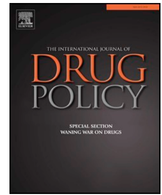
International Journal of Drug Policy 70 (2019) 22–32

Contents lists available at ScienceDirect

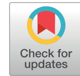
International Journal of Drug Policy

journal homepage: www.elsevier.com/locate/drugpo



Research Paper

Syringe services programs: An examination of legal, policy, and funding barriers in the midst of the evolving opioid crisis in the U.S.



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ARTICLE INFO

Keywords:
Prescription opioid injection
Syringe services program
Injection drug abuse
Heroin injection
Methamphetamine injection
Syringe exchange

ABSTRACT

Background: Syringe Services Programs (SSPs) have been proposed as a key intervention to address increasing rates of opioid injection, overdose, and infectious disease transmission in the U.S. In recent years, multiple states and jurisdictions have enacted laws and policies to enable implementation of SSPs. These statutory and regulatory changes have resulted in the expansion of SSPs in a short period of time under a patchwork of different regulations and policies. Understanding how SSPs are responding to this evolving policy environment in the midst of a worsening opioid crisis can inform the development of strategies to maximize the role SSPs play in the response to the opioid crisis.
Methods: In-depth, semi-structured and audio-recorded interviews were conducted with 25 individuals running 23 SSPs in the U.S. A thematic content analysis was employed to identify and group themes across the domains of interest based on inductive and deductive coding of verbatim interview transcripts.
Results: Despite progress in expanding the number of SSPs in recent years, programs described encountering legal, policy, funding, and community barriers that are limiting the scope, scale, and reach of SSPs. To address these barriers, programs are employing multiple strategies to educate about and advocate for SSPs, engage policymakers and communities, combat pervasive stigma, strengthen funding, and reach at-risk populations.
Conclusion: This qualitative study of a geographically diverse sample of SSPs provides key insights into the legal and policy barriers, funding challenges, and contextual factors impacting SSPs and the strategies programs are pursuing to counter these barriers. Coupling these strategies with policy changes that address the underlying legal and financial barriers and advancing efforts to combat stigma around drug use and addiction stand to substantially expand the role of SSPs as part of the public health response to the opioid crisis in the U.S.

Introduction

The United States is in the midst of a decades-long crisis of prescription and illicit opioid misuse, addiction, and overdose (Jones, Einstein, & Compton, 2018; SAMHSA, 2017). Coincident with the increase in opioid misuse and addiction are rising rates of opioid injection and transmission of infectious diseases such as hepatitis C virus (HCV) and endocarditis (Jones, Christensen, & Gladden, 2017; Jones, 2018; Ronan & Herzig, 2016; Suryaprasad et al., 2014; Zibbell et al., 2018). The 2015 outbreak of more than 180 HIV cases in Scott County, Indiana, associated with injection of the prescription opioid oxymorphone, brought national attention to the intersection of the opioid crisis, increasing opioid injection, and infectious disease transmission (Peters et al., 2016).

In addition to focusing attention on the infectious disease risks associated with prescription opioid injection, the Scott County, Indiana outbreak uncovered a population of people who were injecting drugs that did not have access to interventions such as Syringe Services Programs (SSPs) – evidence-based programs that provide sterile injection equipment and comprehensive infectious disease, substance use, and overdose prevention and treatment services – that can reduce injection-related harms. Further, research published in late 2016 identified hundreds of additional counties in the U.S. that are vulnerable to the rapid dissemination of HIV or HCV due to risky injection drug use (Van Handel et al., 2016). Common among these counties are high rates of opioid use and related mortality and an absence of SSPs, with 93% of the vulnerable counties having no SSP (AMFAR, 2017).

Despite the evidence demonstrating their effectiveness, SSPs have been limited in number, scale, and scope in the U.S. due to persistent legal, policy, political, social, and funding barriers (Bramson et al., 2015; Des Jarlais, Kerr, Carrieri, Feelemyer, & Arasteh, 2016; Lurie & Drucker, 1997; Weinmeyer, 2016). In the U.S., the first SSPs were implemented in the late 1980s in a small number of large cities; however, a lack of political support and opposition from substance use treatment

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https://doi.org/10.1016/j.drugpo.2019.04.006

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providers, law enforcement, and communities substantially limited implementation of SSPs in most areas of the U.S. (Clark et al., 2016; Hurley, Jolley, & Kaldor, 1997; Lurie & Drucker, 1997). Further, in 1988, Congress prohibited the use of federal funds to support SSPs due to concerns this would signal government endorsement of drug use, increase use and injection, and contradict law enforcement efforts (Lurie & Drucker, 1997; Clark et al., 2016). This lack of political support and explicit stigma towards drug use and people who inject drugs led to the implementation of an inefficient and uneven mix of laws, regulations and policies related to SSPs across the country. In many states, laws were enacted to criminalize possession of syringes, needles, and other injection equipment, as well as directly outlaw the implementation of SSPs (Bramson et al., 2015; Lurie & Drucker, 1997; Clark et al., 2016; Weinmeyer, 2016).

In recent years, recognizing the urgent need to address increasing rates of opioid injection, overdose, and infectious disease transmission, and spurred by the 2015 HIV outbreak in Indiana, a number of states and local jurisdictions have enacted laws or policies to enable implementation or expansion of SSPs (Ohio, 2015; Kentucky, 2015; Indiana, 2015; City of Huntington, WV, 2016). In addition, in December 2015, the U.S. Congress partially lifted the ban on Federal funds to support certain SSP services such as HIV testing and naloxone for overdose reversal, once jurisdictions have provided evidence to the Centers for Disease Control and Prevention (CDC) that they are experiencing or are at risk for significant increases in hepatitis infections or an HIV outbreak due to injection drug use. However, the ban on using Federal funds to purchase syringes or needles remained (U.S. Congress, 2015).

These statutory and regulatory changes at the state and Federal level have resulted in an increase in the number of SSPs in a relatively short period of time under a variety of state and local regulations and policies. These policy changes, along with a growing population of people injecting opioids and other drugs (Jones, 2018) and the rapid proliferation of highly potent synthetic opioids such as illicit fentanyl that are fueling a sharp increase in opioid overdoses (Jones et al., 2018), create a pressing need to understand how SSPs are responding to the evolving opioid crisis and policy environment. The aim of this study, using an applied qualitative approach, is to describe the experiences of SSPs as they navigate the evolving policy environment and to identify strategies SSPs are pursuing to maximize the role they can play in response to the opioid crisis in the U.S.

