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Publication Date

2015-10-14

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Supporting policy interventions for injection drug users: The importance of building partnerships between pharmacies and local health jurisdictions

Introduction

Public health policies that increase sterile syringe availability for injection drug users (IDUs) can significantly reduce HIV infection rates if widely and rapidly implemented. The chief mechanisms for increasing sterile syringe availability are pharmacies and syringe exchange programs (SEPs). While SEPs have been extensively researched, studies of community pharmacy access to sterile syringes have not been studied in as much detail despite the fact that numerous states and countries have established such programs and have reported successes in terms of pharmacy acceptance, IDU acceptance, reduction of syringe sharing among IDUs, safer syringe disposal and importantly, reliable access to sterile syringes (Case, Beckett & Jones, 1998; Cooper et al., 2010; Cotton-Oldenburg, Carr, Deboer, Collision, & Novotny, 2001; Deibert et al., 2006; Emmanuelli & Desenclos, 2005; Finkelstein, Tiger, Greenwald, & Mukherjee, 2002; Fuller et al., 2002; Junge et al., 1999; Harbke et al., 2000; Lart & Stimson, 1990; Lewis, Koester & Bush, 2002; Moatti, Vlahov, Feroni, Perrin, & Obadia, 2001; Myer, Cockerill, Millson Rankin & Worthington, 1996; Panda & Sharma, 2006; Quan, Chung, Long & Dondero, 2000; Reich et al., 2002; Rich et al., 2002; Samitca, Huissoud, Jeannin & Dubois-Arber, 2007; Sarang, Rhodes & Platt, 2008; Taussig, Junge, Burris, Jones & Sterk, 2002; Tesoriero, Battles, Klein, Kaufman & Birkhead, 2009; Torre, Lucas & Barros, 2010; Valleroy et al., 1995; Vorobjov et al., 2008; Williams, 2002; Zaller, Jeronimo, Bratbert, Case & Rich, 2010; Zamani et al., 2010).

In California, efforts to implement SEPs and community pharmacy syringe sales were repeatedly defeated until 2000 when provisions for permitting legal SEPs were adopted (Bluthenthal, Heinzerling, Anderson, Flynn & Kral, 2008) and 2005 when pharmacy sale of syringes was permitted under Senate Bill (SB) 1159 (Stopka, Garfein, Ross & Truax, 2007; Rose, Backes, Martinez & McFarland, 2010). California SB 1159 is a statewide law that permits adults 18 and older to purchase up to ten syringes from pharmacies without a prescription and without proof of medical need under the following two preconditions: 1) the public health department in each of the 61 local health jurisdictions (LHJs) must first establish a Disease Prevention Demonstration Project (DPDP) through approval of local policy makers (e.g., board of supervisors), and 2) pharmacies interested in selling syringes must register with the LHJs. The registration process involves the public health department contacting the pharmacy, providing educational materials and then maintaining a list of pharmacies that are willing to sell syringes.

Pharmacy syringe sales are critical since California has the 2nd highest rate of persons living with HIV/AIDS in the United States at 160,760 cumulative cases of AIDS and 43,501 cases of HIV at the end of June 2011. Among these, 18.2% (37,058) are IDUs including men who have sex with men (MSM) who also inject drugs (California Department of Public Health (CDPH), 2012). Injection drug use is also considered the primary risk factor for acquiring or transmitting hepatitis C virus (HCV), and an estimated 2% of Californians are infected with HCV (Armstrong, Simard, McQuillan, Kuhnert & Alter, 2006). The hope of SB 1159 is that by increasing sterile syringe availability through pharmacies, injection-related risk for HIV and HCV will be reduced. Ideally, LHJs with significant burden of HIV and HCV among IDU and especially LHJs without established SEPs will embrace the opportunity to implement a pharmacy

syringe sales policy because it is ostensibly less controversial, low or no cost, and it ensures wider distribution and more hours of availability.

