able to identify individuals most knowledgeable about SB 1159. Surveys were mailed and e-mailed to health officials with an endorsement letter from OA. An online survey option was added in 2007. Responses could be returned by mail, fax, e-mail, Internet, or telephone. LHJ surveys were conducted with health department staff in more than 90 percent of California LHJs during each of the three data collection waves. Non-responders received reminder letters followed by phone calls when needed to assure high response rates.

In-depth Interviews: Colleagues from SF who were funded by CHRP, conducted in-depth interviews with public health staff and policy makers in a number of LHJs across the state to obtain data on contextual factors associated with DPDP authorization and rejection and implementation.

Finally, colleagues from Northern California (Valerie Rose, PI) provided complementary data that were the product of SB 1159 research funded by CHRP. Surveys with pharmacists in additional counties and in-depth interviews with public health staff and policy makers produced findings that also helped to address Aims 1, 2, 6, and 7. Table 1, below, summarizes research methods and data sources by study aims.

Table 1: Summary of Research Methods, Data Sources, and Variable Domains by Study Aim

	Aim 1 (KABP)	Aim 2 (Pharmacy use as a syringe source)	Aim 3 (Syringe disposal among IDUs)	Aim 4 (Publicly discarded syringes)	Aim 5 (Needle-stick injuries)	Aims 6 & 7 (DPDP authorization & implementation)
Research methods	Cross-sectional surveys	Cross-sectional surveys; LA SEP client data	Cross-sectional survey	Prospective street observation and coding	Secondary analysis of administrative data	Cross-sectional survey
Data source	Community, Pharmacy, & IDUs surveys; HIV C&T data	IDU survey SEP client data; HIV C&T data	IDUs survey	Systematic coding forms	California Occupational Health and Safety Administration	LHJ personnel survey
Variable domains	KABP items	Use of pharmacy disposal options by IDUs; disposal of pharmacy purchased syringes at SEPs	Self-reported unsafe syringe disposal	Injection trash	Needle-stick injuries	DPDP implementation barriers and facilitators; local experiences

Research and Evaluation Findings:**HIV/AIDS in California: OA Surveillance and HIV C&T Data**

The following section highlights findings from HIV/AIDS surveillance and HIV C&T data in California. A brief description is provided here to facilitate a better understanding of the details, strengths, and limitations of these data sources.

Surveillance

HIV and AIDS are reportable diseases in all U.S. states and territories, and are captured in HARS. HIV/AIDS surveillance in clinical settings that involves the reporting of confidential HIV tests and AIDS diagnoses is sometimes called “core” or “case” surveillance. HARS is a public health surveillance system through which HIV and AIDS cases are reported from local health care providers and laboratories. HIV infections and AIDS diagnoses are reported to local health departments through a combination of passive and active surveillance. Passive surveillance is conducted through State-required reporting of HIV and AIDS cases by health care providers and reporting of HIV-positive test results from laboratories to local health departments. Active surveillance is accomplished through routine visits to hospitals, physician offices, laboratories, HIV C&T sites, and outpatient clinics to ensure completeness, timeliness, and accuracy of reported data. In California, HIV/AIDS surveillance has traditionally relied upon active case surveillance, through onsite chart reviews and case report completion by local surveillance staff at the health care provider’s office.

Key Strengths: HARS is the only source of population-based AIDS information available in all U.S. states. Standardized reporting of demographic, risk, clinical, and laboratory information for AIDS cases has provided uniform trend and distribution data since 1983. In California, laboratory-based reporting of HIV fosters timely access to

information necessary to measure the burden of disease and support prevention planning efforts. With the implementation of HIV reporting, California has data that is representative of more recent HIV infections, which can be used to identify emerging patterns of disease.

Key Limitations: Not all persons infected with HIV are tested and people test at different stages of infection. Information from a health care provider is necessary to complete all HIV and AIDS case reports. Therefore, HARS cases are only representative of persons who have sought or received care in a clinical or other confidential diagnostic setting. HARS data are not representative of individuals testing at anonymous testing sites. The change from code-based to names-based HIV reporting make it challenging to compare reported HIV cases prior and subsequent to April 2006.

For more information: CDC. "HIV/AIDS Statistics and Surveillance." Available at: www.cdc.gov/hiv/topics/surveillance/index.htm.

HIV C&T Data

The HIV C&T Program is an HIV prevention intervention that provides HIV testing to clients, often with integrated prevention counseling. All states, territories, and selected cities receive funding to support HIV counseling, testing, and referral programs as part of HIV prevention cooperative agreements with CDC. Standardized data on clients who are tested for HIV are available at the local level and data may offer insights into HIV infection rates for a high-risk population in that area. In California, HIV C&T services are provided by 59 of 61 LHJs and their subcontractors at both anonymous and confidential HIV C&T sites. Data from HIV counseling, testing, and referral programs include information on client demographics as well as HIV C&T data (e.g., self-reported testing history and test result). Examples of behavioral data collected by HIV C&T sites include:

- Male-to-male sexual contact;
- Heterosexual relations with a male who has sex with other males;
- Injection drug use; and
- Sex industry work.

Key Strengths: HIV C&T programs provide standardized data on clients who seek free HIV testing in sites throughout the state. At sites where client-based estimates are used, HIV positivity offers one estimate of HIV prevalence within certain high-risk populations. HIV C&T Program data also provides information on risk behaviors, such as syringe-mediated risks, not routinely collected in HARS.

Key Limitations: HIV C&T collects information only from clients who seek HIV C&T services at an OA-funded site. Therefore, HIV C&T data only represents persons who consider themselves at risk for HIV and persons willing to take an HIV test and do so at a publicly funded site; thus they are not representative of the general population. Estimates of new HIV-positive tests are derived from self-reporting of a previous HIV-positive test result, which could introduce response bias in the testing history data.

Population estimation of HIV seroprevalence is not possible at sites where HIV C&T data are test based. Because HIV C&T gathers data on prevention activities, changes should be interpreted with caution as they may reflect changes in program priorities rather than testing patterns of individuals.

For more information: OA's HIV C&T Program. LEO – HIV C&T Guidance Documents. Available at: www.cdph.ca.gov/programs/AIDS/Pages/OALEOCTDocs.aspx.

Findings

Secondary analyses of data from the OA HIV/AIDS Case Registry and HIV C&T data were conducted to assess the historical and current status of the AIDS epidemic in California. These analyses help contextualize the AIDS epidemic among IDUs in California. AIDS surveillance data are portrayed in Figures 2, 3, and 4 below because they have been consistently collected and analyzed since the beginning of the epidemic in California. HIV surveillance methods in California have undergone changes (i.e., from code-based to name-based reporting protocols) during recent years. Such changes in surveillance approaches render trend analyses with HIV surveillance data more difficult.

Figure 2 portrays the epidemic curve for AIDS cases and deaths in California from 1981 to 2007. Reported AIDS diagnoses peaked in the state during the early 1990s, with 12,244 cases in 1992, and then declined steadily until 2007, when less 3,954 cases were reported. AIDS-related deaths peaked in 1994, when 7,969 deaths occurred among people with AIDS, and then, with the advent of highly active antiretroviral therapy, declined precipitously into the late 1990s. Reported AIDS deaths declined more slowly in recent years but have averaged approximately 1,200 deaths per year between 2006 and 2007.

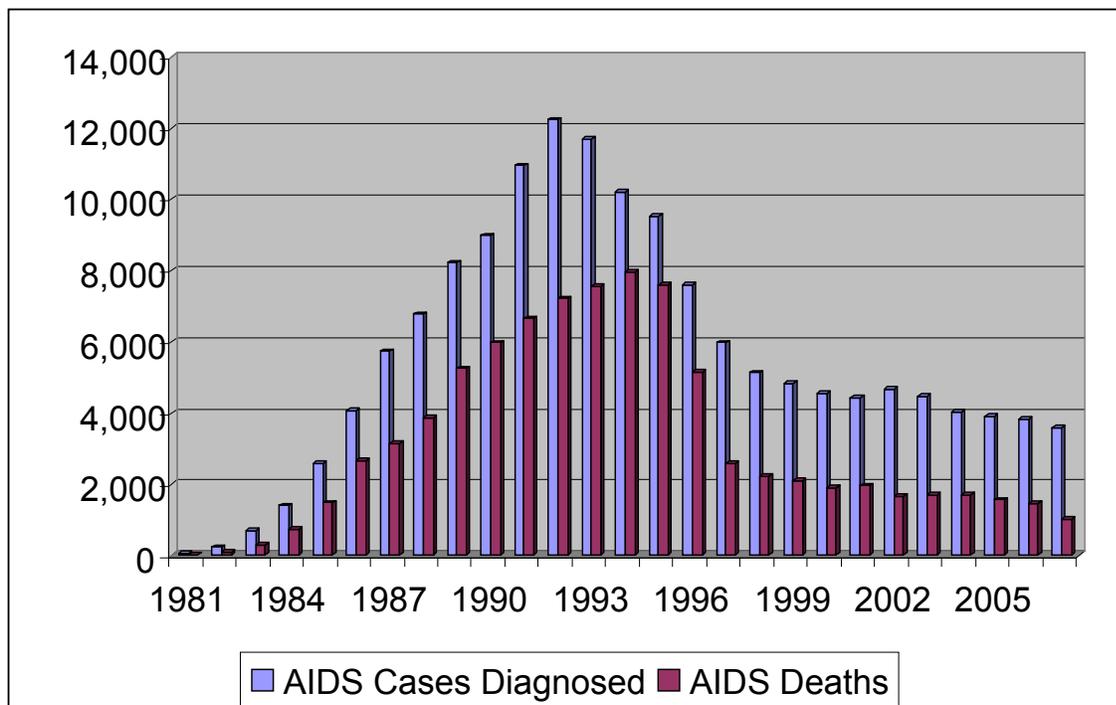


Figure 2: Annual all-cause AIDS Cases and Deaths in California, 1981-2007

Among IDUs in California, annual reported AIDS diagnoses and deaths also increased rapidly during the early years of the epidemic. Reported AIDS diagnoses among IDUs peaked in 1993 at 1,410 cases, and declined steadily through 2007, when 332 cases were reported (Figure 3). Annual AIDS deaths among IDUs were highest in 1994, when 859 deaths occurred among California IDUs, and then declined steadily into the late 1990s. In 2007, 166 AIDS-related deaths were reported among IDUs in California (Figure 3). It is important to note that, due to the long period between HIV infection and AIDS symptoms, changes in AIDS case reports and deaths are typically noted eight to ten years after infection. Thus, any changes in risk behaviors resulting from an intervention like OTC syringe sales would not be likely to influence AIDS case reports and deaths in the years immediately following the intervention.

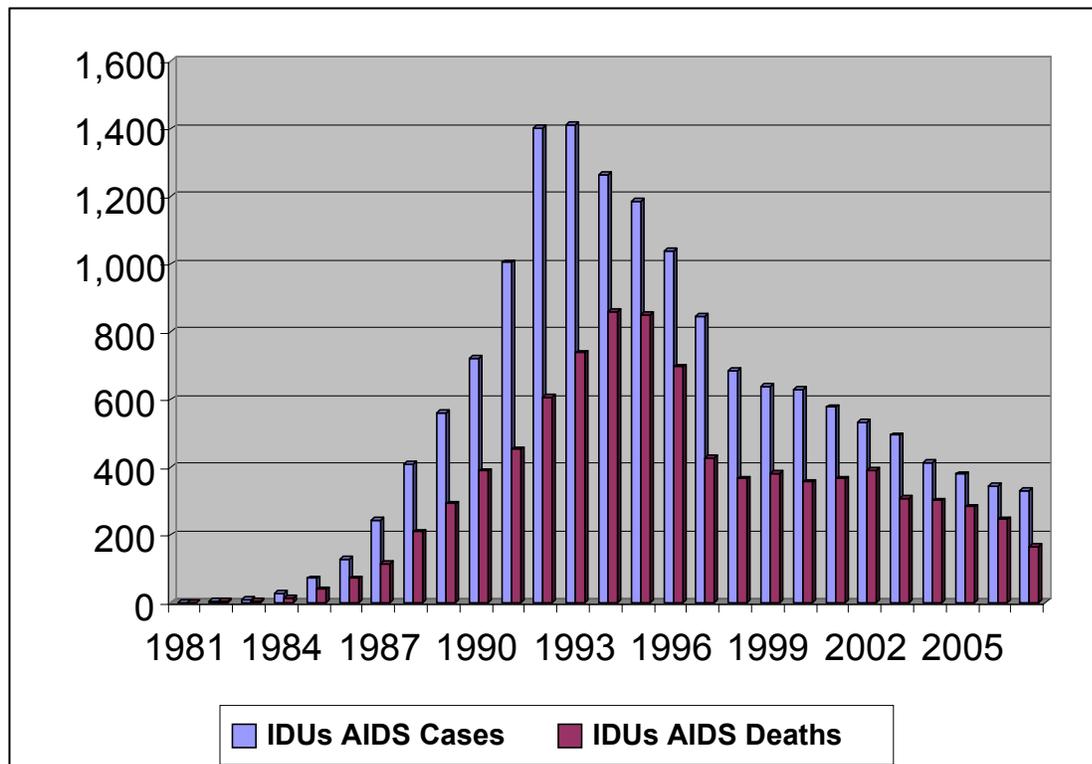


Figure 3: Annual Reported AIDS Diagnoses and Deaths among IDUs in California 1981-2007

Since the beginning of the AIDS epidemic, men who have sex with men (MSM) have comprised the leading risk group for disease transmission. MSM who also inject drugs (MSM-IDUs), and men and women who inject drugs have comprised the second and third leading risk categories, respectively, in terms of numbers of cases reported in California since the beginning of the epidemic. The proportion of AIDS diagnoses among IDUs has declined since the late 1990s from 14.2 percent of all diagnoses in 1997 to 9.2 percent in 2007 (Figure 4). The proportion of AIDS diagnoses among MSM-IDUs decreased steadily from the early 1980s, from 14.8 percent in 1981 to 8.9 percent in 1997 to 8.4 percent in 2007. Through 2007, 29,660 total AIDS cases were diagnosed among IDUs (IDUs and MSM-IDU combined).

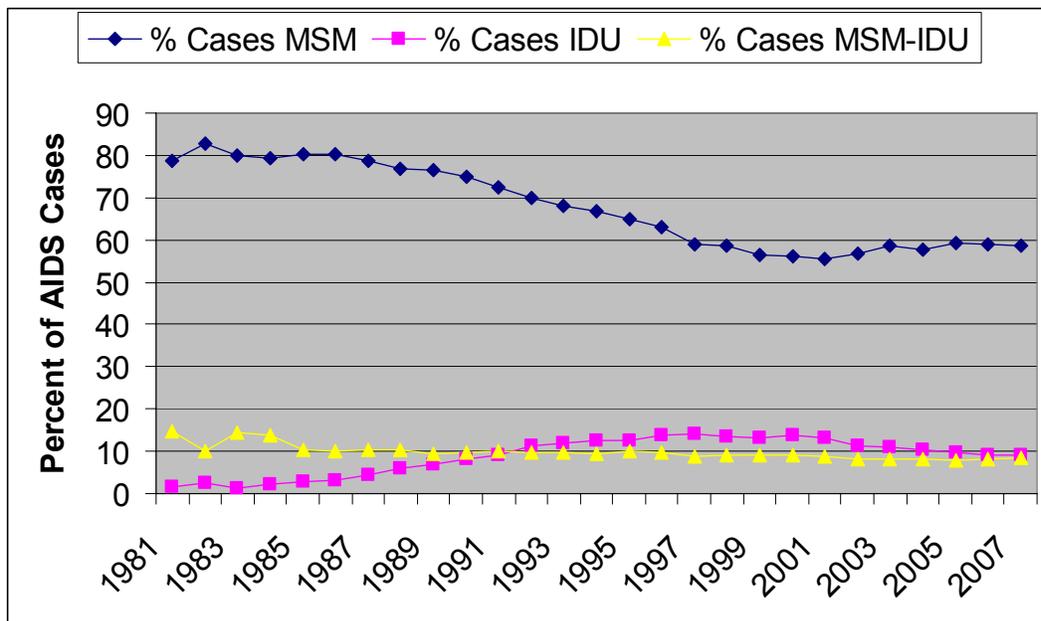


Figure 4: Percentage of AIDS cases reported among MSM, IDUs, and MSM-IDUs in California, 1981-2007

Percentage of IDUs who reported injection drug use during HIV C&T sessions at publicly funded HIV C&T sites

Figure 5 portrays the proportion of HIV C&T clients who reported injecting illicit substances at least once during the two years prior to their HIV C&T session. From 2004 to 2007, the proportion of HIV C&T injection drug using clients who reported injecting illicit substances decreased from 12.4 percent (pre-SB 1159) to 9.7 percent (post-SB 1159).

