Addressing the problem of sterile drug injecting supply acquisition for people who inject drugs.

Barbra Ann Cave

University of Louisville

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ADDRESSING THE PROBLEM OF STERILE DRUG INJECTING SUPPLY
ACQUISITION FOR PEOPLE WHO INJECT DRUGS

By

Barbra Ann Cave
B.A., Bellarmine University, 2003
B.S.N., Bellarmine University, 2005
M.S.N., Bellarmine University, 2010

A Dissertation
Submitted to the Faculty of the
School of Nursing of the University of Louisville
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Doctor of Philosophy
In Nursing

School of Nursing
University of Louisville
Louisville, Kentucky

December 2019
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A Dissertation Approved on

November 18, 2019

by the following Dissertation Committee:

Vicki Hines-Martin, PhD, APRN, FAANP

Celeste Shawler, PhD, PMHCNS-BC

Rachel Vickers Smith, PhD, MPH

Laura Smart, MD
DEDICATION

This dissertation is dedicated to people who use drugs
and the people who lift them up,
restore their dignity,
remember their humanity,
and work to reduce drug-related harms.
ACKNOWLEDGEMENTS

I wish to thank my dissertation chair, Dr. Vicki Hines-Martin for her guidance and support throughout the dissertation process. I wish to also thank the other members of my dissertation committee, Dr. Rachel Vickers Smith, Dr. Celeste Shawler, and Dr. Laura Smart for their help and encouragement over the past two years. Special thanks to the Louisville Metro Department of Health and Wellness Syringe Exchange Program leadership and staff for their enthusiasm and support.

I would also like to express my appreciation and gratitude to my husband, Dr. Matt Cave. Without his love, devotion, compassion, respect, encouragement, willingness to pick up the slack at home, and patience, I would not have achieved the success I have to-date. Thank you to William and Sam Cave for eating my hastily cooked dinners, and respecting my need for quiet. Lastly, I wish to thank my son, Nikolai Goshko, for his kindness, respect, patience, and understanding, and recognize his personal sacrifices to help see me through the PhD journey.
ABSTRACT

ADDRESSING THE PROBLEM OF STERILE DRUG INJECTING SUPPLY ACQUISITION FOR PEOPLE WHO INJECT DRUGS

Barbra A. Cave

December 13, 2019

This dissertation contains five chapters, including three manuscripts, covering harm reduction and some of the challenges people who inject drugs (PWID) face in their effort to reduce the risk of injection drug-related harms through sterile injecting supply acquisition and use. Chapter One discusses some background related to PWID and provides an overview of the issues addressed in this dissertation. Chapter Two includes a literature review covering the harm reduction concept, important aspects of syringe exchange programs as a harm reduction tool, and the social determinants of health model as a potential tool for future research. Chapter Three is a two-phase study that examines the problem of syringe and drug injecting equipment sharing and reuse among PWID participating in a syringe exchange program. This study explores the scope of the problem, then uncovers reasons contributing to syringe sharing and reuse behavior. Findings are applied to the social determinants of health model, with results demonstrating a number of social determinants that influence PWID behavior. In Chapter Four the author highlights approaches to sterile drug injecting supply acquisition used by PWID and presents policy alternatives. Finally, there is a discussion of a case study and
description of how nurses can ethically support harm reduction strategies for PWID.

Chapter Five contains a summary of findings and recommendations for future work.
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CHAPTER I
INTRODUCTION & OVERVIEW

Injection drug use is an increasing problem both worldwide and in the United States. From 2004 to 2014, the United States saw an 89% increase in the rate of opioid injection (Zibbell et al., 2018). Rates of any drug injection increased 76% over the same time period (Zibbell et al., 2018). People who inject drugs (PWID) are at risk for a multitude of negative consequences. Social consequences may include loss of employment, family disruptions, and loss of housing. Legal consequences may include arrest and prosecution, and confiscation of drugs and paraphernalia. Perhaps the most severe consequences are related to health. PWID experience high rates of skin and soft tissue infections, bloodstream infections leading to endocarditis and/or sepsis, and acquisition of infectious disease such as hepatitis C virus (HCV), hepatitis B virus (HBV), and human immunodeficiency virus (HIV) (CDC, 2019; Des Jarlais, 2017; Havens et al., 2013; Zibbell et al., 2018). These negative health consequences lead to significant morbidity and mortality among PWID, and are costly to the healthcare system.

Harm reduction is a set of tools and strategies aimed at reducing the harms caused by drug use, and careful attention is paid to PWID. Harm reduction can take place in any setting—from healthcare provider offices, addiction care centers, syringe exchange programs (SEPs), and more (Hawk et al, 2017). In the United States, one example of increased efforts towards harm reduction has taken place through increasing numbers of SEPs. Kentucky has the most SEPs of any states, and has increased the number of them
from 2015, to 69 in 2019 (KDPH, 2019). As the number of programs grow not only in Kentucky but nationwide, it is important to understand how PWID interact with and participate in such programs. Program evaluation and data tracking are SEP best practices, and they may provide clues to models that are working well as well as identify potential issues. In 2017, a SEP in Kentucky surveyed its participants as part of this process and found reports of continued syringe and drug injecting equipment sharing and reuse among their participants (M. LaRocco and W. Crabtree, personal communication, January 16, 2017). Sharing of drug injecting equipment undermines some of the important health benefits of SEPs.

In an effort to understand the frequency of syringe and drug injection equipment misuse among SEP participants, a literature search was conducted. Some studies included information on syringe sharing for people reporting SEP participation. Luo et al. (2014) found PWID in China who had ever participated in SEP had lower odds of having HIV (n= 3,494), but they also found people who had attended SEP reported higher rates of syringe sharing than non-SEP attendees (OR=1.67, 95% CI=1.19–2.32, p=0.0031). Beletsky et al., (2014) found 51.4% of people with inconsistent use of SEP reported receptive syringe reuse (n=514, (OR=1.15, 95% CI=0.72-1.81, p<0.01). Bluthenthal, et al. (2000) found PWID who had initiated and continued to use SEP reported cessation in syringe sharing behavior (204 of 340 PWID). Hartgers, van Ameijden, van den Hoek, and Coutinho (1992) reported 24% of routine SEP participants engaged in receptive syringe reuse (18 of 75 PWID). Most of the literature was limited to receptive syringe reuse. This author wished to investigate the prevalence of any drug injecting equipment misuse (sharing used equipment with others, personally reusing previously used
equipment, using equipment previously used by another person, and sharing of sterile supplies among PWID engaged SEP), and uncover factors and influences associated with such behavior.

To prepare for such a study, the author reviewed available literature to better understand the perspectives people who use drugs (PWUD) hold of harm reduction. Next, the author examined harm reduction best practice guidelines and thoroughly explored harm reduction elements, concepts, and principles. As SEPs are a common platform for harm reduction, she detailed SEP models and compared them to the best practice recommendations. She then highlighted the models used within Kentucky, and explored how the social determinants of health (SDOH) model could influence PWID participation in a SEP.

The SDOH model was originally described by Marmot and Wilkinson in 2006. The model appreciates health influences are not merely a result of race, ethnicity, genetics, gender or individual behavior, and that actions can be taken to improve the health of populations (Marmot & Wilkinson, 2006). The World Health Organization adapted and refined the model, and identified key concepts such as economic stability, education, health and healthcare, neighborhood environments, and social contexts that include employment conditions, social inclusion, public health programs, women and gender equity, early childhood development, globalization, health systems, and measurement and evidence, and urbanization (WHO, 2019).

The SDOH model has been used by nurses caring for people who use drugs (PWUD) in an opioid substitution program (Gadbois, Chin, & Dalphonse, 2016). The authors recognized limited access to social determinants were substantial barriers to
improving the health of people who use drugs in an addiction care program. The authors used the SDOH model as a tool for developing a quality improvement program that involved nurses and multidisciplinary staff at an urban hospital. Outcomes demonstrated improved assessment of SDOH and care coordination for people in the program (Gadbois, Chin, & Dalphonse, 2016).

The author used the SDOH as a theoretical framework to help design and analyze the study. Having prevalence estimates of syringe misuse behavior helped uncover the scope of the problem, while interviews helped explain what was happening when misuse occurred. Subjects were quantitatively surveyed and/or qualitatively interviewed using a focused ethnographic approach. The study was approved by the University Institutional Review Board, and a certificate of confidentiality was obtained from the National Institutes of Health to help protect this vulnerable population. Subjects were recruited using convenience sampling from an urban SEP in a southern state. Four themes uncovered behavioral/situational factors associated with drug injection equipment misuse. Each theme was explored using the SDOH model and examples of determinants were identified in the data.

After uncovering the scope of drug injecting equipment sharing and reuse among the sample and learning which SDOH impact program participation in terms of visit frequency and supply limitations, the author sought to explore alternative methods of drug injecting supply acquisition, and describe how support for harm reduction is an important ethical undertaking for nurses caring for PWID. Alternative methods included secondary exchange (receiving sterile supplies from someone who attended a SEP), pharmacy syringe sales, injection supply vending machines, and trade or drug dealer sales
(where the dealer supplies sterile equipment in trade or as an outright sale). Policy alternatives aimed at increasing access to sterile drug injecting equipment were explored. Alternatives included supply vending machines, SEPs on mobile units, formal support for secondary exchange practices, elimination of restrictive syringe distribution models within SEPs, and increased support for supply sales within pharmacies. A case study example of policy alternatives in action described how the situation in Kentucky’s SEPs could improve through elimination of supply distribution limits and bolstering pharmacy syringe sales and increased harm reduction support from pharmacists. Informing PWID on ways to access sterile injecting supplies is an ethical nursing activity, and the principles of harm reduction are in line with the American Nursing Association (ANA) *Code of Ethics* (2015). Harm reduction is supported by the ANA, and resources are available to assist them in incorporating principles into patient care (ANA, 2018).

The role harm reduction plays in mitigating the negative health consequences for PWID is especially clear in SEPs. Uncovering and exploring the SDOH’s impact on the ability of PWID to fully participate in harm reduction is important. The work of this author described some of the problems faced by PWID in accessing sterile injecting supplies, and provided evidence on the estimation of syringe and injecting equipment misuse among PWID already engaged in harm reduction services. Future work should identify effective strategies in overcoming SDOH barriers and finding ways to achieve positive change through policy alternatives.
CHAPTER II
EXPLORING HARM REDUCTION, SYRINGE EXCHANGE PROGRAMS, AND SOCIAL DETERMINANTS OF HEALTH: A LITERATURE REVIEW

Overview
Introduction: Kentucky is leading the nation in new cases of hepatitis C virus (HCV) infection and is at substantial risk for a widespread human immunodeficiency virus (HIV) outbreak. These risks are directly tied to the ongoing opioid epidemic, with the Appalachian region of the United States demonstrating the highest rates of injection drug use. Syringe exchange programs (SEP) are a form of harm reduction aimed at reducing drug-related harms, including the spread of infectious disease and the development of skin infections and endocarditis. Syringe exchange programs are widely available across Kentucky, but people who inject drugs (PWID) may be underutilizing their services. The social determinants of health (SDOH) model may help explain PWID behavior in the context of SEP participation and drug injection equipment misuse. The purpose of this review is to describe harm reduction, syringe exchange programs, and SDOH model to guide future research aimed at uncovering what influences PWID decisions regarding drug injection equipment misuse. Methods: A systematic review of literature using PubMed (MEDLINE) and CINAHL were used to briefly synthesize what is known about PWID perceptions of harm reduction and best practices in SEP. Results: PWID have positive perceptions of harm reduction but may remain at risk for acquiring HCV and/or HIV infection through inconsistent use of harm reduction approaches and full utilization
of SEP services. SEP services in the region are not following best practices in limiting distribution quantities of supplies. The SDOH model may help explain why PWID are unable or unwilling to avoid high-risk injection practices, such as sharing used injecting equipment when faced with supply restrictions. Future research should examine the degree of injecting equipment misuse among SEP participants, and describe what influences PWID’s decisions regarding exclusive use of sterile equipment from SEP using SDOH as a framework.
Background

Hepatitis C virus (HCV) is spread through blood-to-blood transmission and may lead to severe morbidity from chronic liver disease, cirrhosis, liver failure, and cancer; in some cases, it leads to death or organ transplantation. Hepatitis C virus infection may lead to complications or worsening diseases outside of the liver, including lymphoma, membranoproliferative glomerulonephritis, lichen planus, porphyria cutanea tarda, and insulin resistance (Ansari, Henderson, Stott, & Parr, 2017; Barsoum, William, & Khalil, 2017; Desbois & Cacoub, 2017; El-Maadawy et al., 2016; Garcovich, Garcovich, Capizzi, Gasbarrini, & Zocco, 2015). Hepatitis C virus infection is the most common blood borne disease in the world (Shepard, Finelli, & Alter, 2005). There are an estimated 170 million people worldwide infected with the virus, representing 2-3% of the world’s population (Averhoff, Glass, & Holtzman, 2012). More than 350,000 people die each year due to complications resulting from HCV infection (Averhoff et al., 2012).

In the United States, an estimated 5.2 million people are infected (Chak, Talal, Sherman, Schiff, & Saab, 2011). Similar to global distribution of HCV, prevalence rates vary state-to-state, and mirror the ongoing issues related to injection drug use. For example, the U.S. Appalachian region, which includes Tennessee, Ohio, Virginia, and Kentucky, opiate prescribing was exceptionally high. This same region is now faced with an HCV epidemic that is perpetuated through the increased use of injected heroin in response to changes in opiate prescribing laws (Christian, Hopenhayn, Christian, McIntosh, & Koch, 2010; Stephens & Havens, 2013). The primary means of acquiring HCV is through injection drug use, but exposure is possible through accidental needle sticks, blood transfusions performed before 1992, having unregulated tattoos, men who
have sex with men, transmission from mother-to-baby during pregnancy, and through healthcare-related procedures (Abdelwahab & Ahmed Said, 2016; Koneru et al., 2016).

Human immunodeficiency virus (HIV) is transmitted via blood-to-blood, in utero, and sexual contact. Infection with HIV may lead to the development of other diseases through opportunistic infection (HCV, Herpes zoster, Cytomegalovirus, *Shigella*, Syphilis, *M. tuberculosis*, Leprsy, *Pneumocystis jiroveci*, Scabies, Trichomonas, etc.), malignancies (Kaposi sarcoma, Hodgkin’s lymphoma, anal carcinoma, etc.), and chronic disease (cardiomyopathy, cerebral vasculitis, sarcoidosis, Guillain-Barre syndrome, Grave’s thyrotoxicosis, etc.) (Lucas & Nelson, 2015).

An estimated 35 million people worldwide are living with HIV; 2.3 million are newly infected each year and 1.6 million die annually (Lucas & Nelson, 2015). In the United States, approximately 1.1 million people are living with the virus (CDC, 2019). The majority of new HIV cases are due to sexual transmission, but injection drug use may lead to HIV infection (CDC, 2019; Des Jarlais, 2017). In 2016, an estimated 9% of new HIV cases were linked to injection drug use (Avert, 2019). Similar to HCV, the prevalence of HIV in the United States varies by region. The Southern states made up 52% of new HIV cases in 2017, even though they make up less than 30% of the United States Population (CDC, 2019).

**Significance**

In general, HCV is more transmissible than HIV, especially among people who inject drugs (PWID) (Havens et al., 2013). Syringe exchange programs (SEP) are one of many harm reduction tools used to help stop the spread of infectious diseases like HCV and HIV. In areas without SEP services, PWID are understandably vulnerable to
acquiring one or both infections because sterile injecting supplies are difficult to obtain, and injection practices are risky due to lack of harm reduction education (Havens et al., 2013). In Kentucky, SEP services began in 2015 in Louisville in an effort to combat the growing opioid injection and HCV epidemics. In 2016, the Louisville Metro Department of Public Health and Wellness (LMDPHW) SEP began receiving reports from clients that they were sharing or reusing used drug injecting equipment despite their participation in the program (M. LaRocco and W. Crabtree, personal communication, January 16, 2017). What was unclear was how often this behavior occurred, and what the driving forces behind it were. In review of literature, few studies reported on the prevalence of sharing of used syringes among participants in a SEP (Luo et al., 2014; Beletsky et al., 2014; Bluthenthal, 2000; Hartgers, van Ameijden, van den Hoek, & Coutinho, 1992), and no literature was found examining prevalence personal syringe reuse or sharing of used equipment with others among PWID already engaged in SEP services. The spread of infectious disease is of high concern to all of Kentucky’s SEPs and those impacted by the opioid epidemic, and it is well understood that syringe sharing and reuse are the primary proponents of disease propagation within networks of PWID (Havens et al., 2013).

The purpose of this literature review is to describe the concept of harm reduction and PWID perceptions of it in order to better understand if PWID have already identified issues with harm reduction affecting the potential for syringe misuse; to describe SEP best practices as a means of harm reduction; and to explore the utility of the social determinants of health model as a framework to guide future research aimed at uncovering what factors influence SEP-participating PWID’s decisions regarding drug injection equipment misuse. Understanding the interplay between PWID perception, SEP
best practices, and SDOH barriers may help future work with PWID to fully engage in SEP services and limit syringe and drug injecting equipment misuse.

**Harm Reduction**

The concept of harm reduction evolved during the early 1990s in response to the acquired immunodeficiency syndrome (AIDS) epidemic. The concept was defined in 1995 by Single, who states “harm reduction focuses on reducing the consequences of drug use rather than eliminating drug use,” (Single, 1995, p. 288) and its applications were described in the 1999 Canadian policy paper, Harm reduction, concepts and practice: A policy paper (Riley, 1999). Harm reduction involves working with people who use or abuse substances such as illicit drugs or alcohol, as well as policy makers, law enforcement personnel, addiction specialists, and healthcare providers with a goal of reducing the adverse physical and social harms associated with substance use (Des Jarlais, Friedman, & Ward, 1993; Erickson, 1995; Gold, 2009).

The primary harm reduction tool is use of a non-judgmental approach to provide straight-forward education, then allow the person using drugs to make their own decisions (Gold, 2009; Single, 1995). Harm reduction is meant to provide behavioral choices based on facts, which encourages substance users to exercise their autonomy to potentially reduce social or physical detriment (Bartlett, Brown, Shattell, Wright, & Lewallen, 2013). This approach is used for other stakeholders such as policy makers and providers to reduce stigma and effect policies to enhance services to the targeted population. In removing judgement and stigma, people who use drugs (PWUD) may be more responsive to their health needs, are more likely to have access to, enter, and receive appropriate addiction treatment, and may overcome difficult situations (Bartlett et
al., 2013). It is important to understand that PWUD often feel stigmatized and undeserving when interacting with healthcare providers; developing a sense of trust through fidelity, competence, honesty, confidentiality, and strong connections with healthcare providers and others who support PWUD increases their sense of trust (Treloar, Rance, Yates, & Mao, 2016).

Eight principles for harm reduction practice have been described by the Harm Reduction Coalition (2019). See Table 1. These principles serve as a flexible guide for creating goals, taking action, and general considerations for PWUD. Harm reduction strategies include syringe exchange programs, medication assisted therapy, supervised injection sites, injection supply vending sites (also known as syringe vending sites), peer exchange services, and more.

Table 1

<table>
<thead>
<tr>
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<tr>
<td>1</td>
<td>Accept that drug use is part of reality, but work can be done to minimize its effects. Drug use should not be ignored, nor condemned.</td>
</tr>
<tr>
<td>2</td>
<td>Understand that drug use encompasses a continuum of behaviors, from severe abuse to complete abstinence, and that there are safer ways of using drugs.</td>
</tr>
<tr>
<td>3</td>
<td>Cessation of all drug use is not a criterion for measuring a successful policy or intervention; consider individual or community quality of life as a criterion for success.</td>
</tr>
<tr>
<td>4</td>
<td>Encourage a non-judgmental and non-coercive approach to providing services (such as syringe exchange programs) in an effort to assist PWUD and their communities to reduce drug-related harm.</td>
</tr>
<tr>
<td>5</td>
<td>Encourage PWUD to have a voice in the creation of programs and policies meant to benefit them, rather than having programs and policies created for them without input.</td>
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Table 1 (continued).

<table>
<thead>
<tr>
<th>Principle</th>
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<td>6 Recognize PWUD are their own primary actors in reducing harms of their own use, and this encourages them to share information and support each other.</td>
</tr>
<tr>
<td>7 Many social inequalities affect PWUD’s vulnerability and capacity to effectively manage drug-related harms.</td>
</tr>
<tr>
<td>8 Harm reduction does not attempt to minimize or ignore the real threats and dangers associated with drug abuse, whether the drugs used are licit or illicit.</td>
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*Note.* (HRC, 2019).

As harm reduction principles are applied to new or expanding areas, knowing that PWUD/PWID recognize the importance of the concept is important. Perceptions of harm reduction among PWID have been reported in the literature. A systematic review using Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidance is shown in Figure 1. PubMed and CINAHL databases were searched without time limits for articles published in English and in the United States using search terms “harm reduction,” “people who inject drugs,” and “perception.” Titles and abstracts were screened for relevance to the perception of harm reduction programs among PWID.

Table 2 displays details from the included studies. Three of the four studies are qualitative and nature, and one was a cross-sectional survey.