Methods

Participant recruitment

Between December 2017 and April 2018, in-depth, semi-structured interviews were conducted with individuals running SSPs (for the purpose of this study termed SSP program administrators). A purposive sample of SSP program administrators using maximum variation sampling was selected to capture a full range of perspectives from: 1) new SSPs (defined as in operation for 36 months or less), as well as established SSPs; 2) urban and rural SSPs; 3) SSPs housed in health departments and those not affiliated with a health department; and 4) SSPs from the four U.S. census regions. A targeted, purposive sample of potential SSP participants was recruited from a list of potential respondents using the list of known SSPs maintained by the North American Syringe Exchange Network (NASEN, 2017). Direct email correspondence with SSP program administrators was the sole method of recruitment for this study. Recruitment and qualitative interviews continued until thematic saturation occurred. A total of 25 administrators representing 23 SSPs (9.0% of the 268 listed SSPs at the time of study recruitment) participated in the study.

Interview procedures

The interview guide was developed based on a review of the scientific literature and discussions with three key thought leaders involved in national and state-level harm reduction policy, SSP-related research, and SSP best practices and implementation of SSPs at the state and local level. The interview guide was designed to elicit responses in the following domains: 1) changing legal/policy environment; 2) funding sources for programs; 3) population served and how it has changed; 4) program operations and services provided; 5) affiliations and interactions with state or local government; 6) interactions with law enforcement; 7) collaborations with the public health and substance abuse communities; and 8) engagement with state or local opioid misuse prevention task forces (see Appendix for interview guide).

All interviews were conducted via telephone and lasted approximately 60 min. The interview format was flexible, allowing the interviewer and interviewees to introduce or elaborate on different topics relevant to the research domains. Each interview was audio-recorded for accuracy and ease of transcription. All audio-recordings were transcribed verbatim into standard word-processing files. All transcriptions were compared to the audio-recording to ensure accuracy. These files were then uploaded into NVivo software (NVivo v12, QSR International, Burlington, MA) for qualitative analysis. Verbal informed consent was obtained from participants before each interview. This study was exempted from Institutional Review Board review by the George Washington University Office of Human Research

Data analysis

A thematic content analysis, using both inductive and deductive coding, was conducted to identify and group key themes across the domains of interest and to identify and summarize similarities and differences across SSPs. The first step in the coding process involved familiarization with the interviews by reading and rereading each of the transcripts and listening to the audio-recordings to identify codes consistent with the interview guide domains as well as to identify emerging codes not explicitly captured by the guide domains. This was followed with line-by-line coding of the text. The coding process was iterative as new interviews were conducted and reviewed, leading to refinement of the initial codes and coding framework. Once all transcripts were coded, the codes were reviewed, refined, grouped, and placed into themes. The matrices and frequency query functions in NVivo software were used to facilitate theme identification and to identify connections of codes and themes across different SSPs characteristics. During this process, a second coder analyzed a 30% sample of interviews that included new rural SSPs, established rural SSPs, new urban SSPs, and established urban SSPs to validate and refine codes and themes. Once themes were finalized, representative quotes were identified and extracted.

Results

Characteristics of SSPs

A total of 23 SSPs were included in the study; five were in the Northeast, eight in the Midwest, eight in the South, and two in the West; 11 were in rural areas and 12 in urban areas; 11 were new programs and 12 established programs (Table 1). The mean and median time of SSP operation was 7.7 years and 3 years, respectively, with a range of 1 month to 29 years. Among SSPs, 14 were operating in states where SSPs were legal, 7 in states that locally permitted SSPs or had no specific law prohibiting SSPs, and 2 in states where SSPs were illegal. Ten SSPs, mostly new programs, were part of the health department. The number of days an SSP was open and the hours they operated, on average, per day per site varied across programs. A large minority of programs (43.5%) were open 1 day per week and 40.9% were open for

Table 1
Characteristics of Syringe Services Programs Participating in Qualitative Interviews.

Program	Census Region	Rural-Urban Status	Program Type	Time in Operation (in months)	Legal Status of SSPs[a]	Component of Health Department	Number of Fixed Sites	Avg. Number of Days Open Per Week Per Site	Avg. Number of Open Hours Per Day Per Site	Mobile Syringe Services	Medicaid Expansion State
SSP1	Midwest	Urban	Established	36	Legal at state level	No	3	1	3	Yes	Yes
SSP2	Northeast	Urban	Established	240	Legal at state level	No	4	5	8	Yes	Yes
SSP3	South	Rural	New	30	Locally permitted or no law exists addressing SSPs	Yes	1	1	5	No	Yes
SSP4	West	Rural	Established	54	Legal at state level	No	1	5	3.8	No	Yes
SSP5	Midwest	Rural	New	36	Legal at state level	Yes	1	5	3.6	Yes	Yes
SSP6	Midwest	Rural	Established	60	Legal at state level	Yes	1	1	3	No	Yes
SSP7	Midwest	Rural	New	1	Legal at state level	Yes	1	5	8	No	Yes
SSP8	West	Urban	Established	348	Locally permitted or no law exists addressing SSPs	No	2	3.5	4.4	No	Yes
SSP9	South	Rural	New	6	Locally permitted or no law exists addressing SSPs	Yes	1	1	2	No	Yes
SSP10	Midwest	Urban	Established	216	Locally permitted or no law exists addressing SSPs	No	2	3.5	6.3	Yes	Yes
SSP11	Northeast	Urban	Established	240	Legal at state level	Yes	1	5	7.5	No	No
SSP12	South	Urban	Established	48	Legal at state level	No	1	5	8	Yes	No
SSP13	Midwest	Rural	Established	60	Locally permitted or no law exists addressing SSPs[b]	No	1	2	3	No	Yes
SSP14	Northeast	Rural	Established	192	Legal at state level	No	3	1	3.7	Yes	Yes
SSP15	Midwest	Urban	New	18	Legal at state level	Yes	1	1	4	No	Yes
SSP16	South	Rural	New	18	Legal at state level	No	1	6	5.2	Yes	No
SSP17	Northeast	Urban	Established	276	Locally permitted or no law exists addressing SSPs	No	3	1	2.3	No	Yes
SSP18	South	Urban	New	12	Illegal	No	1	1	2	No	No
SSP19	Midwest	Urban	New	18	Illegal	No	3	3	[d]	No	Yes
SSP20	Northeast	Rural	Established	144	Legal at state level	No	2	1.5	2	No	Yes
SSP21	South	Urban	New	30	Legal at state level	Yes	1[c]	6	4.3	No	Yes
SSP22	South	Urban	New	27	Locally permitted or no law exists addressing SSPs	Yes	1	1	2	No	Yes
SSP23	South	Rural	New	21	Legal at state level	Yes	1	1	1	No	Yes

[a] Legal status at time of interview.
[b] Program operating underground without any local legal protection.
[c] Program has 4 additional outreach locations.
[d] Varies given illegal status of program.