However, this wider geographical and temporal availability only matters if LHJs and pharmacists participate. In San Francisco City and County, for example, the LHJ created a coalition of key stakeholders, including district pharmacy managers, SEP coordinators, environmental health professionals and local policy makers to fully implement their DPDP in less than 4 months early in 2005 (Rose & Raymond, 2010). Levels of pharmacy participation have been relatively high in San Francisco (Cooper et al., 2010). Other areas with substantial HIV/AIDS cases among IDUs such as Alameda County and 5 additional LHJs, also implemented a DPDP shortly after the law became effective (Rose et al., 2010; Backes & Rose, 2010). Unfortunately for IDUs in most areas of California, the ideal scenario described above was not realized and the experience of these early adopters was not replicated (Bluthenthal & Kral, 2010). The constraints of the law failed to address HIV prevention for IDU precisely because the dual opt in process (i.e., gaining political approval for a DPDP and then recruiting and registering willing pharmacies) creates barriers in LHJs where assumptions of pharmacy disinterest or perceptions of community opposition, coupled with inadequate public health infrastructure and competing priorities override the syringe availability needs of IDUs (Rose et al., 2010; Backes & Rose, 2010; Garfein et al., 2010).

The inefficiency of this approach could have been predicted. The LHJ-level dual opt-in process was also used when SEPs were legalized in California in 2000. This approach was found to limit the initiation and expansion of SEPs, particularly in high-need areas (Bluthenthal, Heinzerling, Anderson, Flynn & Kral, 2010). From studies conducted on the SB 1159 law, a number of similar problems have emerged. For instance, as of 2012, only 20 of the 61 LHJs in

California have established a DPDP (CDPH, 2012), and in approved LHJs, less than 20% of pharmacies have been registered (Garfein et al., 2010). In surveys of pharmacies in Los Angeles and San Francisco, a 2007 study found that only 42% reported selling syringes without a prescription and the majority required proof of medical condition before providing syringes (Cooper et al., 2010). A majority also reported refusing to sell syringes to customers that they suspected of being an IDU.

In the following, we examine another source of implementation challenge – the failure of 4 early adopter LHJs (Humboldt, San Luis Obispo, San Mateo, Santa Cruz) to identify, recruit and register interested pharmacies – after gaining local political consent to establish a DPDP. Prior to implementing the study, 3 of these LHJs advised us that pharmacies were unwilling to register in a DPDP. To test this assumption, we directly assessed pharmacy willingness to sell non-prescription syringes, and included an assessment of key policy makers’ (i.e., elected and non-elected government officials) opinions about barriers to implementation of pharmacy syringe sales in their LHJs.

Methods

Pharmacies.

To collect information on pharmacist attitudes towards syringe sales we sent a self-administered survey to all pharmacies in the 4 LHJs. Pharmacies were identified based on the California Pharmacy Board license file and Internet searches which yielded an updated list of 280 pharmacies. A 51-item self-administered survey was initially mailed to the pharmacy manager in 2008. Unique identifiers, consisting of LHJ code followed by a consecutive numbering system (i.e., Humboldt 1: 1-42; San Mateo 2: 43-121; Santa Cruz 3: 122-231; San

Luis Obispo 4: 232-280) were used to maintain the confidentiality of the pharmacy respondent. The survey asked about non-prescription syringe sales, willingness to sell syringes to IDU; syringe disposal practices; knowledge of the law; attitudes about and experiences with IDU; barriers to participation, and the pharmacy's information or training needs from the LHJ. Survey items were similar to those used by Cooper and colleagues in their California-based pharmacy study (Cooper et al., 2010).