Allen et al. (2019) qualitatively interviewed SEP participants in West Virginia and determined those PWID found the SEP trustworthy, and had demonstrated value in disease and overdose prevention (n=27). In rural Virginia, Baker et al. (2019) quantitatively assessed community stigma of PWID by evaluating whether subjects felt PWID were strong versus weak, deserving versus worthless, and if addiction was seen as a disease versus a choice, where stigma is a negative perception held by others about a population. Scores were compared to scores of community harm reduction support and
compared to the stigma measures. The authors determined subjects who felt more stigma towards PWID were less likely to support community harm reduction measures such as SEP, while support for SEP was strongest among those who believe the program helps reduce the spread of disease. A group of Chicago PWID participated in Carlberg-Racich’s (2016) study which sought to determine if they were interested in receiving harm reduction education as part of their HIV care, and how they perceived harm reduction approaches. Subjects were supportive of harm reduction, and even expressed enthusiasm; however, some reluctance to disclose their substance abuse status with their provider was also present. In Philadelphia, Harris et al. (2018) qualitatively explored PWID perceptions of supervised injection facilities, while also exploring where PWID prefer to inject (i.e. at home, abandoned houses, or secluded public space), and what factors lead to such a preference (n=42 PWID and 20 healthcare providers). The authors found PWID were fully supportive of supervised injection facilities as a harm reduction approach in mitigating the risks of drug injection in unsanitary conditions, and reported that PWID also recognize the benefits to public health and safety with their use.

Results from all studies generally indicated that PWID in the United States perceive harm reduction in a positive light, whether its principles are delivered in a healthcare setting, supervised injection facility, or SEP. Holding a positive view of harm reduction is important for PWID because it may influence their willingness to participate SEPs. Participants in Allen et al (2019) anticipated a positive experience with harm reduction in terms of safer injection counseling and supply provisions; Baker et al. (2016) hope PWID participating in comprehensive harm reduction programs are able to experience increased community support of harm reduction measures. Even when
support for harm reduction exists, PWID remain vulnerable to pressures to engage in syringe sharing and misuse (Allen et al. 2019). Nonetheless, PWID and crack cocaine smokers remain vested in harm reduction programs and optimistic about their potential to reduce drug-related harms, even if it is difficult to discuss ongoing drug use with healthcare providers (Carlberg-Racich, 2016).

Although there appears to be consensus among these studies, many questions remain unanswered. For example, how do perceptions of harm reduction compare among different PWID populations (rural versus urban, those with easy SEP access versus those with difficulty accessing SEP) and how perception of harm reduction might change when multiple types of programs are available. Another question to ask is why do some PWID have negative perceptions of harm reduction practices? Understanding how PWID perceive harm reduction programing may help tailor programs to meet needs at the local level, leading reinforced positive outcomes for PWID.
Figure 1. PRISMA flow diagram showing search results for articles discussing perceptions of harm reduction among PWID in the United States.
<table>
<thead>
<tr>
<th>Citation</th>
<th>Population, Location</th>
<th>Study Design</th>
<th>Description</th>
<th>Findings</th>
</tr>
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<tbody>
<tr>
<td>Allen, S.T., Grieb, S.M., O’Rourke, A., Yoder, R., Planchet, E….Sherman, S.G. (2019). Understanding the public health consequences of suspending a rural syringe exchange services program A qualitative study of the experiences of people who inject drugs. <em>Harm Reduction Journal, 16</em>(33). doi: 10.1186/s12954-019-0305-7</td>
<td>Adult PWID in Kanawha County, West Virginia</td>
<td>Qualitative semi-structured interviews analyzed with an iterative constant comparative technique. Data were collected in September 2018. A convenience sampling strategy was used, although the authors did not explicitly state it.</td>
<td>The Kanawha-Charleston Health Department opened a SEP in December 2015. Due to community-level and political upset about the SEP, the sociopolitical environment changed. This led to unfavorable laws/regulations for the SEP, forcing it to operate outside of best practices. The SEP ultimately suspended services due to these circumstances in March 2018. This study explored the public health implications of the SEP closure, and includes data on the perceptions of SEP as a harm reduction strategy.</td>
<td>Sixteen male and 11 female PWID participated in the study (n=27). The majority (n=21) utilized the SEP. Participants described their participation at the SEP and held a favorable perception of the harm reduction strategies used within the program. Participants described it as a trustworthy program, and highlighted positive attributes including the importance of disease and overdose prevention. The study discusses implications at the public health level due to the SEP closure. This study funded by the Bloomberg American Health Initiative at the Johns Hopkins Bloomberg School of Public Health.</td>
</tr>
<tr>
<td>Citation</td>
<td>Population, Location</td>
<td>Study Design</td>
<td>Description</td>
<td>Findings</td>
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<tr>
<td>Baker, L.S., Smith, W., Gulley, T., &amp; Tomann, M.M. (2019). Community perceptions of comprehensive harm reduction programs and stigma towards people who inject drugs in rural Virginia. <em>Journal of Community Health</em>. doi: 10.1007/s10900-019-00732-8</td>
<td>Adults in Dickenson County, Virginia. Sample includes PWID and non-PWID.</td>
<td>Cross-sectional, community-based participatory research study using a Likert-scale survey with one open-ended question administered via the internet or in-person from June to August 2018. A convenience sampling strategy was used for recruitment.</td>
<td>Investigators aimed to assess community perceptions of harm reduction programs and stigma toward PWID in Dickenson County, Virginia, which is considered a rural community. Assessment of categorical perceptions of PWID (strong v. weak, deserving v. worthless, addiction is a disease v. choice) were compared to ranked level of support for harm reduction programs.</td>
<td>One hundred fifty-three people participated, and 112 of them completed the study online. Ten percent of respondents identified as PWID (current or former), and 50% knew a PWID friend or family member. Respondents who reported high levels of stigma towards PWID were least likely to support harm reduction. Respondents who believed harm reduction programs could reduce the spread of infectious disease expressed a significant, positive correlation with support for programs, demonstrating a positive perception of harm reduction. This study was supported with funds from the Healthy Appalachia Institute at the University of Virginia’s College at Wise.</td>
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Table 2 (continued).

<table>
<thead>
<tr>
<th>Citation</th>
<th>Population, Location</th>
<th>Study Design</th>
<th>Description</th>
<th>Findings</th>
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<tbody>
<tr>
<td>Carlberg-Racich, S. (2016). Harm reduction interventions in HIV care: a qualitative exploration of patient and provider perspectives. PeerJ, 4. Doi: 10.7717/peerj.1932</td>
<td>HIV care providers and HIV patients with active substance use disorder in Chicago, Illinois</td>
<td>Qualitative phenomenological study using semi-structured interviews. Convenience and snowball sampling strategies were used. Peer debriefing and member-checking were employed.</td>
<td>Harm reduction strategies may be employed in clinical care settings, such as HIV clinics, but little is known about how patients and clinicians perceive incorporation of such training into practice. The investigator sought to explore such perceptions and develop implications for practice.</td>
<td>Thirty-one patients and seven clinicians participated in the interviews. All patients used heroin and/or cocaine, but not all injected. Patients were generally receptive to receiving harm reduction counseling in the clinical setting, and most agreed provision of sterile drug use equipment would be helpful. Some patients (n=16) were not comfortable disclosing their drug use to their clinicians due to fear of being labeled, shame, or negative messaging. Providers were supportive of using harm reduction strategies in clinical practice, but time constraints and lack of familiarity were seen as barriers. Overall, patients who use drugs were receptive to having harm reduction counseling and supplies incorporated into clinical care. This study was partially funded by the Sherri Aversa Memorial Dissertation Fund.</td>
</tr>
<tr>
<td>Citation</td>
<td>Population, Location</td>
<td>Study Design</td>
<td>Description</td>
<td>Findings</td>
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</tr>
<tr>
<td>Harris, R.E., Richardson, J., Frasso, R., &amp; Anderson, E.D. (2018). Perceptions about supervised injection facilities among people who inject drugs in Philadelphia. <em>International Journal of Drug Policy</em> 52, 56-61. doi: 10.1016/j.drugpo.2017.11.005</td>
<td>PWID and healthcare providers recruited from a SEP in Philadelphia, Pennsylvania</td>
<td>Qualitative free listing ethnographic exercise and semi-structured interviews were used. Convenience sampling and SEP staff referral served as recruitment strategies.</td>
<td>Two studies in the United States (in San Francisco and Rhode Island) demonstrated quantitative PWID support for supervised injection facilities (SIF). This study aimed to qualitatively explore PWID support for such facilities, and explored the motivations for drug injection location among PWID in Philadelphia.</td>
<td>Nine men and 10 women participated in the interview process (n=19). Forty-two PWID and 20 healthcare providers participated in the free listing exercise. PWID in this study support SIF as a positive harm reduction intervention, although they prefer to inject at home. They note the importance of clinical supervision to reduce overdose death. PWID perceived SIF as a potential “safe haven,” where they could perform injection in a calm environment without fear of assault or arrest. PWID perceived SIF value within the community by reducing community exposure to discarded injection equipment. PWID perceive social and environmental factors such as homelessness and distance as influencers on their degree of SIF use. The authors did not report a funding source for this study.</td>
</tr>
</tbody>
</table>

*Note:* SEP= Syringe Exchange Program. SIF= Supervised Injection Facility.
Syringe Exchange Programs

Syringe Exchange Programs (SEP) are based on harm reduction principles where a non-judgmental approach to the program participant is paramount (Treloar et al., 2016). They have been active in the United States since 1988 (Des Jarlais et al., 2015; Fernandes et al., 2017). Syringe Exchange Programs (SEP) services include provision of injecting supplies such as sterile water, cotton filters, tourniquets, cookers, syringe disposal containers, and an appropriate syringe selected based on the injector’s needs (i.e. the quality of their veins), with the expectation of syringes being returned to the site for safe disposal without re-use or sharing (Hagan, Pouget, & Des Jarlais, 2011). Counseling includes discussion of safer injection techniques, such as using alcohol swabs before injecting and using antibiotic ointment and an adhesive bandage afterward; discussion on infectious disease exposure risk; and the importance of safe syringe disposal (Hagan et al., 2011). An important aspect of SEP is the ability of the SEP staff, which is often comprised of certified drug and alcohol counselors or peers who also used drugs, to identify the aperture (or window of opportunity) for the person who injects drugs to consider entering addiction treatment, and the level of trust the programs can build with people who inject drugs (PWID) seeking care (Treloar et al., 2016). Counselors can make referrals for drug treatment, discuss drug treatment strategies and past experiences, and help match an addiction care program to the person’s needs.

Disease prevention is a critically important aspect, and many SEP sites offer a combination of HIV, HCV, and sexually transmitted infection screening for participants, as recommended by the Centers for Disease Control (CDC, 2012). Syringe exchange program services are increasingly available in the United States, but not all PWID access
such programs, or access them inconsistently for a variety of reasons (Davis et al., 2019). People who use drugs engaging in harm reduction programs have a general understanding of the public and personal health benefits these programs promote, and are supportive of them (Bozinoff, Small, Long, DeBeck, & Fast, 2017; Otiashvili et al., 2019).

Best practice guidelines for SEP exist, and cover aspects from effective practices to community engagement. In order to identify available best practices for SEP, a systematic review was conducted. PubMed (MEDLINE) was used as the primary database as it includes a diversity of literature across health and social sciences, including addiction. Using search terms “syringe exchange program,” or “syringe service program,” or “needle exchange program,” or “needle supply program,” and “best practice,” 37 articles were found. Two additional publications were located using a hand search strategy in an effort to locate resources from professional organizations. Figure 2 displays the PRISMA flow diagram, including reasons for excluding articles. Articles were included without time limitations, and if they were written in English, and stated best practices or provided guidelines for SEP services. Table 3 lists specific best practices from each guidance document.

The most comprehensive guidance on harm reduction appears to be Strike et al.’s 2006 document created with the help of the Ontario Needle Exchange Coordinating Committee, a representative committee from the Ontario Needle Exchange Network. The document covers SEP efficacy, factors involved in starting a program, recommendations for best practices surrounding supply handling and disposal, distribution of equipment, delivery models, and provision of education (including safer sex and overdose prevention), social support, medical care, law enforcement relationships, and tools for
program evaluation. Using the 2006 guidelines as a backbone, Strike and Watson (2017) modified recommendations to better fit the needs of crack cocaine smokers in terms of supply needs, and pipe distribution. The New York City Department of Mental Health and Hygiene 2009 guidance document offers best practice guidelines for SEPs across the United States. Content includes guiding principles, outlines SEP practices to avoid, recommendations for data collection and program evaluation, recommendations to improve SEP access and availability, how to address state paraphernalia laws related to SEP supplies, and additional recommendations such as encouragement of syringe pharmacy sales and prescribed syringes. The authors encouraged the Institute of Medicine to study SEP best practices, and the National Institutes of Health to convene a consensus panel for the purpose of identifying research gaps. Having best practices for SEP is as important as recognizing which practices to avoid. Understanding the challenges of SEP operators and SEP participants face in maximizing best practices while avoiding potentially damaging practices is critical for PWID as individuals, as well as ensuring a successful SEP operation.

All three best practice documents consider the importance of having low-barrier access to sterile drug injecting supplies. Education is a critical piece, including discussions on safer sex, disease transmission, and safer use practices. The best practice guidelines also consider program evaluation to be an important administrative component as a means to track supply distribution and interactions with clients, and to ensure client needs are being met. The guidance documents discuss the importance of providing a referral mechanism or actual healthcare in the SEP setting as many PWUD have health concerns such as abscesses, cellulitis, burns, and more. Linkage to addiction are,
including opioid substitution treatment, is another common recommendation. None of the guidance documents operating costs or detail all budgetary considerations.

Figure 2. PRISMA flow diagram demonstrating systematic search results for best practices for syringe exchange programs.
### Table 3

**Best Practice Guidelines for Syringe Exchange Programs**

<table>
<thead>
<tr>
<th>Source</th>
<th>Country</th>
<th>Description</th>
<th>Recommendations</th>
</tr>
</thead>
</table>
| Strike, C. & Watson, T.M. (2017). Education and equipment for people who smoke crack cocaine in Canada: progress and limits. *Harm Reduction Journal*, 14(1). doi: 10.1186/212954-017-0144-3 | Canada     | Among people who smoke crack cocaine, a number of negative health outcomes exist including oral ulcerations, oral cuts, burns, and increased risk for HIV and HCV. Harm reduction for people who smoke crack has lagged behind such programming for PWID. This work was not funded. | - Provide safer equipment (including stems, mouthpieces, screens, push sticks)  
- Do not require clients to return used equipment  
- Provide the quantity requested by the client  
- Have both pre-packaged kits and individual pieces of equipment available  
- Integrate programming into existing SEP  
- Provide safe disposal options  
- Provide other harm reduction supplies (condoms, lubricant) without quantity limits  
- Educate clients on safer use, risks of sharing smoking supplies, and safer sex  
Provide multiple locations for disposal |
- Provide sterile injecting equipment in quantities requested by clients without requiring them to return used equipment or limiting the number of new equipment provided.  
- Encourage clients to return used syringes for safe disposal  
- Educate clients about the risk of using non-sterile supplies |
### Table 3 (continued).

<table>
<thead>
<tr>
<th>Source</th>
<th>Country</th>
<th>Description</th>
<th>Recommendations</th>
</tr>
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</table>
| New York City Department of Health and Mental Hygiene (NYC DHMH) (2009). Recommended best practices for effective syringe exchange programs in the United States. Retrieved from https://harmreduction.org/wp-content/uploads/2012/01/NYC-SAP-Consensus-Statement.pdf | United States | A group of SEP experts convened to develop this consensus document outlining best practices for SEPs, and points out factors which may limit SEP effectiveness. | Effective SEPs share the following characteristics:  
- Low threshold access to services by  
- Maximum number of locations and available hours  
- Anonymity of participants  
- Minimize administrative requirements of participants  
Promote secondary exchange  
- Train and support peer educators  
- Do not limit syringe quantities  
Address local PWID population  
- Adapt activities and services to local needs  
Provide/coordinate health and social services as needed  
Include community stakeholders in creating supportive SEP environment  

Practices to Avoid:  
- Supplying syringes that may only be used once  
- Requiring one-for-one exchange  
- Limiting participants to a specific geographic location  
- Restricting supply volumes  
- Requiring identification of participants  
- Requiring unnecessary data collection |
SEP best practice guidance encouraged implementing the least restrictive supply
distribution model possible (NYC DHMH, 2009; Strike et al., 2006). There are multiple
models of SEP equipment distribution. They include a one-for-one exchange, less than
one-for-one, one-for-one plus, and needs-based system of supplying and returning used
syringes. Table 4 provides a brief description of each model. While the protocol of all
SEPs involves supply of syringes, provision of other drug injecting equipment varies
from program-to-program. For example, Bixler et al., (2018) evaluated SEPs in
Kentucky, West Virginia, and North Carolina and found wide variation in services
beyond supplying sterile syringes. Kentucky had the most operating programs with
access to injecting supplies (such as cookers, filters, water, alcohol swabs, tourniquets),
while West Virginia and Kentucky were nearly equal on the percentage of programs
supporting HIV and HCV screening, reproductive planning, and education. Regardless of
the syringe distribution model used, PWID have access to sterile syringes when visiting
SEP (Bixler et al., 2018; Bluthenthal et al., 2007).

Table 4

<table>
<thead>
<tr>
<th>Syringe Exchange Program Distribution Models</th>
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<tbody>
<tr>
<td>Model</td>
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</tr>
<tr>
<td>One-for-one exchange</td>
</tr>
<tr>
<td>Less than one-for-one exchange</td>
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<tr>
<td>One-for-one plus exchange</td>
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Table 4 (continued).

<table>
<thead>
<tr>
<th>Model</th>
<th>Program Description</th>
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<tbody>
<tr>
<td>Needs-based</td>
<td>Participants may obtain the number of sterile syringes needed without regard to the number of syringes returned. Participants are not limited on the frequency of their visits. This approach is considered best practice.</td>
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*Note:* (Bluthenthal et al., 2007; Sherman et al., 2015).

In Kentucky, many SEP programs are limited to a one-for-one syringe exchange, despite the fact this is not considered best practice (NYC DHMH, 2009; Sherman et al., 2015). This model may lead to syringe reuse and sharing among people unable to return an adequate number of used syringes (KDPH, 2015; NYC DHMH, 2009). In cities like Vancouver and San Francisco, where transitions from a one-for-one model to a needs-based model of syringe distribution occurred, there were increases in SEP participation, the number of syringes distributed and returned, and an increase in new SEP clients (Sherman et al., 2015). However, a one-for-one model may serve as a stepping stone for communities initially reluctant to provide SEP services, and those with budget limitations (KDPH, 2015). Ultimately, SEPs provide sterile injection supplies to the PWID community, but the impact on reduction in HCV/HIV incidence may be limited due to continued syringe sharing and misuse behavior and the one-for-one approach does not adequately cover PWID needs (Bluthenthal et al., 2007).

SEPs operating under a one-for-one plus model distribute syringes based on the number returned, but supply an additional set quantity per visit. This model is the intermediary between a strict one-for-one policy and a needs-based model (Bluthenthal et al., 2007). SEPs using a needs-based approach may serve as an important aspect in increasing SEP reach through secondary exchange (Brothers, 2016). The Centers for Disease Control (CDC) recommends a sterile syringe be used for each injection, and a
needs-based model of syringe exchange ensures PWID have a sterile syringe for each injection (2019).

What is happening in Kentucky’s Syringe Exchange Programs?

The United States has seen a surge in injection drug use and new cases of hepatitis C virus (HCV) infection since 2004, with sharp increases in both beginning in 2010 (Campbell et al., 2017; Zibbell et al., 2018; J. E. Zibbell et al., 2015). Outbreaks and clusters of human immunodeficiency virus (HIV) infection, which are also associated with injection drug use, have occurred across the United States during the same time frame (Bradley et al., 2019; Moorman, Krolakowski, Mathis, & Pack, 2018; Peters et al., 2016). One of the most serious HIV outbreaks occurred in Scott County, Indiana in 2014-2015, where 181 people were diagnosed with HIV (Peters et al., 2016). Among them, 167 (92.3%) were co-infected with HCV. Nearly 88% of the cases were directly tied to injection opioids (Peters et al., 2016). The Scott County HIV/HCV outbreak served as a wake-up call for the United States to recognize the risk of acquiring infectious diseases among vulnerable PWID populations, especially in Appalachia, where SEP had been illegal (Des Jarlais et al., 2015; Van Handel et al., 2016).

In response to the serious HIV/HCV outbreak in Scott County, Indiana and subsequent recognition of Kentucky’s vulnerability to experiencing a similar event, the Kentucky state legislature passed an emergency provision legalizing SEP in March 2015 (Bixler et al., 2018; Goodin, Fallin-Bennett, Green, & Freeman, 2018). The first SEP to begin operating in Kentucky opened on June 5, 2015 in Louisville, where it continues to operate as the state’s largest and most comprehensive SEP. By October 28, 2019, 69 SEPs had been authorized or became operational in Kentucky, and Kentucky has more
SEPs than any other state (see Figure 3). Each SEP required the approval of local (city), county, and state officials are under the jurisdiction of local health departments or their partners (Bixler et al., 2018).