Table 2
Domains and Themes Identified in Qualitative Interviews.

Domain	Themes
Legal and Policy Barriers	• SSPs are operating in a fragile legal environment • Community resistance as a non-legal barrier • Pervasive stigma fuels legal and policy barriers
Funding Challenges	• SSPs are currently operating with a patchwork of funding • The Federal funding ban is preventing SSP implementation and growth • Perceptions of funding opportunities vary across programs • Stigma perpetuates SSP funding challenges
Changing Drug Use Trends and Illicit Drug Supply	• The expanding number of people injecting drugs and seeking services at SSPs • The emergence of illicit fentanyl has amplified the challenges faced by SSPs • A resurgence of methamphetamine is further challenging SSPs
Strategies SSPs are Pursuing to Overcome Barriers and Challenges	• Advocacy and engagement in the policy process to remove legal and policy barriers • Capitalizing on all potential funding sources • Expanding the reach of SSPs

3 h or less on the days the program was open. Approximately 30% of programs offered mobile syringe services. Finally, all but four programs were located in states that had expanded Medicaid at the time of the study interview.

The key informant interviews covered a broad range of topics across the eight domains included in the interview guide; however, the most salient themes related to how SSPs are responding to the evolving opioid crisis and rapidly changing policy environment revolved around four domains: 1) legal and policy barriers; 2) funding challenges; 3) changing drug use trends and illicit drug supply, and 4) strategies SSPs are pursuing to overcome barriers and challenges (Table 2).

Legal and policy barriers

SSPs are operating in a fragile legal environment

SSP program administrators across nearly all programs described a number of legal and policy barriers that resulted in SSPs operating in a fragile legal environment and constrained their ability to operate SSPs to maximal impact. Although there were differences in how these barriers were operationalized across jurisdictions, programs described them as significantly limiting their ability to establish new SSPs and expand existing programs, creating uncertainty about the long-term viability of SSPs, and constraining the ability of SSPs to reach at-risk populations. In contrast, when laws and policies were supportive, SSPs flourished.

For two programs, the fundamental legal barrier was that SSPs were explicitly prohibited by state law. These programs were operating either completely underground or with implicit agreement that local law enforcement would not take action against them. An additional SSP operating in a state where local jurisdictions could sanction SSPs was operating underground due to a lack of approval of SSPs in the local area. These prohibitions created the most fragile legal environment and uncertainty among the SSPs interviewed.

> "We're seeing entire communities that need our services; we're only in these three communities [due to an implicit agreement with local law enforcement not to pursue legal action], but it would be really ideal to be able to operate in the western parts of the state as well." [SSP 19]

For other programs, the legal status of SSPs was ambiguous – either state law did not expressly prohibit or authorize SSPs or the determination was the responsibility of the local jurisdiction.

> "In our state, SSPs have been neither prohibited nor allowed, explicitly allowed…If I had actual legal authorization, explicit legal authorization at the state level that would really help the program…The prosecuting attorney assured us that what we were doing was not prohibited by law. That's not the way I read the law, and I am certain that that's an interpretation that could change with an administrative change. That makes the service fragile. I would like explicit authorizing language." [SSP 3]

Among the programs where the authority lies with the local government, SSPs detailed convoluted regulatory hurdles that were required before SSPs could be implemented. These hurdles were seen as significant barriers for implementation and expansion.

> "We recognize we should be in more places than we are, but we are just really limited by the city, and by neighborhoods who don't want to have needle exchanges in them. In order for us to set up a syringe exchange site, we have to get community buy in from that neighborhood. Then we have to take that to the board of health, who will approve it, and then we have to take that board of health approval to the city council. Then, they approve it, and then we have to take it back to the board of health one more time. We have to get city council member approval, and we have to get community approval. That is a huge obstacle for us. It just feels really sad knowing that neighborhoods that are across the bridge, that are like an hour bus ride from one of our syringe exchange sites, are seeing three times the amount of fatal overdoses than what we are seeing where our syringe exchange is. That's just hard because that, obviously, says that we're not in the places where we need to be." [SSP 17]

Even in states where the law explicitly authorized SSPs, how the law was operationalized and the policy and regulatory requirements to open, maintain, and expand SSPs often were not conducive to easily establishing SSPs. For some states, local elected officials such as county commissioners or city council members or the board of health had to approve the SSP.

> "They [state legislature] revised the law. Now it is harder to establish an SSP. We only have 7% of the counties in our state [with SSPs]. That's because they made it more difficult now. Thankfully, we have a year under our belt. The county commissioners [who have to vote to approve or renew the SSP every 2 years] saw that it worked, so for us it was okay, but for a lot of other counties, it's going to be really hard for them now to establish [an SSP]…That's unfortunate because we're in a crisis." [SSP 15]

In some states, local elected officials do not play a formal role in approving SSPs; however, regulatory requirements issued by state entities such as the health department have to be met before an SSP can be implemented.

> "Since we are part of public health we did not have the challenges that people will have if they're not public health. That's because we already have, you have to have [per state guidelines] a medical director, so we already have a medical director. You have to have biohazard waste disposal services, we already have that. For us, the

[required state plan to establish an SSP] was easier because we didn't have to jump through as many hoops as somebody that is not part of public health [will have to do]." [SSP 8]

In addition to laws or policies enabling the distribution of sterile syringes and needles, the majority of programs raised the need for broader drug paraphernalia laws that cover more than sterile syringes and needles, as used syringes with drug residue on them and other injection equipment were often not covered or exempted under current statutes. This resulted in individuals not returning syringes to SSPs, not disposing of them properly in the community, and reluctance to engage in the program for fear of arrest.