After 4 weeks, we sent a follow up post card reminder to non-responders. We re-examined the database in light of a large number of returned post cards that indicated an incorrect address and removed these and other pharmacies that were located in surgical or other specialty care centers (n=70) since these pharmacies were not open to the public and it was considered unlikely that IDUs would request syringes from them. After 12 weeks and a consistently poor response to the mailed survey, we designed an abbreviated version (28 items) of the survey that contained general descriptive variables which addressed the key research questions (i.e., willingness of pharmacies to sell syringes and enroll in a DPDP and potential barriers to syringe sales). Due to study resource limitations, we prioritized chain and independent pharmacies only (n=138) for the abbreviated telephone survey that was conducted over a one month period in late 2009. We used 210 eligible pharmacies to calculate the combined response rate for the 4 LHJs (123 total responses/210; 59%). Pharmacies that declined to participate (17% of those contacted by phone) cited three primary reasons: store policy prohibited participation, they were too busy, or were not interested. The majority of refusals resulted from 2 of the LHJs that had alerted us to pharmacy disinterest.

Policy Makers.

In each LHJ, the maximum pool of officials familiar with the provisions of the law is approximately 10. These include: local health officer, HIV/AIDS director, 5 elected county-level supervisors, and an elected county sheriff. We constructed a purposeful sample of between 2 and 4 elected and appointed government officials in the 4 LHJs for brief qualitative interviews that took place in 2009 and early 2010. We interviewed the HIV/AIDS director or the health officer in each LHJ (in Santa Cruz and San Mateo, both were interviewed). These individuals advised us which elected officials to interview, suggesting a maximum of 2 board members (one in favor and one opposed to SB 1159). No LHJ recommended that we interview the county sheriff. In one LHJ, we were asked to interview the county counsel who was responsible for an interpretation of SB 1159 such that only the unincorporated areas outside of the city limits of the LHJ would be covered, thus requiring the LHJ to gain approval from four cities within the county. No policy maker refused the interview, although in San Luis Obispo, only the HIV/AIDS program director was interviewed. The suggested board members in that LHJ did not respond to the request for interview within the data collection timeframe. Extensive field notes were taken during each interview and immediately written up after the interviews. We e-mailed preliminary data from the pharmacy survey to policy makers during confirmation of the interview including the number/per cent of pharmacists who indicated the health department had contacted them, whether or not pharmacists had sold syringes within the past 12 months, and the number of responses from each LHJ. Policy makers were asked about the status of the DPDP, whether there were continuing implementation barriers 3-4 years after the DPDP had been approved, and recommendations for the future of SB 1159. Nine telephone or personal interviews were conducted for an average interview length of 45 minutes, with the exception of the county counsel interview which lasted less than 10 minutes.

Human subjects

Human subjects review and approval was provided by the Institutional Review Committee of Public Health Foundation Enterprises, Inc.

Data Analysis

We used SPSS 16.0 (Chicago, IL) to compute frequencies, proportions, and measures of central tendency for the pharmacy surveys, and used Pearson Chi-square analyses to measure associations at the $p < .05$ level between pharmacists' attitudes and perceptions about IDU behavior and syringe sales, and pharmacy willingness to sell syringes without a prescription. Pharmacies were classified as chain, independent or medical/community health clinic-based. We first examined the pharmacy data in aggregate then systematically examined each LHJ's response to the research questions. To preserve the richness of the entire data set, we analyzed the first 50 surveys from the mailed survey, and then examined selected core variables that were consistent between the initial and abbreviated survey versions. Difference in analysis is noted where applicable. For the qualitative interviews, we reviewed the summary notes, highlighted relevant statements, and then created thematic categories using methods described in Miles & Huberman (1994).

Results

Pharmacies.

Data were available from 123 surveys (50 self-administered; 73 telephone) with pharmacies located in the 4 LHJs. Mean (M) length of time as a pharmacist was 18.6 years; 72% of respondents were pharmacy managers. Chain/retail pharmacies represented 64% of

respondent pharmacies, independent, 29% and medical/community health-center based 7%. Excluding missing or “don’t know” responses, 72% were willing to sell syringes and 61% indicated they had sold syringes without a prescription in the last 12 months ($p < .05$). Fifty-four percent (66/123) saw a need for pharmacy syringe sales in their LHJs. Table 1 provides descriptive characteristics and responses to the key research questions stratified by LHJ.