![Figure 3. Kentucky map showing location by county of SEP in operation or approved as of August 2, 2019. Counties in green (n=54) are among the top 220 counties in the United States considered vulnerable to an HIV outbreak, similar to that seen in Scott County, Indiana (KCHFS, 2019).](image)

Kentucky SEPs are required to track the number of syringes distributed and returned, basic participant demographic factors, type of substance(s) injected, HIV and HCV screening tests, and if available: naloxone education and distribution, fentanyl test strip distribution and results, and linkage to social, addiction, or healthcare services. Over time, the Louisville Metro Department of Public Health and Wellness SEP, which uses a one-for-one plus syringe distribution model, began receiving participant reports of syringe sharing and used equipment reuse in their efforts to collect required data (W. ...
Syringes represent a common piece of equipment shared or reused; however, cookers, cotton filters, and tourniquets are also susceptible to misuse and may spread infectious disease (Kim, Jin, McFarland, & Raymond, 2015; Palmateer et al., 2014). Although many SEPs across the United States support sharing of sterile equipment through peers (secondary exchange), it is not a formally endorsed practice at any of Kentucky’s SEPs (Behrends et al., 2017).

The LMDPHW SEP promotes weekly visits through their efforts to supply participants with enough injecting equipment to last one week. However, participants are not required to return at any particular time interval. For first-time participants who do not have any used syringes to dispose of, 50 syringes are distributed along with all other needed equipment according to protocol (T. Nunez, personal communication, July 10, 2019). The participant has the option to return as many times as needed, as frequently as needed, to build up their syringe supply to last one week or more. Anyone returning syringes for disposal may take that number of sterile syringes, plus 20 if desired. If a returning participant is not able to exchange any used syringes, up to 20 syringes are distributed with the expectation they will begin to build their sterile supply once more through return visits. Notably, choice of substance and degree of dependency impacts the daily frequency of drug injection. PWID may inject opioids, cocaine, methamphetamine or other substance recreationally (less than once per week), and need very few syringes. However, those dependent on cocaine may need 20 or more syringes per day. At the LMDPHW SEP, 62.8% of participants reported injecting five or more times each day (Cave, 2019). Some participants exchange more than 400 syringes at their weekly visits,
suggesting that they are not only acquiring supplies for their own use, but supplies for others (Cave, 2019).

Overall, SEP programs in Kentucky follow most of the best practices for such programs as described in the New York City guidance (2009). They provide client anonymity, an assortment of sterile supplies (not just syringes), education, infectious disease testing, linkage to healthcare, social services, and addiction care, and make use of harm reduction principles in their approach to PWID in the programs. One of the largest gaps between SEP best practices and SEP operations in Kentucky is the distribution quantity limitation where participants may not receive enough sterile supplies. Although there is no limit on the number of visits a client can make to the SEP, this quantity limitation per visit may be a major barrier in ensuring clients are not sharing or reusing supplies. The social determinants of health model may help identify SEP participation barriers, and provide a framework for SEPs to positively adapt their programs to improve access.

Social Determinants of Health Model

The social determinants of health (SDOH) are a group of factors that influence the health, well-being, and longevity of people and has been used worldwide as a framework for improving population health and reducing health disparities. Based primarily on the work of Sir Michael Marmot, the SDOH were recognized as overarching influencers on individual health, and health outcomes and that these influencers occur across a social spectrum (Marmot & Wilkinson, 2006). That is, health influences are not merely a result of race, ethnicity, genetics, gender or individual behavior. Marmot recognized a multitude of factors that influence health, and developed the SDOH model to help enable
action strategies to improve the morbidity and mortality of populations (2006). Marmot and Wilkinson’s (2006) work linked social structure to health through a number of factors, and they presented applied examples and supporting evidence about how such factors could be influenced by experiences in early childhood, culture, socioeconomic factors and genetics (Marmot & Wilkinson, 2006). Figure 4 presents a social determinants of health model.

Figure 4. Social determinants of health demonstrating the link between social structure and pathways which may lead to health or disease (Brunner & Marmot, 2006, p. 9).

Over time, the model has been refined and adapted. The World Health Organization (WHO) (2019) describes SDOH as
…the conditions in which people are born, grow, live, work, and age. These circumstances are shaped by the distribution of money, power, and resources at global, national and local levels. The social determinants of health are mostly responsible for health inequities—the unfair and unavoidable differences in health status seen within and between countries. The World Health Organization (WHO) identifies key concepts within SDOH of economic stability, education, health and healthcare, neighborhood environments, and social contexts that include employment conditions, social inclusion, public health programs, women and gender equity, early childhood development, globalization, health systems, and measurement and evidence, and urbanization. Each of these key concepts are described in detail through publications and policy interventions that provide blueprints for communities (WHO, 2019).

The United States Department of Health and Human Services (HHS) Healthy People 2020 health objectives use five SDOH factors: economic stability, education, health and healthcare, neighborhood and built environment, and social and community contexts to frame objectives that lead to social and physical environments that promote good health (HHS, 2014). Each health determinant contains a subset of factors that may influence an individual’s chance for optimal health (see Table 5).
Table 5

**Social Determinants of Health and Key Influencing Factors for Healthy People 2020**

<table>
<thead>
<tr>
<th>Social Determinant</th>
<th>Factors</th>
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<tbody>
<tr>
<td>Economic stability</td>
<td>Employment, food insecurity, housing instability, poverty</td>
</tr>
<tr>
<td>Education</td>
<td>Early childhood education/development, enrollment in higher education, high school graduation, language and literacy</td>
</tr>
<tr>
<td>Health/Healthcare</td>
<td>Access to health care and primary care, health literacy</td>
</tr>
<tr>
<td>Neighborhood/ built</td>
<td>Access to foods that support health eating patterns, crime and</td>
</tr>
<tr>
<td>environment</td>
<td>violence, environmental conditions, quality of housing</td>
</tr>
<tr>
<td>Social/ Community contexts</td>
<td>Civic participation, discrimination, incarceration, social cohesion</td>
</tr>
</tbody>
</table>

*Note: Adapted from Healthy People 2020 (HHS, 2014).*

The SDOH are easily applied to PWID. Van Handel et al. (2016) noted how the PWID of Scott County, Indiana suffered from unemployment and poverty, had low educational attainment, and had poor life expectancy. People who inject drugs are often subject to incarceration, which may further increase their risk of acquiring HIV and/or HCV (Stone et al., 2018). Low health literacy among PWID is common, especially when trying to understand how their substance use may impact their liver health (Marshall, Grebely, Dore, & Treloar, 2017). In the healthcare setting, PWID are often stigmatized and discriminated against (Bartlett, Brown, Shattell, Wright, & Lewallen, 2013; Couto, Cruz, Salom, Maravilla, & Alati, 2018).

The SDOH model has been used by nurses caring for PWUD in an opioid substitution program in New Bedford, Massachusetts, an area similarly affected by both HCV and opioid epidemics (Gadbois, Chin, & Dalphonse, 2016) like Kentucky. The authors recognized limited access to housing, food, and primary healthcare were substantial barriers to improving the health of PWUD in an addiction care program. The authors used such SDOH as a tool for developing a quality improvement program that
involved nurses and multidisciplinary staff at an urban hospital. Outcomes demonstrated improved assessment of SDOH and care coordination for people in the program (Gadbois, Chin, & Dalphonse, 2016).

Applying the SDOH model in future research may help us understand the driving forces behind SEP participant’s inconsistent use of sterile injecting equipment with each injection episode. The SDOH disparities that may lead some to injection drug use may be the same disparities that limit full use of SEP and adoption of harm reduction strategies. Assessing, addressing, and mitigating potential factors that may be uncovered through research will support PWID to more fully utilize SEP services, thus, reducing the risk of additional spread of HIV, HCV, and other negative health outcomes. It may also help facilitate care coordination between the SEP and other community services.

Conclusion

Understanding why PWID engaging in SEP services are not consistently using sterile drug injection supplies for 100% of injection events needs to be explored. It is clear that sharing or reusing old injecting equipment propagates infectious disease, among other health-related and social harms. Kentucky is leading the nation in new cases of HCV infections, and is at risk for having simultaneous clusters or a widespread outbreak of HIV and HCV co-infection in PWID (Van Handel et al., 2016). Kentuckians now have access to SEP throughout the Commonwealth, but there continues to be syringe and drug injection equipment reuse and sharing among PWID participation in such programs. It is unclear if this dilemma is related to lack of best practice in syringe distribution models in Kentucky’s SEPs, where the majority of programs operate under a one-for-one model. Research is warranted to explore the degree of drug equipment
misuse among SEP clients, and to understand what factors contribute to such behavior.

The SDOH model may offer some explanation as to why PWID continue to share or reuse drug injecting equipment. The SDOH model may provide a framework for future action in addressing the problem.
CHAPTER III
EXAMINING SYRINGE AND INJECTING EQUIPMENT SHARING AND REUSE AMONG PEOPLE WHO INJECT DRUGS PARTICIPATING IN A SYRINGE EXCHANGE PROGRAM

Overview

Introduction: People Who Inject Drugs (PWID) are at risk for negative health consequences. Harm reduction strategies like syringe exchange programs (SEP) help reduce consequences like skin and soft tissue infections, infectious disease, and endocarditis through provision of sterile injecting supplies and education. These services benefit PWID, yet some SEP participants continue to share or reuse (misuse) drug injecting equipment. Although much is known about the behaviors and motivations for PWID to misuse equipment outside of SEPs, little is known about the factors influencing those who utilize SEP services who continue misuse injecting equipment. This study aimed to examine the prevalence of injection equipment misuse with others, personal injection equipment reuse, and to describe the factors leading to equipment misuse among people participating in SEP. Methods: The study utilized a two-phase approach. A cross-sectional survey was used to estimate the prevalence of injecting equipment misuse. Qualitative interviews explored behaviors and motivations leading to injection equipment misuse. Both strategies utilized convenience sampling at a single urban SEP in an Appalachian state. Results: There were 111 surveys were collected. Participants were 21-68 years old, with mean age of 37.8 years (SD=10.7). Most were male (59.5%, n=66);
87.4% (n=97) were white; 45.9% (n=51) visited SEP monthly; and 33.3% (n=37) weekly. The majority (69.4%, n=77) reported providing used equipment to others. Nearly 30% (n=32) reported reusing their old equipment, and 37.8% (n=42) reported using equipment that was used by another person. Fifteen individuals participated in interviews. The average age was 39 (SD=11.6; range=28-60); 53% (n=8) were male, 40% (n=6) were female, one was transgender; and 87% were white. Four themes uncovered behavioral/situational factors associated with drug injection equipment misuse: sterile supply stability issues; high-risk behaviors or attitudes; having the right equipment at the right time; and trying to be safe. Conclusion: Injection equipment sharing and reuse is common, even among people participating in a SEP. There are reasons for sharing and reuse that are related to social determinants of health. Multiple opportunities exist for SEPs to develop interventions and strategies to reduce the prevalence of injecting equipment misuse.
Background and Significance

People who inject drugs are at highest risk for acquiring and spreading hepatitis C virus (HCV) infections, representing up to 80% of HCV infection cases in the United States (Martin, Vickerman, Dore, & Hickman, 2015; Zibbell et al., 2018). Through harm reduction practices such as syringe exchange programs (SEP), also known as needle exchange programs and syringe service programs, participants are educated on best practices for reducing the risk of infection and other harms, and provided with sterile injecting supplies. Despite provision of free sterile injecting supplies and education, there exists some degree of syringe re-use or sharing among SEP participants (Bluthenthal et al., 2004; Bozinoff, Small, Long, DeBeck, & Fast, 2017; Ksobiech, 2006). Such behavior is counter-productive to SEPs and harm reduction as a whole because it allows for spread of infectious disease, skin and soft tissue infections, or blood stream infections. Although behaviors of people who inject drugs (PWID) are well described and the need for harm reduction through SEP is clearly supported in literature, little is known about the factors and behaviors influencing SEP participants who might continue to share or re-use syringes, and the prevalence of such behavior (Allen, Ruiz, Roess, & Jones, 2015; Dunleavy et al., 2017; Hagan, Pouget, & Des Jarlais, 2011; Hesamizadeh, Sharafi, Rezaee-Zavareh, Behnava, & Alavian, 2016; Mateu-Gelabert et al., 2014).

This risky sharing and re-use of supply behavior occurs within all PWID communities. Ksobiech (2006) conducted a meta-analysis demonstrating syringe sharing behaviors were reduced among SEP participants compared to those who do not participate, but the prevalence of syringe sharing was not reported in this analysis. In a broader search conducted in the fall of 2018 using PubMed (MEDLINE), CINAHL,
EMBASE, and PsychINFO, including worldwide articles using search terms “people who inject drugs”, “syringe exchange program,” “needle exchange,” “syringe or needle misuse”, “re-use”, and “sharing”, only one article was found (Kim, Jin, McFarland & Raymond, 2015). Kim et al. (2015) determined the rate of unsafe injecting practices (such as using a syringe previously used by another person, 34.2% [95% CI 24.2-45.2] in 2005 to 12.5% [95% CI 7.5-18.6] in 2012, p<0.001, n=570) had declined, and rates of syringe acquisition from pharmacies (17.8% in 2005 to 32.1% in 2012, p<0.001) or SEP (80.7% in 2009 to 86.5% in 2012, p<0.022, n=570) had increased. Although some literature discusses Secondary Syringe Exchange, which is a practice of visiting SEP to acquire equipment and education to be distributed to others outside of the program (Behrends, Li & Gibson, 2017), no studies could be found that focused on behavioral factors associated with used syringe sharing and personal reuse of equipment by SEP participants completed within the past twenty years.

The purpose of this research was to explore the motivations and behaviors of PWID using SEP in a Southern state who share new or used equipment, or re-use (hereafter, misuse) syringes and drug injection equipment. Drug injection equipment includes syringes, cookers, filters/cotton, sterile water, and tourniquets. The Specific Aims are: 1) to examine the daily, weekly, and monthly prevalence of syringe and equipment reuse and sharing among PWID participating in SEP; 2) to describe the daily, weekly, and monthly personal syringe re-use prevalence; and 3) to identify behaviors and motivations leading SEP participants to misuse SEP-provided syringe and/or injecting equipment.

**Theoretical Framework**
The behaviors of many individuals who inject drugs may not reflect application of knowledge about the risks of acquiring HIV or HCV infection as a consequence of sharing injection equipment or poor sanitation techniques despite availability of SEP and sterile syringe supplies through pharmacies (Golub et al., 2007; Kim et al., 2015; Palmateer et al., 2014). Furthermore, PWID with access to SEP services may not exclusively obtain syringes from a sterile source such as SEP or a pharmacy; they may buy them from drug dealers, share with friends, or use a diabetic’s discarded insulin syringes (Wejnert et al., 2016). This behavior may be due to a multitude of factors that have not been previously identified due to the paucity of research regarding PWID engaged in SEP services. Although some hypotheses have been identified such as defensive behavior in which PWID may prioritize immediate injection to avoid withdrawal symptoms, or social norms that encourage sharing a drug preparation among multiple users in a group setting (Bozinoff et al., 2017; Golub et al., 2007). The lack of research warrants the use of a health model that allows for a complex view of factors that may serve as barriers or facilitators of these behaviors. Therefore, applying a model focused on the social determinants of health (SDOH) is appropriate.

The SDOH model was developed by Marmot in the 1990s. The SDOH model described the ways in which economic and social standing could influence health and health outcomes among individuals and populations. Marmot and Wilkinson’s (2006) SDOH model included determinants such as social structure, social environment, employment, health behaviors, and material factors while considering the influence of early life experiences, genetics, and culture in the overall health or disease status of populations. This socioeconomic model has been adapted across the world, including the
World Health Organization (WHO) which uses the SDOH as a guide to impact the health of diverse populations, even nations. The United States Department of Health and Human Services (DHHS) adopted a list of five determinants on which the Healthy People 2020 health objectives are based. Both the WHO and DHHS models break down the determinants into factors, which can be used as assessment tools and a framework for policy development. Table 1 displays the DHHS disparities and factors.

Table 1

<table>
<thead>
<tr>
<th>Social Determinant</th>
<th>Factors</th>
</tr>
</thead>
<tbody>
<tr>
<td>Economic stability</td>
<td>Employment, food insecurity, housing instability, poverty</td>
</tr>
<tr>
<td>Education</td>
<td>Early childhood education/development, enrollment in higher education, high school graduation, language and literacy</td>
</tr>
<tr>
<td>Health/Healthcare</td>
<td>Access to health care and primary care, health literacy</td>
</tr>
<tr>
<td>Neighborhood/ built environment</td>
<td>Access to foods that support health eating patterns, crime and violence, environmental conditions, quality of housing</td>
</tr>
<tr>
<td>Social/ Community contexts</td>
<td>Civic participation, discrimination, incarceration, social cohesion</td>
</tr>
</tbody>
</table>

*Note: Adapted from Healthy People 2020 (DHHS, 2014).*

For the purposes of this research, the DHHS (2014) SDOH model used in Healthy People 2020 was applied to the findings. This SDOH model is specific to the United States, and the objectives related to SDOH positively impact PWID (see Appendix A). Exploration of the factors within the five social determinants may hold the most potential for understanding the risky PWID behavior as it relates to decisions about syringe and drug injecting equipment misuse, and also serve as a framework for the development of future interventions.

**Methods**

**Study Design**
This was a two-phase study which consisted of quantitative (survey) and qualitative (individual interview) approaches. A two-phase approach was best strategy to quantitatively estimate the frequency of the behaviors of interest, to qualitatively uncover reasons for them, and to avoid the problem of overlooking important evidence while increasing understanding of the problem (Pluye & Hong, 2014). Cross-sectional surveys were used to estimate frequency of behaviors in a given population, and was considered the most appropriate approach to measure drug injecting equipment misuse in this sample. Cross-sectional surveys are a common quantitative approach to assessing prevalence, and may also be used for measuring attitudes, validation studies for different instruments, and assessing reliability (Kesmodel, 2018).

Qualitative methods, particularly a focused ethnography approach, has been used to study people who use drugs worldwide, and have examined multiple types of illicit drugs and/or alcohol, and routes of administration (Ambrogne, 1999; Dilkes-Frayne, 2016; Fast, Kerr, Wood, & Small, 2014; McNeil, Kerr, Lampkin, & Small, 2015; Pagano et al., 2018; Wall, 2015). Studies have centered around identifying barriers for drug users seeking harm reduction (McNeil et al., 2015), how networks of drug use are created and social norms developed at multi-day music festivals (Dilkes-Frayne, 2016), and how people of an ethnic minority who use drugs support each other in addiction treatment (Pagano et al., 2018). Focused ethnography intends to uncover reasons for behaviors, problems with existing programs, and potential solutions to such problems through “mapping of the cognitive world of a culture; a cultures’ shared meanings, semantic rules” (Polit & Beck, 2017, p.249; Rashid, Hodgson, & Luig, 2019; Wall, 2015). Interpretation of data resources, such as interviews, photos and field observations help
researchers form the response to the question, “What is happening here?” amongst a culture or subculture (Wall, 2015).

**Setting**

The study was conducted within a mid-sized metropolitan city in the southeastern United States with a population of 602,000. This community is served by the Syringe Exchange Program. The metropolitan Syringe Exchange Program (SEP) opened in June 2015. From opening through April 2018, the SEP served more than 15,000 unique clients. Table 2 displays demographic details for the SEP participants. In February 2017, the SEP staff informally surveyed participants and found 29% shared syringes (n=497; Y. Chen, personal communication, 2018).

**Table 2**

*Syringe Exchange Program Participant Demographics for All Clients 6/10/15 to 4/30/18*

<table>
<thead>
<tr>
<th>Clients</th>
<th>Number</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Clients</td>
<td>15,325</td>
<td></td>
</tr>
<tr>
<td>Return Clients</td>
<td>6,834</td>
<td>44.59</td>
</tr>
<tr>
<td>Age (years)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>17-29</td>
<td>3,443</td>
<td>32.61</td>
</tr>
<tr>
<td>30-39</td>
<td>4,387</td>
<td>41.55</td>
</tr>
<tr>
<td>40-49</td>
<td>1,834</td>
<td>17.37</td>
</tr>
<tr>
<td>50-59</td>
<td>703</td>
<td>6.66</td>
</tr>
<tr>
<td>60+</td>
<td>191</td>
<td>1.81</td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>3,945</td>
<td>38.41</td>
</tr>
<tr>
<td>Male</td>
<td>6,291</td>
<td>61.25</td>
</tr>
<tr>
<td>Transgender - ID Female</td>
<td>18</td>
<td>0.18</td>
</tr>
<tr>
<td>Transgender - ID Male</td>
<td>17</td>
<td>0.17</td>
</tr>
<tr>
<td>Sex Orientation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Straight/Heterosexual</td>
<td>9,351</td>
<td>90.42</td>
</tr>
<tr>
<td>Gay/Lesbian</td>
<td>380</td>
<td>3.67</td>
</tr>
<tr>
<td>Bisexual</td>
<td>606</td>
<td>5.86</td>
</tr>
<tr>
<td>Questioning</td>
<td>5</td>
<td>0.05</td>
</tr>
</tbody>
</table>
Table 2 (continued).