"Disposal has proven to be one of our biggest challenges. What that legislation [new drug paraphernalia law] did was protect syringe services providers, so staff, volunteers, outreach workers, that kind of thing, from prosecution. But our participants can still get in legal trouble for having a used syringe on their person. There is a lot of resistance still to bringing back syringes for safe disposal." [SSP 4]

Although the vast majority of SSPs described a complex patchwork of legal and policy barriers that had to be navigated when establishing and operating SSPs, two states described positive impacts that resulted after their state laws were modified to either explicitly legalize SSPs or to address other legal barriers like drug residue on syringes and drug paraphernalia laws.

"Our state [several years ago] decriminalized drug residue on the ends of needles if you're returning your needles to a syringe exchange on the day of the exchange. That just happened in our neighboring state this year. This is really the first year where the laws are actually conducive to opening syringe exchange in that state. Now exchange programs are popping up." [SSP 20]

Community resistance as a non-legal barrier

Programs acknowledged that resistance from communities and elected officials was often a barrier to establishing or expanding SSPs, even when the legal environment was supportive.

"A lot of the challenge is the community itself...We have to convince, every year, [county] commissioners, and we're very worried about this upcoming renewal this year, whether or not we will be getting [the SSP] renewed again. Because there is so much critical publicity and people saying, 'If you're up for re-election, and you are supporting a needle exchange I'm not going to vote for you.' We've got politicians that want to keep their jobs…We know what we're doing is working, it's just convincing everyone to continue to let us work." [SSP 5]

The power of community resistance was further captured by several programs that stated that even though they could implement an SSP without approval by local elected officials, they would not pursue opening an SSP if the community was not supportive. This resulted in a delay and in some cases a missed opportunity to implement an SSP, even in communities where there was a clear need for services.

"We're looking to open new syringe exchanges in the state. It's hard though because the boards of the towns are kind of blocking it. Although, technically you can go ahead and do it anyway, I would prefer to get a good community advisory group and go from there with the support of the community." [SSP 20]

Pervasive stigma fuels legal and policy barriers

Programs, both new and established and across geographic areas, stated that the underlying stigma of addiction and drug use, and the notion that SSPs condone or increase drug use, was the most significant obstacle to overcoming legal and policy barriers. Programs characterized stigma as existing at all levels in the community and that combating stigma was a substantial challenge.

"A lot of our folks in the community, especially our elected officials, they'll have that mentality that this is a choice, that this is not a disease, that if we participate in buying clean syringes or supplies, that we are enabling people to continue in this destructive behavior. They don't see it that we are empowering them to make a healthier life eventually." [SSP 16]

Funding challenges

SSPs are currently operating with a patchwork of funding

Programs commonly cited inadequate funding as a primary barrier to establishing new programs or expanding SSPs or the services they offer. It was typical for programs to depict a patchwork of funding, including from foundations, individual donations, merchandise sales, and to a much lesser extent government funding. For many programs, this funding was not stable from year to year and often had restrictions on how the money could be used (e.g., foundations would fund naloxone distribution but not purchase of syringes or needles).

"Our primary sources of funding are- it's really a split between, we get some money from the state, we get some money from foundations, and then we get some money from private donations. It's our three-legged stool of funding…the private money is really how we fund the purchase of needles and syringes." [SSP 17]

Two newly operational programs stated their activities were funded largely through their personal funds or individual donations.

"Up until this year, our program has been strictly funded through either our personal pockets or through donations of family and friends. My budget last year was $1,500 and that's serving hundreds of folks but that's because my syringes were donated. My naloxone, I don't have to pay for it, it's donated to us." [SSP 16]

A small minority of programs expressed optimism about funding; stating their funding had improved or stabilized in recent years. There were no defining features as to the type of SSP that reported improved funding as this small group included SSPs in urban and rural areas as well as programs that were and were not part of health departments. Programs reported that these new funds were enabling programs to expand current operations.

"We have had philanthropic grants. Until this year, that was our biggest funding source. This year, we've received governmental funding from the state and from the federal government for the first time. [This new funding] allows us to expand. We will be able to go mobile because of this and hire the additional staff." [SSP 3]

The vast majority of programs stated their funding was barely covering current operations, and universally, SSPs, including those that said their funding had improved, acknowledged funding was not sufficient to cover the spectrum of services they believed were needed to fully address the needs of people who inject drugs. Cumulatively, these funding challenges resulted in limitations on program operations, including not being able to reach at-risk populations, fund staff positions, conduct mobile operations, and provide needed injection supplies.

"In the past, we would give folks as many [syringes] as they needed to cover them for two to three weeks, but again, because of funding, we've had to cut back. We give individuals about 60 a month, which is not nearly enough, but that's all we have right now." [SSP 16]

The Federal funding ban is preventing SSP implementation and growth

Across all programs, the most significant funding challenge expressed was related to purchasing syringes and needles. Underlying this challenge was the long-standing ban on using Federal funds (and in some cases state and local funds) to purchase syringes and needles.

Programs felt this was a fundamental factor limiting their ability to implement new programs and sustain and grow existing programs and to deliver comprehensive services to people who inject drugs.

> "We can't buy needles with that [federal] funding, which makes absolutely no sense to me whatsoever. You would fund a syringe exchange program but you can't buy syringes…I think that becomes a policy issue because if it's a program that works, if it's effective in reducing the public health crisis of hepatitis C that we live with in this state, then why would you not want to fund it?" [SSP 9]
>
> "You've got to be able to buy the needles with [the funds] too because there's a lot of communities that I'm aware of that would like to consider starting a needle exchange…Some of these communities are just as poor as we are. They don't have the ability [to implement an SSP] because they don't have access to funding [for syringes and needles]." [SSP 5]

Due to the funding ban, programs were forced to rely on other funding sources to purchase syringes and needles; commonly citing that these funds were often insufficient and unreliable. This has forced some programs to limit the number of syringes and needles they can provide to participants, undercutting the primary intent of SSPs.