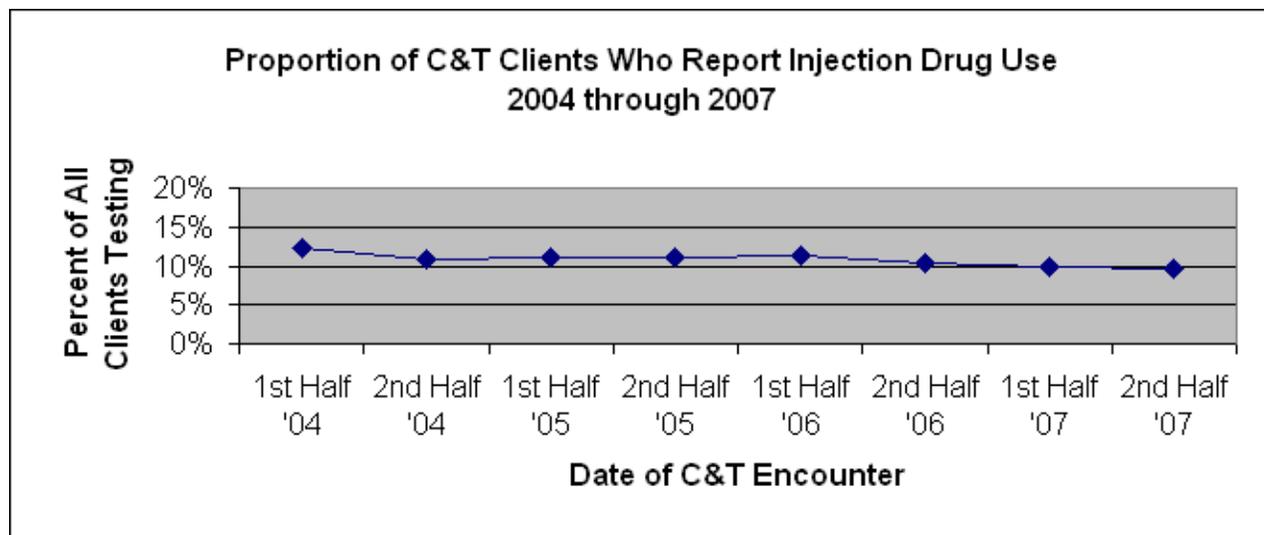


Figure 5: Proportion of HIV C&T clients reporting injection drug use, 2004-2007 (n=436,774)

Drug-specific injection practices among IDUs at OA-funded HIV C&T sites

Figure 6 displays the proportion of HIV C&T clients who reported injecting amphetamines, heroin, cocaine, and crack during the years spanning SB 1159 ratification. The percentages of HIV C&T clients reporting injecting these four substances remained stable during the years immediately preceding and following the authorization of local DPDPs in California.

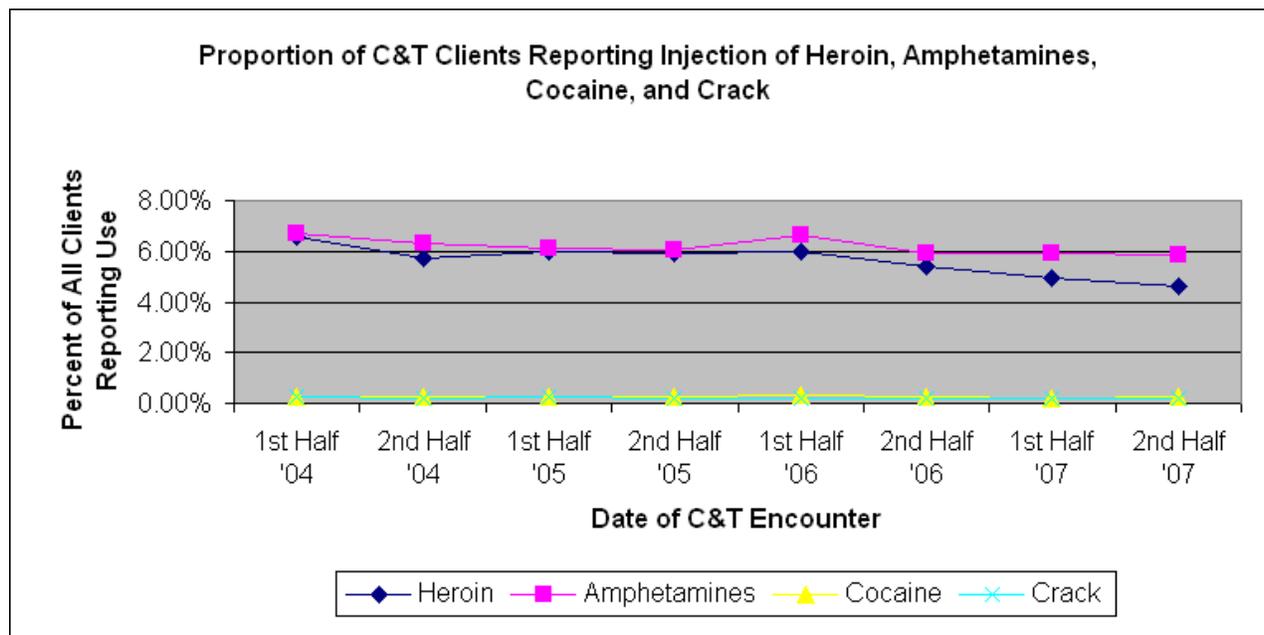


Figure 6: Proportion of HIV C&T clients reporting injection by drug type, 2004-2007 (N=436,774)

Syringe sharing trends among IDUs at HIV C&T sites

Between 2004 and 2007, the proportion of IDUs at HIV C&T sites who reported syringe sharing practices remained static. During this timeframe, 44,273 HIV C&T sessions were conducted with IDUs across California. Between 32.4 and 37.2 percent of IDUs tested for HIV at these sites reported that they never share syringes (Figure 7).

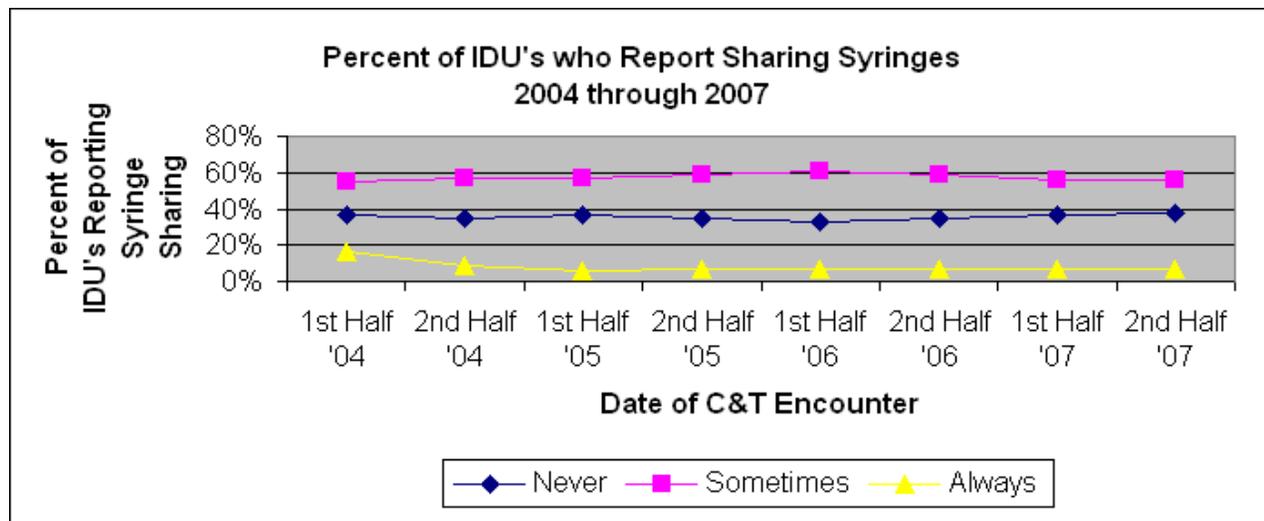


Figure 7: Proportion of IDUs receiving HIV C&T who reported syringe sharing, California 2004-2007 (N=44,273)

Discussion:

The surveillance findings should be considered in light of the following limitation. The current HIV surveillance system may be considered immature. Changes in HIV reporting policy during April 2006, from code-based to names-based reporting, present challenges to comparisons and trend analyses of HIV surveillance data. As a result, the current epidemic trends often rely on AIDS surveillance data. AIDS data may more accurately represent disease burden from previous years rather than the current state of affairs. Further, not all HIV and AIDS cases are captured in the OA surveillance system and, thus, may not be representative of all individuals who are infected. HIV C&T data are only representative of IDUs who seek HIV testing from publicly funded sites. Despite these limitations, the HIV/AIDS surveillance and HIV C&T data provide the most comprehensive portrayal of the breadth and severity of the epidemic across California LHJs.

LHJ Surveys:

Brief Summary:

Methods: California’s 61 LHJs were surveyed annually from 2005 to 2007 to monitor the progress of DPDP implementation and to assess program coverage, facilitators, and barriers. Completed surveys were returned by mail, fax, e-mail, phone, or Internet. OA analyzed 2007 survey data to describe current DPDP status; data from all years were analyzed for trends in approval and implementation status.

Results: By 2007, 17 (28.3 percent) LHJs approved DPDPs, of which 14 (82.4 percent) had registered 532 (17.8 percent) of the 2,987 pharmacies in these 14 LHJs. Although only three LHJs added DPDPs since 2006, the number of registered pharmacies increased 102 percent from the 263 previously reported. Among LHJs without approved DPDPs in 2007, 1 (2.3 percent) was in the approval process, 7 (16.3 percent) planned to seek approval, and 35 (81.4 percent) reported no plans to seek approval. Of 35 LHJs not planning to seek approval, the top four reasons were: limited

health department time (40 percent) or interest (34 percent), pharmacy disinterest (31 percent), and law enforcement opposition (26 percent). Among eight LHJs pursuing approval, the main barriers were time management (13 percent), educating stakeholders (13 percent), and enlisting pharmacy participation (13 percent).

Discussion: While the LHJs that approved DPDPs represent 52 percent of California's residents, they included 62 percent of HIV diagnoses and 59 percent of injection drug using-related HIV diagnoses, suggesting that LHJs where over one-half of the cases in the state were diagnosed have approved DPDPs. Outcome studies are needed to determine whether SB 1159 had the desired impact on increasing syringe access and reducing blood-borne viral infection risk among California IDUs. **[SB 1159 evaluation mandates 1, 2, and 4; Specific Aims 6 and 7.]**

Detailed LHJ Survey Summary

The LHJ surveys provided us with our first systematic glimpse of SB 1159 and DPDP authorization and implementation status. The questionnaire was developed in consultation with the SB 1159 EAP described above. Questionnaire topics included DPDP approval and implementation status, program characteristics, facilitators, and barriers to approval and implementation, pharmacy registration status, syringe disposal, and TA needs. The 2007 survey was used to describe the current status of SB 1159, while data from all three surveys were used to describe trends in approval and implementation of DPDPs over time. To assess whether DPDPs were approved in communities most needing HIV prevention, OA compared DPDP coverage to California population estimates (California Department of Finance, 2008) and cumulative HIV/AIDS statistics (OA, 2008).

Overall, 57 (93.4 percent) LHJs responded in 2005, 55 (90.2 percent) responded in 2006, and 60 (98.4 percent) responded in 2007. One LHJ (City of Pasadena) did not respond in 2007, but participates in LA County's DPDP. Respondents in 2007 consisted of health department staff (33 percent), LHOs and deputy health officers (30 percent), public health executives (15 percent), HIV/AIDS program coordinators/directors (12 percent), and public health nurses (10 percent).

By December 2007, 17 (28.3 percent) LHJs approved DPDPs, of which 14 (82.4 percent) had registered 532 (17.8 percent) of the 2,987 pharmacies in these 14 LHJs (Table 2, Figure 8).

Table 2: Status of DPDP Approvals Allowing OTC Syringe Sales by Year among California's 61 LHJs

DPDP Status	2005	2006	2007
Approved	9	14	17
In process of approving	8	2	1
Plan to approve	17	9	7
Approval process on hold	2	0	0
No plans to approve	18	25	35
Status unknown	3	5	0
Survey not completed	4	6	1

Although only three LHJs added DPDPs since 2006, the number of registered pharmacies by 2007 increased 102 percent from the 263 reported as of 2006 (Table 3). Among LHJs without approved DPDPs in 2007, 1 (2.3 percent) was in the approval process, 7 (16.3 percent) planned to seek approval, and 35 (81.4 percent) reported no plans to seek approval. Of 35 LHJs not planning to seek approval, the top four reasons were: limited health department time (40 percent) or interest (34 percent), pharmacy disinterest (31 percent), and law enforcement opposition (26 percent). Among eight LHJs pursuing approval, the main barriers were time management (13 percent), educating stakeholders (13 percent), and enlisting pharmacy participation (13 percent). Of note, the Santa Cruz County Board of Supervisors approved a DPDP in 2005 for cities within the unincorporated areas of the county, but the cities were held responsible by the county for also authorizing the program.



Figure 8: Approval Status for DPDP Allowing OTC Syringe Sales by LHJs in California

Table 3: Pharmacies Registration by Year among 17 LHJs with Approved DPDPs

LHJ	Approval Date	N (%)*		
		Pharmacies Registered		
		2005	2006	2007
Contra Costa	Dec. 2004	32 (22)	62 (43)	64 (42)
Yuba	Jan. 2005	3 (38)	3 (38)	3 (38)
Marin	Mar. 2005	12 (35)	13 (37)	14 (41)
Alameda/Berkeley**	Mar. 2005	41 (19)	75 (34)	66/6 (33)
Santa Cruz	Mar. 2005	-	-	0 (0)
SF	Apr. 2005	35 (26)	64 (49)	71 (55)
Yolo	May 2005	10 (42)	19 (76)	17 (61)
LA	Jun. 2005	-	-	183 (11)
Santa Barbara	Sep. 2005	-	-	23 (38)
Solano	Sep. 2005	-	15 (29)	15 (29)
Humboldt	Oct. 2005	-	-	0 (0)
San Mateo	Dec. 2005	-	-	0 (0)
Santa Clara	Jan. 2006	-	6 (2)	53 (21)
San Luis Obispo	Mar. 2006	-	-	1 (2)
Sonoma	Sep. 2006	-	6 (9)	6 (9)
Sacramento	Dec. 2006	-	-	10 (5)
Total		133 (23.6)	263 (28.2)	532 (17.8)

*Percentages were calculated by dividing the number of registered pharmacies by the number of commercial, non-clinic-based, pharmacies licensed by the California Board of Pharmacy in the county during the year of the survey.

**Alameda and Berkeley are classified as independent LHJs, but total pharmacy data are aggregated between the two.

Of the 35 LHJs without plans to approve DPDPs in 2007, 40 percent cited “competing priorities–limited time” as a reason for not approving a DPDP. Additionally, “competing priorities–limited interest” (34 percent), “lack of pharmacy interest” (31 percent), and “law enforcement opposition” (26 percent) were other major reasons for not authorizing DPDPs. The greatest implementation challenges for the 17 LHJs with DPDPs were: “time management” (24 percent), “enlisting pharmacy participation” (24 percent), and “securing DPDP approval” (24 percent). Similarly, the eight LHJs planning or in the process of approving a DPDP cited “time management” (13 percent), “educating stakeholders” (13 percent), and “enlisting pharmacy participation” (13 percent) as barriers to approval.

Syringe disposal costs and SEP presence were also examined because these factors may be considered by governing boards deciding whether or not to approve a DPDP. In 2007, respondents estimated that DPDP costs for syringe disposal ranged from \$0 to \$850 per month. Costs were reportedly absorbed by “integration into existing waste management” (29 percent), “subsidization by local health department” (21 percent), and “surcharges added to syringe price” (7 percent); 21 percent reported that “syringe disposal posed no additional cost.” As of July 2007, California had 39 SEPs operating in 17 LHJs (Ross, 2007), 13 (76.5 percent) of which overlapped with the 17 LHJs with DPDPs versus 5 (11.6 percent) SEPs in the 43 LHJs surveyed without a DPDP.

Evaluating TA needs and coalition status across all 60 responding LHJs in 2007 revealed that only 15 (25 percent) received TA for SB 1159 during the previous year from: OA (80 percent), peers in other LHJs (53 percent), an OA-developed Web site (Center for Health Improvement, 2009) (40 percent), and other sources (20 percent). Eight (47 percent) of the 17 LHJs with a DPDP had established coalitions to assist with DPDP approval and implementation while only 5 (11.6 percent) out of 44 LHJs without DPDPs formed coalitions.

A comparison of survey data to California Census and HIV Case Reporting data revealed that approximately 52 percent of California's population resided in the 17 LHJs with DPDPs (Table 4). These LHJs reported 62 percent of registered HIV diagnoses and 59 percent of injection drug using-related HIV diagnoses. LHJs with no plans to approve a DPDP represent approximately 43 percent of California's population, 32 percent of reported HIV diagnoses and 35 percent of reported injection drug using-related HIV diagnoses. Although California's most populous LHJ (LA) has a DPDP, the next four most populous LHJs (Orange, Riverside, San Diego, and San Bernardino Counties), including a combined total of over 10 million residents, do not.

Table 4: DPDP Authorization Status by Population, Reported Living HIV Cases, and Reported Living Cases Attributed to Injection Drug Use Exposure among California's 61 LHJs as of December 2007

	California Population		Living with HIV		HIV cases attributed to injection drug use exposure	
	N	(%)	N	(%)	N	(%)
Authorized already	19,680,200	(51.7)	15,160	(62.0)	2,099	(59.4)
In process of obtaining approval	492,642	(1.3)	1,163	(4.8)	142	(4.0)
Not in process but plan to	1,388,209	(3.6)	228	(0.9)	47	(1.3)
No plans to obtain approval	16,340,285	(42.9)	7,846	(32.1)	1,239	(35.0)
Did not complete survey	148,126	(0.4)	69	(0.3)	8	(0.2)
Total	38,049,462	(100)	24,466	(100)	3,535	(100)

Source: The OA HIV/AIDS Case Registry Section and California Department of Finance.

Syringe Sources and HIV Risk Behaviors among IDUs

Abstract

Methods: By analyzing Counseling Information System (CIS) data (described above), OA assessed changes in self-reported syringe sources and syringe sharing by county among IDUs pre- and post-implementation of the pharmacy-based syringe sale program. The 2004 to 2006 data originated from State-funded HIV C&T sessions across California counties. Data from 38,420 testing sessions where clients reported drug injection in the previous two years were analyzed.

