Title: Against the Odds: Syringe Exchange Policy Implementation in Indiana

Abstract

Background: Indiana recently passed legislation allowing local governments to establish syringe exchanges. While the effectiveness of syringe exchange programming is established, there is a dearth of studies about associated policy adoption and implementation.

Objectives: This study documents the experiences of 24 Indiana counties engaged in the process of establishing syringe exchange programming under new state law.

Methods: A mixed method, qualitative, exploratory case study was conducted from May 2015 to April 2016.

Results: We observed rapid and widespread policy adoption interest, and yet counties reported significant policy ambiguity, epidemiologic and resource capacity issues. The emergence of health commons involving information and tangible resource sharing networks allowed institutional rearrangement in the midst of resource scarcity; however, such rearrangement appeared to be a central threat to policy adoption and implementation given state structural barriers.

Conclusions: The emerging commons could be a critical policy success factor, as it would achieve efficiencies not possible in the current resource environment, and can help achieve institutional rearrangement for the improvement of population health. Several recommendations for improvement are offered.

Introduction

In May 2015, Indiana enacted a law to establish syringe exchange programs (SEP) by counties and municipalities.[1] This was in response to a rural outbreak of HIV associated with sharing contaminated syringes used for opioid injection.[2]

The evidence shows that SEPs reduce HIV, hepatitis C(HCV), hepatitis B;[3,4,5] and the use and/or sharing of contaminated syringes.[6,7,8] SEPs have been found to be cost effective,[9,10] and do not increase discarded syringes.[11,12,13] While these studies have informed whether to pursue SEP policies, they do not address the process of policy adoption and implementation. This is an important gap in our understanding.

Policy adoption and implementation refer to government decisions to accept and implement new policy.[14,15] In the case of SEP policy, adoption and implementation occur when states pass syringe access policies similar to other states, when counties or municipalities pass policies enacted by peers, or when state law is adopted or implemented by local governments.

Local level policy adoption and implementation is relevant in the case of Indiana, because the new law (SEA 461) limited the establishment of SEPs to local units of government. Policy adoption involved three steps: 1) the local health officer must declare that the jurisdiction is experiencing an HIV or HCV epidemic primarily associated with injection drug use, and that an SEP is both medically

necessary and appropriate; 2) the local commission/council must conduct a public hearing and adopt the declaration and SEP plan set forth by the local health officer; and 3) the commission/council must notify the state health commissioner about these actions and request public health emergency declaration for the county or municipality. The state health commissioner evaluates the submitted evidence and if s/he declares a public health emergency for that area, the submitted SEP proposal would effectively be approved. Additional guidance was published by the Indiana State Department of Health (ISDH) regarding approval to operate SEPs for one year, with annual renewals possible through legislation expiration: July 1, 2019.[16]

Since the law's enactment, 24 counties have moved forward with syringe exchange policy adoption (Figure 1). As of this writing, these counties are at various policy implementation stages: 16 counties have begun community conversations to establish an SEP, and 8 counties received state approval for an SEP.

Figure 1 about here

The study objective was to document and understand policy adoption and implementation experiences by the 24 Indiana counties.

Methods:

We conducted a mixed method, qualitative, exploratory case study of Indiana counties adopting SEP policy from May 2015 to April 2016. Findings will focus only on county level policy adoption and implementation, as no municipalities adopted state policy during the study period.

Study Setting

The study setting is Indiana and the 24 counties engaged in SEP planning. Indiana has experienced severe, persistent public health underinvestment, and ranks poorly among peers in federal per capita funding focused on public health prevention and primary care. Indiana is 50th among state peers in per capita funding from Centers for Disease Control and Prevention (CDC), and 47th in per capita funding from Health Resources and Services Administration (HRSA).[17] While the per capita calculations include federal funding for all health conditions covered by these agencies, they do fund the majority of HIV prevention (CDC) efforts, and most of HIV treatment and primary care (HRSA). While these funds are often competitive or distributed based on burden of health condition or disease, a state's policy decisions or state agency actions (or inactions) may contribute to comparably low per capita funding from CDC.