<table>
<thead>
<tr>
<th>Race</th>
<th>Number</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>White</td>
<td>9,589</td>
<td>92.52</td>
</tr>
<tr>
<td>Black/African American</td>
<td>469</td>
<td>4.53</td>
</tr>
<tr>
<td>Native American</td>
<td>89</td>
<td>0.86</td>
</tr>
<tr>
<td>Pacific Islander</td>
<td>12</td>
<td>0.12</td>
</tr>
<tr>
<td>Asian</td>
<td>15</td>
<td>0.14</td>
</tr>
<tr>
<td>Other</td>
<td>190</td>
<td>1.83</td>
</tr>
<tr>
<td>Hispanic Yes</td>
<td>248</td>
<td>2.44</td>
</tr>
<tr>
<td>Hispanic No</td>
<td>10,118</td>
<td>97.59</td>
</tr>
<tr>
<td>Employed Yes</td>
<td>3,452</td>
<td>33.36</td>
</tr>
<tr>
<td>Employed No</td>
<td>6,897</td>
<td>66.64</td>
</tr>
<tr>
<td>Insurance Medicaid</td>
<td>5,944</td>
<td>56.21</td>
</tr>
<tr>
<td>Insurance Medicare</td>
<td>348</td>
<td>3.29</td>
</tr>
<tr>
<td>Insurance Private/Commercial</td>
<td>1,140</td>
<td>10.78</td>
</tr>
<tr>
<td>Insurance Other</td>
<td>72</td>
<td>0.68</td>
</tr>
<tr>
<td>Insurance Uninsured</td>
<td>2,796</td>
<td>26.44</td>
</tr>
<tr>
<td>Drug(s) Used Heroin</td>
<td>8,446</td>
<td>79.88</td>
</tr>
<tr>
<td>Drug(s) Used Other Opioids</td>
<td>370</td>
<td>3.50</td>
</tr>
<tr>
<td>Drug(s) Used Cocaine</td>
<td>314</td>
<td>2.97</td>
</tr>
<tr>
<td>Drug(s) Used Methamphetamine</td>
<td>3,202</td>
<td>30.28</td>
</tr>
<tr>
<td>Drug(s) Used Methadone</td>
<td>9</td>
<td>0.09</td>
</tr>
<tr>
<td>Drug(s) Used Suboxone</td>
<td>10</td>
<td>0.09</td>
</tr>
<tr>
<td>Drug(s) Used Other Drugs</td>
<td>183</td>
<td>1.73</td>
</tr>
<tr>
<td>Drug Use Frequency 1 or 2</td>
<td>1,430</td>
<td>13.52</td>
</tr>
<tr>
<td>Drug Use Frequency 3 or 4</td>
<td>2,500</td>
<td>23.64</td>
</tr>
<tr>
<td>Drug Use Frequency 5 or more</td>
<td>6,644</td>
<td>62.83</td>
</tr>
</tbody>
</table>

*Note.* Unpublished data provided courtesy of the staff of the SEP. The SEP received anecdotal reports from PWID using their services that they are sharing or reusing syringes and supplies (M. LaRocco and W. Crabtree, personal communication, January 16, 2017). Drug(s) used does not equal 100% as some participants may report simultaneous heroin and methamphetamine use.

**Projection of human subjects.**

The University Institutional Review Board reviewed and approved this study. A waiver of informed consent was approved for quantitative survey participants; full
informed consent was required for interviews. Pseudonyms were used for consent signatures. A National Institutes of Health Certificate of Confidentiality was approved for participants in the qualitative interviews. Both quantitative survey and qualitative interview participants remained anonymous to the investigator.

**Sample**

Inclusion criteria for the quantitative portion of this study were as follows: subjects must be a SEP participant (having visited the SEP at least once), age 18 years or older, a current injection drug user, agreeable to participation, and had not previously taken the survey. They were excluded from participation if they were under 18 years, even if they were an emancipated minor, had taken the survey previously, or if they could not read or understand English. Subjects completed the self-administered survey with an investigator nearby to clarify any questions as needed.

For the qualitative interviews, subjects were eligible to participate if they were a SEP participant who reported at least monthly attendance over a six-month period, was aged 18 years or older, able to provide informed consent, a current injection drug user with at least six months of reported injection drug use experience, and any reported history of syringe misuse. Participants were eligible even if they were recreational drug users who did not inject on a regular basis. Subjects were excluded if they were under age 18, unwilling to be audio-recorded, could not speak or understand English, or unwilling to provide informed consent. Subjects completing surveys could be included in the interviews, and no link was made between the subject’s survey and interview.

**Recruitment.**
From February 13 through May 8, 2019, a convenience sample of subjects visiting in a metropolitan syringe exchange program were invited to complete the eight-item survey. Potential subjects were approached by the investigator as they waited for SEP services. After a brief introduction and explanation of the study, participants reviewed key study information, including study purpose, benefits/risks of participation, and alternatives to participation (preamble consent) and decided if they wished to participate by completing the survey, or declining. Surveys were self-administered on a single sheet of paper and took two-to-three minutes to complete.

Interview participants were introduced to the investigator by SEP staff or were recruited as they waited for SEP services. After the investigator introduced herself, potential participants were taken to a private area of the SEP where informed consent was completed. Subjects completing the consent were interviewed using an interview guide containing questions addressing equipment procurement, motivation and situational factors leading to supply sharing, and questions surrounding supply reuse. The interviews lasted 15-30 minutes each. Interview subjects were recruited until the newest subjects were consistently reporting experiences similar to previous subjects (data saturation). Field notes, observations, photographs taken within the SEP, and printed materials available in the SEP were collected and reviewed per the focused ethnography guidelines of Polit & Beck (2017, p.333).

Study Procedures

Cross-sectional surveys were used to quantitatively describe the frequency of personal drug injecting equipment reuse, and sharing of new and used drug injecting equipment to fulfill aims one and two of the study. The survey was modeled after an
informal survey the SEP had distributed to participants in February 2017. The investigator refined the survey based on content expert input and SEP participant feedback. The eight-item paper survey consisted of multiple choice and a fill-in-the-blank response for age (see Appendix D). Table 3 defines frequencies of behaviors, as listed on the survey and use for analysis purposes. Potential participants were approached face-to-face by the investigator within the SEP and invited to participate in the study. Those agreeing to participate reviewed the consent (Appendix E) with the investigator. Any questions potential participants had about participating in the study were answered. Those agreeing to take part in the study completed the survey on their own.

Table 3

<table>
<thead>
<tr>
<th>Behavior Frequency Definitions</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Never</td>
<td>The participant has never engaged in the specified behavior.</td>
</tr>
<tr>
<td>Less Than Monthly</td>
<td>The behavior occurs less than once per month.</td>
</tr>
<tr>
<td>Monthly</td>
<td>The behavior occurs 1-3 times most months</td>
</tr>
<tr>
<td>Weekly</td>
<td>The behavior occurs 1-4 times most weeks</td>
</tr>
<tr>
<td>Daily</td>
<td>The behavior occurs 5-7 times most weeks</td>
</tr>
</tbody>
</table>

One-time semi-structured interviews qualitatively addressed factors and motivations around syringe misuse behavior. Interview questions were open-ended and conducted one-on-one with the author. Like the quantitative survey, interview questions were developed by the investigators and refined by a content expert (see Appendix C). These focused ethnography questions explored the culture and environment surrounding sterile drug supply acquisition, use, and reuse. Two pilot interviews were conducted with SEP participants prior to formal data collection to ensure clarity of questioning from a participant perspective, and to assist the investigator in developing interview skills. All
interviews were conducted face-to-face in a private room within the SEP over 15-30 minutes. The investigator did not have a prior relationship with interview participants; participants were informed the interview was part of the author’s dissertation process before informed consent was completed.

**Data Analysis**

**Quantitative analysis.**

Quantitative data were analyzed using SPSS version 25.0 (IBM, Armonk, NY). Descriptive statistics explored demographic characteristics such as age, gender, ethnicity, and frequency of SEP equipment misuse. Frequency of misuse were collapsed into binary variables (ever and never) to avoid small cells. Further analysis explored groups using Cochran-Mantel-Haenszel tests to detect differences between age and gender across drug injecting equipment sharing and reuse.

**Qualitative analysis.**

For qualitative analysis, interviews were transcribed using NVivo Transcribe (QSR International, Melbourne, Australia) then verified by the investigator for accuracy. Qualitative data management was facilitated with the use NVivo 12 Plus (QSR International, Melbourne Australia). Transcripts were not shared with participants due to the need to preserve their anonymity and logistical difficulty setting appointments for such a purpose. Transcripts were coded line-by-line using an open-coding strategy to identify common categories and concepts that may help explain the subculture of people who use drugs who participate in a syringe exchange program. Coding was an iterative process, with initial codes such as equipment cleaning, transportation problems, avoiding withdrawal, and protection of anonymity identified as important factors. Open coding
allows investigators to label concepts and define categories based on properties or dimensions in text (Khandkar, n.d.). A second reader helped validate initial codes for investigator triangulation (Rashid, Hodgson, & Luig, 2019). Secondary coding grouped codes together into themes (Polit & Beck, 2017, pp 574-579) which describe the culture surrounding syringe and injection equipment misuse.

**Results**

**Quantitative Sample Characteristics**

There were 111 individuals who completed the survey. Table 4 displays demographics and overview of syringe misuse behaviors. The age range for survey participants was 21 to 68 years with mean age of 37.7 (SD=10.7) and median of 36 years.

Table 4

<table>
<thead>
<tr>
<th>Survey Item</th>
<th>Frequency (%)</th>
<th>Binary Frequency (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Gender, n=111</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>66 (59.5)</td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>45 (40.5)</td>
<td></td>
</tr>
<tr>
<td><strong>Race/Ethnicity, n=110</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>White, non-Hispanic</td>
<td>97 (87.4)</td>
<td></td>
</tr>
<tr>
<td>Black, non-Hispanic</td>
<td>9 (8.1)</td>
<td></td>
</tr>
<tr>
<td>Hispanic/Latino/Latina</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>4 (3.6)</td>
<td></td>
</tr>
<tr>
<td>Missing</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td><strong>Visit Frequency, n=106</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>First Time</td>
<td>5 (4.5)</td>
<td></td>
</tr>
<tr>
<td>Less Than Once Per Month</td>
<td>10 (9.0)</td>
<td></td>
</tr>
<tr>
<td>Monthly</td>
<td>51 (45.9)</td>
<td></td>
</tr>
<tr>
<td>Weekly</td>
<td>37 (33.3)</td>
<td></td>
</tr>
<tr>
<td>Daily</td>
<td>3 (2.7)</td>
<td></td>
</tr>
<tr>
<td>Missing</td>
<td>5 (4.5)</td>
<td></td>
</tr>
</tbody>
</table>
Table 4 (continued).

<table>
<thead>
<tr>
<th>Survey Item</th>
<th>Frequency (%)</th>
<th>Binary Frequency (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Provide Used Equipment to Others, n=111</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Never</td>
<td>77 (69.4)</td>
<td>Never: 77 (69.4)</td>
</tr>
<tr>
<td>Less Than Once Per Month</td>
<td>20 (18.0)</td>
<td>Ever: 34 (30.6)</td>
</tr>
<tr>
<td>Monthly</td>
<td>4 (3.6)</td>
<td></td>
</tr>
<tr>
<td>Weekly</td>
<td>3 (2.7)</td>
<td></td>
</tr>
<tr>
<td>Daily</td>
<td>7 (6.3)</td>
<td></td>
</tr>
<tr>
<td><strong>Provide New Equipment to Others, n=109</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Never</td>
<td>46 (41.4)</td>
<td>Never: 46 (42.2)</td>
</tr>
<tr>
<td>Less Than Once Per Month</td>
<td>16 (14.4)</td>
<td>Ever: 63 (57.8)</td>
</tr>
<tr>
<td>Monthly</td>
<td>19 (17.1)</td>
<td></td>
</tr>
<tr>
<td>Weekly</td>
<td>17 (15.3)</td>
<td></td>
</tr>
<tr>
<td>Daily</td>
<td>11 (9.9)</td>
<td></td>
</tr>
<tr>
<td>Missing</td>
<td>2 (1.8)</td>
<td></td>
</tr>
<tr>
<td><strong>Personal Reuse, n=110</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Never</td>
<td>32 (28.8)</td>
<td>Never: 32 (29.0)</td>
</tr>
<tr>
<td>Less Than Once Per Month</td>
<td>16 (14.4)</td>
<td>Ever: 78 (70.9)</td>
</tr>
<tr>
<td>Monthly</td>
<td>26 (23.4)</td>
<td></td>
</tr>
<tr>
<td>Weekly</td>
<td>18 (16.2)</td>
<td></td>
</tr>
<tr>
<td>Daily</td>
<td>18 (16.2)</td>
<td></td>
</tr>
<tr>
<td>Missing</td>
<td>1 (1.0)</td>
<td></td>
</tr>
<tr>
<td><strong>Receptive Reuse, n=111</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Never</td>
<td>69 (62.2)</td>
<td>Never: 69 (62.2)</td>
</tr>
<tr>
<td>Less Than Once Per Month</td>
<td>5 (4.5)</td>
<td>Ever: 42 (37.8)</td>
</tr>
<tr>
<td>Monthly</td>
<td>13 (11.7)</td>
<td></td>
</tr>
<tr>
<td>Weekly</td>
<td>6 (5.4)</td>
<td></td>
</tr>
<tr>
<td>Daily</td>
<td>18 (16.2)</td>
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</table>
Quantitative Findings

Sharing of new syringe and injection equipment among SEP participants was common (n=63, 57.8%) with 28 (25.7%) reporting the sharing of new supplies with others on a daily or weekly basis. Reuse of personally-used drug injecting equipment was the most common misuse behavior (n=78, 70.9%), with up to 32.7% (n=36) of participants reusing equipment on a daily or weekly basis. Reuse of equipment obtained from another individual was reported by 42 (37.8%) survey participants, 30 of whom were male. Sharing of used syringes was reported by 34 (30.6%). A higher proportion of males under 30 years of age reported using injection drug equipment that was previously used by another person (63%, n=19) compared to women, regardless of age (31.3%, n=16 for women under 30 and 27.6%, n=29 for women 30 years and older), and older men (40.4%, n=47). Overall, syringe and injection equipment misuse was a familiar activity to many SEP participants. Table 5 displays syringe misuse prevalence by age and gender, where no particular form of syringe misuse was significant when stratifying across age and gender.

Table 5

<table>
<thead>
<tr>
<th>Variable</th>
<th>Gender</th>
<th>Age (years)</th>
<th>Never</th>
<th>Ever</th>
<th>Total</th>
<th>Chi Square</th>
<th>DF</th>
<th>p-value</th>
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<td>12</td>
<td>19</td>
<td>1.373</td>
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<td></td>
<td>&gt;30</td>
<td>29</td>
<td>18</td>
<td>47</td>
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<td></td>
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<tr>
<td></td>
<td>Female</td>
<td>≤ 30</td>
<td>12</td>
<td>4</td>
<td>16</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>&gt;30</td>
<td>20</td>
<td>9</td>
<td>29</td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Personal Reuse</td>
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<td>19</td>
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<td>1</td>
<td>0.687</td>
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<td></td>
<td></td>
<td>&gt;30</td>
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<td>31</td>
<td>46</td>
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<td></td>
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</table>
Table 5 (continued.)

<table>
<thead>
<tr>
<th>Variable</th>
<th>Gender</th>
<th>Age (years)</th>
<th>Never</th>
<th>Ever</th>
<th>Total</th>
<th>Chi Square</th>
<th>DF</th>
<th>p-value</th>
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<tr>
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<td></td>
</tr>
<tr>
<td>Sharing New</td>
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<td></td>
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<td></td>
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<td>&gt;30</td>
<td>8</td>
<td>21</td>
<td>29</td>
<td></td>
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</tbody>
</table>

**Qualitative Sample Characteristics**

Interview participants (n=15) ranged in age from 28 to 60 years; eight were male (53%), six were female (40%), and one was male-to-female transgender (7%). All were Caucasian (n=13, 87%) except for one African American and one Hispanic. Seven (47%) participants self-disclosed a positive HIV or HCV infection status.

**Qualitative Findings**

Line-by-line coding produced 54 codes on the first reading of transcripts. Through re-reading and iteration, initial coding was reduced to 35 concepts. The concepts were used to develop four themes that help explain syringe and injection equipment misuse among people in the SEP. Experiencing sterile supply stability issues and having a high-risk behavior/attitude were associated with motivations and behaviors or situations that made sharing or reusing old equipment likely. Having the proper injecting equipment and trying to be safe were themes associated with reduced equipment misuse behavior and improved motivation to use only sterile supplies. Major concepts within these themes and their related SDOH are listed in Table 6.
### Table 6

**Major Themes and Associated Social Determinants of Health**

<table>
<thead>
<tr>
<th>Theme</th>
<th>Behavioral, Situational, or Motivational Concept</th>
<th>Related Social Determinant(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sterile supply stability issues</td>
<td>- Transportation problems (n=4)</td>
<td>Economic stability</td>
</tr>
<tr>
<td></td>
<td>- Problems with supply limitations (n=3)</td>
<td>Health and healthcare</td>
</tr>
<tr>
<td></td>
<td>- Limited SEP locations/hours (n=4)</td>
<td>Health and healthcare</td>
</tr>
<tr>
<td></td>
<td>- Fear of arrest (n=3)</td>
<td>Community context</td>
</tr>
<tr>
<td>High risk behaviors or attitudes</td>
<td>- Saving drugs for later use (n=11)</td>
<td>Health and healthcare</td>
</tr>
<tr>
<td></td>
<td>- Intimate partner sharing (n=10)</td>
<td>Social context</td>
</tr>
<tr>
<td></td>
<td>- Ambivalence about using old Equipment (n=10)</td>
<td>Health and healthcare</td>
</tr>
<tr>
<td></td>
<td>- Not considering sterility of equipment aside from syringe (n=4)</td>
<td>Health and healthcare</td>
</tr>
<tr>
<td></td>
<td>- Knowing HIV/HCV status (n=12)</td>
<td>Social context</td>
</tr>
<tr>
<td>Having the right equipment at the right time</td>
<td>- Using proper equipment for successful, comfortable, sterile injection (n=6)</td>
<td>Health and healthcare</td>
</tr>
<tr>
<td></td>
<td>- Convenience in getting new supplies (n=4)</td>
<td>Built environment, community context, economic stability</td>
</tr>
<tr>
<td></td>
<td>- Wanting to avoid using other’s medical supplies (n=4)</td>
<td>Social context</td>
</tr>
<tr>
<td>Trying to be safe</td>
<td>- Cleaning used equipment (n=10)</td>
<td>Health and healthcare</td>
</tr>
<tr>
<td></td>
<td>- Maintaining adequate stock of sterile Supplies (n=5)</td>
<td>Health and healthcare</td>
</tr>
<tr>
<td></td>
<td>- Concern for the safety of other PWID (n=9)</td>
<td>Social context, health and healthcare</td>
</tr>
<tr>
<td></td>
<td>- Concern for personal safety (n=4)</td>
<td>Health and healthcare</td>
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<tr>
<td></td>
<td>- Knowing HIV/HCV status (n=12)</td>
<td>Health and healthcare</td>
</tr>
<tr>
<td></td>
<td>- Concern for public safety (n=2)</td>
<td>Health and healthcare, Community context</td>
</tr>
</tbody>
</table>

*Note:* Behavioral or situational concepts are actions or circumstances that influence misuse. Motivational concepts are thoughts/feelings/desires that lead to misuse.
Sterile supply stability emerged as a theme correlated with the likelihood of sterile drug equipment sharing and reuse. Having high risk behaviors or attitudes surrounding injection drug use emerged as a theme because participants may disregard infection control measures (sterility) due to ambivalence about sharing with sexual partners, or because PWID culture suggested that a practice may have been safe or low-risk. Having the right equipment at the right time had a positive impact on participants’ use of sterile injecting supplies; however, when the proper equipment was not available, reuse of used supplies was common. Despite the high-risk nature of injection drug use, participants valued safety from both public and personal health views.

**Sterile Supply Stability**

Lack of access to sterile equipment at the time of injection was a significant factor in personal drug injecting equipment re-use, receptive syringe re-use, and sharing of used equipment with others. Interview participants reported personal equipment reuse was commonly practiced when sterile supplies were not immediately available. Participants were aware of their need to return to SEP, but may have been unable to do so due to transportation difficulties or limited SEP hours, reflective of the economic stability social determinant (limited money for transportation) and health/healthcare (SEP is closed).

Joe finds that limiting supplies to 20 syringes more than what is returned may not be enough for some drug injectors. In cases where Ashlee could not make it to the SEP in time for a resupply of equipment, she notes “I’ll try to just use them once, but then things will come up, and I won’t make it [to the SEP] by the time they close, or whatever else. And then I’ll end up going in to my ‘just been used once’ stash in my little container. And I’ll end up using it again. Just until I can make it here.”
Three SEP participants reported “laziness” as an inhibiting factor in using sterile equipment for 100% of injections. Bolivar recognized bacterial contamination of cotton filters, but admitted he may reuse them because he is “just being lazy.” Chris explained how he and others may not “feel like they can get up and go to the other room to get [a syringe]. They get the same one they already used. Most of us think it’s safe, you know. I mean, if I used it, I think it’s clean. So why can’t I reuse it again?”

Motivation to use sterile supplies fluctuates for Joe, who said, “…if I know that I’m low, or if I’m out in the field and I don’t have the motivation to get up and go get more, then I say, ‘Who cares?’ So, it’s just…it’s petty.” Interestingly, Joe points out a low supply and fear of arrest (community context social determinant) contribute to the problem of equipment reuse. “If I had more [supplies], you know, the laws would help, too. I could carry more with me.” Joe goes on to say, “Because you can’t carry [syringes], so I mean if they catch anything on you, then you’re in trouble. So, I don’t want to carry a whole bunch of stuff with me. But also, if I went into a situation where I run out, then I’m going to have to reuse.”