Results: Reported use of pharmacies as a sterile syringe source for IDUs increased three-fold in California from 2004 to 2006, from 5 percent to 16 percent ($P < .05$) in counties that adopted the legislation. Early adopters (i.e., enacted in 2005) of OTC syringe sales experienced the largest increases in IDUs use of pharmacies: Sonoma (2.9 percent in 2004 versus 28.8 percent in 2006), LA (6.5 percent versus 21.3 percent),

Contra Costa (1.5 percent versus 16.2 percent), SF (1.9 percent versus 13.5 percent), and Alameda (1.5 percent versus 5.3 percent). Use of other syringe sources decreased in some counties post-implementation of SB 1159. Self-reported syringe sharing risk behaviors were consistently lower in counties that authorized SB 1159 both pre- and post-implementation. From 2004 to 2006, between 30 percent and 47 percent of IDUs reported never sharing syringes in authorizing counties while never sharing rates ranged from 22 percent to 32 percent in counties that did not authorize OTC sales. In aggregate, the most popular syringe sources reported by IDUs who sought HIV C&T were SEPs (45 percent), diabetics (11 percent), pharmacies (9 percent), and secondary syringe exchange (6 percent). Higher proportions of amphetamine injectors (11 percent) and Latino (13 percent) and White (10 percent) IDUs reported relying on pharmacies as a source of syringes ($P < 0.05$).

Discussion: Self-reported data among IDUs receiving State-funded HIV C&T services indicate IDUs are increasingly using pharmacies as a source of sterile syringes in California. Areas with increased syringe access appear to have lower rates of syringe sharing. Further, pharmacies may be reaching different subpopulations of IDUs in California than other syringe access programs. Additional research on the impact of OTC syringe access on HIV risk is needed. **[SB 1159 evaluation mandates 1, 2, 5, and 6; Specific Aims 1-3.]**

Detailed Summary: Syringe Sources and HIV Risk Behaviors

In 2004 to 2006, more than 500,000 HIV C&T sessions funded by OA were conducted in California. HIV C&T was conducted in approximately 2,000 venues, including health clinics, community-based organizations, mobile vans, and public health agencies. Client-centered counseling and risk assessments were conducted prior to disease screening. A Client Information Form was used by trained HIV counselors to guide discussions and to collect self-reported client level data on demographics, sexual behavior, substance use and injection drug use, risk behaviors, sexually transmitted diseases, and referrals to complementary services. Substance use history questions pertain to the client's experience during the past two years. Clients were asked which substances they used and, of those, which they injected. Next, injecting clients were asked with what frequency they 'shared needles' or 'cleaned works' (responses: 'never,' 'sometimes,' or 'always'). Finally, injecting clients were asked to report 'needle/syringe sources' used and response categories included 'needle exchange program,' 'secondary exchange,' 'pharmacy/drug store,' 'needle dealer/seller,' 'shooting gallery,' 'diabetic,' 'close friend,' 'sexual partner,' and 'other source.'

Data from 38,420 HIV C&T sessions where clients reported injection drug use in the previous two years were segregated from the larger dataset. A five-point matching criteria system was used to remove repeat testers from the dataset during each of the three study years, 2004 to 2006.

Cross-sectional analyses were conducted to observe comparisons between counties that had and had not adopted OTC pharmacy syringe sales. Descriptive analyses were conducted to characterize IDUs who reported using pharmacies along sociodemographic, substance use, syringe source, and HIV risk parameters.

Chi-square tests and student t-tests were used to assess significant differences within categorical and continuous variables, respectively. Trend analyses with Cochran Armitage tests for significance were also conducted to assess changes in syringe source utilization and injection mediated risks over time. All data analyses were conducted using SAS software, version 9.1 (Cary, NC).

In aggregate, the most popular syringe sources reported by IDUs who sought HIV C&T were SEPs (45 percent), diabetics (11 percent), pharmacies (9 percent), and secondary syringe exchange (6 percent). Higher proportions of amphetamine injectors (11 percent), and Latino (13 percent) and White (10 percent) IDUs reported relying on pharmacies as a source of syringes than injectors of other drugs and IDUs of different race/ethnicities. Higher proportions of IDUs in all categories, however, reported using SEPs than pharmacies (Table 5).

Table 5: Percentage of IDUs Who Use Pharmacies and SEPs as a Syringe Source by Race/Ethnicity, Drug Preference, and Disease Status, 2004-2006 (n=38,420)

	Use Pharmacy (%) (n=3,232)	Use SEP (%) (n=12,565)
Race/Ethnicity		
Native American	6	46
African American	6	58
Asian/Pacific Islander	8	35
White	10	44
Latino/a	13	35
Other	9	48
Injection Drug Preference		
Cocaine	6	39
Heroin	8	54
Amphetamine	11	37
Other	12	17
HIV Status (% positive)	1.9	14.6
Self-reported HCV Status (% positive)	3.4	29.5

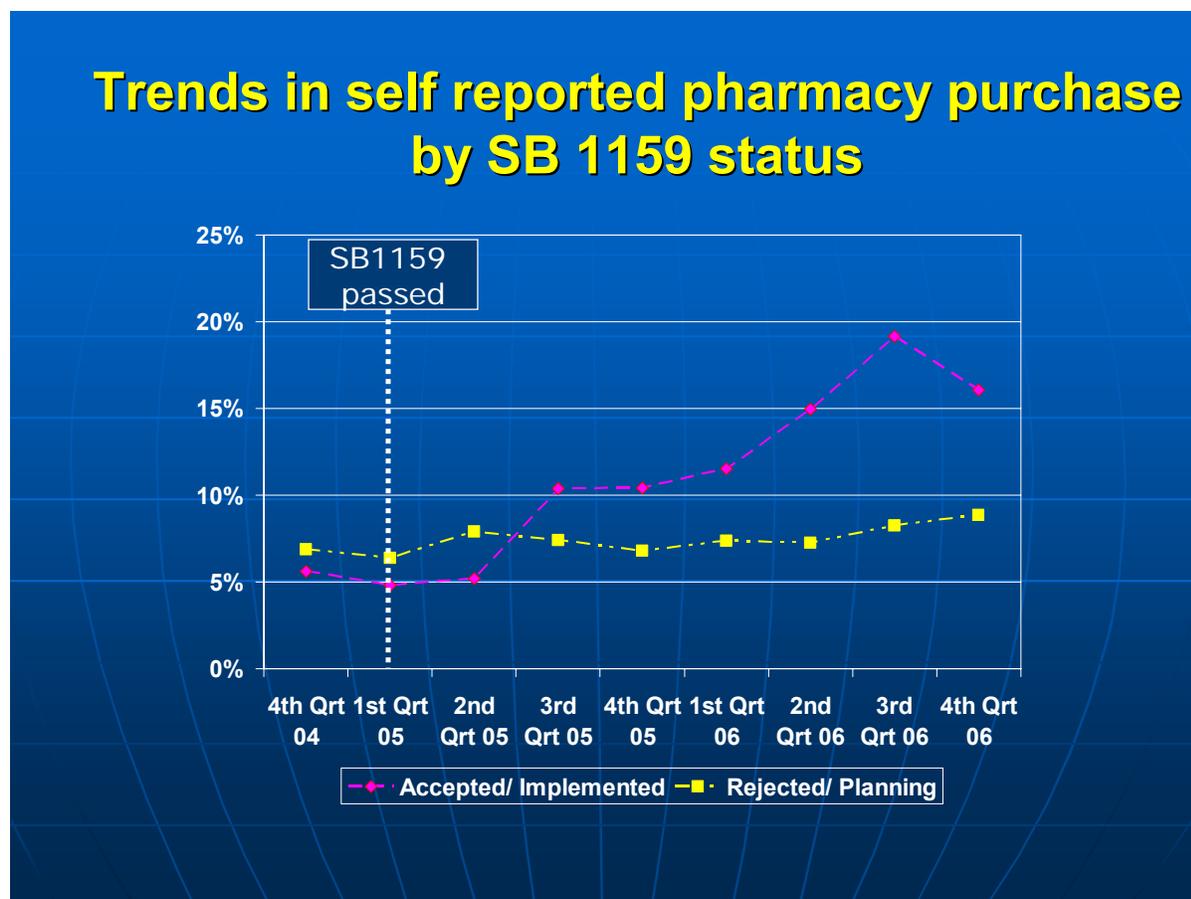


Figure 9: Reported Syringe Purchase at Pharmacies among IDUs at OA-funded HIV C&T Sites by DPDP Status Across California Counties, 2004-2006

Reported use of pharmacies as a sterile syringe source for IDUs increased three-fold in California from 2004 to 2006, from 5 percent to 16 percent ($p < .05$) [Figure 9]. Counties that authorized OTC legislation early (2005) experienced the largest increases in use of pharmacies: Sonoma (2.9 percent versus 28.8 percent), LA (6.5 percent versus 21.3 percent), Contra Costa (1.5 percent versus 16.2 percent), SF (1.9 percent versus 13.5 percent), and Alameda (1.5 percent versus 5.3 percent) [data not shown].

Use of other syringe sources decreased in some counties after implementation of SB 1159 while increasing elsewhere. Secondary syringe exchange as a source of syringes decreased from 2004 to 2006 in SF (9.4 percent versus 3.9 percent) and Sonoma (9.4 percent versus 1.3 percent); however, an increase was observed in Alameda (7.8 percent versus 16.6 percent). Additionally, in some counties, IDUs reported obtaining syringes from pharmacies prior to implementation of OTC sales programs.

Self-reported syringe sharing risk behaviors were consistently lower in counties that authorized SB 1159 pre- and post-implementation. In counties that authorized OTC sales, between 30 percent and 47 percent of IDUs reported never sharing syringes during the two years prior to HIV testing. In counties that did not authorize OTC sales, never sharing rates ranged from 22 percent to 32 percent (Figure 10).

Syringe Access, Syringe Disposal, and Risk Behaviors among IDUs: SF

Abstract

Methods: This study determined the extent of uptake in accessing syringes at pharmacies among IDUs and estimated its association with safer injection and disposal practices. Two years after the implementation of a local DPDP, IDUs were recruited through street outreach in SF and interviewed regarding recent syringe acquisition, disposal, and use.

Results: The sample of 105 persons included a high proportion of men (67 percent), people of color (49 percent), and homeless persons (71 percent). The most common syringe source was a SEP (80 percent), with pharmacies being accessed by 39 percent of respondents. The most commonly cited source of disposal was a SEP (65 percent), with very few reports of pharmacy disposal (2 percent). Adjusted analysis showed that unsuccessful attempts to purchase syringes at a pharmacy increased the odds of both injecting with a used syringe and giving away a used syringe. Using a SEP decreased the odds of unsafe injection and disposal practices.

Discussion: Thus, two years after the initiation of the California DPDP, SEPs still provide the majority of syringe distribution and disposal services to SF IDUs; however, pharmacies now augment syringe access. In addition, unsafe injection behavior is reported more often among those who do not use these syringe sources. These results suggest that increasing the availability of syringes through SEPs and pharmacies, and developing bridges between them, may further reduce syringe-related risk. **[SB 1159 evaluation mandates 1, 2, 5, and 6; Specific Aims 1-3.]**

Detailed Summary: Syringe Access, Syringe Disposal, and Risk Behaviors in SF

A convenience sample of IDUs was recruited for this study by outreach workers who were deployed to high drug-traffic areas in SF during July 2007. SF ZIP codes with the highest per capita drug use were chosen and the selection of recruitment locations was based on rates of drug treatment entry.

Recruitment efforts resulted in 105 individuals being interviewed during the month of July 2007. Less than 2 percent of self-identified IDUs refused to participate. The sample population was comprised of 51 percent White, 14 percent African American, 12 percent Latino/a, and 18 percent “other” persons, while women comprised 33 percent of the sample population (Table 7). Almost three-quarters (71 percent) of respondents were homeless, the median age was 42 years (Interquartile Range [IQR]=35-49) and the median age at first injection was 17 years (IQR=14-26). The median number of injections was five during the prior week (IQR=2-20); the most common drugs last injected were heroin (51 percent) and methamphetamine/speed (35 percent). HIV infection was self-reported by 17 percent of respondents, while 64 percent self-reported HCV infection.

Syringe Sources

The most common source of syringes in this population was a SEP, with 80 percent of respondents reporting SEP use. The use of pharmacies as a syringe source was

reported by 39 percent of respondents (Table 6). Among those who obtained syringes at a pharmacy, 24 percent reported obtaining at least one-half of all syringes used during the prior 30 days there. By comparison, 89 percent of participants who obtained syringes at a SEP obtained at least one-half of all syringes there. The only significant correlate of obtaining syringes from an unsafe source (non-SEP and non-pharmacy) was homelessness (odds ratio [OR]=2.95, confidence interval [CI]=1.19-7.33) (Table 7).

Table 6: Most Common Syringes Sources Reported by IDUs Recruited from the Streets of SF, July 2007 (N=105)

- 80 percent - syringe exchange
- 46 percent - friend
- 39 percent - pharmacy
- 37 percent - "on the street"
- 7 percent - drug dealer
- 3 percent - diabetic

Twelve individuals (11 percent) reported injecting with a syringe during the past 30 days that had been previously used by another person. After adjusting for White/Caucasian race (Adjusted OR [AOR]=5.23, CI=1.08-25.21), reporting a failed attempt to purchase syringes at a pharmacy increased the odds of injecting with a used syringe (AOR=12.00, 95% CI=2.79-51.66), while obtaining syringes at a SEP decreased the odds of injecting with a used syringe (AOR=0.18, 95% CI=0.03-0.75) (Table 7).

Table 7: Unadjusted and Adjusted Characteristics of IDUs Recruited from the Streets of SF, July 2007 (N=105)**

Characteristic (referent group)		Relative odds of obtaining syringes from an unsafe source [△] OR (95% CI)	Relative odds of injecting with a used syringe OR (95% CI)	Relative odds of giving away a used syringe OR (95% CI)	Relative odds of unsafe syringe disposal OR (95% CI)
SOCIODEMOGRAPHIC					
Age > population median	Median = 42	0.49 (0.22-1.11)	0.45 (0.12-1.59)	1.33 (0.28-6.29)	0.82 (0.37-1.79)
White race	51%	2.02 (0.90-4.53)	5.23** (1.08-25.21)	5.87 (0.68-50.68)	1.37 (0.63-2.97)
Female sex	33%	1.14 (0.48-2.68)	0.92 (0.26-3.30)	0.29 (0.03-2.50)	1.16 (0.51-2.62)
Monthly income > population median	Median = \$900	0.63 (0.27-1.48)	0.57 (0.16-2.03)	0.88 (0.19-4.20)	0.77 (0.34-1.74)
Homeless	71%	2.95** (1.19-7.33)	4.44 (0.54-36.19)	2.36 (0.27-20.60)	3.75** (1.41-9.95)
SELF-REPORTED INFECTIONS					
HIV positive	17%	0.52 (0.19-1.45)	1.64 (0.40-6.80)	0.76 (0.09-6.77)	0.62 (0.22-1.76)
HCV positive	64%	1.62 (0.71-3.67)	7.33 (0.91-59.29)	1.46 (0.27-7.92)	0.75 (0.34-1.67)
DRUG USE					
Injection frequency > population median	Median = 6 times/week	2.15 (0.95-4.89)	3.92 (1.00-15.46)	1.48 (0.31-6.988)	1.11 (0.51-2.42)
Drug last injected = methamphetamine/speed	35%	1.33 (0.60-2.96)	0.52 (0.15-1.86)	1.48 (0.31-6.98)	1.85 (0.85-4.03)
Age at first injection > population median	Median = 18	1.96 (0.87-4.43)	0.82 (0.24-2.77)	0.87 (0.18-4.10)	1.35 (0.62-2.92)
Fear of arrest for carrying paraphernalia	44%	1.04 (0.46-2.31)	1.57 (0.45-5.52)	0.23 (0.03-2.06)	2.18 (0.98-4.83)
SYRINGE SOURCES					
Pharmacy	39%	†	2.00 (0.59-6.73)	0.75 (0.14-4.09)	1.45 (0.66-3.19)
Unsuccessful attempt to buy syringes at a pharmacy	10%	†	12.00** (2.79-51.66)	9.32** (1.73-50.19)	2.78 (0.68-11.41)
SEP	80%	†	0.18** (0.05-0.65)	0.15** (0.03-0.75)	0.17** (0.05-0.55)

[△]non-pharmacy and non-SEP syringe source; **AOR from the final model; † Not considered due to co linearity. Statistically significant findings in boldface text (P-value<0.05).

Syringe Disposal

The most common source of syringe disposal in this population was a SEP, with 65 percent of respondents reporting SEP disposal. Only 2 percent of respondents reported pharmacies as a source of syringe disposal (Table 8). Among those who disposed of syringes at a SEP, 82 percent reported disposing at least one-half of all syringes used during the prior 30 days there.

Table 8: Most Common Sources of Syringe Disposal Reported by IDUs Recruited from the Streets of SF, July 2007 (N=105)

- 65 percent - syringe exchange
- 41 percent - trash
- 12 percent - flushed down the toilet
- 9 percent - gave away
- 2 percent - pharmacy
- 1 percent - left in public place

Seven individuals (7 percent) reported giving away their used syringes. Adjusted analysis showed that reporting a failed attempt to purchase syringes at a pharmacy increased the odds of giving away a used syringe (AOR=9.32, 95% CI=1.73-50.19), while obtaining syringes at a SEP decreased the odds of giving away a used syringe (AOR=0.15, 95% CI=0.03-0.75)(Table 7).

Fifty individuals (48 percent) reported unsafe disposal of their syringes (i.e., trash, toilet, or public place) during the past 30 days. In adjusted analysis, obtaining syringes from a SEP decreased the odds of unsafe disposal (AOR=0.17, CI=0.05-0.95) and being homeless increased the odds of unsafe syringe disposal (AOR=3.75, CI=1.41-9.55) (Table 7).