--Table 1 about here--

We examined associations between willingness to sell syringes and several variables associated with attitudes about IDU and pharmacy syringe sales (Table 2). Pharmacists who had never or rarely refused to sell syringes without a prescription reported willingness to sell syringes to IDU (44/48; $p < .01$). Pharmacists “agreed” that IDU would continue to share syringes even with increased access (28/73; $p < .05$) and “disagreed” that increased access would result in increased unsafe syringe discard, although the difference was not statistically significant (33/65; $p = .118$)

--Table 2 about here--

Needs of Pharmacists Related to Pharmacy Syringe Sales

Pharmacists cited specific needs for information associated with syringe sales under SB 1159. Seventy-five percent identified recordkeeping requirements; 70%, information on LHJ policies, and 63%, assistance with developing store policies. These questions were asked only on the initial self-administered survey and were reported by just under two-thirds (64%) of the respondent pool of 50. In comparison, the total sample of 123 provided information on what would make it easier to participate: 70%, a simple registration process; 67%, free educational

materials to distribute to patients; 67%, limited recordkeeping requirements; 60%, easy communication with the LHJ, and 60%, not having to accept used syringes.

Barriers to Participation

Greater than 25% of respondents cited several barriers to syringe sales. The most frequently cited barriers were: “*don’t want to be seen as a supplier of syringes to IDU*” (38%); “*don’t agree that we should sell syringes*” (38%); “*managing difficult patients*” (26%), and barriers associated with “*recordkeeping*” (26%).

We also examined factors that might prevent pharmacies from participating among those willing to sell syringes. Pharmacies were instructed to check one of two choices: “no barriers” or “the LHJ has not contacted pharmacy to participate.” These two choices resulted in significant differences ($p < 0.05$). Pharmacists largely disagreed that other factors, such as the potential to lose business or the time involved to implement a program were barriers to participation. Pharmacists were not concerned about an increase in crime due to syringe sales. Thirty percent perceived the level of crime in the pharmacy’s neighborhood was moderate to very high; 56% perceived that the level of drug activity was moderate to very high and yet 79% thought the level of crime would “stay the same” with full implementation of the law. Consistent with data presented earlier, pharmacies were willing to sell syringes; however, one of the most significant barriers to participation was their perception of “no contact” from their local LHJs.

Syringe Disposal/Syringe Discard

We asked about current practices and proposed approaches for syringe disposal. Preferences for syringe disposal options were clearly related to not accepting used syringes (Table 1). One additional barrier to enrolling in a DPDP was related to the potential for unsafe

syringe discard: 83% were concerned about IDU leaving used syringes in or around the pharmacy. However, when assessing the difference between willingness to sell syringes and concern about unsafe syringe discard, the results were not statistically significant ($p = .20$). This finding is consistent with a separate variable that measured the perception of increased access to syringes leading to unsafe discard (Table 2).

Policy Makers' Reactions, Opinions and Identified Implementation Problems

We identified three consistent overarching themes from the interviews with all of the policy makers: 1) Surprise at the pharmacy survey results showing that a large number of pharmacist were willing to sell syringes, 2) a belief that pharmacy syringe sales is a public health benefit, and 3) an obvious lack of responsibility around implementation. In one LHJ, an elected official said, *"I'm not a fan of handing people needles, but if they [the health department] can demonstrate through cold hard facts that it's a benefit to society as a whole, and they would do a good job, I'm all for it."* All respondents indicated that the health of IDUs was a concern in the LHJ. In one LHJ, the county counsel said, *"I'm all for the program and see that it could be expanded, but that's not the policy question; policy is to be set by the health department."* In one LHJ, a board member said, *"I thought the health department had already established a program."*

Implementation problems were identified in 5 of the policy maker interviews. In the LHJ with a restrictive interpretation of the law (i.e., wherein the law extended only to areas outside the city limits), advocacy from the HIV/AIDS program director and the health officer, failed to convince the county counsel to reconsider how the interpretation affected implementation by the LHJ. In another LHJ, the health officials indicated that inadequate staffing prevented them from

moving forward with implementation. In one LHJ, health department officials received no registration forms from pharmacies in response to an invitation letter. This non-response was interpreted as no interest. In another LHJ, the health department conducted outreach via regional pharmacy association meetings and was advised that pharmacies were not interested in selling syringes under the law. In this LHJ, syringe disposal issues compounded the ability to implement a DPDP. A health official said, *“Syringe disposal is costly and ultimately we have to pay for it.”*