The majority of interview participants expressed a strong desire to preferentially give away sterile supplies should another PWID be in need, even if it meant depleting their personal sterile equipment stockpile. In turn, this leads SEP participants to personally re-use their own equipment in order to provide sterile equipment to another PWID, reflective of the social context social determinant. Some participants were willing to share their used supplies with others when they were personally out of sterile supplies; however, attempts to sanitize/sterilize the used equipment took place.
Applying the SDOH model to sterile supply stability uncovered how PWID utilizing SEP encountered a number of socio-economic factors that limited their ability to use only sterile injecting equipment. For Joe, transportation barriers (economic stability determinant) limited his ability to consistently access SEP. He was also hastened by fear of arrest (community context determinant), as carrying drug paraphernalia is illegal in Kentucky. For Ashlee, the SEP operating hours created a barrier (access to healthcare or community context determinant). Interestingly, the preference to give away sterile supplies to other PWID was an example of the social context determinant, and was as a positive form of social cohesion for the recipient. For the equipment provider, however, this social cohesion created a barrier to consistent sterile supply access because supplies were reused, and they were not necessarily sterilized properly.

**High Risk Behaviors and Attitudes**

Injection drug use is already considered a high-risk behavior, but in the context of PWID using SEP services, high risk behaviors and attitudes may occur due to low health literacy. One such high risk behavior is the common practice of making a wash, which is a common practice described by participants throughout the study. A wash is made from collecting used filters such as cottons or cigarette filters, then adding water to release leftover drug residue from the original and/or subsequent preparations. A used cooker is sometimes kept for the same purpose. Amanda describes a wash: “I just let the drugs build up in [the cotton]. If I come up hard one day, I throw a couple of cottons in the water, smash them around [then inject the solution].”

Having a wash available addresses an addicted person’s urgency to use drugs by helping them to avoid withdraw symptoms. A wash may provide enough drug to limit
withdrawal symptoms long enough for the PWID to obtain a new supply of drugs. SEP participants may save their cottons or cookers for their own wash at another time, or give away their used supplies for a wash to another in need. Regardless of who might be using a wash, there was a general lack of recognition that bacterial or viral contamination takes place with these particular pieces of drug injecting equipment (low health literacy). Shay said she “never even thought about [used cookers] being dirty…I was just thinking needles, you know?” And Amanda reflected, “The cookers and things like that; I guess I’m probably not careful with those. And I probably should be, because I forget about them. You know, you stick a syringe in your cooker, and it’s just the same as, you know [the syringe]. You know, and I guess I don’t think of [the cooker] that way.” Shay and Amanda’s examples of low health literacy, part of the health social determinant, explain why some SEP participants do not hesitate to use a wash, especially the urgency to inject is secondary to experiencing unpleasant withdraw symptoms.

Injecting drugs with an intimate partner appears to be another common high-risk behavior driving reuse of drug injecting equipment that was previously used by another person. Sharing used equipment with an intimate partner was felt to be relatively safe or easy. Kitty reported sharing used equipment from her boyfriend of 10 years: “We were always together and I had to keep up with everything in my bag... It’s just easier to mix all of our stuff up together, and then you know, draw it up and split it. It was just easier.” Liz explains, “It seems different if you actually share with your boyfriend or girlfriend or whatever, because you have been together for so long. So whatever one of you has, you both have. That’s how I see that.” Shelby reported receiving used equipment from her boyfriend, and explained, “A lot of the time we share stuff just because we keep all our
stuff together, usually. So, it’s kind of hard to know whose is whose sometimes. If you were using, which we do reuse a lot, if we end up reusing [a syringe], it’s hard to know who has used it before. Same thing with cottons.”

Eight interview participants were against the notion of sharing their used equipment or receiving used equipment from people outside of an intimate relationship, suggesting their degree of health literacy was adequate enough to understand the risk of disease transmission from person-to-person through shared equipment. However, those with drug injecting intimate partner relationships described ambivalence about re-use and sharing with that partner. Amanda and Kitty readily shared with their intimate partners because it was easy or convenient, and accepted in the social context determinant. Others still preferred to not share at all with their partners, but might do so when there were no supplies or the injection was proving to be difficult. There was no concern for acquiring new infectious disease as they both assumed to have the same infection, or no infection at all. However, none of the participants appreciated the risk of developing bacterial infection as a result of contaminated equipment when asked about it, suggesting an element of low health literacy persists despite the social context between injecting partners creating a sense of well-being. Participants described feeling safe when injecting drugs with an intimate partner.

For participants who injected with non-intimate partners, it was important to know the serostatus of the used equipment provider. Meaning, if the recipient knew about the HIV or HCV infection status of the equipment provider, they would consider using the non-sterile equipment. From Tim’s perspective, asking about serostatus would determine who he may take used equipment from: “Whenever you reuse a syringe of
somebody else, depending if you already have hep C or are…basically, if I do use from anybody, I know at least a little bit of their background as far as their blood, from asking.” Having the same serostatus as an injecting intimate partner was assumed, and further contributed to ambivalence in accepting used equipment. From a SDOH perspective, understanding serostatus is an important, positive indicator of health literacy.

The cohesion (social context determinant) between intimate partners appeared to contribute to syringe and injection equipment misuse because a sense of convenience (Kitty and Amanda) and safety (Ashlee) had developed. When supplies were already in the environment, it was convenient for both parties to share. The practice was not perceived as high-risk because participants did not appreciate the risk of negative consequences beyond the spreading of infectious disease when sharing with their partners, and a sense of safety was achieved. For non-intimate partners, sharing of used equipment was avoided except when the provider’s infectious disease status was known. This, too, is an example of social cohesion. Participants with known HIV or HCV were unlikely to give away used equipment to others without the disease.

**Having the Right Equipment**

Comfort during the injection procedure emerged as a theme supporting the desire to limit syringe and equipment misuse. Using a filter/cotton helped limit debris from the drug preparation process from entering the body and reduced “cotton fever” for Ashlee. Several participants suggested that using a filter helped limit dulling of a new needle, making for a more comfortable injection. Used cottons become hard, which damages the needle bevel. Multiple participants endorsed desire to always use a new syringe in order to avoid discomfort while injecting. Recognition that sterile supplies help with injection
comfort supports continued behavior of using only sterile equipment. Unfortunately, participants reported they were likely to engage in equipment reuse if they ran out of supplies, rather than waiting until they could visit the SEP again.

In some instances, not having the proper syringe available at the time of injection may lead to misuse behaviors. This was particularly evident between intimate partners, as previously described. In cases of personal reuse, Amber noted how important having the proper syringe size was to her in determining if she would reuse one of her personally used syringes, “…I actually had a couple of the short ones on accident, and you know, I can’t use those.” For cookers, Kitty described how she had adapted her cookers to avoid burns before the SEP began carrying cookers with a handle:

I finally got rid of the spoon when they impounded my car. They took my spoon, and then I started coming here and these caps, the big ones that you guys have…So I do heroin, and I always put heat to it to cook out as many impurities as I can because I still don’t know what I’m sticking in my arm. But, you know, I try to be as safe as I can. So, you know the barrettes? The snap barrettes? Like, I bought a six pack of Hello Kitty snap barrettes and that’s how I would hold the cap to heat it up before they started having ones with handles. I would put that little snap barrette on it.

Having the desired or proper drug injecting equipment helped ensure comfort during injection or the drug preparation process. Participants tried to maintain sterile stock of their preferred equipment, but some reused old preferred equipment in the setting of non-preferred sterile equipment if it meant for a more comfortable injection. Having the right equipment for injection does not clearly fall within a SDOH. Rather, it speaks to the need
for SEP to provide a variety of injecting equipment choices, and the need to provide them in adequate quantities.

**Trying to Be Safe**

Unfortunately, syringe and injection equipment misuse and sharing were common among interview participants. Participants tried to be safe by avoiding any need to share or reuse by always having ample supplies of sterile equipment on-hand. When this was not possible, participants continued to convey a sense of the need to be safe from multiple perspectives. Most participants attempted to clean equipment before reuse out of concern for personal safety and the safety of other PWID. Knowledge of one’s HIV and/or HCV status also contributed to perceived safety when reusing or sharing supplies. Secondary exchange practices not only helped provide sterile supplies when possible, but also allowed SEP participants to disseminate education and best practices to non-SEP PWID.

According to interview participants, maintaining adequate sterile injecting supplies limited their perception of the need to share or reuse equipment. However, if supplies were depleted, whether from unexpected secondary exchange or inability to return to the SEP, equipment reuse behavior became common. Providing people outside of SEP with SEP supplies and education is considered secondary exchange. Bolivar says he “will maintain a stockpile whether I’m using much or not at all, for those acquaintances of mine. I'm omitting the exchange program” because he understands there other PWID who do not use SEP services. Chris feels sterile SEP supplies are in demand, “mostly everybody I know comes here. Or you know, gets them from somebody else who does come here.” Kitty also supports secondary exchange while noting how important it is to inject using sterile supplies:
I break the rules of the program and it's pretty messed up. But I pick up syringes from a lot of people who live close to where I live, and I bring them back for them because they do not have the means to get here, and I bring things back for them. And while that does violate the rules of the program, I... (Pause) I have been in situations where I had no way to get syringes, or you know, the things that I needed to safely inject... and I just don't want to let people around me be in that same situation if I can prevent it.

Some SEP participants acquire equipment or supplies in order to trade them for drugs or sell them for cash. This behavior creates an economy around sterile SEP supplies, which speaks to the importance of economic stability. Billy has bartered SEP supplies for drugs:

I befriended a guy in camp, and he needed some new needles and stuff. And he offered to give me some dope if I would come down here, and get some needle exchanges, and leave, that for him. So, I come down here and get my little I.D. so I can get a needle exchange, and I figured, ‘What? Why not?’ So, I sat down and had him shoot me up the first time, and taught me how to do it myself. So, I've been on [heroin] ever since. But he was the reason I came down here. To mainly start picking up the needles.

Billy also said, “Well sometimes I will give them [bartering partners] new stuff still in the bag and not ever been used yet... for, you know, if I'm running low on dope or something... I'll trade some for a couple of shots of what dope that they got.” Chris recognized the supply-and-demand principle: “People with the dope pretty much... like, they can pretty much get what they want. A clean [syringe], a dirty [syringe]. They'll find one or they'll buy it from somebody who does have one. I've seen that a lot of times. People get it from
the [syringe] exchange [program] and sell them on the street. People who don't even use [will sell them].”

Interview participants preferred to provide sterile equipment to others, but some situations could increase the likelihood of a SEP participant sharing used equipment with another PWID. For instance, when sterile equipment was not available, interview participants described cleaning their equipment before sharing as a sentiment of preventing injury, which is a demonstration of positive health literacy. Amanda explained she does not “give my syringes away freely. I’m not going to. Those are mine. Those are to protect me, and keep me safe. And, unless it’s just a desperate situation for someone else. I do not want to give my used things away.” Ashlee was surprised when people asked for her used equipment: “It astounds me how many people are so comfortable with that, and they don’t even clean them. I know cleaning them with bleach or alcohol, or whatever, doesn’t necessarily make it okay. But still, they throw caution to the wind.” She attributes the asking behavior to younger injectors:

The girl I live with, she’s like 23. And a lot of the friends she has that are asking for these things a lot are super young, you know, in their early 20s. And I guess they just don’t know, just like when I was young and dumb and just careless. They haven’t seen all this stuff yet. It hasn’t affected them. So, it doesn’t really hit home, and I guess that stuff just comes with age. Just seeing it, and it really sinking in.

When sharing or reuse is necessary, the majority of interview participants described a variety of attempts at cleaning or sterilizing their equipment. Those who personally re-used items such as filters/cottons made no attempts to clean them before the
next use. For cookers, Tim might use an alcohol swab before use. Shay would reuse her cooker until “it looked dirty.” In some cases, however, no cleaning procedures took place. Joe prepared a single syringe to be used throughout the day, without regard to the possibility of it becoming contaminated with bacteria or debris. Although most participants reported attempts at cleaning procedures for syringes they intended to re-use or share, they did not consider the cleanliness or sterility of other equipment.

Disappointingly, most cleaning procedures described by participants were not in line with the Centers for Disease Control recommendations (CDC, 2018). The CDC recommends only pure bleach with water rinses for sanitizing used syringes. Tim reported using hand sanitizer; five participants suggested using alcohol as a rinsing agent. Only Bolivar was able to describe a cleaning procedure close to the CDC recommendations, which uses a series of bleach and rinse water. Interestingly, participants describing any type of sanitizing procedure also noted that they did not believe their methods to be effective in prevention HCV and/or HIV transmission. Ashlee thought, “I know cleaning them with bleach or alcohol, or whatever, doesn’t necessarily make it okay.” Shay said, “…I read that you can use alcohol and it will clean the needle, but I don’t trust it.”

Trying to be safe was very important to Tom, who refuses to share his used equipment with anybody, regardless of circumstance, because he has human immunodeficiency virus (HIV). He explains, “I wouldn’t give them used ones. That’s just something I won’t do. Just because it’s such a big deal to me. And I don’t know if I could deal with it very easily if I knew that somebody became [HIV] positive because they used one of my used syringes and didn’t clean it properly or something. I mean, I know that’s
a risk they’re taking, and they’re assuming. But I would still feel responsible.” Chris, who has hepatitis C virus infection, prefers to know the serostatus of people he may share one of his used syringes with: “They usually got it, too. It’s not like I don’t have anything more, but, you know, I wouldn’t just give it to someone that didn’t have it. And I hate for people to reuse… I would give anybody [a new] one if I had it instead of selling it or reusing it. Just for the fact of the health issues.” Tom and Chris’ regard for the safety of other PWID because of their own infections further support the concept that PWID are interested in the safety of others when it comes to syringe and equipment sharing practices.

Trying to be safe demonstrated a strong sense of community among PWID. It demonstrated elements of positive and negative health social determinants (clarifying serostatus before sharing versus ineffective cleaning procedures for used equipment), as well as social contexts that may lead to equipment misuse. Understanding the need to provide sterile equipment for personal safety and the safety of other PWID was consistent with social cohesion (community context determinant) and the desire to maintain a safe environment through proper syringe disposal via secondary exchange (neighborhood environment determinant). For people like Tom, trying to be safe also meant he had good health literacy (health determinant).

**Limitations**

There are several limitations to this study. The study was conducted for a specified period and this sampling strategy may have missed people who visit SEP outside this time period. Convenience sampling allowed for subject self- selection which may have failed to identify additional social determinants influencing drug injecting
equipment misuse, as well as failed to capture additional motivations, situations, and behaviors by those who did not participate in the study. This study took place in an urban setting where the majority of subjects in both the qualitative and quantitative portions were white. Differences were not explored between people injecting different substances, making comparison of behaviors specific to heroin, methamphetamine, or other substances beyond the scope of this study.

**Conclusion**

Syringe and drug injection equipment sharing and reuse are common among people participating in SEP. There appears to be common SDOH that lead to personal reuse, receptive reuse, sharing of used equipment, and sharing of sterile equipment despite participation in SEP. The most common SDOH influencing drug injecting equipment misuse was social context, wherein PWID see themselves as a community sharing common needs and practices. These behaviors appear to be similar to those who are not engaging in SEP services, including injecting with an intimate partner and having friends who inject (Munoz et al., 2015). Health and healthcare determinants were also identified, mainly in terms of low health literacy regarding disease transmission risk for misusing non-syringe equipment such as filters and cookers.

Having consistent access to sterile supplies through SEP helped most participants avoid personal and receptive reuse, as well as limited sharing of used equipment. It helped facilitate secondary exchange or providing various pieces of sterile equipment to others in need. When participants reported sterile supply stability was compromised, drug injecting equipment misuse took place. The literature supports this occurs outside of SEPs, where having limited access to sterile syringes and homelessness increases the
likelihood of sharing used equipment (Bozinoff et al., 2017; Munoz et al., 2015). Sterile supply stability issues brought about by fear of arrest or strong police presence may lead to increased sharing of used equipment (Flath et al., 2017; Munoz et al., 2015).

SEPs should ensure services are easily accessible by considering neighborhood and built environment determinants such as SEP hours, locations, and PWID safety. The economic instability (including issues around transportation, the incompatibility of SEP hours and typical working hours) of SEP participants should be considered. SEPs should continue working with police to ensure the threat of arrest and incarceration among participants is limited, and work with stakeholders to change drug paraphernalia laws. Policies protecting participant anonymity and setting boundaries with law enforcement are critical. It is important to consider economic stability in determining supply distribution models as those with the least stability appear to have the most difficulty maintaining adequate sterile supplies.

Despite the education PWID in SEP receive, high-risk behaviors and attitudes persist around saving drugs for later use (a wash). Although the intent of using a wash is to avoid withdrawal symptoms, PWID may experience cotton fever, a flu-like illness resulting from contamination of used cotton filters with fungi or bacteria (Xie, Pope, & Hunter, 2015). Such an infection may lead to hospitalization and withdrawal. There is lack of recognition that injection equipment aside from the syringe becomes contaminated with viruses and bacteria that pose a risk for harm. Heimer et al. (2018) demonstrated hepatitis C virus can be transmitted in water from contaminated syringe to a cotton filter, and from the cotton filter into a new syringe. As such, it is important for PWID using SEP services to understand that the risk of acquiring infectious disease goes
beyond used syringe sharing. SEPs should work to continuously improve the health literacy of participants in an effort to avoid such health-related harms.

Other high-risk behavior centers around injecting with others, especially intimate partners. Outside of SEP, Morris et al. (2014) noted a five times higher risk of receptive syringe reuse among intimate partners, leading to increased incidence in infections such as hepatitis C virus. Simmons, Rajan, and McMahon (2012) suggest that emotional and practical influences (such as convenience) contribute to intimate partner injecting. It is important for SEP participants to understand the risk of bacterial and viral contamination that occurs in used drug injecting equipment. SEPs must understand the needs of participants who inject with intimate partners may be different from those who do not. Exploring the social contexts in which each SEP participant injects could help staff determine which resources should be employed, and which educational components are offered.

Future studies may look to replicate both the quantitative and qualitative findings at SEPs in other areas, as well as consider differences in SDOH among urban and rural PWID in SEP. Interventions can be developed to reduce the likelihood of intimate partner sharing and reuse. Policy changes using SDOH as a framework can be implemented to ensure PWID in SEP have access to ample sterile supplies, rather than limiting new supply distribution based on what is returned. Secondary exchange initiatives may be piloted, explored, and developed to help improve access to SEP services among PWID unable or unwilling to participate in the primary program, especially those with substantial difficulty with economic stability. Using SDOH as a framework for policy
development at the local level could provide meaningful changes. The SDOH may be used for future research to further explore PWID.
CHAPTER IV
HARM REDUCTION, SYRINGE MISUSE, AND NURSING’S CODE OF ETHICS

Executive Summary

People who inject drugs (PWID) often face shortages in their sterile injecting equipment supply. They may use a number of strategies for acquiring sterile drug injecting equipment, including participation in harm reduction programs such as syringe exchange programs, engaging in pharmacy syringe sales, or purchasing sterile supplies from a drug dealer. In light of ongoing hepatitis C virus (HCV) infection and the opioid epidemics, harm reduction strategies that improve PWID access to sterile drug injecting equipment are critical. This policy brief describes ways in which PWID may access their sterile supplies, discusses the strengths and limitation of various supply acquisition approaches, highlights the ethical importance of harm reduction-based nursing care, and presents ideas for improving sterile supply access through nursing care. Incorporating harm reduction concepts into nursing care will help reduce health disparities among PWID, and may increase their ability to consistently use sterile injecting supplies with each injection episode.

Introduction

The concept of harm reduction was developed during the 1980s in response to the growing human immunodeficiency virus (HIV) epidemic, with rapid growth after HIV was linked to injection drug use. Harm reduction uses a pragmatic, non-judgmental approach to educating PWID on safer use practices, disease prevention, wound care, and
other areas such as legal needs, housing support, employment opportunities, and more (HRC, 2019). Table 1 displays the principles of harm reduction.

Table 1

<table>
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<th>Principle</th>
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Note. (HRC, 2019).

Harm reduction tools include syringe exchange programs (SEP), syringe vending machines, secondary or peer exchange, and supervised injection facilities. Each harm reduction tool employs a basic program of supplying sterile drug injection equipment to PWID with the expectation used supplies will be returned for proper disposal. Education may be provided face-to-face, or in written materials. These programs have been shown to reduce the spread of infectious diseases such as hepatitis C virus (HCV) and HIV. The purpose of this policy brief is to explore the problem of sterile drug injection supply
access among PWID both in and outside of SEP programs, explore policy alternatives, and describe how nursing can ethically support such policy alternatives.