These results have implications for further reductions in syringe-related risk that may be possible in the context of legal syringe access through pharmacies. First, increasing the number of pharmacies that sell syringes without a prescription may decrease the number of persons who unsuccessfully attempt to purchase syringes at a pharmacy. In addition, as reported in New York, an increase in the use of pharmacies over time would be expected among IDUs who have not yet accessed them (Fuller et al., 2007). Increased availability through pharmacies and increased uptake by IDUs could decrease the risk of injecting with a used syringe and giving away used syringes. Second, efforts to develop more accessible systems of accepting and disposing used syringes at pharmacies, and efforts to encourage IDUs to dispose of used syringes at pharmacies, may increase pharmacy-based syringe disposal. Third, developing bridges between pharmacies and SEPs would increase options for safe acquisition and disposal. Educating SEP staff and IDUs about pharmacy options and locations, as well as educating pharmacists about SEP options and locations, would be important.

Thus, two years after the implementation of California's DPDP, SEPs still provide the majority of syringe distribution and disposal services to SF IDUs. However, 39 percent of sampled IDUs now also access sterile syringes from pharmacies in LHJs where both sources are available. After adjusting for SEP use, unsuccessful attempts to purchase syringes at a pharmacy were significantly associated with using and giving away previously used needles. These data suggest public health benefits from reducing barriers to syringe access at pharmacies. It is likely that increasing the number of options for syringe access and disposal in other California LHJs would facilitate lower risk behaviors, thereby decreasing the risk of infections with blood-borne pathogens.

Pharmacy Surveys

Abstract

Methods: The current analysis describes pharmacy participation in OTC syringe sales in two counties and examines factors associated with such sales. Telephone and in-person interviews were conducted in LA and SF with a total of 238 pharmacies in 2007 (SF=67; LA=171). Quantitative survey items captured pharmacy registration with the county, pharmacy policies/practices, episodes, and conditions of OTC syringe sales and refusals to sell, potential negative consequences of OTC sale, and staff attitudes regarding HIV and HCV prevention for IDUs. Multivariate logistic regression was used to determine independent correlates of OTC.

Results: Overall, 42 percent of pharmacies reported OTC sales of syringes (LA=28 percent; SF=81 percent) although only 33 percent had registered with the county as required by law (17 percent in LA; 76 percent in SF). Many pharmacies required proof of a medical condition (80 percent in LA; 31 percent in SF) and refused to sell OTC syringes if the customer was a suspected IDU (74 percent in LA; 33 percent in SF). Few negative consequences of OTC syringe sales were reported. In addition to important differences in pharmacists participation by county, the odds of OTC syringe sales were significantly higher among pharmacists who thought syringe access was important for preventing HIV among IDUs (AOR=2.95; 95% CI=1.10, 7.92), were employed by chain pharmacies (AOR=12.5; 95% CI=4.55, 33.33), and were located in SF (AOR=4.88; 95% CI=1.94, 12.28).

Discussion: These results suggest that OTC syringe sales were influenced by pharmacists' perception. OTC sales of syringes might be increased through greater educational efforts directed at pharmacists, particularly those in non-chain pharmacies.

[SB 1159 evaluation mandate 5; Specific Aims 1-3.]

Detailed Summary: Pharmacy Surveys

Methods

Data for the pharmacy study came from quantitative surveys conducted with pharmacies in SF and LA Counties. Licensed pharmacies as of February 1, 2007, were identified from a list obtained from the California Board of Pharmacy. Surveys were restricted to retail pharmacies, thus excluding those that were not open to the general public. All retail pharmacies in SF (n=132) were originally included in the sample. However, during recruitment we discovered that 27 pharmacies had closed, moved without providing forwarding information, or discontinued the pharmacy component of their business, leaving our overall sample size for SF at 106. Since LA County had over

1,700 retail pharmacies in 2007 and we lacked the resources to adequately contact all of them, we restricted our LA sample in the following ways. First, we selected three Special Planning Areas (SPAs) in LA County that had the highest rates of injection-related HIV/AIDS. Within these three SPAs (4, 6, and 8), using data from the LA Alcohol and Drug Program, we calculated total number of IDUs in treatment and average number of IDUs in treatment for each ZIP Code from 2004 to 2006. ZIP Codes with both above average counts of IDUs and above average IDUs in treatment per capita were identified (n=100). From this list, 33 ZIP Codes were selected with the highest counts and average. In these ZIP Codes, 211 pharmacies were listed and efforts were made to recruit all eligible pharmacies.

Each selected pharmacy was sent an informational letter and received a follow-up call one week later, during which the phone interviewer asked to speak with the pharmacy manager or another person who was knowledgeable about pharmacy practices (e.g., pharmacy technicians). Various methods were used to improve response rates including in-person interviews in LA, and mailed and faxed surveys (in both locations). Using these methods, 67 (or 63 percent of total) surveys were completed in SF and 171 (or 81 percent of total) were completed in LA for an overall response rate of 75 percent.

After completing verbal informed consent, pharmacists were asked a series of questions about their participation in the local DPDP, including registration and syringe sales; conditions of syringe sales; any refusal of sales and refusal reasons; knowledge, attitudes, and beliefs (KABs) about syringe access; and any perceived problems related to OTC sales. For completing the survey, pharmacists received a ten dollar bookstore gift card. All study procedures were reviewed and approved by the Institutional Review Board at CSU/Dominguez Hills and the Committee for the Protection of Human Subjects, California Health and Human Services Agency.

Results

Two-hundred thirty-eight surveys were completed (67 in SF and 171 in LA). Overall, 52 percent of pharmacies were chain stores, 43 percent were independents, and 5 percent were care pharmacies (i.e., Kaiser or community clinic-based facilities). In terms of location, 45 percent were free standing retail pharmacies, 20 percent were inside a grocery store, 20 percent were inside a mall, and 15 percent were located in a hospital or clinic.

In our sample, only 32 percent (17 percent in LA and 76 percent in SF) of the pharmacies reported being registered to sell non-prescription syringes. However, a total of 43 percent of pharmacies reported OTC in the last 12 months (28 percent in LA and 81 percent in SF), suggesting that some pharmacies sold without being registered. Based on estimates provided by respondents, in January 2007 a total of 13,715 syringes (ranging from 10 to 7,100 per pharmacy) were sold in SF and 4,490 (range 10 to 1,000) were sold in LA. The estimated proportion of IDUs among syringe buying customers was 66 percent in SF and 16 percent in LA ($p < 0.001$). Due to the consistent differences by county in pharmacy participation, we present the remaining data on pharmacy participation by county.

Information provided (i.e., pamphlets) and syringe disposal options offered by pharmacists that conducted OTC in the last 12 months differed by county (Table 9). A higher proportion of pharmacies in SF offered information about syringe disposal and SEPs compared to those in LA. In terms of syringe disposal, a higher proportion of SF pharmacies provided free sharps containers, an on-site syringe drop box, and acceptance of personal sharps containers. A higher proportion of LA pharmacies offered sharps containers for purchase. No county differences were observed in the availability of mail-back sharps containers, providing counseling on syringe disposal, and referring customers to other syringe disposal locales.

Table 9: Information and Syringe Disposal Options Provided by Pharmacies that Sold Syringes without a Prescription During the Past 12 months in LA and SF, January 2007 (n=101)

	LA (n=47)	SF (n=54)
Information given		
Drug treatment	39%	56%
HIV/HCV prevention and testing	34%	47%
SEP~	28%	76%
Syringe disposal~	54%	91%
Syringe disposal options		
Free sharps containers~	11%	76%
Drop box~	9%	46%
Sharps containers for sale~	76%	38%
Mail-back containers	20%	24%
Accepts sharps containers~	13%	73%
Accepts loose syringes	11%	15%
Literature on syringe disposal options~	22%	64%
Counseling on syringe disposal	56%	67%
Referral to other locations for disposal	47%	33%

~p<0.001

Table 10 presents data on the type of requirements pharmacies used before conducting an OTC syringe sale. The most prevalent requirement was proof of medical condition (80 percent in LA and 29 percent in SF), followed by logging customer name (70 percent in LA and 22 percent in SF). In all cases, requirements were used more frequently in LA.

Table 10: Requirements for OTC Syringe Sales in LA and SF, 2007 (n=101)

	LA (n=47)	SF (n=54)
Medical condition~	80%	28%
Picture identification~	54%	19%
Customer name~	63%	17%
Justification*	39%	13%
Log customers~	70%	22%

*p<0.05; ~p<0.001

We also assessed whether OTC syringe sales requests were refused and the reasons for the refusals. Overall, 39 percent reported never refusing, 36 percent reported rarely refusing, and 25 percent reported sometimes or often refusing. County differences were noted, however, with 87 percent of SF pharmacies reporting never or rarely refusing to sell syringes, while in LA, 60 percent reported never or rarely refusing to sell. In LA, another 33 percent also reported sometimes refusing to sell syringes.

Table 11 reports reasons cited by pharmacies for not selling syringes. Differences by county were found for all reasons, with LA pharmacies more likely to endorse every reason for refusing than their SF counterparts. The most common reasons for refusing to sell OTC syringes in LA was customer intoxication followed by known IDU, and safety concerns. In SF, the most frequently endorsed item was safety concerns, followed by intoxication. SF pharmacists also endorsed excessive purchases and risk of theft as reasons for not selling syringes.

Table 11: Reasons for refusing to sell OTC syringes in LA and SF, 2007 (n=101)

	LA (n=47)	SF (n=54)
Unfamiliar customer~	65%	11%
Known IDU~	72%	11%
Disheveled appearance~	35%	4%
Intoxication~	78%	32%
Excessive purchases*	46%	26%
Safety concerns*	67%	43%
Concerns about unsafe disposal*	46%	19%
Risk of theft*	46%	26%

*p<0.05; ~p<0.001

We also explored how pharmacist's KABs, pharmacy type, and pharmacy location might influence OTC sales decisions. Pharmacists who thought OTC syringe sales would be

effective, that syringe access was important for HIV prevention, and that HIV is a problem in their area were significantly more likely to have sold syringes (Table 12). Chain pharmacies and those located in grocery stores were more likely to report sales of OTC syringes as compared to pharmacies in care settings. In multivariate analysis, We found that pharmacist endorsement of syringe access as important for HIV prevention (AOR=2.95, 95% CI=1.10, 7.92), chain pharmacy (AOR=12.5; 95% CI=4.55, 33.33), and being in SF (AOR=4.88; 95% CI=1.94, 12.28) were independently associated with providing OTC syringe sales.

Table 12: Bivariate Analysis of Factors Significantly Associated with One or More Sales of OTC Syringes during the Past Year in LA and SF, 2007 (n=238)

	No Sales (n=137)	Sales (n=101)
Pharmacists' attitudes and belief IDUs will continue to share syringes at the same rate even if they have increased access to clean syringes - agree*	43%	30%
It is important to provide clean syringes to people who cannot stop injecting drugs – agree~	68%	86%
Pharmacy access to syringes is an important public health measure – agree*	83%	93%
An increase in syringe access will increase the number of syringes found on the street and on playgrounds – agree*	55%	37%
HIV/AIDS is an important health concern in the area served by my pharmacy – agree*	72%	83%
Pharmacy type		
Chain (n=120)~	32%	68%
Independent (n=99)	87%	13%
Care (n=10)	90%	10%
Pharmacy setting		
In grocery – Yes*	40%	60%
No	62%	38%
In hospital or clinic – Yes~	85%	15%
No	53%	47%

*p<0.05; ~p<0.001

Lastly, we looked at reported problems related to OTC syringe sales. Roughly, 60 percent of pharmacists reported no problems at all. In addition, the problem cited most (~25 percent) in both LA and SF was verbal abuse by buyers. Approximately 15

percent of pharmacists also reported theft in the store as a problem. Self-reports by pharmacists of both criminal activity and illegal drug activity in the areas where pharmacies are located found no difference in levels of illegal activities for pharmacies that sold syringes as compared to those that did not.

Discussion

Two years after the implementation of SB 1159, substantial differences existed in the implementation of OTC sales in LA and SF. SF pharmacies were more likely to conduct OTC syringe sales and less likely to impose requirements on OTC sales than their LA counterparts. These differences may be explained by a number of factors including the earlier start of DPDP in SF (2005 as compared to 2007 in LA), higher per capita HIV rates in SF as compared to LA, and/or differences in political attitudes and priorities. This study, and others like it, indicates that detailed research on adoption of OTC sales among pharmacies is needed to determine how to improve pharmacy participation in these important public health strategies.

We also found that within OTC sales approaches, a number of operational barriers are apparent. In LA, the current level of implementation is moderate (<30 percent of pharmacies participate) and the reports of OTC syringe sale refusals suggests that syringe access through pharmacies could be increased. Given that pharmacists' attitudes were related to OTC sale participation levels, one way to increase pharmacy participation might be through educational programs. Other investigators have recommended pharmacists education as one way to increase participation in OTC sales. In fact, at least one study has found that efforts to inform community members and pharmacists about the importance of sterile syringe access appeared to have positive impacts on pharmacy participation in OTC sales in New York (Fuller et al., 2007). Such efforts should be considered in areas where pharmacy participation rates appear low.

The results from the pharmacy surveys should be considered in light of the following limitations. Interviews were completed with a variety of pharmacy personnel (i.e., managers, technicians), some of whom may not have had complete information on relevant pharmacy policies or practices. However, it is worth noting that rates of participation in OTC sales in SF are similar to those found in another survey using mailed questionnaires (Rose, 2007). In terms of our attitude items, these were asked of individuals and may not reflect the overall attitudes of other professional staff in a pharmacy. As with all self-reported data, there are concerns regarding socially desirable responding and recall bias. For some items, we also asked pharmacists to estimate activities such as syringes sold or frequency of refusing to sell syringes; in those cases, it is impossible to know the accuracy of these estimates.

Our sampling frames and recruitment methods differed by county due to resources and geographic proximity. The large number of pharmacies in LA County (~1,700) prevented us from attempting to contact them all and so the LA sample should not be considered representative of all pharmacies in LA County. Further, in LA, we focused on a sub-sample of pharmacies in high-need areas. This difference in sampling frame

may have influenced our outcomes. Some studies have found that pharmacies in high-need areas (i.e., elevated injection drug use and HIV rates) were more likely to participate in OTC syringe sales than those in lower need areas. So our site comparison may well be over-estimating LA pharmacy participation in OTC sales.

Differential response rates in the pharmacy survey (63 percent in SF versus 81 percent in LA) could have been attributed to different interviewing techniques utilized in SF and LA. Because of geographic proximity of study team members, in addition to phone and mailed interviews, our team was able to also conduct in-person recruitment and interviews at pharmacies in LA. We conducted two additional analyses to account for this difference in approaches. First, to determine if site differences in OTC sales participation were due to response rate differences, we re-calculated OTC sales participation for SF assuming it had the same response rates as LA (81 percent) and that all non-responders reported not participating in OTC sales (the most conservative assumption). In this analysis, we found that the OTC sales participation rate in SF would be 59 percent (54/86) and that as compared to LA (28 percent), this difference would still be significant ($p < 0.0001$) using Pearson chi-square test. Second, we re-ran the multivariate logistic regression predicting OTC sales participation separately by site (data not shown). In LA, we found that both endorsement of the importance of syringe access and chain pharmacy predicted OTC participation while, in SF, only pharmacy type significantly predicted OTC participation. However, it is worth noting that we did not have any care pharmacies in our SF site and that the point estimate of the importance of syringe access was in the predictive direction in SF as well. The smaller sample size in SF also impacted this re-analysis. We conclude that chain pharmacy involvement has been key in expanding OTC syringe sales and that pharmacists' attitudes in LA are an important contributor to OTC sales involvement. Why chain pharmacy participation rates are higher was not an issue we could address given our methods and resources. Findings from a four-state study that focused on OTC syringe purchase success, found no consistent pattern of syringe purchase for chain versus independent pharmacies (Compton et al., 2004). Further research in this area could help to better elucidate OTC syringe sale experiences across different pharmacy types in California.

Four County Pharmacist, IDUs, and Policy Maker Study

Abstract

Methods: A study funded by CHRP was conducted during 2008 and 2009 in four counties that had authorized local DPDPs, but which had failed to implement a DPDP. The study aimed to determine pharmacist interest in participating in a DPDP if it were to be implemented (Valerie Rose, PI). Despite these counties' early indication of political support, none had vigorously approached pharmacies to determine their interest in participating in a DPDP. Surveys were sent to pharmacy managers with a cover letter that explained the study and which served as their consent to participate. Follow-up faxes and telephone calls were made two weeks after the initial mailing. Telephone interviews were conducted for two months with an abbreviated version of the pharmacist survey used in LA and SF (above) in an effort to improve response rates. Interviews with policy makers were also conducted to determine mechanisms for

overcoming barriers to establishing a DPDP in the county. Finally, a brief survey among a limited number of IDUs recruited from SEPs was also conducted to document their willingness to use pharmacies as an alternative source for sterile syringes.

Results: One hundred twenty-three pharmacies were surveyed across the four counties (Humboldt [n=21], Santa Cruz [n=28], San Mateo [n=47], and San Luis Obispo [n=27])

Response rates from pharmacists ranged from 52 percent to 75 percent. Results revealed a strong interest on the part of pharmacists in each county to participate in a DPDP and sell OTC syringes. In Santa Cruz County, 71 percent of pharmacists expressed a willingness to participate in the health department DPDP; 57 percent in Humboldt; 56 percent in San Luis Obispo County; and 49 percent in San Mateo County. In all counties combined, approximately 40 percent of pharmacists had been asked by customers to sell OTC syringes within the last year. Fifty-nine percent indicated that IDUs should be able to purchase syringes from a pharmacy and 62 percent thought the cap of ten syringes was “just right.” **[Specific Aims 1 and 6.]**

Detailed Summary: Four County Pharmacist, IDU, and Policy Maker Study

Methods

The SF and LA pharmacy study design and methodology described above (Pharmacy Surveys) provided a foundation for a similar research study conducted during 2008 and 2009 in four counties that approved local legislation, but which had failed to establish a DPDP (Valerie Rose, PI). The counties included in the study are: Santa Cruz (approved March 2005); San Mateo (approved August 2005); Humboldt (approved October 2005); and San Luis Obispo (approved July 2006).