> "[The ban] is our biggest challenge, we are totally dependent on donations and should we lose those donations, I don't know what we would do. We cannot afford – we don't have any money to afford to buy these syringes…It has caused us to limit them to 30 [syringes] a week. There have been times when we've run out [of syringes] and didn't have any money." [SSP 6]

Programs felt a shift by the federal government to more openly support SSPs and develop dedicated funding for them could have a significant impact on the implementation and expansion of SSPs.

> "I wish that the federal government would do a little more with regards to funding because all of these things are not going to happen without appropriate funding. We provide a lot of lip service and a lot of community conversations around these issues. A lot of people are talking about it, but when the rubber hits the road, you've got to actually put a program together. That takes money. Money doesn't solve everything but you certainly can't do these programs without the appropriate amount of funding." [SSP 9]

Perceptions of funding opportunities vary across programs

There were diverging perspectives on the expectations and requirements for non-governmental funders depending on whether the SSP was a new or established program. Established programs recounted challenges in obtaining funding because funders wanted to fund new, innovative programs, not sustain established programs and operations.

> "The money comes with strings attached, that you'll do this and you'll do that. Grantors want to see certain things. They don't want to fund sustainment. They want to fund new, exciting developments, which really taxes the abilities of our organization." [SSP 10]

New programs felt they were at a disadvantage because they had not established themselves for a certain period of time.

> "We have no money. Even as we're trying to get more money and we've gotten more and more legit, a lot of the funders seem to have gotten a lot more advanced over the years. They don't want to fund programs unless they've been operating for three years or more. That's almost impossible then to start a new program." [SSP 19]

A unique challenge expressed by some programs that were part of health departments was the perception that being in the health department guaranteed funding for program operations and supplies. Programs felt this contributed to being less competitive for non-governmental funding opportunities.

> "When we're looking at grants and such, especially now that we do have increased support from the city, we don't look as good on paper anymore. We never really did because we fall under the health department umbrella. Even before when we weren't really getting any city funding, it was always a really hard sell to say 'yes I know we are within the city public health division, but I really do need money, like we really don't have any money'. That has always been a barrier for us." [SSP 11]

Limitations on funding opportunities were amplified for SSPs operating in states where SSPs are illegal. These programs expressed frustration that many funding opportunities were beyond their reach given the legal status of SSPs in their state. For example, one program stated that even when potential funding opportunities were available, such as those resulting from the partial lifting of Federal funding ban, the program couldn't apply for those funds because syringes were still illegal in their state.

> "Because syringes are paraphernalia, we're really just barred from a lot of funding streams that would actually go towards running our needle exchange, or funding the staff…We can get money for all sorts of things, but not the actual running of the needle exchange because it's considered paraphernalia." [SSP 17]

Stigma perpetuates SSP funding challenges

Similar to legal and policy barriers, there was strong consensus among SSPs that stigma and the historically controversial nature of SSPs was a substantial contributor to the current funding situation. Compounding this is the recent increase in number of SSPs across the U.S. that has led to greater competition for the already limited funding opportunities for SSPs.

> "One of the biggest barriers to funding is still stigma and that people don't want to fund these kinds of programs when they don't understand, and they think that it's encouraging, condoning drug use. I think, for us, one of the barriers is – because there are so few funders for syringe access, that it just is incredibly competitive." [SSP 4]

Changing drug use trends and illicit drug supply

The expanding number of people injecting drugs and seeking services at SSPs

Both new and established programs across census regions reported an increase in the number of people accessing their programs in recent years. For some programs, the increase was characterized as rapid or exponential growth.

> "Our growth hasn't been linear at all. It's pretty logarithmic. We see a radical increase in the number of people we interact with per week over time. For a couple of months, it seems like we'll stabilize for a little bit. October, November, part of September, we were giving out maybe like 2,000 syringes a month, maybe 3,000. Now, a lot of times we'll do at least that many every week or every couple of days. The demand has been increasing really rapidly." [SSP 19]

Other programs depicted slower and more predictable growth in the number of SSP participants coming to their program.

> "Very first week, first week of May, I think we had two people. We had four people the second week. I believe we had eight, eight, and eight for the next three weeks. Then it started to grow a little bit. I think we spent about three months between 15 and 30 people. In the last four months, we've averaged between 40 and 60." [SSP 9]

Across programs there were no distinguishing features (e.g., new versus established, geographic placement, affiliated with the health department) of the SSPs that saw rapid increases in growth compared to those that experienced slow and steady increases. Responses were mixed on whether the increase in people seeking services from SSPs was due to increasing numbers of people injecting drugs or driven by increased trust and awareness of programs leading to a larger proportion of people who inject drugs seeking services.

> "I know our client base is increasing, but I don't know whether that's because more people are finding out about the exchange. I think overall more people are injecting." [SSP 20]

Patients are gaining trust and our program has been established for over two years…I think that there is more of them using. Or there's more of them finding out about our services, but, probably a little bit of both." [SSP 22]

A number of SSPs, in both rural and urban areas in the South, Midwest, and Northeast – areas with historically higher prevalence of prescription opioid misuse compared to the West – specifically identified the clamp down on prescription opioids and the resultant switch to heroin use among people previously misusing prescription opioids as contributing to the rise in number of people injecting drugs.

> "The program grew because we have more people that are injection drug users. It really kind of had to deal with losing the supply of pills and then heroin came. It's sort of naturally caused more people to start injecting." [SSP 6]

Other programs in the West and western part of the Midwest reported that changes in the underlying population in their communities was contributing to the increase in people injecting.

> "We're seeing a population move in that is new to our state, has started moving in with the oil boom. We got some big box stores that have come in and brought people, so our population is definitely changing, and as that population changes we're just having trouble…we're seeing more drugs coming in. Methamphetamine has been around a while, but the opioids are definitely picking up here." [SSP 7]

In addition to increases in the number of people injecting, some programs, both established and new as well as those in rural and urban areas, reported demographic shifts in recent years, including an increase in women accessing SSPs. Programs characterized this shift as a result of not only an increase in injection among women, but also an increase in trust between the programs and women.

> "When we first started, we had more males and we're seeing more females as time goes on. That's because I think females have a lot more at stake and there's more of a trust issue associated with that because of children." [SSP 21]

Although programs reported the vast majority of people seeking services from SSPs were from their local geographic area, a number of programs, both new and established, reported that some participants were traveling significant distances to obtain syringes, needles, and other services. This was most common among SSPs that were operating in states with one or only a few SSPs.