Accessing Sterile Injecting Supplies

Drug injecting supply access within SEP

Multiple models of SEP supply distribution exist, and are briefly described in Table 2. There are variations in the types of supplies available at SEP as well, with some offering robust selections, and others only syringes. For example, SEPs in West Virginia and North Carolina may be limited to syringes and alcohol swabs. However, SEPs in the neighboring state of Kentucky have a wide assortment of available supplies such as filters, water, cookers, and alcohol swabs available (Bixler et al., 2018). Having availability of multiple choices for each type of equipment, including different sizes (gauge and needle length) of syringes and needs-based distribution models of SEP programs are considered best practice (NYC DHMH, 2009). Depending on where a SEP is accessed, participants may be able to acquire enough supplies to share with other PWID (secondary exchange), or conversely experience limitations on sterile supply access based on the quantity of syringes returned.
Table 2

*Syringe Exchange Program Distribution Models*

<table>
<thead>
<tr>
<th>Model</th>
<th>Program Description</th>
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<tbody>
<tr>
<td>One-for-one exchange</td>
<td>For each used syringe returned, participants may replace it with a sterile one.</td>
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<tr>
<td>Less than one-for-one exchange</td>
<td>Like one-for-one, this program requires an exchange of used-for-new syringes, but the syringes must originate from the SEP. For example, a syringe from a pharmacy can be returned after use, but it will not count towards a sterile replacement because it did not come from that particular SEP.</td>
</tr>
<tr>
<td>One-for-one plus exchange</td>
<td>Participants may exchange the number of syringes returned and take an additional pre-determined amount in an effort to build up a stable supply of sterile equipment between SEP visits. For example, a participant may return 20 syringes and have 30 provided in exchange (plus 10).</td>
</tr>
<tr>
<td>Needs-based</td>
<td>Participants may obtain the number of sterile syringes needed without regard to the number of syringes returned. Participants are not limited on the frequency of their visits. This approach is considered best practice.</td>
</tr>
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*Note:* (Bluthenthal et al., 2007; Sherman et al., 2015).

**Drug injecting supply access outside of SEP**

When not participating in a SEP, PWID engage in a number of ways to secure sterile injecting supplies. Strategies include purchasing syringes and other needed supplies from a pharmacy, receiving supplies from a peer who is involved in SEP (secondary or peer exchange), trading drugs for sterile supplies, obtaining sterile equipment from their drug dealer, diverting syringes from patients with medical needs (like a diabetic on insulin), and more (Behrends, Li, & Gibson, 2017). How PWID obtain their sterile supplies influences their degree of syringe reuse, as described in the following paragraphs.
Pharmacy sales.

In the United States, 23 states have legalized prescription sales of syringes to PWID (CDC, 2017). Figure 1 displays the distribution of states in which PWID might obtain supplies through a pharmacy. In several states, pharmacists are required to maintain a log of customer names, addresses, and the reported intended use of the syringes sold (Goodin, Fallin-Bennett, Green, & Freeman, 2018). Recording of such information is a barrier to some PWID, as anonymity is critical (Goodin et al., 2018). However, access to syringe sales through pharmacies is an important source for sterile supplies, and uptake of syringes from pharmacies has been seen nationwide (Zaller et al., 2012). Importantly, some PWID purchasing syringes through pharmacies continue to engage in high-risk injection behavior, including reuse of used syringes (Zaller et al., 2012; Zlotorzynska, Weidle, Paz-Bailey, & Broz, 2018). In a study of young PWID, up to 49% reported reusing equipment despite access to pharmacy sales (Zaller et al., 2012). Studies have identified barriers such as stigma and denial of sales by pharmacists (despite legality) contribute to PWID avoidance or limiting of pharmacy syringe purchasing, but in areas with high drug use and overdose incidence, pharmacy sales are an integral part of harm reduction (Goodin et al., 2018; Meyerson et al., 2018).
Figure 1. Pharmacy syringe sales are legal in much of the United States. Delaware and Tennessee are the only states in which pharmacy syringe sales to PWID is explicitly illegal. Twenty-two states do not have a specific policy for or against syringe sales to PWID (CDC, 2017).

Secondary or peer exchange.

Participants in SEP obtain enough injecting supplies for themselves, but may also collect supplies to be distributed to other PWID. This practice is known as secondary exchange or peer exchange. Secondary exchange is common across the United States and serves as an opportunity for SEP harm reduction principles to reach PWID who might not directly engage in SEP services (Behrends et al., 2017). Brothers (2016) suggests there are a number of reasons PWID may not visit SEP, including distance, operating hours, disability, fear of police, fear of being identified, and feelings such as shame, anxiety, and stigma. PWID attending SEP who provide sterile supplies to other PWID serve important role in sterile supply access solutions (Behrends et al., 2017; Brothers, 2016). The SEP participants providing secondary exchange are often friends, family members, or intimate
partners of those receiving supplies as part of secondary exchange (Behrends et al., 2017). Secondary exchange helps improve health equity because of its ability to reach PWID who might not otherwise have access to sterile drug injecting supplies and harm reduction education.

**Trade and drug dealer supply sales.**

Kuyper and colleagues (2006) described sterile syringe trade and sales among PWID, noting that such supplies may be obtained from medical patients such as diabetics, pharmacies, SEPs, or other PWID. In areas without SEP or before a SEP opened, many PWID reportedly obtained their injecting supplies through trading drugs for supplies, or by purchasing sterile supplies directly from their drug dealer (Kuyper et al., 2006). In Los Angeles, where SEP and pharmacy sales are legal, up to 16% of respondents reported obtaining their syringes from an unauthorized source (i.e. not a SEP or pharmacy) within the past six months (Quinn, Chu, Wenger, Bluthenthal, & Kral, 2014). In Australia, syringes received through trade or dealers were typically in small amounts (four or less) (Bryant & Hopwood, 2009). Anecdotal reports from the SEP studied by Cave (2019) suggest trading syringes and supplies for drugs or acquiring syringes from dealers occurs despite SEP and pharmacy coverage in the area; however, little else is known as it has not been studied.

**Policy Alternatives: Increasing Access to a Consistent Supply of Sterile Equipment**

Despite the use of SEP or other means of acquiring drug injecting supplies, significant numbers of PWID share or reuse equipment (Behrends et al., 2017; Cave, 2019; Des Jarlais et al., 2015; Flath, Tobin, King, Lee, & Latkin, 2017; Golub et al., 2007). Reasons for sterile supply interruptions and challenges are numerous, and may
include difficulties with transportation (Canary et al., 2017; Cave, 2019), seasonal changes (Allen, Ruiz, Roess, & Jones, 2015), police presence or fear of arrest (Beletsky et al., 2014; Cave, 2019; Davis et al., 2019; Flath et al., 2017; Munoz, Burgos, Cuevas-Mota, Teshale, & Garfein, 2015), and problems with SEP supply limits or operating hours (Bluthenthal et al., 2007; Cave, 2019; Davis et al., 2019). It is important to recognize there are a number of mechanisms that may help overcome such barriers, resulting in improved sterile injecting supply stability for PWID. These mechanisms include the use of sterile supply vending machines, utilizing mobile distribution units, scaling up secondary or peer exchange practices, eliminating one-for-one SEP restrictions, and increasing pharmacy coverage of sterile injecting supplies. Increased access to a consistent supply of sterile drug injecting equipment will improve the health of PWID.

Vending Machines

Syringe vending machines distribute sterile injecting supplies and serve as a return receptacle for used syringes (Philbin et al., 2009). They are used worldwide and may reduce SEP staffing costs, provide anonymity, allow 24/7 access, and may attract PWID who otherwise would not engage in harm reduction services (Philbin et al., 2009). Vending machines were first operational in the United States in Las Vegas, Nevada beginning in 2017 (O’Hara, 2017). The machines provide sterile injecting equipment, wound care kits, and safer sex kits. The machine supplies are free, but people wishing to use them must first register with a local harm reduction program to obtain a unique code that helps the program track machine and PWID interactions (O’Hara, 2017).
first year of the Las Vegas program, machines distributed 37,000 syringes to more than 400 participants (Young, 2018).

In Europe and Australia, where syringe vending machines have been used since 1987, syringes are distributed after monetary payment or exchange of used syringes (Islam, Wodak, & Conigrave, 2008). Like the Las Vegas machines, European and Australian machines are stocked with healthcare items, but also have educational pamphlets (Islam et al., 2008). They have been shown to increase access to sterile injecting supplies, reduce incidence of used syringe sharing, increase access to health information and health services, and demonstrated safe syringe disposal (Islam et al., 2008; Obadia, Feroni, Perrin, Vlahov, & Moatti, 1999). The machines may lead to cost savings, and are considered cost effective in their ability to reduce HIV and HCV transmission among PWID, even if the equipment was provided at no charge to the participant (Islam et al., 2008; Otiashvili, Kirtadze, Vardanashvili, Tabatadze, & Ober, 2019). Public perception of the syringe vending machines is generally positive among Australians (White, Haber, & Day, 2016), and PWID report positive experiences with them in the country of Georgia (Otiashvili et al., 2019). There is some evidence that syringe vending machines reach PWID who would otherwise not access any type of harm reduction program (Islam & Conigrave, 2007). Currently, there is no literature describing perceptions/attitudes towards syringe vending machines among United States PWID or stakeholders. To-date, Las Vegas remains the only location in the United States utilizing this harm reduction strategy.

**Mobile Units**
SEP participants report location and transportation difficulties as reasons for not regularly attending. Strike and Miskovic (2018) conducted a literature review and provided a detailed description of mobile units providing SEP services, where traditional SEP services have been provided in brick and mortar, fixed locations. They included literature from the United States, Canada, and Russia to describe how mobile SEP units typically operate in a van or bus. Services provided by mobile units nearly mirrored fixed SEP services, although physical space may have been a reason for limiting some services such as HIV/HCV testing. Mobile units have the advantage of home delivery for disabled participants; they can quickly adapt their routes and service locations based on PWID demand or changes in police presence (Islam & Conigrave, 2007; Strike & Miskovic, 2018). Limitations for mobile unit services include limited hours at a specific location may result in PWID missing services until the next scheduled stop in that location (Strike & Miskovic, 2018). This sentiment was reflected in work by this investigator (2019), where interview participants acknowledged past inconsistent interaction with mobile units due to limited service hours despite its convenient location. Nonetheless, mobile units are an effective way to improve sterile supply access and harm reduction service equity to PWID who might otherwise not engage in care (Islam & Conigrave, 2007).

**Support Secondary Exchange**

At SEPs without quantity restrictions, like those in California, Europe, and Australia, secondary or peer exchange services are encouraged and recognized as a means to reaching PWID who would otherwise have limited access to sterile supplies (Newland, Newman, & Treloar, 2016). In California, 75-89% of SEP clients engage in secondary exchange, and 89% of SEPs in the United States as of 2007 supported the
activity (Behrends et al., 2017). In Baltimore, Maryland, nearly 65% of program syringes were distributed through secondary exchange (Behrends et al., 2017). The practice addresses SEP barriers such as limited operating hours, transportation difficulties, fear of police, protection of anonymity, and physical disability (Behrends et al., 2017; Brothers, 2016). Benefits of secondary exchange do not exclusively address access to sterile supplies as many PWID serving as the peer exchanger also provide harm reduction education, information about overdose prevention, and assisting in referrals to medical and substance use treatment (Behrends et al., 2017). PWID reached by secondary exchangers include friends, family, intimate partners, and injecting drug customers (Brothers, 2016). Secondary exchange was reported by 56.8% (n=63) of SEP participants in a study by this investigator (2019), suggesting SEPs do not need to formally support secondary exchange in order for the behavior to occur.

Although access to information and sterile supplies for non-SEP receivers of supplies is increased, secondary exchange has notable limitations. Evidence suggests those receiving supplies are still likely to reuse syringes and may choose to use equipment previously used by other people (Behrends et al., 2017). Not all secondary exchangers provide their equipment at no-cost to recipients (Brothers, 2016), which creates a potential barrier for some to acquire adequate sterile supplies due to economic instability. Trust is an important factor in willingness to receive supplies from others, so the potential reach of PWID suppling secondary exchange is limited to their individual networks (Bryant & Hopwood, 2009). Nonetheless, secondary exchange fills a critical void for many PWID to obtain sterile injecting supplies.

Elimination of One-for-One and Less than One-for-One Exchange
One-for-one and less than one-for-one syringe exchange models are not best practice for harm reduction, and may lead to increased syringe and drug equipment reuse and sharing, as previously discussed. Existing SEPs that currently operate under these restrictive exchange models may find evidence-based practice a useful tool in changing policy to a needs-based model. Baltimore, Maryland is an excellent example of the impact moving from a less restrictive exchange policy (one-for-one) to the most restrictive policy (less than one-for-one), then back again (Sherman et al., 2015). During the time of most restriction, the SEP saw fewer new clients, and distributed and collected about half the number of syringes they had during the one-for-one exchange period (Sherman et al., 2015). During the most restrictive policy period, syringes were in circulation longer with the highest chances of being reused, resulting in public health concern for increased spread of infectious disease and other harms (Sherman et al., 2015). Conversely, less restrictive syringe dispensing policies have demonstrated reduced likelihood of syringe reuse and sharing (Bluthenthal et al., 2004; Kral, Anderson, Flynn, & Bluthenthal, 2004).

**Improving Pharmacy Coverage**

States and locales with legal access to syringes and injecting supplies at pharmacies have shown greater uptake of such services by PWID when compared to areas requiring a prescription to purchase syringes (Siddiqui et al., 2015). Pharmacies serve as an important source for PWID to obtain sterile injecting supplies, especially when SEP services are not legal (Meyerson et al., 2018; Siddiqui et al., 2015). Studies have also shown that the ability to purchase syringes without a prescription is associated with less syringe sharing among PWID (Sherman et al., 2015; Siddiqui et al., 2015).
Pharmacists have the potential to serve as harm reduction ambassadors in not only supplying sterile injection equipment, but also providing naloxone and overdose prevention education, HIV and HCV testing, and linkage-to-care for medical concerns including vaccinations (Rose, Lutnick, & Kral, 2014). In Kentucky, pharmacists have shown willingness to engage in harm reduction and syringe exchanges services, although community pharmacists favor the role more so than those from chain stores, which may lead to inequality among pharmacies (Goodin et al., 2018). Pharmacies serve as a critical access point for some PWID in terms of accessing sterile supplies, but more work is needed to ensure PWID are able to successfully complete a purchase and are not subjected to dissuasion, stigma, or discrimination by pharmacy staff (Chiarello, 2016; Goodin et al., 2018; Meyerson et al., 2018).

**Case Study**

The Commonwealth of Kentucky is facing dual epidemics: the spread of hepatitis C virus (HCV) infection, and the opioid epidemic. Syringe exchange programs were legalized in the state in 2015 in an effort to curtail the spread of infectious diseases among people who inject drugs (PWID), among other goals. There are now 69 approved SEP sites throughout the commonwealth. Even as these resources were made available, reports were made that SEP-supplied drug injecting equipment was being shared or reused among some SEP participants. Cave (2019) examined the frequency of, and factors associated with, drug injection equipment reuse and sharing using cross-sectional surveys (n=111) and estimated greater than 70% (n=78) of program participants personally reused equipment, regardless age and gender. Cave (2019) also identified that more than 37% (n=42) of SEP participants received used injecting equipment from
others. Sharing of new equipment (secondary exchange) was common (56.8%, n=63), while sharing of used equipment was less-so (30.7%, n=34). In order to understand what influenced SEP participant’s equipment sharing and reuse behaviors, a qualitative study was conducted. Cave (2019) identified that unstable access to sterile injecting equipment supplies was a fundamental reason for SEP participants’ sharing and reuse of equipment, while the sharing of new equipment was done in the interest of keeping other PWID safe.

Multidimensional factors that are best reflected by the social determinants of health (SDOH) model influenced subject’s ability to access sterile supplies at the SEP. Cave discovered the economic stability determinant impacted consistent, predictable transportation to the SEP, as well as the health/healthcare social determinant. Subjects with limited funds for bus or rideshare fares or fuel reported inconsistent time intervals between SEP visits that might leave them without any sterile supplies due to a longer than anticipated visit interval. Although many subjects understood one of the many benefits of SEP participation is a reduced risk of acquiring HIV or HCV infection, low health literacy contributed to unsafe syringe and other drug injecting equipment sharing and reuse practices, especially among intimate partners. The social/community context health determinant kept some participants from routinely accessing SEP due to fear of loss of anonymity and arrest.

Using a policy alternative such as eliminating restrictive SEP distribution models could help overcome these barriers by ensuring participants can acquire adequate or more than adequate sterile supplies, including supplies for secondary exchange purposes. Having adequate supplies allows participants to have flexibility in visit frequency and may reduce transportation hardships by increasing visit intervals. Furthermore, improving
access to sterile injecting supplies through bolstering pharmacy syringe sales and harm reduction education by pharmacists could improve sterile supply acquisition through location convenience and expanded operating hours.

Nurses have the opportunity to support PWID in accessing sterile injection supplies. They can advocate for less restrictive SEP distribution policies and increased pharmacy syringe sales at the local level. Nurses can address SDOH when PWID present as patients by assessing health determinants, recognizing potential barriers to sterile supply acquisition, then advocating for alternatives and solutions, or supplying pragmatic education and strategies for overcoming barriers. Nurses are needed to support and advocate for harm reduction, especially access to sterile drug injecting supplies, which is supported by the American Nurses Association Code of Ethics.

Harm Reduction and Nursing Ethics

Canadian nurses have considered harm reduction in the context of the Canadian Nurses Association Code of Ethics, but application of the concept to the American Nurses Association Code of Ethics has not been described. In 2007, Pauly and colleagues described harm reduction and its alignment with the ethical standards for Canadian nurses across the principles of health and well-being, dignity, choice, and justice. The authors encouraged nurses to recognize how some drug policies adversely affect patient health and advocate for equitable change. They contend that criminalization of drug use has created unjust circumstances and environments for people who use drugs leading to poor health and negative social outcomes, and that nurses can empower patients by providing evidence-based information to improve safety. They also contend that all nurses should
insist on harm reduction strategies for individuals in all settings as they are in line with the code of ethics.

The American Nurses Association (ANA) has published the *Code of Ethics for Nurses with Interpretive Statements* since 1950, and it has been through numerous revisions since that time (ANA, 2015). Like the Canadian code of ethics, the American code uses principles of well-being, dignity, choice and justice within several of the code’s provisions. In Table 3, this author identified pertinent ethical provisions in the 2015 version of the *Code* and their application to people who use drugs, then paired them with related harm reduction principles. Examples of nursing care situations are described showing the relatedness between the *Code of Ethics* and harm reduction principles.

Although the ANA has not specifically applied harm reduction to the code of ethics directly, they have described the role of nurses in the ongoing opioid epidemic in the United States (ANA, 2018). The ANA (2018) has recognized nurses are face-to-face with PWUD, and encourage nurses to provide pragmatic, harm-reduction based interventions and education to such people. Furthermore, the ANA (2018) supports nurse practitioners in prescribing medication assisted therapy, opioid prescribing training to prevent/recognize use behavior that may lead to patient addiction, learning to recognize patients at-risk for overdose death and providing naloxone prescriptions and naloxone training, and encourages work leading to safe disposal of unused medications. All of these ANA-encouraged approaches are consistent with harm reduction strategies and lead to improved health outcomes for PWUD.
<table>
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<tr>
<th>Provision (ANA, 2015)</th>
<th>Application to PWUD (Including PWID)</th>
<th>Relevant Harm Reduction Principles (HRC, 2019)</th>
<th>Ethical Nursing Application to the Care of PWUD (Including PWID)</th>
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<tr>
<td>One: “The nurse practices with compassion and respect for the inherent dignity, worth, and unique attributes of every person.”</td>
<td>Many nurses and healthcare professions have negative views of PWUD which leads to stigmatizing behaviors against such patients, and is a major barrier to accessing safe, quality, equitable healthcare for patients (Mundy, 2012).</td>
<td>Recognize that drug use takes place and that it should not be ignored or condemned, but faced with pragmatic strategies that reduce harms. Cessation of drug use is not the standard for measuring success; improvements in quality of life and well-being are markers for showing such success.</td>
<td>Nurses have a duty to avoid stigmatizing behavior that leads to reduced patient dignity, lack of respect, and increased patient harm. Providing education on how to access sterile injecting supplies through SEP, vending machines, secondary exchange, pharmacy sales, etc. is consistent with this provision. Providing such information in a dignified, respectful manner may lead to reduced harm.</td>
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<tr>
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<td>Three: “The nurse promotes, advocates for, and protects the rights, health, and safety of the patient.”</td>
<td>SDOH may influence PWUD health literacy and ability to access healthcare, leading to unsafe injection practices, overdose, and other harms.</td>
<td>Drug use encompasses a continuum of behaviors, and there are safer ways of using drugs.</td>
<td>Nurses are the primary educators in many healthcare settings, and are very well-equipped to provide PWUD with pragmatic education and approaches to improve drug injection technique, review the risk of harm with various routes of administration (inhaled via smoking or intranasal use versus injection or rectal administration), and strategies for infection prevention to reduce the incidence of skin and soft tissue infections, endocarditis, sepsis, and infectious diseases such as HIV and HCV. Nurses may further advocate for patient safety through overdose prevention education and ensuring access to naloxone for opioid users.</td>
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<td>Four: Discusses the role of the nurse in acting “consistent with the obligation to promote health and provide optimal care.”</td>
<td>Ensuring PWUD are educated on harm reduction strategies effectively promotes health through reducing the risk of drug-related harm while building a quality patient-nurse relationship leading to optimal care.</td>
<td>Social inequalities, such as access to healthcare and health literacy, impact PWUD’s vulnerability and capacity to effectively manage drug-related harms.</td>
<td>Building trust is a fundamental nursing skill; nurses have the ability to build trust with PWUD. Nurses may provide health promotion and optimal care by ensuring PWID understand drug-related harms and disease prevention.</td>
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Table 3 (continued).