Research questions were modified from the SF and LA study to capture willingness (versus practices) to enroll in their health department DPDP; current or future practices with syringe disposal options; identification of potential barriers to participation, general KAB questions on SB 1159 legislative provisions and impressions of the need to sell syringes to IDUs. Included in the research methods were interviews with policy makers to determine mechanisms for overcoming barriers to establishing a DPDP in the county. Also included was a brief survey among a limited number of IDUs recruited from SEPs to document their willingness to use pharmacies as an alternative source for sterile syringes.

Surveys were sent to pharmacy managers with a cover letter that explained the study and which served as their consent to participate. Follow-up faxes and telephone calls were made two weeks after the initial mailing. Telephone interviews were conducted for two months with an abbreviated version of the pharmacy survey used in SF and LA in an effort to improve response rates. Response rates from pharmacists in San Luis Obispo, San Mateo, Humboldt, and Santa Cruz were 52 percent, 53 percent, 58 percent, and 75 percent, respectively. Personal interviews were conducted with IDUs between May and September 2008. Telephone interviews were conducted with LHOs and/or local policy makers (e.g., County Counsel, Board of Supervisor) between October 2008 and May 2009.

Findings: Pharmacy Survey – Four County Study

The study revealed a strong interest on the part of pharmacists in each county to participate in a DPDP and sell OTC syringes. In Santa Cruz County, 71 percent of pharmacists expressed a willingness to participate in the health department DPDP; 57 percent in Humboldt County; 56 percent in San Luis Obispo County; and 49 percent in San Mateo County. In all counties combined, approximately 40 percent of pharmacists had been asked by customers to sell OTC syringes within the last year. Fifty-nine percent indicated that IDUs should be able to purchase syringes from a pharmacy and 62 percent thought the cap of ten syringes was “just right.”

When asked about potential barriers to enrolling in the health department DPDP, few significant challenges were anticipated. Several exceptions were reported by a minority of respondents and are portrayed in Figure 10.

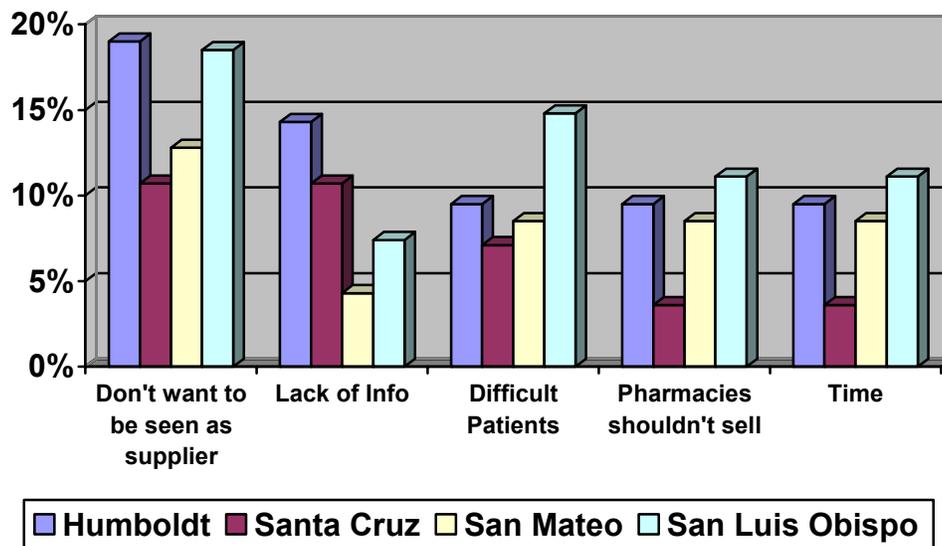


Figure 10: Potential Barriers to DPDP Participation Perceived by Surveyed Pharmacists in Four Counties, 2008

Next, pharmacists were asked about their current practices for syringe disposal (Figure 11). Across the four counties, 60 percent of pharmacies sell sharps containers while only 12 percent indicated that they would accept used personal sharps (i.e., syringes). Responses by county can be seen in Figure 11.

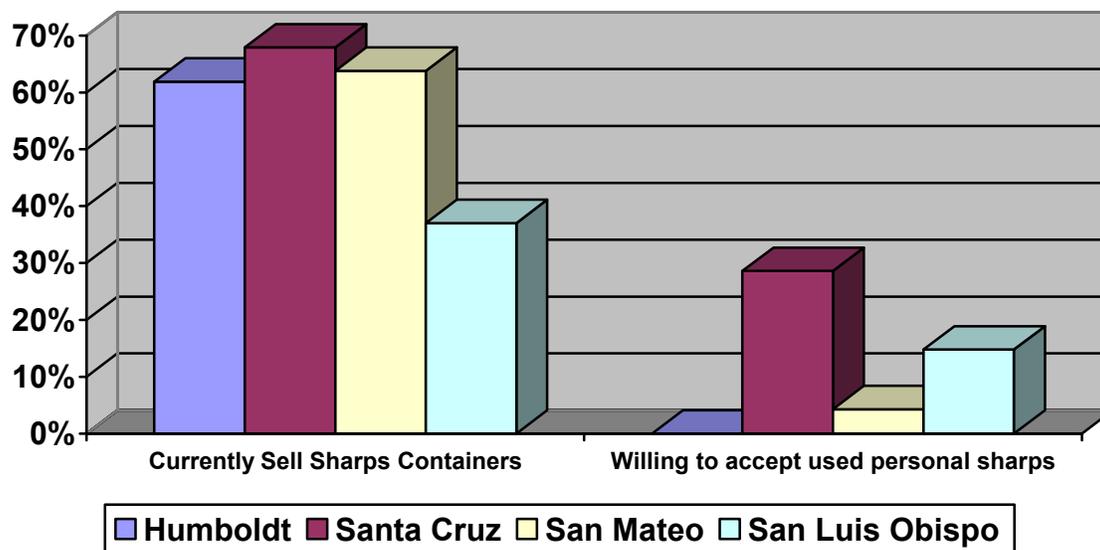


Figure 11: Percentage of Pharmacies that Currently Sell Sharps Containers and Pharmacy Willingness to Accept Used Personal Sharps (i.e., Syringes), 2008

Insight into pharmacists’ willingness to participate in a DPDP depending on several variables was explored next. Variables of interest included: years of experience, management versus non-management role, seeing a need, asked by public health department to sell, type of pharmacy (i.e., chain versus independent). Although most differences were not significant at the 95 percent confidence level, there were significant differences in one county. In San Mateo County, willingness to participate in a DPDP was positively associated with seeing a need to sell syringes (P=.02). Marginal significance (P=0.6) was observed for this relationship in San Luis Obispo County. Seeing a need to sell OTC syringes was associated with the opinion that IDUs should be able to purchase syringes (P<.05) in San Mateo and San Luis Obispo Counties (data not shown).

Findings: IDUs Interviews – Four County Study

A combined total of 46 IDUs completed a personal interview across the four counties. Eighty-three percent of participants were White, 59 percent were male, 6 percent reported that they were HIV positive, and 59 percent reported being HCV positive. The two most common drugs injected among respondents were heroin (65 percent) and methamphetamine (20 percent).

The majority of IDUs (94 percent) had gotten their sterile syringes from a SEP in the last 30 days. Among IDUs who reported using a SEP, 17 percent had also purchased syringes from a pharmacy and, of these, 84 percent indicated that it was a simple process. Eighty-two percent of surveyed IDUs indicated a willingness to use pharmacies as an alternative source for sterile syringes. Eighty percent of IDUs reporting using the SEP for syringe disposal. Of the 49 percent of IDUs who indicated an interest in drug treatment, 87 percent thought it would be “somewhat to very hard” to get the treatment they wanted.

Findings: Policy Maker Interviews – Four County Study

One policy maker from each of the four counties was also interviewed using semi-structured interviewing techniques. Either the LHO or a member of the Board of Supervisors or County Counsel agreed to a brief qualitative interview. Each believed SB 1159 to be an important public health intervention. As a result of salient data shared by the PI (V. Rose) with each of the counties regarding the willingness of pharmacists to participate in local DPDPs and of IDUs to use pharmacies as another source of sterile syringes, three of the four pledged to implement a DPDP before the law is scheduled to sunset at the end of 2010.

Syringe Discard

Syringe Disposal in the Vicinity of Pharmacies

Abstract

Methods: In the following study, we examined the association between publicly discarded syringes and syringe access through OTC syringe sales in two California counties. The main goal of this study was to determine whether DPDP adoption was associated with increases in publicly discarded syringes while controlling for pharmacy participation. In addition, we examined how participation in a DPDP relates to public discard of syringes in the immediate environment of pharmacies that did and did not participate in a DPDP.

Results: Observational data on 235 pharmacies in 2007 and 205 pharmacies in 2008 were analyzed. Observations of syringe trash were low in each year, with less than 5 percent of observation areas having any publicly discarded syringes. In 2007, a total of 15 syringes were found in the over 900 face blocks that were observed. In 2008, the total was 12 out of over 800 face-block observations. Drug-related items that were not syringes increased in 2008, but overall garbage observed declined in this year as compared to 2007. In these analyses, no association was observed between DPDPs, OTC syringe sales, and syringe trash in either year. Results from 2007 found that only other garbage predicted any syringe trash (AOR=4.94; 95% CI=1.01, 24.05). In 2008, no variables were significantly associated with any syringe trash. **[SB 1159 evaluation mandates 5; Specific Aim 4.]**

Detailed Summary: Syringe Disposal in the Vicinity of Pharmacies

Methods

Data were assembled from several sources. First, we used data from quantitative surveys conducted with pharmacies in SF and LA Counties as described above.

A second data source was systematic observation of physical environments in the immediate vicinity of pharmacies in LA and SF that did and did not engage in OTC sales during 2007 and 2008. Using methods developed and previously used by investigative team members (Doherty et al., 1997; Doherty et al., 2000; Kral et al., 2009; Riley et al., 1998), we conducted annual street observations to document changes in publicly discarded injection-related trash (defined as syringes, syringe caps, cookers, bag/baggies/foil wrap, cotton, and ties). Observations were conducted on the face

block where a pharmacy is located, as well as face blocks adjacent to the block on which the pharmacy is located.

Frequencies and proportions were used to describe the sample population and central tendencies. Chi-square and Fisher's exact test indicated significant bivariate associations between any trash, city, DPDP registration, and National Private Security Survey (NPSS) for each year (2007 and 2008). Using multivariate logistic regression, OA also constructed yearly models that predict any syringe trash while controlling for city and other garbage reports.

Results

In 2007, we obtained observational data on 235 pharmacies and in 2008, we obtained observational data on 205 pharmacies. Table 13 presents pharmacy survey data on enrollment in DPDP and sales of OTC syringes, as well as, observational data on any reported syringe, cooker, drug container, and glass and can garbage by year of observation/interview. In each year, between 40 percent and 46 percent of pharmacies reported being registered for DPDP and between 40 percent and 42 percent reported selling OTC syringes. Observations of syringe trash were low in each year, with less than 5 percent of observation areas having any publicly discarded syringes.

Table 13: Frequencies of Pharmacies Participation in a DPDP, OTC Syringe Sales, and injection-related Trash, 2007 and 2008

	2007 % (yes/n)	2008 % (yes/n)
DPDP registered	39.8% (76/191)	46.4% (97/209)
OTC Syringe Sale	42.0% (97/231)	40.2% (94/234)
Any syringe trash	4.7% (11/235)	2% (5/204)
Any cooker trash	7.7% (18/235)	11.8% (24/204)
Any drug container trash	3.8% (9/235)	7.8% (16/205)
Any other garbage	23.8% (56/235)	15.1 (31/205)

Count data of drug-item discard was enumerated for observations conducted during 2007 and 2008. In 2007, a total of 15 syringes were found in the over 900 face-blocks that were observed. A mean of 0.06 syringes per pharmacy were found in 2007. Twenty-three cookers, 12 drug containers, and 130 other garbage items were observed across these same face-blocks.

In 2008, a total of 12 (mean=0.06/pharmacy) syringes were found in over 800 face-block observations. Sixty-one cookers, 28 drug containers, and 45 other garbage items were observed during these face-block observations. In comparing 2007 and 2008 observations, drug-related items that were not syringes increased in 2008, but overall garbage observed declined in this year as compared to 2007.

Table 14 presents bivariate analysis of pharmacies registered for DPDP and those who conducted OTC syringe sales by city and observational data for each year. Important differences in pharmacy participation in DPDP and OTC sales by city were observed in each year with SF pharmacies reporting three to four times as much enrollment in DPDP and sales of OTC syringes than their LA counterparts. In these analyses, no association was observed between DPDP, OTC syringe sales, and syringe trash in either year. In 2007, any garbage was associated with DPDP and OTC sales and, in 2008, any cooker trash and any drug container trash was associated with DPDP and OTC syringe sales.

Table 14: Bivariate Analyses of DPDP and OTC Syringe Sales by Year and Key Variables

			2007			
	DPDP – No	DPDP – Yes	P=	OTC Sale-No	OTC Sale-Yes	P-value
City						
SF	24.2%	75.8%	<0.05	19.4%	80.6%	<0.05
LA	77.5%	22.5%		72.2%	27.8%	
Any syringe trash	5.8%	8.6%	ns	5.0%	6.4%	ns
Any cooker trash	8.7%	8.6%	ns	7.4%	9.0%	ns
Any drug containers	6.7%	5.2%	ns	3.3%	6.4%	ns
Any garbage	25.0%	41.4%	<0.05	19.0%	35.9%	<0.05
			2008			
City						
SF	19.4%	80.6%	<0.05	27.0%	73.0%	<0.05
LA	59.2%	40.8%		75.0%	25.0%	
Any syringe trash	2.4%	5.0%	ns	1.7%	6.2%	ns
Any cooker trash	3.6%	15.0%	<0.05	5.9%	16.9%	<0.05
Any drug containers	2.4%	11.3%	<0.05	4.2%	12.3%	<0.05
Any garbage	12.0%	12.5%	ns	10.9%	16.9%	ns

For Table 15, we report multivariate models by year that predict any syringe trash. In each year, we controlled for city and OTC sales participation. In 2007, we controlled for any garbage; in 2008, we controlled for any cooker or drug container trash. Results from 2007 found that only other garbage predicted any syringe trash (AOR=4.94; 95% CI=1.01, 24.05). In 2008, no variables were significantly associated with any syringe trash controlling for any cooker or drug container trash, but not garbage (which was not associated with syringe trash in bivariate analysis). We duplicated the above analyses using Poisson loglinear models to predict counts of syringe trash. In these analyses (data not shown), no significant associations were observed.

Table 15: Multivariate models predicting any syringe trash for each observation year

	2007 AOR (95% CI)	P=	2008 AOR (95% CI)	P=
OTC syringe sales in last 12 months	0.37 (0.77, 1.80)	0.22	2.71 (0.41, 18.06)	0.30
Any other garbage	4.94 (1.01, 24.05)	0.05		
Any cookers	NA		1.66 (0.14, 19.38)	0.69
Any drug containers	NA		3.70 (0.26, 52.49)	0.33
City- San Francisco	5.37 (0.94, 30.83)	0.06	1.25 (0.11, 14.12)	0.86

Discussion:

DPDPs and OTC syringe sales were not found to be associated with unsafe discard of syringes in either SF or LA during 2007 and 2008. Presence of other garbage in the vicinity of pharmacies was the only statistically significant predictor of syringe trash and this was only during 2007.

These findings should be considered in light of several limitations to our observational technique. Issues such as time of day, street cleaning activities either formal or informal, and recognition of drug paraphernalia by observers may all influence results. Observers did receive extensive training in the observational protocol including dry-runs, photographs of drug paraphernalia, and procedures for resolving discrepancies regarding interpretation of items.

Lastly, we were not able to observe the physical environments around pharmacies prior to the initiation of DPDP. For a limited number of cases, we do have information on uptake of DPDP in 2008. Fifteen pharmacies reported no participation in OTC syringe sales in 2008 after engaging in such sales in 2007. Another 19 pharmacies initiated OTC sales in 2008 after not participating in OTC sales in 2007. There were no differences in rates of syringe trash near pharmacies that initiated OTC sales in 2008 as compared to those who stopped sales in 2007. This finding may be due to underlying social, demographic, and economic characteristics of communities that were unmeasured in this study.

Syringe Disposal among IDUs in SF**Abstract**

Methods: The objective of this study was to assess the prevalence of improperly discarded syringes in SF and examine syringe disposal practices of IDUs. Research staff in SF walked through 1,000 blocks in 11 neighborhoods to determine the prevalence of improperly discarded syringes, and conducted a survey of 602 IDUs to examine disposal practices and the acceptability of publicly situated syringe disposal boxes.

Results: Twenty syringes were found on streets, none of which would have produced a needle stick without extensive handling. Sixty-seven percent of participants reported improper disposal during the past 30 days, and 13 percent of all syringes were disposed of improperly. In multivariate analysis, improper syringe disposal was independently associated with injecting in a public place, injecting crack in the past 30 days, and

obtaining syringes from an unauthorized source. Obtaining syringes from a SEP was independently associated with safe disposal. Overall, 87 percent of participants said they would use a disposal box if it were located in a convenient public place.

Discussion: Very few improperly discarded syringes were observed in SF. Although many IDUs report improper disposal, very few syringes pose a public health threat. **[SB 1159 evaluation mandate 5; Specific Aims 1-4.]**

Detailed Summary: Syringe Disposal among IDUs in SF

Methods

During 2008, researchers with RTI International, SF State University and SF Department of Public Health conducted a collaborative study focused on syringe disposal among IDUs. The study included street observations that were conducted during walks through 1,000 randomly selected SF blocks within 11 neighborhoods and a survey of IDUs (n=602) to examine syringe disposal practices and the acceptability of publicly-available syringe disposal boxes (Wenger et al., 2009).