> "We actually have a significant number of people traveling from other parts of the state because there are no other services. We do see people traveling 50 plus miles pretty regularly." [SSP 4]

Among these programs, this was seen both as a positive in that there was interest in seeking services but also as a negative because it reflected the reality that there is much greater demand for SSPs than there are SSPs, underscoring the disconnect between where SSPs are located and where the populations that could benefit from them live.

The emergence of illicit fentanyl has amplified the challenges faced by SSPs

Since 2013, the proliferation of highly potent illicitly-made synthetic opioids such as fentanyl has significantly fueled the rise in opioid overdose deaths (Jones et al., 2018). Programs expressed substantial concern about how this rapid change in the illicit drug supply has impacted their participants and programs.

> "I think fentanyl has really changed everything, just the way people are overdosing and the way people are using. I think behaviors are different. I think the daily hustle looks different. I think the way overdose reversals are happening is different." [SSP 11]

A number of programs described how the emergence of illicit fentanyl changed the way SSPs and participants interact, including discussing steps such as using tester shots and not injecting alone, and how participants are changing their behavior to reduce their overdose risk in the context of increasing fentanyl availability.

> "Definitely [people are taking additional steps to mitigate their risks]. We are seeing tester shots, not using alone, watching each other, using less at first to test it if it's an unknown bag or an unknown source." [SSP 2]

However, other programs expressed concern and some frustration that participants were not engaging in risk reduction behaviors even when steps to reduce risk were discussed with them.

> "I don't really feel like [people are taking extra steps to protect themselves in the wake of fentanyl]. I feel like the people that use alone still use alone. Nobody ever wants to do test shots. They say that it doesn't matter anyway, you can buy the same two bundles from the same dealer and one would have fentanyl and the other will have Wellbutrin [bupropion] in it, so doing a test shot doesn't matter." [SSP 20]

Recently, the use of fentanyl test strips has been proposed by drug policy researchers as an important overdose risk reduction intervention (Krieger et al., 2018); however, programs were mixed on whether they were pursuing this strategy.

> "We give out test strips, they either will test for their friends, or if they all know they've got the same batch, they'll share the results from that test. Many of our people have actually said that they've gone back to their dealer and said "I don't want this, get me some heroin." [SSP 14]
>
> "We don't use test strips. We reviewed the fentanyl test strip concept and found that would be probably of little value here since it can be assumed that we have fentanyl in every product…Testing for fentanyl doesn't change behavior in that setting. We do recommend smaller doses and test dosing and slower injection." [SSP 3]

A resurgence of methamphetamine is further challenging SSPs

Sixteen of the 23 programs interviewed, including programs in each census region and programs in both rural and urban areas, reported an increase in methamphetamine injection in the past two to three years. The general sentiment was this increase was connected to the opioid crisis. In some cases, SSPs reported they had seen an increase in individuals injecting opioids and methamphetamine together.

> "We are seeing way more meth[amphetamine] injections than we were seeing even two or three years ago…about 80% of people who reported being primarily opiate users reported having injected methamphetamines in the last three months. That's 50% more than it was; 30% had reported that [two years prior]." [SSP 8]

Other programs stated that some of their SSP participants were switching to methamphetamine from opioids due to concerns about the unpredictability of fentanyl and other synthetic opioids. This sentiment was more commonly expressed by programs operating in the Eastern part of the U.S. where illicit fentanyl and other synthetic opioids have

been more prevalent.

> "Yes, that [methamphetamine use] is changing. It used to be where they didn't use opioids and methamphetamine together. They're mixing them and even some of them are transitioning over to methamphetamine because of the danger of heroin overdose. Of course, now we're finding out that they're putting fentanyl in methamphetamine." [SSP 21]

Programs expressed significant concern about the impacts of increasing methamphetamine use, both from a policy perspective and from an intervention perspective. Programs felt this emerging trend could significantly impact SSP efforts and add fuel to the already worsening opioid crisis.

> "Overall I would say that the increase in methamphetamine use has created a lot more 'not in my backyard' than we've seen historically. We've had a lot more problems with people being upset about discarded syringes and things like that…Here we're seeing a huge shift away from just opiates to opiates and methamphetamines. There are good interventions around opiate addiction; we've got great medication-assisted treatment options. We've got nothing for meth." [SSP 8]

Strategies SSPs are pursuing to overcome barriers and challenges

Advocacy and engagement in the policy process to remove legal and policy barriers

Programs stressed the importance of advocating for SSPs and engaging in the policy process as a key strategy to advance implementation and expansion of SSPs. Programs operating in states where SSPs are illegal described the power of engaging and educating policymakers about their experiences running a SSP.

> "The thing that I think has been most valuable is that we are running an underground exchange while advocating for a change in the law because it gives us a lot of real-world experience to speak from. Legislators have a lot of curiosity about how these programs fundamentally work. Being able to speak to some of their questions from life's experience is really valuable." [SSP 19]

Other programs operating in states where local approval of SSPs is required described the importance of engaging partners and curating champions as key components to a successful strategy. In some cases, this approach involved influencing local elected leaders.

> "I find identifying people that have a good relationship with that person [the political leader in a community who opposes the SSP] and working with them to help navigate and figuring out how to move things forward. I guess you could call those gatekeepers. A lot of times it's not necessarily having a relationship with an ally to gain access to the elected person, but rather to try to get others to advocate for syringe access and all of that stuff. That's really been what's moved our work forward." [SSP 2]

For other programs, the strategy entailed engaging other community leaders such as law enforcement that can influence community acceptance of a SSP.

> "Our local law enforcement has been very pro what we're doing. In fact, before the new police chief was sworn in…I just walked up to him the day he got sworn in and I was like, 'Chief, this is who I am, this is what we do. This [SSP] is going to be legal in less than a week. I need your guys just to leave me alone until then.' He just kind of looked at me in shock…Then, he was like, 'You do it.' It really kind of blew me away. Ever since then, he has been one of our biggest champions." [SSP 16]

Multiple SSPs, across all programs types, described how the implementation of naloxone distribution and overdose education in their program opened doors for new relationships and opportunities to create new support for syringe services, even among stakeholders that historically had opposed SSPs. This was seen as an important opportunity to advance SSP advocacy and policy efforts.