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<tr>
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</tr>
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<tr>
<td>Eight: Nurses should collaborate with other health professionals leading to reduced health disparities</td>
<td>Health disparities are abundant for PWUD, where many have medical co-morbidities in addition to addiction or mental health problems (Grebely, Dore, Morin, Rockstroh, &amp; Klein, 2017). Many PWUD are socioeconomically disadvantaged, have high frequency of mental health problems, encounter high rates of homelessness, and suffer from stigma (Grebely et al., 2017; Pauly, 2008).</td>
<td>Social inequalities, such as access to healthcare and health literacy, impact PWUD’s vulnerability and capacity to effectively manage drug-related harms.</td>
<td>Nurses should feel empowered to address health disparities, especially in collaboration with health allies. SEP services are provided by a combination of mental health specialists and social workers; nurses have the ability to navigate referral systems for social support, mental health support, and other healthcare needs such as reproduction, infectious disease services, and dental care. There are natural relationships between nurses and other healthcare providers; nurses should leverage these relationships to benefit PWID.</td>
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<tr>
<td>Nine: Nurses “must articulate nursing values, maintain the integrity of the profession, and integrate principles of social justice into nursing and health policy.”</td>
<td>For PWUD, social justice is difficult to come by. Pauly (2008) argues that for PWUD and harm reduction principles to reach social justice, PWUD, harm reduction providers, and nurses all need to come together to ensure policies are beneficial.</td>
<td>Encourage PWUD to have a voice in the creation of programs and policies meant to benefit them, rather than having programs and policies created for them without input.</td>
<td>Nurses are ethically obligated to ensure all patients have the opportunity to receive equal care, and ensure effective policies are in place that assure social justice. To help ensure social justice, PWUD should be included in program and policy development. Such work will increase equity of care and maintain the integrity of the nursing profession.</td>
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Note: PWUD=people who use drugs; PWID= people who inject drugs
Discussion

Some limitations should be considered in relation to this discussion. SEPs, non-prescription syringe sales, and other harm reduction policies vary substantially from state-to-state, and often from locale to locale. Such diverse approaches to the problem of ensuring PWID have consistent access to sterile injecting supplies limits the ability of this author to locate all relevant exemplars and policies. Several articles presented were qualitative in nature and may not fully represent the magnitude of effects on sterile injecting supply acquisition or PWID behavior. Critical data specific to Kentucky’s PWID was not available in regard to uptake of pharmacy syringe sales and degree of SEP participation in rural settings.

Policy Recommendations

To prevent the spread of HIV, HCV, and other infectious disease as well as mitigate potential harms associated with injecting drugs with unsterile, used equipment, it is critical for PWID to have consistent access to sterile drug injecting equipment. A number of strategies to obtain sterile equipment have been employed across the United States for decades, with needs-based models of syringe exchange programs demonstrating the ability to consistently reduce drug-related infection and harm. PWID can benefit from ensuring consistent access to sterile injecting supplies, especially syringes, through reduced restrictions on SEP distribution models and formal support for secondary exchange. Nurses should be educated on local syringe supply access and acquisition strategies in order to provide needed information to PWID in their care, and recognize the ethical obligation to do so.
Given the high risk of acquiring HIV or HCV through injection drug use, it is especially important to consider best practices in harm reduction and syringe exchange services. Any SEP services are preferred over no services, but one-for-one or less than one-for-one exchanges do not have the public health benefits that less restrictive policies demonstrate. As community stakeholders, nurses should advocate for existing SEPs to adopt the least restrictive syringe exchange policy as it should reduce the time and number of used syringes in circulation. Nurses working with their community will recognize the needs of PWID vary, but support for SEP services helps permit secondary exchange practices for otherwise unreachable populations, and is in line with CDC recommendations (Abdul-Quader et al., 2013; Behrends et al., 2017; Davis et al., 2019). The PWID participating in this investigator’s (2019) study were supportive of the one-for-one plus model used in their SEP, but acknowledged they often ran out of sterile supplies due to barriers reflected by SDOH leading to unexpected secondary exchange, difficulty with SEP hours or transportation, and more. A needs-based syringe exchange approach is best practice (NYC DHMH, 2009), and ensures that PWID have consistent access to sterile injecting equipment. Nurses can work alongside PWID at the local level to help overcome challenges to sterile injecting supply acquisition.

Reducing restrictions among SEP distribution models may build upon existing programs and relationships, and may reduce public health costs through increased prevention of infectious disease. Certainly, moving to a needs-based syringe exchange model could help the problem of sterile supply access for the participants in this investigator’s (2019) study because it may lead to: 1) fewer SEP visits resulting in reduced transportation difficulties; 2) consistent sterile supply availability for those
engaging in secondary exchange, whether planned or unplanned; 3) recognition that PWID experience inconsistent motivation to use only sterile equipment, and that procrastination plays a role in not returning at regular intervals; and 4) reduced demand on SEP participants time in relation to the need for frequent visits. Future policy changes may wish to consider sterile supply distribution via vending machines and improved implementation of non-prescription syringe sales at pharmacies.

Nurses should recognize that harm reduction approaches are generally well-received by PWUD, but access to harm reduction services may be limited (Davis et al., 2019). A number of resources to assist nurses with incorporating harm reduction strategies into clinical care are available (ANA, 2018; Drug Policy Alliance, 2019; HRC, 2019). Without solid understanding and use of harm reduction strategies, it will be difficult for American nurses to fully support PWUD in the context of continued health disparities. Nurses should use ethical guidance as a means to reflect on their approach to the care of PWUD and recognize that harm reduction principles pair well with the ANA Code of Ethics (2015). In time, nurses should feel comfortable recommending harm reduction strategies to PWUD as part of routine patient care, including information about syringe exchange programs, secondary exchange, pharmacy syringe sales, and more. Such evidence-based, cost-effective, and ethical strategies help to ameliorate the harms faced by PWUD (Bartlett et al., 2013; Drucker et al., 2016; Nguyen et al., 2014). Without harm reduction in patient care, PWUD may not receive the full spectrum of pragmatic education required to reduce the spread of infectious disease, reduce the risk of endocarditis or skin and soft tissue infections, and other health-related harms. Harm reduction is equitable healthcare.
Future work using harm reduction strategies and principles should begin with implementation of healthcare policies and approaches for nurses caring for PWUD. Both nurses and PWUD should be part of policy development, and they should aim to ensure nurses are competent in the care of PWUD, the nature of the nurse-patient relationship is free from stigma, and that community harm reduction services are accessible. Emphasis on improving access to sterile drug injecting supplies should be paramount, as this is a key issue in PWID syringe reuse and sharing behavior. Nurses should increase their awareness of harm reduction by incorporating the concept into nursing curricula and continuing education. Recall that development of trust is critical for PWUD engaging in harm reduction: nurses may develop and validate tools measuring nursing attitudes and beliefs towards various aspects of harm reduction and adapt education and policies accordingly. Educational programs that improve nurse-PWUD relationships within a harm reduction framework, supported by the SDOH model, may improve the quality and equity of care PWUD receive. Future work should also explore areas in which harm reduction is failing, and find ways to determine the root cause for its failure.
CHAPTER V
CONCLUSION

People who inject drugs (PWID) face many problems in trying to acquire a consistent supply of sterile drug injecting equipment. The principles of harm reduction are meant to provide guidance on ways to protect this vulnerable group from social, legal, and health-related harms. Harm reduction focused on prevention of negative health outcomes may be practiced in many settings—from healthcare provider offices and hospitals, to syringe exchange programs (SEPs), to supervised injection facilities, and more. Chapter II outlined harm reduction in detail, and provided some evidence that PWID generally have positive perceptions of harm reduction. Best practice guidelines for syringe exchange programs use the harm reduction principles to support PWID engaging in such services. Not all models of SEPs fulfill the recommend best practices, which may lead to failure to fulfill all potential benefits of harm reduction. The social determinants of health (SDOH) model is a useful tool and has been used to study PWID. In nursing, SDOH has been used in quality improvement to better engage PWID in care coordination.

Chapter III utilized the SDOH model as a conceptual underpinning for the study aimed at estimating the prevalence of syringe and injecting equipment sharing and reuse among PWID participating in a SEP. The urban SEP used a one-for-one plus exchange model, and had received reports that participants were not using sterile drug injecting equipment for 100% of their injecting episodes. The author found rates of
personal syringe reuse, reuse of equipment previously used by others, and rates of sharing used equipment were common. The SDOH contributed to subject’s inconsistent access to a stable sterile drug injecting supply, even when SEP participants were aware of some of the harms associated with reuse of drug injecting equipment. Subjects were clear that they valued personal and public safety despite the harms associated with injection drug use, but SDOH could supersede their ability to maintain consistent harm reduction practices (such as injecting with someone of the same serostatus when sterile supplies are not available due to supply access difficulty). Future work should aim to discover interventions to limit sharing of equipment between intimate partners, examining the impact of implementing full support of secondary exchange and a needs-based distribution model, and identifying ways to overcome SDOH barriers such as limited transportation limited PWID understanding of or engagement in health and healthcare.

The policy brief presented in Chapter IV highlights some of the difficulties PWID have in accessing a consistent source of sterile drug injecting equipment. It reviewed methods of supply acquisition for PWID who are both involved and not involved in SEPs. Opportunities exist to bolster sterile supply access to PWID outside of SEP through supply vending machines, increased pharmacy supply sales and harm reduction support, and supporting secondary syringe exchange among PWID peers. Moving to a needs-based supply distribution model within SEPs could have a significant impact on PWID who are adversely affected by SDOH. The concept of harm reduction is important not only for PWID, but for those caring for this population. The nursing code of ethics is in line with harm reduction principles; nurses should feel empowered to help PWID overcome SDOH and/or sterile injecting supply access issues.
Implications for this body of work include recognition that PWID are faced with many challenges in achieving full use of harm reduction practices. Nurses have the opportunity and ethical obligation to provide harm reduction education and care coordination and assistance in helping PWID access sterile drug injecting equipment. Models of SEP sterile supply distribution that limit PWID access to all of the needed supplies is problematic, especially for PWID who face disadvantages from a SDOH perspective. Additionally, a needs-based distribution of drug injecting supplies and increased harm reduction principle implementation across all healthcare settings should be implemented as it has been shown to improve health outcomes and is ethical practice.

Overall limitations include the possibility that all related publications were not discovered due to the search strategy used and multiple synonyms across search terms. Time constraints made it difficult to explore alternative literature resources such as gray literature, editorials, and work published outside of journals. Research participants were self-selected, and limited reports were available to compare/contrast findings.

Future directions for research may use the SDOH model as a tool to identify issues and improve access to harm reduction services. Common SDOH barriers should be addressed with policy change recommendations. A replication study among PWID in a rural SEP should be considered in order to compare drug injecting equipment misuse prevalence estimates to those in this urban sample, and to qualitatively examine potential differences in behaviors and barriers among rural PWID. Future policy work should aim to improve access to sterile drug injecting equipment through any of the means presented, but also consider new avenues of supply delivery.
REFERENCES


doi:10.1016/j.jare.2016.07.004


doi:10.1016/j.drugpo.2008.06.006

doi:10.15585/mmwr.mm6618a2


Cave, B. (2019). *Examining syringe and injecting equipment sharing and reuse among people who inject drugs participating in a syringe exchange program.* Unpublished manuscript, School of Nursing, University of Louisville, Louisville, Kentucky

Centers for Disease Control (CDC). (2012) Integrated prevention services for HIV infection, viral hepatitis, sexually transmitted diseases, and tuberculosis for persons who use drugs illicitly: Summary guidance from CDC and the U.S.


inject drugs. *Journal of Infectious Diseases, 204*(1), 74-83. doi:10.1093/infdis/jir196


doi:10.1016/j.drugpo.2015.01.015


doi:10.1371/journal.pone.0109282


doi:10.1016/j.drugpo.2018.08.019
APPENDIX A: IRB APPROVAL LETTER

DATE: February 14, 2019
TO: Dr. Vicki Hines-Martin RN FAAN, Ph.D.
FROM: The University of Louisville Institutional Review Board
IRB NUMBER: 18.1109
STUDY TITLE: Examining syringe and drug injection equipment misuse among people who inject drugs participating in a syringe exchange program
REFERENCE #: 674483
IRB STAFF CONTACT: Sherry Block 852-2163 sibloc04@louisville.edu

This study was reviewed on 02/13/2019 by the Chair/Vice Chair of the Institutional Review Board and approved through the Expedited Review Procedure, according to 45 CFR 46.110(b), since this study falls under Category 7: Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

This study now has final IRB approval from 02/13/2019 through 02/12/2022.

This study was also approved through 45 CFR 46.116 (C), which means that an IRB may waive the requirement for the investigator to obtain a signed informed consent form for some or all subjects if it finds either:

- That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject’s wishes will govern; or
- That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

The following items have been approved:

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<th>Outcome</th>
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<tr>
<td>Qualitative Interview Guide</td>
<td>Version 1.0</td>
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<td>Approved</td>
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<td>Letter of Support</td>
<td>Version 1.0</td>
<td>10/30/2018</td>
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<tr>
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<tr>
<td>Full informed consent (clean) 02/04/2019</td>
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APPENDIX B: CERTIFICATE OF CONFIDENTIALITY

DEPARTMENT OF HEALTH & HUMAN SERVICES

Date: 4/8/2019

University of Louisville
Dr. Vicki Hines-Martin
Med Center One
501 E. Broadway Suite 200
Louisville, KY 40202

Dear Dr. Hines-Martin,

Enclosed is the Confidentiality Certificate, protecting the identity of research subjects in your single-site/single-protocol project entitled "Examining syringe and drug injection equipment misuse among people who inject drugs participating in a syringe exchange program".

Please note that the Certificate expires on 12/31/2019.

NIH expects investigators to inform research participants of the protections and the limits to protections provided by a Certificate of Confidentiality issued under the NIH Policy. NIH has provided sample language for informed consent forms that researchers are free to use or adapt as needed and appropriate for their participants.

If you determine that the research project will not be completed by the expiration date, 12/31/2019, you must submit a written request for an extension of the Certificate three (3) months prior to the expiration date. If you make significant changes to the protocol for this study (e.g., change of principal investigator or institution), you should contact the COC Coordinator regarding modification of this Certificate. Any requests for modifications of this Certificate must include the reason for the request, documentation of the most recent IRB approval, and the expected date for completion of the research project.

Please contact the NIH CoC Coordinator if you have any questions about the Certificate of Confidentiality at NIH-CoC-Coordinator@mail.nih.gov.

Correspondence should be sent to: NIH COC Coordinator
BG RKL1 RM 3524
6705 ROCKLEDGE DR
Bethesda, MD 20817

Sincerely,

[Signature]

Approved Date: 04/08/2019

NIH Certificates of Confidentiality Coordinator
Office of Extramural Research
National Institutes of Health
# APPENDIX C: INTERVIEW GUIDE

## Examining Syringe and Drug Injection Equipment Sharing and Re-use Among People Who Inject Drugs Participating in a Syringe Exchange Program

**Interview Guide**

Introduction: I have invited you here today to participate in research that will help me and others to understand the behaviors of individuals who participate in a syringe exchange program re-use personal equipment, use other’s equipment, or share used injection equipment with others. This session will last 45-60 minutes and will be audio recorded to ensure we capture what you think is important. Neither you nor your comments will be identified.

<table>
<thead>
<tr>
<th>Domains</th>
<th>Primary Questions</th>
<th>Probes/ Secondary Questions (if needed)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Procurement</strong></td>
<td>Tell me about your experiences in obtaining sterile injecting equipment.</td>
<td>What is easy/difficult about continuing to use only sterile equipment?</td>
</tr>
<tr>
<td>How one obtains sterile syringes, water, cookers, cotton, and other needed equipment to perform sterile injection</td>
<td></td>
<td>What might help you or people you know who inject drugs stop reusing or sharing their used syringes and equipment?</td>
</tr>
<tr>
<td><strong>Personal re-use</strong></td>
<td>What might cause you to re-use your own syringe/equipment?</td>
<td>What prompts you to re-use your own equipment?</td>
</tr>
<tr>
<td>Using a personally used syringe or pieces of injection equipment again. Items have not been shared with anyone.</td>
<td>What happens when you decide to use only sterile equipment?</td>
<td>What happens when you decide to use only sterile equipment?</td>
</tr>
<tr>
<td><strong>Receptive re-use</strong></td>
<td>Tell me about a time you used equipment previously used by another person.</td>
<td>What factors might keep you from using a sterile syringe/equipment 100% of the time?</td>
</tr>
<tr>
<td>Being the recipient of a syringe/injection equipment previously used by another person, regardless of the age of equipment, number of uses, or cleaning procedures</td>
<td>What motivated you to do this? What was going on at the time?</td>
<td>Tell me what might be done through the syringe exchange program or other program to</td>
</tr>
</tbody>
</table>
APPENDIX D: SURVEY

Please take a moment to complete this short, confidential survey. The results will help us improve our services for you and others who use the syringe exchange program.

Your ability to participate in the syringe exchange will not be affected in any way by your answers or your decision on whether or not to complete this survey.

1. What is your age (in years)?

________________________

2. Are you...?

- Male
- Female
- Transgender – ID Female
- Transgender – ID Male
- I self-identify as __________________

3. Which of the following best describes you? Check all that apply.

- White, non-Hispanic
- Black, non-Hispanic
- Hispanic/Latino/Latina
- Other (please specify) __________________

4. How often do you visit a syringe exchange program?

- This is my first time
- Less than once per month (Less than monthly)
- 1-3 times most months (monthly or almost monthly)
- 1-4 times most weeks (weekly or almost weekly)
- 5-7 times most weeks (daily or almost daily)

5. How often do you share your used syringes, cookers, cotton, water, or any items used to prepare your injection with other people? (You used these items first, then shared them.)

- Never
- Less than once per month (less than monthly)
- 1-3 times most months (monthly or almost monthly)
- 1-4 times most weeks (weekly or almost weekly)
- 5-7 times most weeks (daily or almost daily)

6. How often do you share NEW syringes, cookers, cotton, water, or any items used to prepare your injection with other people? (Do you share extra, unused equipment, or pick up extra equipment to give to people who did not go to the syringe exchange?)

- Never
- Less than once per month (less than monthly)
- 1-3 times most months (monthly or almost monthly)
- 1-4 times most weeks (weekly or almost weekly)
- 5-7 times most weeks (daily or almost daily)

7. How often do you use syringes, cookers, cotton, water, or any items used to prepare your injection previously used by other people? (These items were used and given to you after they had been used.)

- Never
- Less than once per month (less than monthly)
- 1-3 times most months (monthly or almost monthly)
- 1-4 times most weeks (weekly or almost weekly)
- 5-7 times most weeks (daily or almost daily)

8. How often do you re-use your own syringes, cookers, cotton, water, or any items used to prepare your injection?

- Never
- Less than once per month (Less than monthly)
- 1-3 times most months (monthly or almost monthly)
- 1-4 times most weeks (weekly or almost weekly)
- 5-7 times most weeks (daily or almost daily)
APPENDIX E: PREAMBLE

Examining Syringe and Drug Injection Equipment Sharing and Re-use Among People Participating in a Syringe Exchange Program

Date: ____________

This study is about learning how often people who inject drugs who are participating in a syringe exchange program share or re-use their injection equipment with others, and it has been approved by the University of Louisville Institutional Review Board. You are being invited to participate in this research study by providing the information on the attached survey. The survey will take approximately 3 minutes time to complete.

Information provided by you will be added to the information provided by others. It will be mathematically analyzed to estimate the rates of syringe and injection equipment sharing and re-use. The information collected may not benefit you directly. The information learned in this study may be helpful to others.

Taking part in this study is voluntary. The Health Insurance Portability and Accountability Act of 1996 (HIPAA) provides federal safeguards for your protected health information (PHI). State and federal privacy laws also may also require your health information to be protected. By taking part in this survey, you provide your permission, called your “authorization,” for the use and disclosure of PHI. If you participate, the research team working on this study may use and share your health information to answer the research questions described in this document, and to make sure that the research was done correctly. This includes things learned from the procedures described in this consent form. Your health information may be shared with a public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury, or disability, and conducting public health surveillance, investigations or interventions. The time period when information can be used or shared ends when all activities related to this study are completed. By answering survey questions, you agree to take part in this research study. You do not have to answer any questions that make you uncomfortable. You may choose not to take part at all. If you decide to be in this study you may stop taking part at any time. If you decide not to be in this study or if you stop taking part at any time, you will not lose any benefits for which you may qualify.

There are no significant research-related risks, but you may experience psychological discomfort (feelings of guilt, shame, embarrassment). The survey does not contain any information that will identify you, and the Louisville Metro Department of Public Health will not know of your survey participation in this study.

Individuals from the University of Louisville, the Louisville Metro Department of Public Heath, the Institutional Review Board (IRB), the Human Subjects Protection Program Office (HSPPO),
and other regulatory agencies may inspect the survey records. In all other respects, however, the data will be held in confidence to the extent permitted by law. Should the data be published, your identity will not be disclosed.

If you have any questions, concerns, or complaints about the research study, please contact: Barbra Cave at 502-852-2010

If you have any questions about your rights as a research subject, you may call the Human Subjects Protection Program Office at (502) 852-5188. You can discuss any questions about your rights as a research subject, in private, with a member of the Institutional Review Board (IRB). You may also call this number if you have other questions about the research, and you cannot reach the study doctor, or want to talk to someone else. The IRB is an independent committee made up of people from the University community, staff of the institutions, as well as people from the community not connected with these institutions. The IRB has reviewed this research study.