Results

Extrapolating their observational findings to the 2,114 census blocks within the 11 SF neighborhoods with the highest concentrations of drug treatment admissions and drug-related arrests, the investigators estimate that there are 23.25 improperly discarded syringes on any given day between February and June. Similarly, the investigators estimated that there are approximately 12 improperly discarded syringes in Golden Gate Park on any given day. None of the discarded syringes found were an immediate risk to the public as all of the syringes found had the protective cap in place or had the needle broken off of the syringe. Further, the majority of the syringes found during the street observations were in hard-to-reach locations (e.g., behind a fence, in the gutter, or in a deep crack in the sidewalk [Wenger et al., 2009]). Considering the fact that there are an estimated 16,789 IDUs in SF (McFarland, 2006) who, on average, discard one syringe per day, the number of improperly discarded syringes is very low and the risk or needle-stick injuries in SF is also very low.

Among surveyed IDUs in SF, 67 percent of participants reported improper disposal during the past 30 days. In multivariate analyses, improper disposal of syringes was independently associated with injecting in a public place, injecting crack in the past 30 days, and obtaining syringes from an unauthorized source. Further, having obtained syringes from a SEP was independently associated with safe syringe disposal. Of note, 87 percent of IDUs surveyed indicated that they would use a disposal box if it were located in a convenient place.

Table 18. Factors Associated with Any Improper Syringe Disposal in Bivariate and Multivariate Analysis (N = 602)

Factor	Bivariate OR (95% CI)	Multivariate AOR (95% CI)
Ever injected in a public place in the past 6 months	2.3 (1.6, 3.3)	2.4 (1.6, 3.6)
Male	1.5 (1.0, 2.2)	--
Considers self homeless	1.7 (1.2, 2.5)	--
HIV positive (self-reported)	0.60 (0.36, 0.93)	--

Drugs injected, past 30 days		
Speedball (heroin and cocaine or crack)	1.7 (1.2, 2.5)	--
Goofball (methamphetamine and heroin)	0.90 (0.55, 1.50)	--
Power Cocaine	1.60 (0.97, 2.70)	--
Crack cocaine (injected)	2.3 (1.3, 4.1)	1.9 (1.0, 3.5)
Methamphetamine	0.91 (0.64, 1.30)	--
Heroin	1.20 (0.79, 1.80)	--
Syringe sources, past 6 months		
Syringe exchange program (SEP)	0.25 (0.13, 0.47)	0.20 (0.10, 0.40)
Someone else who goes to SEP	1.4 (1.0, 2.0)	--
Pharmacy purchase	1.6 (1.1, 2.4)	--
Purchase from unauthorized source (e.g., stranger on the street, dealer)	3.7 (2.4, 5.7)	3.0 (1.9, 4.7)

The authors conclude that: “there are very few inappropriately discarded syringes in SF. Although many IDUs report improper disposal, very few syringes pose a public health threat.”

Discussion

This is the first study of which we are aware to map, systematically inspect, and document the occurrence of improperly discarded syringes in public places. We found 20 syringes in a 4-month period and estimated that there are 38 syringes present at any given time in the 11 neighborhoods most affected by drug use, the Golden Gate Park, and public toilets in San Francisco. This is very low, considering that there is an estimated 16,789 IDUs in San Francisco, each of whom discards an average of one syringe per day. The potential danger posed by found syringes was very low, with none being able to produce a needlestick without substantial handling. We found there to be very low risk of needlestick injuries in San Francisco.

Our epidemiologic survey of 602 IDUs showed that, while there was a high proportion of IDUs who at some point in a 6-month period disposed of their syringes improperly, the number of syringes that they disposed of improperly was small (13% of total syringes used). We attributed the difference between the few numbers of syringes that we found and the larger number of syringes that IDUs reported disposing of improperly to our broad definition of improper disposal. Our definition of improper disposal included methods such as flushing syringes down the toilet and throwing syringes into the trash, neither of which pose a large threat to the general public.

An additional strategy for potentially decreasing improper disposal of syringes is the installation of public disposal drop boxes. One-third of our study participants reported purchasing syringes in a pharmacy, but less than 1% reported disposing of syringes at a pharmacy. Increased efforts to educate IDUs regarding the legality, safety, and accessibility of pharmacy disposal, as well as efforts to educate pharmacy workers about social issues related to IDUs, are needed to increase disposal in pharmacies.

This study had several limitations that need to be considered when interpreting its findings. First, visual inspection did not include all census blocks in San Francisco; therefore, it is possible that we missed pockets where improper disposals were more frequent, underestimating the number of syringes on city streets or in parks other than Golden Gate. Also, while we randomized blocks, it was not logistically possible to randomize the times of day or year that each block was inspected. However, we did inspect a large proportion of blocks (1,000 / 2,114) in the 11 San Francisco neighborhoods where drug-related arrests and drug treatment admissions are highest. The study survey relied on self-reported data by study participants, which always have the potential of being biased by recall and social desirability. Specifically, it is reasonable to assume that there was some underreporting of improper syringe disposal. Finally, our survey field sites were located in three neighborhoods with high numbers of IDUs, but do not represent other areas of the city where syringe disposal behaviors may differ. Despite these limitations, this study makes a unique contribution to our understanding of a complex social problem that intersects the spheres of public health and public opinion. The study highlights that the factors associated with improper syringe disposal are rooted in social structural issues such as having to inject in public and obtaining syringes from unauthorized sources. It would be prudent to consider structural solutions, such as lengthening SEPs' hours of operation, installing public disposal boxes in heavily trafficked drug use areas, promoting pharmacy disposal.

Drug-Related Crime Pre- and Post-Implementation of DPDPs

Abstract

Methods: The objective of this study was to assess drug-related crime pre- and post-implementation of OTC pharmacy syringe sales programs in California. Specifically, OA aimed to assess whether spatial clustering of crime explains, at least in part, the distribution of drug-related crime in California. Drug-related arrest data, demographic data, and pharmacy syringe sales data were aggregated for all 58 California counties.

Results: Global clustering of drug-related crime was observed in 2004 ($P=0.045$) but not in 2006, post-implementation of OTC sales ($P=.299$). Local clustering of crime occurred in 2004 in Northeastern California (Modoc and Lassen Counties; $P<0.05$), and in 2006, in Northern California (Sutter and Colusa Counties; $P<0.05$). Local clustering of drug-related crime did not occur in counties that implemented OTC syringe sales in 2005 and 2006.

Discussion: In aggregate, drug-related crime remained static in California pre- and post-implementation of OTC sales, providing evidence that OTC syringe sales did not lead to elevated crime rates in counties that authorized such sales. **[SB 1159 evaluation mandate 4; Specific Aim 6.]**

Detailed Summary: Drug-Related Crime Pre- and Post-Implementation of DPDPs

Methods

In the current study, each of the 58 counties served as an observation in the database. Drug-related arrest data were obtained from the California Department of Justice. Crime variables were created to provide measures of drug-related crime for each county during 2004, one year prior to enactment of the SB 1159 legislation, and 2006, one year

post-enactment. Felony drug-related crime rates per 100,000 were calculated from aggregated crime data for: 1) all drug offenses; 2) narcotics arrests; 3) marijuana arrests; and 4) 'other' drug arrests. For these measures, the population represented in the denominator is the number of 'at-risk' adults (18 to 69 year olds, as delineated in California Department of Justice crime data). Arrest rates were calculated using annual population estimates obtained from the California Department of Finance. Data from California Department of Finance were also used to construct variables for racial/ethnic population proportions, median age, median income, unemployment rates, and political majority by county. A dichotomous variable for OTC status was also included in the dataset for counties that permit sales versus counties that do not (Garfein et al., 2008).

Preliminary data analyses included bivariate comparisons and visualization techniques (e.g., scatterplots, geographical information system [GIS] maps) for variables believed to be appropriate for inclusion in the final linear regression model. The outcome variable of interest was drug-related crime rates. Potential predictors and covariates (i.e., OTC syringe sale, race/ethnicity, median income, unemployment, and political predisposition) were also visualized and assessed for inclusion in the final linear regression model. GIS maps were created (ArcGIS 9, 2008 ESRI) to compare crime rates and the covariates of interest for 2004 and 2006 to provide preliminary findings of potential pre- and post-OTC differences across counties. Geographic centroids were calculated for each of the 58 counties by using the field calculator in ArcMAP (ArcGIS 9, 2008 ESRI). This facilitated subsequent spatial and statistical analyses focused on point tests in which the area location (i.e., county) is described by a single point (e.g., the geographic centroid).

Linear regression models were constructed to assess factors associated with drug-related crime outcomes using SAS (SAS 9.1, 2007). Covariates believed to be associated with drug-related crime were included in separate models for 2004 and 2006, to assess predictors of drug-related crime pre- and post-implementation of OTC. Using approaches discussed by Anselin and colleagues (1995 and 2004), final results focused on the residual error term in the model. Predicted values and residuals for drug-related crime were calculated for all counties based on the linear regression model.

Residual values and latitude and longitude data for the geographic centroid of each county were ultimately used to conduct Moran's I autocorrelation statistical tests for point data (SSTAT, Version 4.7) to assess whether global clustering of drug-related crime was present across California counties.

Results

Portraying drug-related crime in GIS maps, it is evident that crime rates are primarily lower in counties along the Pacific Coast, including those that have authorized OTC syringe sales. From 2004 to 2006, most OTC syringe selling counties experienced drug-related crime rates of 204 to 500 per 100,000. Increases in drug-related crime rates occurred between 2004 and 2006 in the southeastern portion of the state, in counties that do not permit sales of OTC syringes and that are not adjacent to counties that permit OTC sales.

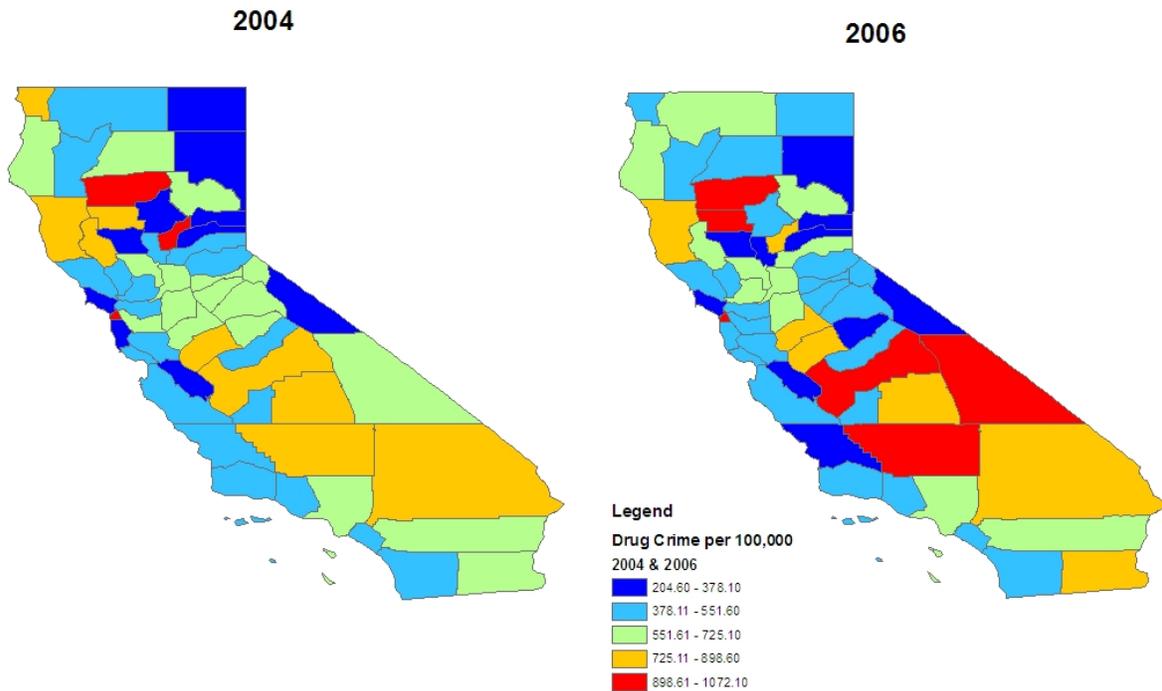


Figure 12: Drug-related Crime per 100,000 Population by County, California, 2004 and 2006

During 2004 and 2006, the majority of the counties with the highest proportion of pharmacies registered to sell OTC syringes were located in Northern California, where between 12 percent and 61 percent of pharmacies reported OTC syringe sales practices (Figure 12).

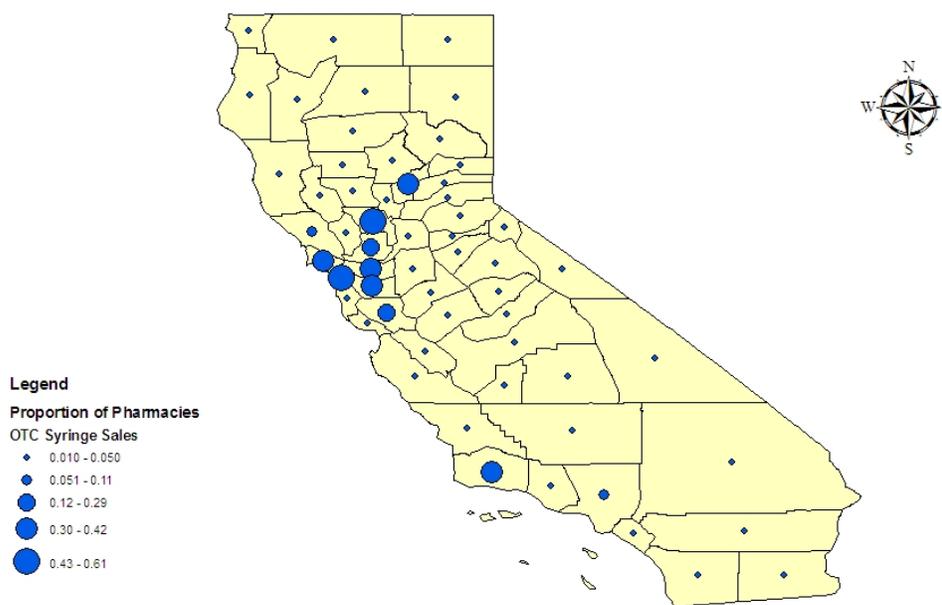


Figure 13: Proportion of California Pharmacies Selling OTC Syringes by County, 2006

Linear regression analyses for 2006 indicate that the biggest predictors of drug-related crime were median income levels ($P= 0.002$), White race/ethnicity ($P= 0.02$), and Latino/Hispanic ethnicity ($P=0.07$, marginally significant). Approximately one-third of drug-related crime could be explained by predictors and covariates included within the model ($R^2 = 0.30$). Moran's I autocorrelation statistical tests for spatial clustering indicated that there was no global clustering of drug-related data crime in California during 2006. ($P= 0.299$).

Next, in conducting Anselin Local Moran's I (Spatial Statistics), OA found that local spatial clustering of drug-related crime was present in both 2004 and 2006. Local clustering of crime occurred in 2004 in Northeastern California (Modoc and Lassen Counties; $P<0.05$), and in 2006, in Northern California (Sutter and Colusa Counties; $P<0.05$). Local clustering of drug-related crime did not occur in counties that implemented OTC syringe sales in 2005 and 2006.

Discussion

In aggregate, drug-related crime remained static in California pre- and post-implementation of OTC sales, providing evidence that OTC syringe sales did not lead to elevated crime rates in counties that authorized such sales.

Several limitations exist in the current study. First, data analyses focus primarily on two cross-sectional time points, pre- and post- OTC syringe sales. The post-OTC data from 2006 represent crime outcomes that occurred relatively soon after implementation dates during 2005 and 2006. While more data will be available in the near future that may facilitate even more detailed analyses, focus on 2004 and 2006 time points permit good preliminary analyses of drug-related crime. Second, analyses focus solely on county level data. While crime rates at the city, census tract or police reporting district level could provide even more informative results, it would be time consuming and expensive to conduct, if such data were available.

In summary, we found that drug-related crime did not change significantly between 2004 and 2006 and any increases in crime rates were observed far from counties that permit OTC syringe sales. It appears that clustering of drug-related crime is more strongly associated with characteristics other than those associated with SB 1159 and OTC syringe sales (e.g., population density and sociodemographic factors).

Accidental Needle Sticks

Abstract

In 1993, OA began documenting reported accidental needle-stick injuries among California law enforcement personnel. Between 1993 and 2009, a total of 186 needle-stick injuries were voluntarily reported to the OA HIV/AIDS Registry, 101 in LHJs that had authorized DPDPs and 85 in LHJs that had not. The differences were not statistically significant. Between 2005 and 2009, post-authorization of DPDPs, 19 accidental needle-stick injuries were reported among law enforcement in LHJs that had authorized DPDPs and 15 accidental needle-stick injuries were reported among law enforcement in LHJs that had not authorized DPDPs, and the differences were not statistically significant. Currently, there is no consistent statewide system to report needle-stick injuries among employees within waste management organizations. **[SB 1159 evaluation mandate 3; Specific Aim 5.]**

Table 14: Accidental Needle-stick Injuries Reported among California Law Enforcement by LHJ and OTC Syringe Sale Status, 1993-2009

LHJs grouped by DPDP Authorization Status	Total Number of Reports by Year																	Total***
	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	
LHJs Authorizing OTC Syringe Sale*	11	23	5	3	4	5	3	5	3	0	3	1	5	1	3	6	4	85
LHJs Not Authorizing OTC Syringe Sale**	7	20	10	14	11	5	6	2	1	4	4	2	2	1	4	4	4	101

*Counties and the city that reported needle-stick injuries include: Alameda, Contra Costa, LA, SF, San Luis Obispo, San Mateo, Santa Clara, Santa Cruz, Sonora, and Yolo Counties and the City of Sacramento.