The more telling indicator of the state's public health commitment is seen in the state public health per capita investment which includes state appropriations for agencies, departments or divisions in charge of public health services. This figure consistently decreased in Indiana since 2013: $17.43 in 2013, $13.08 in 2014,

and $12.40 in 2015.[17,18,19] The lack of investment yields deleterious outcomes for HIV testing access in Indiana as shown by a 2011 study finding that 20% of HIV test attempts at state-funded sites failed to result in a test;[20] and a 2014 study finding that only 10.7% of the state's 40 Community Health Centers operating 134 clinical sites were providing routine HIV screening for adolescents to adults age 65 years.[21]

Indiana's population lives primarily in urban areas, and 71% of the counties have populations of ≤ 50,000.[22] Like their rural peers elsewhere in the U.S., these rural communities face drug addiction and significant increases in opioid overdose deaths[23] compounded by weak public health systems and limited addiction treatment access.[24,25,26]

This study uses the analytic framework of health commons.[27] Commons refers to a system of shared information or other tangible resources requiring collective management. They are shared, organic, dynamic "ecosystems" limited or enhanced by sociopolitical relationships and institutions.[28] The key elements are dynamism and creative force which can recreate and reshape the very relationships and institutions which limit commons.[29,30,31] The commons lens helps to explain both the identified issues associated with SEP policy adoption and implementation, as well as the observed emerging configurations of resource and knowledge sharing.

Data

Data included telephone and email correspondence with 75 key informants directly engaged in local policy adoption and implementation, and 50 participant observations at state and county-level SEP policy meetings during the study period. Participants included county health department leadership, county commissioners, mental health and HIV community coalition advocates, state and local law enforcement, ISDH employees, state legislators and local residents seeking access to HIV, HCV and/or substance abuse treatment (See Table 1).

Table 1 about here

An *a priori* framework was used to code field data with focus on: 1) policy adoption and implementation challenges and successes, 2) conceptualizations of the commons and its functioning, and 3) how the commons mitigates policy adoption and implementation challenges.

Results

By design, the SEP law identified two levels of policy implementation: county level (adoption and implementation of state law) and state level (approval of county implementation plans and policy/epidemic declarations). Table 2 identifies the key themes by implementation level.

Table 2 about here

Policy Adoption and Implementation Challenges

Policy Ambiguity

A frequent reported challenge to policy adoption and implementation was ambiguity about what constituted an epidemic, what ISDH required for SEP approval, and what renewal would entail.

> *"(M)y biggest challenge is what constitutes an epidemic of HIV or hepatitis C. I tried to bring up this issue at the* (Indiana) *Opiate Symposium last year and was unable to get a clear answer. So how do I convey to community members that we need a syringe exchange?"* (County Health Officer)

> *"I have been trying to get information* (from the state) *related to overdoses and…deaths related to injection drug use, as well as arrest records related to injection drug use, but have not had any luck. It is hard to make our case if we cannot associate injection drug use with our HIV rates."* (County Health Board Member)

The law's requirement to declare an "epidemic" of HIV and/or HCV was initially problematic for counties because, technically, none of the counties experienced an epidemic per standard definitions.[32] Scott County was the epicenter of the 2015 HIV *outbreak*, and many Indiana counties experienced *consistent and troubling increases* in HCV in recent years. However, no county had by definition an "epidemic" of HCV or HIV. Thus, counties found themselves without clear definitions of what constituted an epidemic for the purposes of SEP approval.

Challenges with the initial SEP application to ISDH were repeated in the first quarter of 2016 as two counties approached SEP reapproval.

> *So it is my understanding that we will have to go through this proposal process every year. That means the few staff that we have available in our health department will have to again dedicate time putting this thing together…and if we prove that the syringe exchange is working then there should no longer be an epidemic. All of the time and resources needed, to me it hardly seems worth it.* (County Commissioner)

Observed capacity differences between Scott County and other counties exacerbated the policy ambiguity. Financial and human resources, as well as technical assistance were provided to Scott County by ISDH during the initial SEP year and during the renewal process. Information sharing among the counties indicated perceived differences in county process requirements, although it was hoped that the renewal process would be less onerous than the initial application process. The lack of clear, public communication about these processes intensified the confusion, which elevated to the legislature.

> *If all Scott County had to do was submit a letter from their commissioners* (to renew the SEP)*, then that is breaking the law. They need to go through the entire proposal process just like everyone else.* (State Legislator)

Paucity of Epidemiologic and Program Capacity

Counties making the case for SEP relied on epidemiologic data documenting HIV and HCV cases, as well as overdose deaths. All but three counties (Scott, Monroe and Allen) historically relied on ISDH to generate epidemiologic profiles for SEP policy adoption. These counties uniformly reported data access issues. While county-level HCV data were published on-line by the state department of health, information was current only through 2013.

> *I have been trying for over 3 months to get the most recent HIV and hepatitis C rates. No one calls you back! I filled out the form* (data request) *too. I think the information that is on the website is too old…. we need to get the current numbers.* (County Community Member)

Counties requesting updated data from the state department of health were often frustrated in their attempts. Several counties shared various '*special'* methods to get data for their counties. Some were able to get data from the ISDH with direct requests, while others had to work through gatekeepers to obtain updated information.