> "When we go and do a presentation or training [on naloxone] we're able to slip in the philosophy of harm reduction…why we believe it's important to take care of people who use drugs…we've had some really positive experiences with people that I never would have expected would get on board with our work." [SSP 11]

Underlying their advocacy and policy engagement efforts was a strong sense of duty, doing the right thing for people who inject drugs, and feeling resolute that the science and evidence were on their side. A key point of these efforts was combating the pervasive stigma that was seen as a fundamental barrier to expanding the reach and impact of SSPs.

> "Everything we do, all the people we serve, they are stigmatized groups in some way. I think that, so often, people that are in this world don't understand. When we're talking to potential funders or community members, I think there's still so much misinformation out there. I really view one of our roles is really doing our best to educate folks and educate our policy makers, educate people in the community." [SSP 4]

Capitalizing on all potential funding sources

Recognizing the necessity to braid multiple funding streams together to sustain and grow SSPs, programs described a number of strategies they were pursuing to improve and sustain their funding. The partial lifting of the Federal funding ban was cited as an important new funding stream, even after accounting for near universal frustration about not being able to purchase syringes or needles with these funds. This was a pragmatic reflection that in an unstable and competitive funding environment, every potential funding source is valuable. Further, programs stated this new funding stream could be used to offset other funds that were not subject to the same restrictions and could be shifted to purchase syringes and needles.

> "Prior to that appropriations law, as a government entity, we would not have been able to utilize any money for SSPs. It currently does not allow purchase of syringes and needles, but it pretty much covers everything else…When we receive our allocation from the state, it'll go towards others supplies and salaries to run the program." [SSP 9]

Capitalizing on opportunities to engage with Medicaid to obtain reimbursement for certain services for the program or to get program participants covered by Medicaid was cited by several programs as an important strategy, this was particularly true for SSPs operating in states that expanded Medicaid under the Affordable Care Act (ACA). However, direct billing for services by the SSP was not common among study participants.

> "The ACA has been incredibly helpful in helping folks be able to access both our medical clinic and treatment options. We went from having our medical clinic with 90% uninsured patients to 80% insured." [SSP 8]

Additional strategies to improve SSP funding included engaging in traditional and crowd-sourced fundraising, cultivating new donors and non-governmental funding partners, improving data collection and hiring grant writers to strengthen grant applications in an increasingly competitive funding environment, and expanding relationships with state and local government agencies to access new funding opportunities.

> "We've raised a ton of money recently through individual donors. Between September and December 2017, we raised $11,000 through

individual donations and selling merchandise in an online shop… We've actually gotten a ton of money through Facebook's giving platform, which has been really awesome." [SSP 19]

"One of the big ones is being really good about keeping our data systems updated constantly so we really can show our numbers and that things are actually working and that we are actually growing, that we need more money now than ever. I think that helps with securing more funding in our state." [SSP 4]

Expanding the reach of SSPs

Despite the barriers described by SSPs during study interviews that were viewed as limiting the ability of SSPs to reach at-risk population, programs depicted multiple approaches they are deploying to expand their reach.

Seven of the 23 programs currently provide mobile exchange services and an additional four programs indicated they were planning to start mobile exchange services in the coming year. Programs described mobile services as a key part of their ability to access populations that for a variety of reasons were not able to get to the SSP's fixed site.

"We bought a mobile health unit and we started taking it to different neighborhoods. That increased access, especially among different demographics that weren't accessing our services downtown." [SSP 10]

In addition, more than half of interviewed SSPs stated they engaged in some form of secondary syringe exchange – where participants distribute sterile syringes and injection equipment to peers within their social and drug-using networks – as a strategy to reach at-risk populations.

"We recognize we should be in more places than we are, but we are just really limited by the city, and by neighborhoods who don't want to have needle exchanges in them…One way that we try to address that is through secondary exchange…If somebody comes from an area that we know doesn't have pharmacies that sell syringes, or it took them 40 min to get here, we'll make sure they get hundreds of syringes to distribute out among their drug user group." [SSP 17]

However, a minority of programs, including new and established programs, were not able to engage in secondary exchange because either their authorizing statute, regulation, or policy restricted them to one-for-one exchange with limits on the number of syringes that could be given out or the program had limits on the number of syringes per person that were dispensed (e.g., 30 per week) due to funding constraints.

"I would say [secondary exchange] is limited because we're a one-for-one program and against best practices we have caps on the number of syringes we give out, which is a nightmare." [SSP 8]

In addition to mobile and secondary exchange, programs described using traditional and social media to increase awareness of the program, combat stigma, and encourage individuals to seek services. Programs routinely discussed engaging with local television and print media (both proactively and reactively), and maintaining program websites, Facebook pages, and engaging in other social media platforms. One particularly innovative approach described by a new program operating in a state where SSPs are illegal involved the use of Instagram.

"We had an Instagram ad that we ran over the Christmas holidays, we got a decent number of calls on our hotline from really young people like 16–18 years old. That was really interesting because the normal demographic of people who engage with our content on Instagram, it is usually women between 25 and 34. After that Instagram ad campaign, it was all 15–23 year old males…They would never show up at one of our sites. They didn't want deliveries. They all wanted to receive supplies in the mail. They were probably the most fearful of making contact than anyone else." [SSP 19]

Marketing the availability of SSP services to pharmacies, substance abuse treatment facilities, recovery community organizations, healthcare providers, emergency departments, and other healthcare and social services settings likely to interact with people who inject drugs was a commonly employed strategy, especially by programs operating under a supportive legal framework. Programs that were operating underground or under a fragile legal agreement with local jurisdictions or law enforcement were much more limited in their marketing efforts. Finally, programs stressed the importance of engaging with people who inject drugs as a critical step in reaching at-risk populations and developing programming to meet the needs of this population.

Discussion

This qualitative study of a geographically diverse sample of SSPs provides key insights into the legal and policy barriers, funding challenges, and contextual factors currently impacting SSPs. Despite progress in expanding the number of SSPs in recent years, interviewed programs identified multiple legal, policy, funding, and community barriers that are limiting the scope, scale, and reach of SSPs. However, programs also described strategies they are deploying to address these barriers, strategies that can be implemented by other programs encountering similar challenges.