**Counties that reported needle-stick injuries include: Butte, Colusa, Imperial, Kings, Mendocino, Merced, Monterey, Nevada, Orange, Riverside, San Bernardino, San Diego, San Joaquin, Shasta, Stanislaus, Sutter, Tulare, and Ventura Counties.

***P=0.097, comparing the proportion of needle sticks in DPDP authorizing and non authorizing LHJs.

Source: OA, HIV/AIDS Case Registry Section, data as of September 15, 2009.

In 1993, OA began documenting reported needle-stick injuries among California law enforcement officers. Between 1993 and 2009, a total of 186 needle-stick injuries were reported to the OA HIV/AIDS Registry, with 101 reported in LHJs that ultimately have not authorized a DPDP and 85 reported in LHJs that have authorized a DPDP (Table 18; P=0.097).

Table 16: Accidental needle-stick injuries reported by law enforcement officers in LHJs by OTC syringe sale status, 1993-2004 versus 2005-2009

LHJs grouped by DPDP Authorization Status	Total Number of Reports		Total (%)^
	1993-2004 (%) ***	2005-2009 (%)****	
LHJs Authorizing OTC Syringe Sale*	66 (43.4)	19 (55.9)^^	85 (45.7)
LHJs Not Authorizing OTC Syringe** Sale	86 (56.6)	15 (44.1)	101 (54.3)
Total	152	34	186

*Counties and the city that reported needle-stick injuries include: Alameda, Contra Costa, LA, SF, San Luis Obispo, San Mateo, Santa Clara, Santa Cruz, Sonoma, and Yolo Counties and the City of Sacramento.

**Counties that reported needle-stick injuries include: Butte, Colusa, Imperial, Kings, Mendocino, Merced, Monterey, Nevada, Orange, Riverside, San Bernardino, San Diego, San Joaquin, Shasta, Stanislaus, Sutter, Tulare, and Ventura Counties.

*** P=0.022, comparing the proportion of needle sticks in DPDP authorizing and non authorizing LHJs.

****P=0.166, comparing the proportion of needle sticks in DPDP authorizing and non authorizing LHJs.

^P=0.097, comparing the proportion of needle sticks in DPDP authorizing and non authorizing LHJs.

^^P=0.094 comparing the proportion of needle sticks in LHJs authorizing OTC syringe sale pre- and post SB 1159 adoption

Source: OA, HIV/AIDS Case Registry Section, data as of September 15, 2009.

Between 2005 and 2009, 19 accidental needle-stick injuries among law enforcement were reported in LHJs that have authorized DPDPs and 15 were reported among law enforcement in LHJs that have not authorized DPDPs (Table 16; P=0.166).

Our team of researchers attempted to obtain data on accidental needle sticks among waste management employees on the state and county level. OA learned that there is no consistent statewide system to report needle-stick injuries among employees within the waste management organizations.

Surveys with Community Members, Service Providers and Pharmacy Staff

Abstract

Methods: Research team members in LA collected 385 KAB surveys at 22 educational presentations at community forums during 2006 to 2007 to obtain perspectives on SB 1159 and local DPDPs from community members, business owners, HIV/AIDS and medical service providers, pharmacists and other pharmacy employees, community/business advocates, government representatives, public health experts. The primary goal of the KAB survey was to assess changes in KABs about SB 1159 pre-and post-presentation. Bivariate statistical tests using Pearson Chi-Square test

were conducted to identify whether any changes between the pre- and post-presentation results were significantly different at the 0.05 level.

Results: Findings indicate persistent confusion about the details of SB 1159 among community members even after information on the bill was presented. SB 1159 does not require pharmacies to sell syringes to adults without a prescription, yet the percent of participants agreeing with this statement increased from pre- to post-presentation. Survey items stating that “SB 1159 authorizes pharmacies to sell unlimited quantities of syringes to adults 18 years of age and over with a prescription” and survey items stating that “all California pharmacies are required to sell syringes to adults without a prescription” had significant increases in the percentage of participants agreeing with these statements. This provided further evidence of confusion about SB 1159 policy.

On a positive note, participants increasingly agreed with the statement that syringe disposal programs are required as part of OTC under SB 1159. Regarding attitudes, general increases in the acceptability of each syringe disposal method were observed. Most participants endorsed providing syringe drop-off boxes at or near pharmacies. Acceptability of providing free sharps containers or selling sharps containers increased significantly. Positive and significant results were observed after the presentation for participants who stated that increased syringe access would result in declines of publicly discarded syringes, crime, violence, drug use and drug dealing, and HIV and HCV rates.

Discussion: Survey findings provide mixed results. Participants demonstrated improved knowledge about some aspects of SB 1159 and related public health policy after the SB 1159 training, but decreased knowledge of other aspects of SB 1159 policy. Poor understanding of public health policy can be improved through health education but it may be challenging to measure the effect and overall influence of such efforts over the long term. **[SB 1159 evaluation mandate 5; Specific Aim 1.]**

Detailed Summary: Community KAB Surveys

Methods and Participants

Research team members in LA collected 385 KAB surveys at 22 educational presentations during 2006 to 2007 to obtain community perspectives on SB 1159 and local DPDPs. The demographic and professional characteristics of survey participants are reported below (Table 17). Educational sessions were held at community-based agencies, college classrooms for pharmacy technicians in training, and professional pharmacist meetings. At community forums, Drug Policy Alliance staff provided a 30 to 45 minute presentation that covered three broad areas: 1) HIV and HCV epidemiology and prevention strategies related to injection drug use; 2) the history, goals, and rules of SB 1159 DPDP; and 3) an interactive discussion period to address issues and questions of concern to audience members. The majority of participants were under 34 years of age and female. Hispanics comprised 32 percent of participants, because the largest educational session was held at a conference for HIV-positive Latinos. Pharmacy employees comprised only 12 percent of the participants, but a large number of participants were pharmacists or pharmacy technicians in training who identified

themselves in the “Other” affiliation category. Of those who identified as pharmacists, most worked at independent pharmacies (Table 17).

Table 17: Survey participants characteristics (n=385)

Characteristic	N (%)
Sex (26 missing)	
Male	161 (42%)
Female	195 (51%)
Age (26 missing)	
<25	109 (29%)
25-34	83 (22%)
35-44	66 (17%)
45-54	60 (16%)
55-64	30 (8%)
65 or older	8 (2%)
Race/Ethnicity (26 missing)	
White, not Hispanic	68 (18%)
African American, not Hispanic	48 (13%)
Hispanic, Latino, Chicano	124 (32%)
American Indian or Alaskan Native	23 (6%)
Asian or Pacific Islander	65 (17%)
Other	28 (7%)
Affiliation (46 missing)	
Community member	53 (14%)
Business owner	2 (0.5%)
Pharmacist	36 (9%)
Employee at pharmacy	12 (3%)
Community/business advocate	16 (4%)
Government representative	2 (0.5%)
Service provider	84 (22%)
Public health expert	22 (6%)
Other	109 (29%)
Pharmacy type (Among pharmacists and other pharmacy employees)	
Chain	4 (15%)
Independent	16 (59%)
Hospital or clinic-based	7 (26%)
Pharmacy job title	
Intern Pharmacist	2 (7%)
Registered Pharmacist	24 (89%)
Pharmacy Technician	1 (4%)

One important goal of the KAB survey was to assess changes in KABs about SB 1159. Knowledge of SB 1159 was assessed through five questions related to details of the SB 1159 implementation and an overall knowledge rating. Attitudes were assessed through six items – one on the importance of providing clean syringes to drug users and

five on acceptable methods of syringe disposal. Finally, beliefs were assessed through 11 items on increased syringe access and possible positive or negative consequences. Table 18 reports responses from the pre- and post-presentation surveys. We also conducted the bivariate statistical test using Pearson Chi-Square test to identify if any changes between the pre- and post-presentation results were significantly different at the 0.05 level.

Table 18: SB 1159 KABs among Community Members Pre- and Post-SB 1159 Presentation (n=385)

KAB item	Pre-presentation	Post-presentation	P<
KNOWLEDGE			
SB 1159 makes it illegal to dispose of syringes on playgrounds, beaches, parks, and schools.	Agree – 39% Disagree – 47% Not sure – 14%	Agree – 26% Disagree – 65% Not sure – 9%	n.s.
Syringe disposal programs are required as part of OTC under SB 1159.	Agree – 84% Disagree – 12% Not sure – 5%	Agree – 94% Disagree – 5% Not sure – 1%	.001
SB 1159 authorizes pharmacies to sell unlimited quantities of syringes to adults 18 years of age and over with a prescription.	Agree – 58% Disagree – 12% Not sure – 30%	Agree – 76% Disagree – 13% Not sure – 11%	.001
All California pharmacies are required to sell syringes to adults without a prescription.	Agree – 50% Disagree – 7% Not sure – 43%	Agree – 73% Disagree – 15% Not sure – 12%	.001
How would you rate your knowledge of SB 1159?	High – 10% Moderate – 28% Low – 62%	High – 34% Moderate – 56% Low – 10%	.001
ATTITUDES			
It is important to provide clean syringes to people who cannot or will not stop injecting drugs.	Agree – 37% Disagree – 47% Not sure – 16%	Agree – 25% Disagree – 60% Not sure – 15%	.02
It is acceptable to you if pharmacies that sell syringes provide a syringe disposal box in or adjacent to their location?	Acceptable – 84% Unacceptable – 9% No opinion – 7%	Acceptable – 92% Unacceptable – 5% No opinion – 3%	.001
It is acceptable to you if pharmacies that sell syringes provide sharps containers for free.	Acceptable – 69% Unacceptable – 21% No opinion – 10%	Acceptable – 87% Unacceptable – 8% No opinion – 6%	.001
It is acceptable to you if pharmacies that sell syringes require purchase of sharp containers.	Acceptable – 51% Unacceptable – 32% No opinion – 18%	Acceptable – 67% Unacceptable – 23% No opinion – 10%	.001

TABLE 18 (continued): SB 1159 KABs among Community Members Pre- and Post-SB 1159 Presentation (n=385)

KAB item	Pre-presentation	Post-presentation	P<
It is acceptable to you if pharmacies that sell syringes require purchase of mail-back sharp containers.	Acceptable – 47% Unacceptable – 30% No opinion – 23%	Acceptable – 64% Unacceptable – 24% No opinion – 13%	.001
Preferred method of syringe disposal: On-site or adjacent; Free sharps distribution and pick-up; Required purchase of sharps; and Required purchase of mail-back sharps.	45% 38% 13% 4%	46% 40% 10% 4%	ns
BELIEFS			
IDUs will continue to share syringes even if they have increased access to clean syringes.	Agree – 15% Disagree – 53% Not sure – 32%	Agree – 35% Disagree – 60% Not sure – 5%	.001
OTC pharmacy access to syringes sends mixed messages to kids about drug use.*	Agree – 15% Disagree – 60% Not sure – 25%	Agree – 30% Disagree – 65% Not sure – 5%	.001
An increase in syringe access will increase the number of syringes found on the street and on playgrounds.	Agree – 43% Disagree – 40% Not sure – 17%	Agree – 25% Disagree – 66% Not sure – 9%	.03
Increased syringe access will cause crime to...*	Increase – 35% Decrease – 23% No effect – 27% Don't know – 16%	Increase – 13% Decrease – 39% No effect – 40% Don't know – 9%	.01
Increased syringe access will cause needle-stick injuries to law enforcement to...*	Increase – 33% Decrease – 23% No effect – 22% Don't know – 22%	Increase – 16% Decrease – 43% No effect – 29% Don't know – 22%	ns
Increased syringe access will cause drug use to...*	Increase – 42% Decrease – 9% No effect – 38% Don't know – 11%	Increase – 18% Decrease – 20% No effect – 55% Don't know – 8%	.001
Increased syringe access will cause HIV and HCV rates to...*	Increase – 32% Decrease – 57% No effect – 3% Don't know – 8%	Increase – 11% Decrease – 79% No effect – 6% Don't know – 4%	.001

TABLE 18 (continued): SB 1159 KABs among Community Members Pre- and Post-SB 1159 Presentation (n=385)

BELIEFS (continued)			
Increased syringe access will cause violence to...*	Increase – 26% Decrease – 20% No effect – 38% Don't know – 17%	Increase – 12% Decrease – 33% No effect – 47% Don't know – 9%	ns
Increased syringe access will cause drug dealing to...*	Increase – 40% Decrease – 9% No effect – 37% Don't know – 14%	Increase – 16% Decrease – 21% No effect – 53% Don't know – 11%	.001
Increased syringe access will cause syringes found on the streets and playgrounds to...*	Increase – 47% Decrease – 23% No effect – 15% Don't know – 16%	Increase – 18% Decrease – 51% No effect – 21% Don't know – 9%	.001

* Missing 24 Spanish language responses due to error in translation.

Changes were observed for most items and several were statistically significant. For the knowledge items, confusion about the details of SB 1159 persists among participants, despite an increase in the participants that described their self-rated knowledge as increasing as a result of the presentation. SB 1159 does not require pharmacies to sell syringes to adults without a prescription, yet the percent of participants agreeing with this statement increased from pre- to post-presentation. Items stating that SB 1159 authorizes pharmacies to sell unlimited quantities of syringes to adults 18 years of age and over with a prescription, and all California pharmacies are required to sell syringes to adults without a prescription had significant increases in the percentage of participants agreeing with these statements. On a positive note, participants increasingly agreed with the statement that syringe disposal programs are required as part of OTC under SB 1159.

Regarding attitudes, general increases in the acceptability of each syringe disposal method were observed. Most participants endorsed providing syringe drop-off boxes at or near pharmacies. Acceptability of providing free sharps containers or selling sharps containers increased significantly.

Lastly for beliefs, results were mixed. After the presentation, participants' agreement and disagreement increased with the statement that IDUs will continue to share syringes even if they have increased access to clean syringes, with fewer people stating that they were unsure about their position. However, more people overall stated that they disagreed after they heard the educational presentation. Similar results were seen for the belief that syringe access sends mixed messages to kids. Positive and significant results were observed after the presentation for participants who stated that increased syringe access would result in declines of publicly discarded syringes, crime, violence, drug use and drug dealing, and HIV and HCV rates.

SECTION 4: DISCUSSION AND CONCLUSIONS

In this section, we review SB 1159, discuss research findings, and delineate recommendations for future public health policy and evaluation. Salient subsections include:

- ❖ SB 1159: The Two-Step Authorization Process
- ❖ Community Impacts
- ❖ General Discussion
- ❖ Future Directions
- ❖ Conclusions

SB 1159: The Two-Step Authorization Process

California's legislation (SB 1159) permitting sale of OTC syringes on the local level presents public health policy that is unique from that in other states. In other states, OTC sales legislation and deregulation were applied uniformly across the state. SB 1159 requires that a two-step authorization and implementation process take place on the city or county level. Under SB 1159, the first step mandates that the County Board of Supervisors or the City Council first authorize a local DPDP. The second step subsequently mandates that local pharmacies within the authorizing city or county register with their local health department to participate in the authorized DPDP and initiate OTC syringe sales.

Community Impacts

SB 1159 required that CDPH evaluate six indicators of the effect of the OTC syringe sales pilot. While lack of funding for SB 1159 evaluation limited the breadth and sophistication of SB 1159 and DPDP research and evaluation, our team was able to address each of these six indicators, with the most salient findings reiterated below. Limitations, strengths and recommendations for further research for each indicator follow.

- 1) "Hypodermic needle or syringe sharing practices among those who inject illegal drugs."

Injection-mediated risks are lower among IDUs in LHJs that have authorized access to sterile syringes through pharmacies.

Limitations: HIV C&T data on IDUs are not representative of all IDUs in California. Other factors, such as enhanced syringe access through SEPs may also play a large role in reducing injection-mediated risk behaviors in LHJs that implemented DPDPs.

Strengths: HIV C&T data are collected at publicly funded sites throughout California and provide a broad snapshot of HIV risk among IDUs in all 61 LHJs across the state over many years.

Recommendations: Adequately funded population-based, cross-sectional studies and longitudinal cohort studies, that follow IDUs over several years, could provide

more detailed and representative findings on associations between OTC syringe access and blood-borne disease transmission risk.

- 2) “Rates of disease infection caused by hypodermic needle or syringe sharing.”

More time is required to determine the effect of SB 1159 on HIV incidence rates.

Limitations: HIV incidence data were not available in California until after SB 1159 was implemented and California does not have an HCV incidence surveillance system. Additionally, because the California names-based HIV case surveillance data system is still relatively new, the system does not currently permit accurate measurement of recent infection rates (i.e., incidence).

Strengths: The only surveillance system currently addressing this question is for AIDS cases and this system demonstrates decreases in reported AIDS diagnoses among IDUs since 1993.

Recommendations: The CDC-funded HIV Incidence Surveillance (HIS) was recently initiated in California. This system will be used to facilitate calculation of systematic incidence rates among IDUs during the years to come. Additionally, adequately funded longitudinal studies to determine incidence rates among IDUs could determine incidence rates among IDUs with differing levels of syringe access, as well as different exposure risks.

- 3) “Needle-stick injuries to law enforcement officers and waste management employees.”

Reported needle-stick injuries among law enforcement officers remain rare.

Limitations: Currently, needle-stick injuries among law enforcement are voluntarily reported to CDPH/OA. It is possible that such injuries are under-reported. We do not know of any consistent needle-stick injury reporting system for waste management employees.

Strengths: The needle-stick reporting system at CDPH/OA has been in place for over a decade and relies on a reporting form that has remained consistent over time.

Recommendations: None.

- 4) “Drug crime or other crime in the vicinity of pharmacies.”