Discussion

We were interested in LHJs that failed to implement pharmacy syringe sales even though authorization of the law had been established for several years. We knew from a previous study (Rose et al., 2010; Backes & Rose, 2010) and a more extensive LHJ survey (Stopka et al., 2007; Garfein et al., 2010) that time constraints and limited public health infrastructure prohibited some LHJs from pursuing implementation. We were also advised by 3 of the 4 LHJs in this study that pharmacies in their LHJs were unwilling to enroll in the DPDP. In this study, we determined that pharmacists were willing to participate in a local DPDP; 74% indicated that they were not asked by the LHJ. We believe that many pharmacists mistook the fact that the LHJs had gained political approval for a DPDP to mean they were permitted to sell syringes under SB 1159. Two of the 4 LHJs implemented a DPDP upon receiving preliminary data from our study. We argue that more pharmacies throughout California would register to sell syringes under SB 1159 if LHJs reached out to them to determine their interest in participating in a DPDP.

Study limitations include a moderate response rate, the possibility that pharmacists responded in a socially desirable manner, and a limited number of qualitative policy-maker interviews. A recently published study of two California LHJs, however, reported pharmacy

attitudes very similar to what we found in our survey (Cooper et al., 2010). The opinions reflected by the small number of policy makers cannot be construed as representative of the total pool of potential policy makers (approximately 40). It is possible that only favorable attitudes were expressed during policymaker interviews because we provided preliminary data prior to the interview. We believe that potential bias was minimized since 2 of the board members interviewed were recently elected, and were therefore unaware of any previous barriers to implementation of the law, and 2 were former board members who may have had little incentive to bias their responses. Had we interviewed additional board members and/or the county sheriff, we may have discovered oppositional perspectives. Despite these limitations, we believe that these perspectives and opinions are useful to our understanding of the underlying reasons for failure to implement a DPDP.

This study has broad implications for public health policy related to injection drug use especially where the burden of HIV is high and where legal restrictions on syringe availability exist. LHJs in CA lost momentum and interest once the initial urgency stimulated by the 2005 law had passed. Then in 2009, state fiscal cutbacks created considerable deficits in HIV prevention budgets further inhibiting a public health response to the law. Among the 41 LHJs without a DPDP, the majority have no plans, no funding and no political will to engage pharmacies or policy making entities to renew an interest in pharmacy syringe sales (Garfein et al., 2010). Even with new legislation passed in 2011 (Senate Bill 41) which permits pharmacies to sell syringes at their own discretion without registering with the LHJ, there remains a need to educate pharmacies about the need for syringe sales especially in LHJs where there are no SEPs. In light of this new law, we believe an intervention to mobilize pharmacists around selling syringes could be beneficial, and additional observational studies among the LHJs that have

adopted a pharmacy syringe sales policy could demonstrate the efficacy of this policy intervention statewide. Failure to implement injection drug use policy results in unequal distribution of HIV prevention interventions and fosters continuing health disparities among IDU, even though significant evidence exists to support the efficacy of syringe availability programs (Bluthenthal et al., 2001; Bruneau et al., 2011; Centers for Disease Control and Prevention, 2012; Deibert et al., 2006; Fisher, Fenaughty, Cagle & Wells, 2003); Gibson et al., 2002; Kerr et al. 2005; Kral, Anderson, Flynn & Bluthenthal, 2004; MacDonald, Law, Kaldor, Hales & Dore, 2003; Pouget et al., 2005; Rich et al., 2007; Riley, Kral, Stopka, Garfein, Reuckhaus & Bluthenthal, 2010; Rudolph et al., 2010). This study underscores the need to define an empirical science for HIV policy implementation.