> *I know someone who has been able to get data. We were at a* (SEP) *planning meeting last week in* (County)*. I will ask her how she was able to get it, or maybe she can get us the numbers.* (County SEP Service Provider)

Policy Implementation Capacity

It is notable that the legislation prohibited state funding for SEPs. Further, no additional state funding was appropriated for county public health services during that time period by the state legislature. Counties with an SEP interest would therefore have to independently underwrite services.

Scott County was the unique recipient of tremendous "top-down" provided state and federally resources for testing, linkage to treatment and SEP implementation guidance due to being the site of the outbreak. These resources were provided to the county well before the state law was passed, and continue as of this writing.

This state capacity provision was in stark contrast to what other counties experienced when considering SEP policy adoption and implementation; it and caused reported consternation with other counties because several felt that they were *sitting on the same kind of outbreak situation, but because we do not have resources to test anyone* (for HIV) *we don't know it yet"* (County Health Commissioner).

Capacity and Resources to Demonstrate Need

As counties considered their lack of capacity, many discussed efficiencies of scale for SEPs. This is where evidence of the commons began to emerge. Discussions of cross-county resource sharing occurred, informing local policy adoption. At the time of the outbreak, ISDH funded 36 of Indiana's 93 local health departments to serve their region's HIV testing needs. However, this resource was not sufficient to demonstrate need for an SEP in a specific county, or to provide ongoing HIV testing at an SEP.

Counties reported that this was due to restrictive state HIV testing policy. As in many states, HIV testing was limited to high risk groups identified by CDC: men who have sex with other men and injection drug users. Populations injecting opioids were not necessarily known to county health departments given the significant stigmatization accompanying injection drug use. Thus, communities wanting to screen broadly and in populations of known opioid use (injection or otherwise) were not able to tap into these state provided and regionally available

HIV testing resources. Further, when counties requested state assistance to meet the need, they encountered inconsistent responses:

> *I own a company here in (*town*). I know we have a heroin problem… I have had to send current employees to rehab in Kentucky because we don't have any (*addiction*) services here…. So I am hosting a community event with this national group and asked the state health department to provide testing. They said they would but when I called to confirm...they told me now they can't do it*. (Local Business Owner)

Policy Adoption and Implementation Successes

Rapid, Widespread Policy Interest

There was rapid and widespread interest in SEP policy adoption and implementation at the county level. By August 7th, 3 months after law's signing, 18 counties reported moving forward with SEP policy planning; two counties (Madison and Scott) had already received state approval to operate an SEP.[33] Notably, Scott's application for an SEP under the newly enacted law was quickly approved given the Governor's two executive orders allowing an SEP in March and April prior to the law's enactment.[34,35]

Emergence of Resource and Epistemic Commons

Information sharing between and among counties was the first commons to emerge. At the time, counties sought to demonstrate their need for SEP services and submit plans in response to the law prior to the issuance of state guidance. This expression of commons emerged early in the summer of 2015, and was articulated through small networks of counties working at the same stage of

policy implementation. These networks mobilized state and national organizations to collectively access and/or share technical assistance focused on network building for local support, program planning, and grants development. An example was the sharing of experts and policy briefs in preparation for testimony at county commission meetings. In several cases, the Indiana Attorney General attended these meetings to help counties make the case for syringe access.

As more Indiana counties moved forward with policy adoption, commons were expanded to build local implementation capacity. This included tangible resources such as start-up syringe supplies, or offers to share mobile van resources; and was particularly important for counties in the absence of local grant funding or similar pledged resources. Notably, although none of the participating counties held abundant resources, we observed tremendous generosity.

> *Until we can get some donations and grant money* (other County) *is giving us* (SEP) *supplies so we can get started.* (County Hospital Administrator)

> *We want to test more but we don't have the budget. I have run out of hepatitis C tests.* (County SEP Service Provider)

> > *I'll give you hepatitis C tests, we have more that I think we need.* (County Outreach Worker from a different county)

Early in the process, counties began to plan cross-county contractual arrangements to access SEP service delivery resources. This included HIV testing, addiction services and primary health care consultation.

> *We have the opportunity to use the mobile unit from Dr.* (name) *and* (organization). (Medical School) *will provide first year medical students for our needle exchange to provide wound care and other services. We will also have services from a pharmacy tech.* (County Health Department Director)

Structural Limitations to Commons

The emerging commons appeared to protect policy adoption and implementation; however, there were palpable structural limitations. We observed the following corresponding relationship: plans resulting from commons rearrangement of local institutional assets were rejected by the state agency (ISDH). For example, the emerging multi-county SEP plans allowing tangible resource sharing (mobile vans, personnel) were consistently disapproved by the ISDH during initial SEP plan review. Counties were asked by ISDH to identify vertical system resources, even when such would duplicate services and costs.