Programs depicted multiple layers of legal and policy barriers that constrain their current operations. It was common for programs, even those with state laws supporting SSP operations, to describe a complex process for receiving local approval or attaining community buy-in to implement new SSPs or expand existing ones. These barriers resulted in missed opportunities to implement or expand SSPs in communities where there was a clear need for services. Other policies such as how many syringes could be distributed to an individual at one time and drug paraphernalia laws that only provided protection for sterile injection equipment were viewed as undercutting the public health mission and impact of SSPs. Thus, revising state and local policies to ensure there is a supportive legal environment for SSPs is paramount to their long-term growth and sustainability. In particular, there is a need to enact policies that explicitly authorize syringe distribution and possession, exempt both sterile injection equipment distributed from and used injection equipment returned to SSPs from drug paraphernalia laws, and streamline the process for approval and implementation of SSPs.

Similar to the effect legal and policy barriers are having on SSPs, the funding challenges SSPs described are restricting their ability to meet the needs of people who inject drugs and reach at-risk populations. Emblematic of these challenges are the limited number of locations, days, and hours SSPs in this study were operating – with nearly 45% open a single day per week and 41% open 3 h or less on the days the programs were open. As acknowledged by many SSPs, these limited windows of opportunity to engage with people who inject drugs are incongruent with the patterns and needs of individuals using drugs and inconsistent with best practice recommendations for SSPs (Harm Reduction Coalition, 2010). Coupled with limited funding to purchase syringes that necessitated some programs to place arbitrary limits on the quantity of syringes distributed, it is clear that the current funding challenges are inhibiting SSPs from reaching their maximum public health impact.

Although the recent change in Federal appropriations law allowing use of funds for certain SSP services was viewed as a positive and important policy change, the continued ban on using funds to purchase syringes and needles was a universally identified barrier to opening new SSPs and operating at an optimal level. Compounding these challenges is the fact that there are no Federal funding programs dedicated to SSPs. The Federal funding that is available is targeted broadly for substance use or infectious disease prevention and treatment; thus, SSPs

are competing with numerous other potential recipients for these funds. It is highly unlikely that SSPs will achieve sufficient numbers and scale to reach at-risk populations and provide comprehensive services for people who inject drugs until a full repeal of the funding ban is implemented and dedicated funding programs are developed. Taking these steps will provide much needed stability to current programs and would likely induce, both politically and financially, additional jurisdictions to open and expand SSPs.

The increase in methamphetamine injection reported by the majority of SSPs in this study is concerning. These findings corroborate emerging evidence of increased methamphetamine injection, in particular in combination with heroin, in certain jurisdictions in the U.S. (Al-Tayyib, Koester, Langegger, & Raville, 2017; Glick et al., 2018). Study respondents indicated that not only were they seeing an increase in combined injection of opioids and methamphetamine, but that some individuals were switching from opioids to methamphetamine due to concerns about increased risk for overdose from fentanyl and the contaminated heroin supply. Although individuals may believe switching to methamphetamine can protect them from fentanyl and the changing illicit opioid supply, data indicate that the U.S. supply of methamphetamine is also being contaminated with fentanyl and other synthetic opioids (DEA, 2017). Thus, SSPs can take additional steps to mitigate overdose risk by educating people injecting drugs about the risks of exposure to opioids when using other illicit drugs as well as equipping individuals with naloxone to reverse an opioid overdose if their methamphetamine or other illicit drug supply unknowingly contains opioids.

Finally, stigma at all levels in the community was identified as a primary factor that enabled many of the barriers SSPs face to persist. As part of their advocacy and policy engagement strategies, SSPs were pursuing multiple approaches to combat stigma. Although these strategies can be influential, taking actions at the Federal level such as removing the Federal funding ban, creating dedicated funding opportunities for SSPs, and implementing anti-stigma campaigns for addiction and harm reduction have the potential to substantially change social norms and facilitate the implementation of policies at all levels of government to expand SSPs and other services for people who inject drugs.

Limitations

This study is subject to several limitations. First, although steps were taken to capture the experiences of a geographically diverse sample of SSPs, the findings represent the experiences of a purposive sample of SSPs and may not be representative of all SSPs or generalizable to SSPs that did not participate in the study. Second, important barriers and facilitators may not have been captured by the interview guide or through the semi-structured interviews. Thus, relevant factors that are impeding as well as enabling SSP implementation and operation may not have been identified in this study. Third, because a single investigator reviewed and coded the responses, it is possible that the findings are influenced by researcher bias and may not solely reflect the experiences of study participants. Steps taken to mitigate these limitations and strengthen the rigor of the analysis included: 1) using maximum variation purposive sampling that included a sample of approximately 9% of all known SSPs in the U.S. and was based on a priori criteria to capture both new and old programs, programs in rural and urban areas, and programs in all four U.S. census regions; 2) use of a second coder to review transcripts and to validate and refine themes; and 3) explicitly exploring deviant cases and concepts identified during the interviews with interview participants and employing member checking to examine interpretations of the data and to clarify concepts during interviews.

Conclusion

The opioid crisis in the U.S. continues to expand and evolve. In recent years, significant progress has been made in expanding SSPs in the U.S. However, programs continue to encounter multiple barriers that are limiting the number, scope, and reach of SSPs. To counter these barriers, SSPs are employing multiple strategies to engage policymakers and communities, strengthen their funding base, and reach at-risk populations. Coupling these strategies with policy changes that address the underlying legal and financial barriers and advancing efforts to combat stigma around drug use and addiction stand to substantially expand the role of SSPs as part of the public health response to the opioid crisis in the U.S.

Author Contributions

Dr. Jones had full access to the data and takes responsibility for the integrity of the data and the accuracy of the data analysis. Dr. Jones conceived of the study design, conducted the data analysis and interpreted the findings, and drafted the manuscript.

Funding

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

Declarations of Interest

None.

CRediT authorship contribution statement

Christopher M. Jones: Conceptualization, Data curation, Formal analysis, Methodology, Project administration, Software, Validation, Visualization, Writing - original draft, Writing - review & editing.

Acknowledgments

Dr. Jones would like to thank Drs. Jeffrey Levi, Marsha Regenstein, and Katherine Mead for their critical review of the manuscript. In addition, Dr. Jones would like to thank Teresa Manocchio, M.A for her assistance with coding and the thematic content analysis.

Appendix A. Supplementary data

Supplementary material related to this article can be found, in the online version, at doi:https://doi.org/10.1016/j.drugpo.2019.04.006.

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