Drug-related crime remained stable in the LHJs that authorized DPDPs.

Limitations: Research focused on crime rates and OTC syringe access on the county level, rather than on the local and individual level.

Strengths: Complex statistical and spatial analyses were employed to detect global (statewide) and local (county) clustering of crime pre- and post-DPDP implementation.

Recommendations: With adequate funding, analysis of crime counts and crime rates in the vicinity of pharmacies on the city, police reporting district, neighborhood, or individual level could assess more intricate associations between OTC syringe purchase and crime.

5) "Safe or unsafe discard of used hypodermic needles or syringes."

Low levels of unsafe discard of used hypodermic needles or syringes were observed around DPDPs.

Limitations: Syringe discard research and observations were conducted in limited locations (i.e., SF and LA).

Strengths: Syringe discard surveys with IDUs and systematic street observations across SF and LA neighborhoods provided detailed information on syringe discard practices in areas of high IDU density.

Recommendations: Replication of the syringe discard survey and observation methodologies in additional locations (i.e., beyond SF and LA) could provide a better understanding of syringe discard practices across a broader representation of California LHJs.

6) "Rates of injection of illegal drugs."

Levels of injection of illegal drugs decreased among publicly funded HIV testing clients since implementation of SB 1159.

Limitations: HIV C&T data on IDUs are not representative of all IDUs in California.

Strengths: HIV C&T data are collected at publicly funded sites throughout California and provide a broad snapshot of HIV risk among IDUs in all LHJs across the state over the course of many years.

Recommendations: Adequately funded population-based, serial cross-sectional studies and longitudinal cohort studies, that follow IDUs over several years, could provide more detailed and representative findings on rates of injection of illicit drugs.

General Discussion

Based on our assessment, there has been a measured but well targeted response to SB 1159 within California LHJs. As of December 2007, only 17 of California's 61 LHJs had approved DPDPs, in which less than one-fifth of the pharmacies had registered to sell non-prescription syringes. Most DPDPs were authorized shortly after SB 1159 passed and few additional LHJs were considering implementation of DPDPs three years after passage. While most LHJs lack DPDPs, LHJs with DPDPs include LHJs where 70 percent of California's currently living HIV/AIDS cases were diagnosed and 52 percent of the state's population.

Finding barriers such as lack of time, resources, and interest, but not lack of need for syringes, suggests that the two-step authorization process for legalizing OTC syringe sales (i.e., first on the county or city level and second on the pharmacy level) limited

potential risk-reduction intentions of the legislation and deletion of this stipulation from a future bill could provide better access to this important prevention intervention. For example, two counties (Humboldt and San Mateo) approved DPDPs in 2005, but have yet to register any pharmacies. Santa Cruz County approved a DPDP, but required city government approval before pharmacies in that county's four cities could register with DPDP. To date, no city has authorized a DPDP. The inconsistency between county- and city-level approvals in Santa Cruz highlights a potential problem with decentralized responsibility for OTC syringe sales.

SB 1159 was designed to allow LHJs sovereignty to choose to participate since OTC sales might be a lower priority where injection drug use is rare or alternate interventions are available. This has merit given that local governments, informed by their LHOs, may be best suited to understand and serve the needs of their community. Nonetheless, implementation barriers cited by LHJs suggest that leaving DPDP implementation to the discretion of local government entities could require more time and commitment than some already over-burdened health departments can handle. Anecdotal reports from survey respondents suggest that the two-step opt-in process creates inconsistency, increases ambiguity, and causes health departments to operate under different guidelines making it difficult to help one another implement the law and avoid redundant effort.

The SB 1159 approval process was similar to California's legalization of SEPs (Assembly Bill 136 [Mazzoni, Chapter 762, Statutes of 1999]), and provides an important contrast to other states that legalized syringe sale or exchange on a statewide basis. While SB 1159 gave localities the choice of legalizing these programs according to local needs, consequences of this approach include preventing willing pharmacies in non-approved LHJs from selling syringes, complicating TA to LHJs because DPDPs lack uniformity, and possible confusion among consumers about where they can and cannot legally purchase syringes.

It is too early to determine the impact of OTC syringe sales on pharmacy practices and IDUs vis-à-vis HIV and hepatitis prevention in the 14 LHJs with registered pharmacies. However, our research team found that there have been few problems related to OTC sales and that pharmacists were more likely to sell syringes without a prescription if they considered it an important HIV prevention intervention. There is also evidence from other states that OTC sales decrease syringe sharing and acquisition from unsafe sources (Cotton-Oldenburg et al., 2001; Groseclose et al., 1995; Rich et al., 2007). Conversely, despite having pharmacies registered to sell OTC syringes, pharmacists' beliefs and attitudes may hinder IDUs from actually purchasing them as one study found pharmacists unwilling to sell syringes to certain customers discriminating by race or other factors (Compton et al., 1992). In other studies, pharmacists opinion's toward syringe sales varied according to their perceptions of whether OTC prevents HIV or increases drug use, and their concerns about how selling syringes to IDUs will affect their business and the community (Lewis et al., 2002; Coffin et al., 2000). Our team (Riley et al., 2009) found that, two years after legalizing OTC sales in SF, pharmacies effectively augmented SEPs as a source of clean syringes for IDUs. However, it is

unknown whether IDUs at highest risk for blood-borne infections are aware of the law or are able to afford syringes from pharmacies. Among IDUs enrolled in a treatment facility in New York where OTC sales were legalized in 2001, less than 50 percent of the IDUs samples were aware that they could obtain syringes from pharmacies and even fewer actually did so (McNeely, 2006). Additional pharmacy and consumer-level assessments of SB 1159 are needed to determine the impact of DPDPs in California.

Use of pharmacies as a source of sterile syringes increased three-fold in clients using these services between 2004 and 2006, from 5 percent to 16 percent in counties that adopted the SB 1159 legislation, while use of pharmacies in non-adopting LHJs remained static between 7 and 9 percent. Overall prevalence of injection drug use among these clients declined from 2004 to 2007.

Early adopting counties (authorized in 2005) experienced significant increases in IDUs' use of pharmacies as a source of sterile syringes. Additionally, between 30 percent and 47 percent of IDUs in DPDP authorizing counties reported never sharing syringes and in counties that did not authorize OTC sale, never sharing rates were lower, ranging from 22 percent to 32 percent. Amphetamine injectors, Latino and White IDUs were more likely to report relying on pharmacies as a source of syringes than other groups. In summary, there was an increase in the proportion of IDUs who reported using pharmacies to obtain sterile syringes in California since the advent of SB 1159 and pharmacies may be reaching a different subpopulation of IDUs.

Two years after the implementation of SB 1159, substantial differences existed in the implementation of OTC sales in LA and SF. SF pharmacies were more likely to conduct OTC syringe sales and less likely to impose requirements on OTC sales than their LA counterparts. These differences may be explained by a number of factors including the earlier start of DPDP in SF (2005 as compared to 2007 in LA), higher per capita HIV rates in SF as compared to LA, and/or differences in political attitudes and priorities. This study, and others like it, indicates that detailed research on adoption of OTC sales among pharmacies is needed to determine how to improve pharmacy participation in these important public health strategies.

OA also found that within OTC sales approaches, a number of operational barriers are apparent. In LA, the current level of implementation is moderate (<30 percent of pharmacies participate) and the reports of OTC syringe sale refusals suggests that syringe access through pharmacies could be increased. Given that pharmacists' attitudes were related to OTC sale participation levels, one way to increase pharmacy participation might be through educational programs. Other investigators have recommended pharmacists education as one way to increase participation in OTC sales. In fact, at least one study has found that efforts to inform community members and pharmacists about the importance of sterile syringe access appeared to have positive impacts on pharmacy participation in OTC sales in New York (Fuller et al., 2007). Such efforts should be considered in areas where pharmacy participation rates appear low.

As vital as increasing sterile syringe access is to the reduction of HIV risk among IDUs, it is also important that such efforts do not result in unintended negative consequences. In this report, OA documents that OTC syringe sales are not associated with syringe or drug-related trash near participating pharmacies. Other data in this report indicate that needle-stick injuries have been flat or have declined since the advent of DPDPs, bolstering the notion that expanded sterile syringe access has not resulted in community harms.

There has been substantial progress in legal and political support for sterile syringe access over the last 20 years. While there has continued to be research on ways to improve HIV prevention attributed to sterile syringe access there has been limited study of potential negative consequences of such programs. In our evaluation, OA found no association between syringe trash and OTC sales among pharmacies in SF or LA. In addition, because we were able to link actual pharmacy OTC syringe sales to evidence of neighborhood syringe discard, OA is able to look more closely at this association than previous studies.

Our analysis of drug-related crime in California built on previous research that focused on spatial analyses of crime data including research that examined spatial analyses of drug-related crimes in close proximity to SEPs (Marx et al., 2000). OA believes our study is the first to examine global and local clustering of drug-related crime as it relates to OTC syringe sales. Overall, OA found that drug-related crime did not change significantly during 2004 and 2006 and any increases in crime rates were observed far from counties that permit OTC. It appears that clustering of drug related crime is tied to characteristics other than SB 1159 and DPDPs (e.g., population density and sociodemographic factors).

Future Directions for Research and OTC Implementation

Substantial legal and policy changes to prevent HIV and HCV infection among IDUs have been made in the last decade. However, as law and policies are changed to promote infectious disease prevention for IDUs, attention must be paid to the implementation of these policy changes, particularly for OTC syringe sales, where local adoption has been found to be inversely related to local public health need. This study indicates substantial differences in authorization and implementation of local DPDPs across California LHJs. To maximize the impact of syringe access policy change, additional efforts appear needed to increase local acceptability, thus broadening implementation among and within counties. Studies indicate that outreach and educational programs for pharmacists on the need for OTC syringe sales can affect pharmacy participation rates (Weinstein et al., 1998).

Findings and Conclusions

SB 1159 appears to be having the desired effect of augmenting access to sterile syringes as part of a strategy to prevent transmission of HIV and other blood-borne viral infections among IDUs. At the same time, negative outcomes tied to SB 1159 have not been observed. While some parts of the state with high HIV prevalence now allow OTC syringe sales as a result of SB 1159, there are regions that lack legal access to sterile

syringes that have not engaged in the political process necessary to authorize a DPDP. To date, just 17 of the eligible LHJs have implemented local programs, and just four of the hundreds of California cities have taken action to participate in the pilot. Although the number of new LHJs adopting SB 1159 has diminished each year since 2005, those that have adopted it (n=17) are responsible for reporting 70 percent of currently living California HIV/AIDS cases.

Our research finds that counties that authorized OTC sale of syringes without a prescription possess lower syringe sharing levels among IDUs than counties that have not authorized OTC syringe sale. While we cannot attribute lower syringe sharing levels to OTC syringe sales alone (i.e., SEPs also play a large role), such findings are favorable. Cumulative scientific knowledge of the epidemiology of HIV suggests lower syringe sharing levels should result in lower rates of HIV transmission among IDUs over time.

Our research found no evidence of an increase in drug use or crime in California in the state as a whole or in areas that authorized sale of syringes without a prescription. Since implementation of SB 1159, fewer clients presenting for testing for HIV at State-funded testing sites report injecting illegal drugs.

Our research found that voluntarily reported accidental needle-stick injury to law enforcement officers remains rare in the state, and differences pre- and post-implementation of local DPDPs were not statistically significant. Furthermore, our research finds no increase in unsafe discard of syringes since implementation of SB 1159.

The overall fiscal impact of SB 1159 and implementation of local DPDPs on public health departments is relatively low. OTC syringe sales programs, which depend on point of service (i.e., syringe sales) costs to customers, place the largest aggregate expenditures on the consumer and allow for pharmacies to cover their costs and earn profit on sales. Public health department staff time and syringe disposal costs are the primary expenditures that LHJs may need to consider. While these costs are relatively low, with LHJs generally spending less than \$850 per month on disposal, and dedicating one part-time employee to DPDP activities, local planning is required to fit these activities in with competing public health priorities. It is noteworthy that universal authorization of OTC syringe sales in California could reduce such costs by eliminating the need for staff time and resources to support local authorization processes. Enhanced access to sterile syringes can yield substantial savings to the health care system on the local and state level as the average estimated lifetime cost of treating a person infected with HIV is \$195,000 and a liver transplant costs upwards of \$300,000 (Cohen et al., 2005).

Our overall findings are consistent with those of other states that have transitioned, as California has, from a complete prohibition on sale and possession of syringes, to allowing a limited number to be sold to adults.

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Abbreviations

AIDS – acquired immunodeficiency syndrome
AOR – adjusted odds ratio
CDPH – California Department of Public Health
CHRP – California HIV/AIDS Research Project
CI – confidence interval
CIS – Counseling Information System
CSU – California State University
C&T – counseling and testing
DPDP – Disease Prevention Demonstration Project
EAP – Evaluation Advisory Panel
E&P – education and prevention
GIS – geographical information system
HCV – hepatitis C virus
HIV – human immunodeficiency virus
IDUs – injection drug users
IQR – interquartile range
KABs – knowledge, attitudes, and beliefs
KABPs – knowledge, attitudes, beliefs, and preferences
LA – Los Angeles
LHJs – local health jurisdictions
LHOs – local health officers
MSM – men who have sex with men
MSM/IDUs – MSM and inject drugs
NIH – National Institutes of Health
NPSS – National Private Security Survey
OTC – over-the-counter
OA – Office of AIDS
OR – odds ratio
PI – principle investigator
RQs – research questions
SB – Senate bill
SEPs – syringe exchange programs
SF – San Francisco
SPAs – Special Planning Areas
TA – technical assistance
UC – University of California

Appendix 1:

NIH PROPOSAL FOR EVALUATION OF SB 1159 (NOT FUNDED)

PI: Richard Garfein, UC San Diego.

Co-Investigator: Thomas J. Stopka, OA, CDPH.

SPECIFIC AIMS

The purpose of this study is to evaluate the impact of a new California law allowing OTC for reducing risk behaviors among IDUs associated with HIV, HCV, and other blood-borne infections. On January 1, 2005, SB 1159 went into effect permitting California counties and cities to approve a DPDP that makes it legal for registered pharmacies to sell up to ten syringes without a prescription to customers 18 years old and older. Furthermore, the law decriminalizes possession of up to ten syringes obtained from an authorized source, and an unlimited number of syringes containerized for disposal from any source.

Injection drug use is the second most commonly reported source of HIV infection and the primary source of HCV infection in California. However, legally sanctioned syringe access for IDUs is relatively new to California because local governments have only been allowed to authorize SEPs since 2000. Since only 9 percent of California's SEPs provide IDUs with the number of syringes they need, expanding syringe access to include distribution by pharmacies could dramatically decrease needle sharing and further spread of HIV and blood-borne infections.

Prior evaluations done in states passing similar laws (e.g., New York, Washington, Michigan, Connecticut, Rhode Island) reported promising results with few adverse findings. However, these studies used simple before/after designs that are prone to bias. Second generation questions include whether effects can be seen concurrently in areas with early versus delayed program implementation versus no implementation. Studies are also needed to identify components of program success or failure. Given that California's law first requires authorization by local governing bodies followed by registration of willing pharmacists, this dual opt-in process creates a natural experiment through which OA can advance science in two unique ways: 1) by assessing program implementation across communities that opt-in using concurrent controls (i.e., communities that opt-out); and 2) by assessing IDUs' risk behaviors statewide using data collected before and after the law passed, controlling for program implementation factors. Because DPDPs may be established immediately, over time, or not at all, OA can further refine our analyses based on these strata. A novel aspect of the proposed study is the unique opportunity presented to examine the effects of differential program implementation by locality, thereby offering identification of components that are ultimately related to program effectiveness.

Our team of investigators has led several studies on expanded syringe access through pharmacies and SEPs and the epidemiology of HIV, HCV, and other blood-borne infections among IDUs, including molecular studies for distinguishing syringes used by

one or more than one person. OA plans to evaluate the impact of SB 1159 at multiple levels including communities' and pharmacists' willingness to adopt the law, program implementation factors, IDUs behaviors, and adverse affects on the community (e.g., accidental needle sticks, drug abuse, crime, and HIV prevalence). The specific aims of the study are as follows:

1. To identify factors associated with local approval for OTC and establishment (or later closing) of a DPDP among communities. Factors of interest include: population size, drug-related arrests, accidental needle-stick incidents, HIV prevalence, the existence of SEPs, local public health staffing and programmatic priorities, community coalitions, and pharmacists' willingness to participate.
2. To determine whether there is a significant decrease in receptive syringe sharing and syringe re-use in communities with a DPDP compared to those without after controlling for potential confounders (i.e., implementation methods; local public health staffing and programmatic priorities; pharmacists' knowledge, attitudes, and practices; SEP availability and IDUs' syringe acquisition practices).
3. To determine whether syringes collected from IDUs are less likely to show biological evidence of multi-person use (i.e., syringe sharing) in communities with a DPDP compared to those without a DPDP.
4. To describe trends in HIV prevalence, drug treatment admissions, drug related arrests, and needle stick injuries among police and sanitation workers before versus after enactment of SB1159.

To achieve these aims, all study outcomes will be compared between DPDP versus non-DPDP communities statewide. Outcomes from established surveillance systems will also be compared pre- and post-DPDP implementation within participating communities. This study is time-sensitive in that communities have just begun to opt-in. At the time of submission, 9 of the 61 LHJs had approved a DPDP, but few had begun selling syringes. If funded, our findings will be included in a report mandated by law and sent to the Governor and Legislature by January 15, 2010; therefore, this study will directly impact future California policy decisions. Findings will also inform legislatures in 10 states that still have laws preventing pharmacists from selling syringes to IDUs and 22 other states with ambiguous laws. This study provides a rare opportunity to obtain new insights on the impact of expanded syringe access through pharmacies in the nation's most populous and heterogeneous state which can influence public health policy and legislation nationwide.