Discussion

While it is early in Indiana's SEP policy implementation process, we observed sufficient policy experience to identify issues with and opportunities for policy adoption and implementation. Issues of transparency, clarity and resource scarcity loomed large; yet emerging health commons leveraged county potential to establish health policy and programming despite challenges. The question

remains whether emerging commons can sufficiently alter local and even state institutional arrangements and mitigate structural barriers to policy adoption and implementation.

The law's state funding prohibition and county-specific focus may be part of the problem in this public health resource-strapped environment, as they appeared to encourage and simultaneously undermined resource sharing by low resource communities with deficits in essential prevention, testing and treatment services.

However, policy barriers experienced by counties might have less to do with those challenges and more to do with the potential of commons and its inherent threat of institutional rearrangement. As counties rearranged their own institutions to allow tangible resource sharing for SEP implementation, they encountered rejection of their SEP plans by ISDH. At issue was an emerging, yet unstated, requirement of a vertical county SEP system. Given this policy experience, it may be the case that emerging county institutional rearrangement posed sufficient threat to state health agency hegemony. This point is specific to the health agency (ISDH) because the state Attorney General's office participated in several of the local emerging commons to assist local law enforcement and county commissioners as they considered policy adoption.

This structural barrier may appear to be a 'deal breaker' for commons in the short term, while in the long term might yield hope for the future of public health in

Indiana and similar under-resourced areas. Continued observation of policy adoption and commons emergence will be necessary.

An additional and recent federal policy change allowing federal funding for syringe programing[36,37] may provide Indiana with SEP resources. It, however, requires assistance by state agencies with extant federal fiduciary relationships and the sharing of federal funding to support county SEP programming. Only one Indiana county (Marion) has a direct federal funding relationship. The remaining counties must rely on state agencies who receive funding as per the recent federal guidance. The threat of institutional rearrangement observed thus far in Indiana may overshadow the opportunity of this resource for county SEP policy adoption.

Based on this analysis, we advance the following recommendations. First, transparency about policy expectation should be continuously evaluated and improved. This involves both state legislation and state agency regulation. Establishing continuous policy learning feedback loops would reduce uncertainty and increase trust in the state or local governmental partner. As this is a new experience with syringe exchange policy, both local and state partners are actively learning. Establishing transparency is more of a process than a destination, as policy experience will unveil continued issues with transparency, as was the case in Indiana. As the state agency has the regulatory power to grant SEP approvals and re-approvals, it should lead this transparency effort

guided by feedback from county partners about encountered problems. Transparency should include clarified definitions of epidemic, expectations of vertical county systems and the state's intent and process toward maximizing the now available federal funding resources to direct toward syringe access programming for the prevention of HIV and HCV.

Legislatively, transparency would involve clarifying the expectation of county-specific policy adoption as well as county policy latitude. The emerging commons resulting in inter-county sharing of information and planned resources was an example of policy innovation in a resource scarce environment. That such innovation was rejected, indicates a need for legislative clarification and direction to that state agency. Are counties truly the policy unit for the adoption of state law with responsibility and freedoms which come with it? Or, is the state law truly a state-wide law that requires counties to adopt an as yet unclarified but pre-determined state regulatory framework? The law cannot be both without injurious impact. Counties will likely soon grow tired of such a policy architecture and may eventually de-adopt SEP policy in subsequent years. In this case study, Indiana counties demonstrated the possibilities inherent for cash-strapped communities relying on local solutions to policy challenges. These solutions should be incubated and studied over time for their ability to rearrange scant institutional assets to meet public health need.

Finally, it is recognized that every state faces its own funding challenges. Indiana, however, has the opportunity to invest more in the population's health having reported a 2016 structural surplus of $50.6 million and another $545 million in a 'rainy day fund.'[38] The HIV outbreak should establish sufficient concern for targeted HIV and HCV screening in communities using opioids and other injection drug use. Establishing the evidence of need for the targeting of public health resource should be of primary interest, particularly for resource-strapped counties and for the state that heretofore had not known of the need for syringe exchange programs prior to the outbreak.

Indiana is fortunate to have experienced such an enthusiastic uptake of syringe exchange policy consideration because it will translate into engaged policy partnerships throughout the state and across counties. This is a valuable asset for the improvement of health not just in Indiana, but in communities throughout the U.S. addressing dire public health need in the face of tremendous stigma around HIV, HCV and opioid addiction.

Compliance with Ethical Standards

This research was not underwritten by a grant or contract.

The authors do not have any potential conflicts to disclose.

Ethical approval: All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

This article does not contain any studies with animals performed by any of the authors.

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