If you have concerns or complaints about the research or research staff and you do not wish to give your name, you may call 1-877-852-1167. This is a 24-hour hot line answered by people who do not work at University of Louisville.

Thank you,

Barbra Cave, APRN, Vicki Hines-Martin, PhD, RN, FAAN, M. Celeste Shawler, PhD, Rachel Vickers Smith, PhD, MPH, and Laura Smart, MD
APPENDIX F: INFORMED CONSENT

Subject Informed Consent Document

EXAMINING SYRINGE AND DRUG INJECTION EQUIPMENT MISUSE AMONG PEOPLE WHO INJECT DRUGS PARTICIPATING IN A SYRINGE EXCHANGE PROGRAM

Investigators name & address:
Vicki Hines-Martin, PhD, RN, FAAN
School of Nursing
University of Louisville
4055 K Building
555 S. Floyd St.
Louisville, KY 40202

Barbra Cave, MSN, APRN, FNP-BC, PhD
Clinical Trials Unit
University of Louisville
401 E. Chestnut St. Suite 460
Louisville, KY 40202

M. Celeste Shawler, PhD, PMHCNS-BC
School of Nursing
University of Louisville
4038 K Building
555 S. Floyd St.
Louisville, KY 40202

Rachel Vickers Smith, PhD, MPH
School of Nursing
University of Louisville
4058 K Building
555 S. Floyd St.
Louisville, KY 40202

Laura Smart, MD
School of Medicine Division of Gastroenterology, Hepatology & Nutrition
University of Louisville
Study sponsor: University of Louisville School of Nursing
Site where the study is to be conducted: Louisville Metro Department of Public Health and Wellness, 400 E. Gray St. Louisville, KY 40202
Phone number for subjects to call with questions: 502-852-2010

**Introduction and Background Information**
You are invited to participate in a research study. The study is being conducted by Dr. Vicki Hines-Martin, Barbra Cave, Dr. Celeste Shawler, Dr. Rachel Vickers Smith, and Dr. Laura Smart. The study is sponsored by the University of Louisville School of Nursing. The study will take place at the Louisville Metro Department of Public Health and Wellness, 400 E. Gray St., Louisville, Kentucky. Approximately 20 subjects will be invited to participate.

**Purpose**
The purpose of this study is to explore the motivations and behaviors of people who inject drugs using a syringe exchange program who share or re-use syringes and drug injection equipment.

**Procedures**
In this study you will be interviewed in a private session expected to last 45-60 minutes. The interview will take place in a private room in the Louisville Metro Department of Public Health and Wellness. The interview will be led by one of the members of the study team. The interviewer will ask you to share through thoughts and experiences about syringe and injection drug equipment sharing and re-use while participating in a syringe exchange program. The interviewer is a member of the study team and will use an interview guide to begin and guide the discussion. You do not have to answer any questions that make you uncomfortable. The interview will be audio recorded to make sure that all points identified in the interview are accurate. The entire study will last about six months.

**Potential Risks**
There are no foreseeable risks other than possible breach of confidentiality, legal problems, and discomfort in answering personal questions. **There may also be unforeseen risks.**

**Benefits**
The information collected may not benefit you directly. The information learned in this study may be helpful to others.

**Compensation**
No compensation is available for your participation in this study.
HIPAA Research Authorization
The Health Insurance Portability and Accountability Act of 1996 (HIPAA) provides federal safeguards for your protected health information (PHI). State and federal privacy laws also may also require your health information to be protected. By signing this form, you provide your permission, called your “authorization,” for the use and disclosure of PHI.

If you sign this form, the research team working on this study will use and share your health information to answer the research questions described in this document, and to make sure that the research was done correctly. This includes things learned from the procedures described in this consent form. They may also collect other information including your name, address, date of birth, medical history, and other information from your medical records from this institution and other institutions involved with this research, as well as from your other healthcare providers (which may include information about HIV status, drug, alcohol or STD treatment, genetic test results, or mental health treatment). Those persons who receive your health information may not be required by Federal privacy laws (such as the HIPAA Privacy Rule) to protect it and may share your information with others without your permission, if permitted by laws governing them.

In most cases, the health information that identifies you can be used or shared by the research team only if you give your permission by signing this form. Your health information may be shared with a public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury, or disability, and conducting public health surveillance, investigations or interventions.

The time period when information can be used or shared ends when all activities related to this study are completed.

Revocation of Research Authorization

You may withdraw the authorization you have given to use and share your protected health information at any time. This means you can tell us to stop using and sharing your protected health information. If you withdraw/revoke your authorization:
• We will stop collecting information about you.
• You may not withdraw information that we had before you told us to stop.
• We may already have used it or shared it.
• We may need it to complete the research.
• We may need it to search records that are available to the public.

Staff may ask your permission to follow-up with you if there is a medical reason to do so.

To withdraw your authorization, you will be requested to complete a written “Revocation of Research Authorization” form located at the end of this document. You may also obtain a copy from your study doctor, designated personnel or from the Human Subjects
Confidentiality
Total privacy cannot be guaranteed. Your privacy will be protected to the extent permitted by law. If the results from this study are published, your name will not be made public. While unlikely, the following may look at study records:

The University of Louisville Institutional Review Board, and Human Subjects Protection Program Office, and/or the Office of Human Research Protections (OHRP).

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information or documents that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence. Information or documents protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse, but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings) if you have consented to the disclosure, or if it is used for other scientific research, as allowed by federal regulations protecting research subjects. If you report child abuse, or the intent to harm yourself or others, the investigator is legally required to report such information which may result in a breach of confidentiality and legal problems.

You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to any other person not connected with the research, you must provide consent to allow the researchers to release it.

Security
Your information will be kept private by placing it in a secure, locked cabinet and a password protected computer accessible only by members of the study team.

Voluntary Participation
Taking part in this study is voluntary. You may choose not to take part at all. If you decide to be in this study you may stop taking part at any time. If you decide not be in this study or if you stop taking part at any time, you will not lose any benefits for which you may qualify. It will not impact your relationship with the University of Louisville or the Louisville Metro Department of Public health.

Contact Persons, Research Subject’s Rights, Questions Concerns, and Complaints
If you have any concerns or complaints about the study or the study staff, you have three options.
You may contact the principal investigators, Barbra Cave, at 502-852-2010 or barbra.cave@louisville.edu or Vicki Hines-Martin at 502-852-8511 or vphine01@louisville.edu

If you have any questions about your rights as a study subject, questions, concerns or complaints, you may call the Human Subjects Protection Program Office (HSPPO) at 502-852-5188. You may discuss any questions about your rights as a subject, in secret, with a member of the Institutional Review Board (IRB) or HSPPO staff. The IRB is an independent committee composed of members of the University community, staff of the institutions, as well as lay members of the community not connected with these institutions. The IRB has reviewed this study.

If you want to speak to a person outside the University, you may call 1-977-852-1167. You will be given the chance to talk about any questions, concerns, or complaints in secret. This is a 24-hour hotline answered by people who do not work at the University of Louisville.

**Acknowledgement and Signatures**

This informed consent document is not a contract. This document tells you what will happen during the study if you choose to take part. Your signature indicates that this study has been explained to you, that your questions have been answered, and that you agree to take part in the study. You are not giving up any legal rights to which you are entitled by signing this informed consent document. You will be given a copy of this consent form to keep for your records.

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Relationship of Legal Representative to Subject

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<td>Vicki Hines-Martin</td>
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CURRICULUM VITAE

Barbra A. Cave, MSN, APRN, FNP-BC

956 Willow Creek Lane
Louisville, KY 40245
502-648-9904
Barbra.Cave@louisville.edu

EDUCATION

University of Louisville, Louisville, KY
School of Nursing, MSN to PhD Program
Anticipated Graduation Date: October 2019

Bellarmine University, Louisville, KY
Donna & Allan Lansing School of Nursing, Family Nurse Practitioner
Master of Science in Nursing, August 2010

Bellarmine University, Louisville, KY
Donna & Allan Lansing School of Nursing, Accelerated BSN
Bachelor of Science in Nursing, December 2005

Bellarmine University, Louisville, KY
Bellarmine College of Arts & Sciences, Biology
Bachelor of Arts, May 2003

PROFESSIONAL EXPERIENCE

May 2015-Present
University of Louisville, Family Nurse Practitioner, Louisville, KY
Serving in the Clinical Trials Unit as sub-investigator or coordinator for clinical trials involving Hepatology and Gastroenterology (0.2 FTE) and providing specialty hepatology care for patients as lead provider in the Jewish Hospital Hepatitis C Treatment Clinic June 2015-June 2017 and as Hep C Program Lead for the University of Louisville Hospital Hep C Center July 2017-present (0.6 FTE). Clinical trial duties include physical exams, Fibroscan assessment, screening and recruitment, lab review, site initiation visit attendance, and reporting. Duties within the NP-led Hep C Center include consulting with and evaluating HCV patients for treatment, prescribing treatment, Fibroscan, monitoring/reviewing labs, reviewing liver biopsies and various tests while
maintaining standard of care. Comprehensive Hepatology care for special/difficult to treat populations such as those with co-infections, liver transplant, renal disease, or cirrhosis is provided within the Hep C Center. Serving as a hepatology consultant for primary care providers wishing to treat hepatitis C infection through the Kentucky Hepatitis Academic Mentorship Program (KHAMP). Assisted Gastroenterology Associates, part of KentuckyOne Health, from August through December 2015 by providing general gastroenterology care. Responsibilities there included assessment and treatment of Inflammatory Bowel Disease, IBS, Diarrhea/Constipation, and common GI complaints.

May 2016-August 2016  
Robley Rex Veterans Affairs Hospital. Family Nurse Practitioner, Louisville, KY.  
(FEE basis, 0.2 FTE) Providing specialized care for Veterans with Chronic Hepatitis C with duties including liver assessment, physical exams, lab/Fibroscan, viral resistance mutation analyses, medical imaging, and prescribing treatment.

January 2012-February 2015  
University of Louisville Physicians, Family Nurse Practitioner, Louisville, KY  
Provided outpatient healthcare services for patients of the University of Louisville’s Division of Gastroenterology, Hepatology, and Nutrition. Patient duties included health management, ordering and interpreting tests, reviewing medical imaging, and prescribing medication and treatments with emphasis on Hepatitis C, cirrhosis, IBD, and hospital follow-ups, including those with serious and acute illness. Assisted clinical research faculty/staff as Sub-Investigator on numerous clinical trials, including physical exams, result reviews, and attendance at Investigator Meetings. Additional activities included attendance at weekly Medical Grand Rounds, GI/Hepatology Grand Rounds, and other research and clinical meetings as appropriate. Assisted faculty physicians in facilitating patient-physician communication, and evaluating acutely-ill patients when requested. Played an integral role in the opening of the Healthcare Outpatient Center outpatient infusion services center.

October 2010- December 2011  
University Children’s Kidney Specialists, Family Nurse Practitioner, Louisville, KY  
Provided specialized nephrology care to pediatric and adolescent patients.  
Preformed urinalysis, ordered/interpreted labs and imaging, prescribed medication as necessary. Educated families on the natural history and treatment of pediatric kidney diseases, including dietary modifications, treatment expectations, renal transplantation, and medication regimens. Coordinated Pediatric Nephrology Multidisciplinary Team meetings for complex chronic patients with a goal of providing patient-specific, multidisciplinary care for patients pre- and post-transplant, or progressing to ESRD.

January 2006-October 2010  
Jewish Hospital & St. Mary’s Healthcare. Staff Nurse, Louisville, KY  
ICU South, Clinical Ladder Level III. Specialized in adult critical care including neuroscience and solid organ transplantation with emphasis on liver and kidney. Experienced in sepsis/multisystem organ dysfunction, peri-operative care, and palliative
care. Specialized training on VAD (Heartmate, Heartmate VTE, Heartmate II), CRRT, IABP, ICP monitors, and ventilators. Served as new-hire and student preceptor, Member of Skin Care Committee, and Nursing Ambassadors.

October 2008-October 2010
**Isaacs & Isaacs Law Firm**, Registered Nurse Consultant, Louisville, KY
Reviewed medical records as needed to determine if client cases/claims are supported by documentation. Organized complex medical case files into time lines, related diagnoses, and re-presented the information in a useful manner for attorney and courtroom use.

**CERTIFICATIONS**

*American Nurses Credentialing Center (ANCC), Family Nurse Practitioner,* Board Certified since September 2010.

*American Heart Association BLS certified,* December 2004-Present.

*American Heart Association ACLS certified,* December 2006-December 2010 and July 2015-Present.

*Modified Rankin Scale Certified,* University of Glasgow, April 2016-Present

*Certified Critical Care Registered Nurse (CCRN),* February 2008-February 2011.

**MEMBERSHIP ORGANIZATIONS**


*Sigma Theta Tau International* Iota Zeta Chapter of the Honor Society of Nursing, University of Louisville, member since January 2018. Lambda Psi Chapter of the Honor Society of Nursing, Bellarmine University, inducted October 2010.

*American Association of Nurse Practitioners (AANP),* member since April 2015.

*Kentucky Coalition of Nurse Practitioners and Nurse Midwives (KCNPNM),* member since August 2009.

*Association of Community Health Nursing Educators (ACNHE),* member April 2018-April 2019.
American Association of Critical-Care Nurses (AACN), member November 2007-November 2010.

FACULTY

Gastroenterology/Hepatology Advanced Practice Providers (GHAPP), Faculty, March 2018-Present. In conjunction with the CLDF, GHAPP serves to provide peer-developed and led learning opportunities for nurse practitioners and physician assistants specializing in gastroenterology and/or hepatology.

Kentucky Hepatitis Academic Mentorship Program (KHAMP), Faculty and planning committee member, March 2018-Present. KHAMP goals include establishing a primary care provider network trained by hepatitis C experts who can complete the HCV care continuum from screening to cure, and to remove barriers to care for patients living with hepatitis C in rural/underserved communities.

Chronic Liver Disease Foundation (CLDF), HCV Faculty, April 2017-Present. CLDF is a non-profit organization that provides educational programs to physicians, nurses, nurse practitioners, physician assistants, and pharmacists to provide the most up-to-date information surrounding liver diseases available.

Scripps Clinic Liver Research Consortium, CME Faculty, March 2016-Present. The SC Liver Research Consortium is committed to the education of health care providers treating patients with liver disease, regardless of background or practice setting. Topics include nonalcoholic fatty liver disease, hepatocellular carcinoma, primary biliary cholangitis, primary sclerosing cholangitis, and viral hepatitis.

GRANT FUNDING

Harm Reduction Coalition/Gilead HepConnect Grant, Principal Investigator. Funded September 2019-present. This educational grant allows for development and distribution of harm reduction education for nurses and nurse practitioners across Kentucky. The program incorporates non-nurse stakeholders, including people who use drugs. 18 months funding: $100,000

Gilead Frontlines of Communities in the United States (FOCUS), Principal Investigator. Funded December 2017-Present. This grant allows for universal HCV screening at UofL Hospital Labor & Delivery and creates registries to follow both infected mothers and exposed infants to the primary outcomes: HCV cure for mothers and confirmation of HCV infection or clearance in the child. Second year project includes HCV screening expansion to the ULH emergency department with goals of linking all HCV-infected adults to care. First year funding: $193,372. Second year funding: $313,812.

PEER-REVIEWED JOURNAL PUBLICATIONS

Crittenden, N. E., Buchanan, L. A., Pinkston, C. M., Cave, B., Barve, A.... & Kuns-Adkins, C.B. (2016). Simeprevir and sofosbuvir with or without ribavirin to treat recurrent genotype 1 hepatitis C virus infection after orthotropic liver transplantation. Liver Transplantation. PMID 26915588


PUBLISHED ABSTRACTS


CONFERENCE PRESENTATIONS

Cave, B.A. “HCV: Current state and elimination strategies” presented at the 2019 Gastroenterology/Hepatology Advance Practice Providers Conference in Las Vegas, NV on September 6, 2019. (Podium)

Cave, B.A. “Quick assessment and management of viral hepatitis” presented at the 2019 University of Louisville Hospital Advanced Practice Provider Conference in Louisville, KY on August 23, 2019. (Podium)

Cave, B.A. “KHAMP: The role of expert mentoring in hepatitis C elimination” Presented at the 6th Annual Kentucky Viral Hepatitis Conference on July 31, 2019 in Lexington, KY. (Podium)
**Cave, B.A.** “UofL FOCUS: HCV care navigation for mothers and infants” Presented at the 6th Annual Kentucky Viral Hepatitis Conference on July 31, 2019 in Lexington, KY. (Podium)

**Cave, B.A.** “Trifecta! Kentucky leads in viral hepatitis A, B, & C” Presented at the 2019 Kentucky Coalition of Nurse Practitioners and Nurse Midwives Conference on April 24, 2019 in Covington, KY. (Podium)


**Cave, B.A.** & Hanson, C. “Recent Hepatitis C Treatment Advances” presented at the inaugural Gastroenterology/Hepatology Advance Practice Providers Conference in Las Vegas, NV on September 7, 2018. (Podium)

**Cave, B.A.** “The Next Era in Hepatitis C Treatment: Bringing Cure to Primary Care” presented at the Center for Health, Education, and Research in Morehead, KY on August 7, 2018. (Podium)


**Cave, B.A.** “NASH: From Steatosis to Cirrhosis” presented at the 30th Annual Kentucky Coalition of Nurse Practitioners and Nurse Midwives Conference on April 20, 2018 (Podium)


**Cave, B.A.** “Justifying the Cure: Kentucky’s Drug Users Should Have Access to HCV Treatment” presented at the 4th Annual Kentucky Viral Hepatitis Conference in Lexington, KY on July 27, 2017 (Podium)

Cave, B.A. “The New Age of Hepatitis C: Diagnosis and Treatment” (Abstract# 9197387) presented at the 29th Annual Kentucky Coalition of Nurse Practitioners and Nurse Midwives Conference on April 20, 2017 in Covington, KY (Podium)


Cave, B.A. “The Viral Hepatitis Epidemic in Kentucky” presented at the Kentucky Public Health Association Annual Conference, Owensboro, KY on April 12, 2016. (Podium)


Cave, B.A., Lunn, S. M., Smart, L.E., Sanders, K.J., Cave, M.C., Carrico, R.M. (2015, October).”Viral Hepatitis Screening at the 2015 Kentucky State Fair Determined a Rate of Hepatitis C Infection Approximately Three Times the National Average.” Research! Louisville 2015 in Louisville, KY. Abstract #RS-82 (Poster)


CONSULTING


ADVISORY BOARD MODERATING

Abbvie: Assessing the needs of new HCV treaters, Chicago, IL; December 2018.

SPEAKER BUREAUS


Salix. Xifaxan (rifaxamin) and Relistor (methylnaltrexone), November 2012-January 2016, and Xifaxan (rifaximin) January-December 2018.


CLINICAL TRIALS

Co-Primary Investigator 386540: Analysis of Hepatitis C Data from the Screening Performed at the Kentucky State Fair. 15.0748

Sub-Investigator 0151003(ANDANTE): A Double-Blind, Randomized, Placebo-Controlled, Dose-Ranging Study to Evaluate the Efficacy and Safety of PD-04236921 in Subjects with Crohn’s Disease who are Anti-TNF Inadequate Responders 11.0228. B0151005 (ADANTE II): Extension study. 11.0467

Sub-Investigator TU100P2T2 - A Multi-Center, Randomized, Double-Blinded, Placebo-Controlled Study of Daikenchuto (TU-100) in Subject with Moderate Crohn's Disease. 11.0568 (Completed)

Sub-Investigator CNDO 201-003: A Phase II Study to Evaluate the Efficacy and Safety of 12 Weeks of Treatment with Oral CNDO 201 Trichuris Suis Ova Suspension (TSO) as compared to Placebo, Followed by a 12 Week Open-Label Treatment Period in Patients with Moderately to Severely Active Crohn's Disease 12.0364 (Completed)
Sub-Investigator **CNT01275CRD3003 (IMUNITI):** A Phase 3, Randomized, Double-blind, Placebo Controlled, Parallel-group, Multicenter Study to Evaluate the Safety and Efficacy of Ustekinumab Maintenance Therapy in Subjects with Moderately to Severely Active Crohn’s Disease 11.0476 (Completed)

Sub-Investigator **Protocol CNT01275CRD3002 (UNITI-2) / A Phase 3, Randomized, Double-blind, Placebo-controlled, Parallel—group, Multicenter Study to Evaluate the Safety and Efficacy of Ustekinumab Induction Therapy in Subjects with Moderately to Severely Active Crohn’s Disease 13.0362 (Completed)**

Sub-Investigator **IM129-005:** A Phase IIb Randomized, Placebo-Controlled Study to Evaluate the Clinical Efficacy and Safety of Induction and Maintenance Therapy with BMS-936557 in Subjects with Active Ulcerative Colitis (UC) 11.0226 (Completed)

Sub-Investigator **MK5172-038:** A Phase II Randomized, Dose Ranging, Clinical Trial to Evaluate the Safety, Tolerability and Efficacy of Different Doses of MK5172 when Administered Concomitantly with Peginterferon alpa-2b and Ribavirin in Treatment Naive Subjects with Chronic Hepatitis C Virus Infection 12.0564 (Completed)

Sub-Investigator **MK5172-068:** A Phase III Randomized Clinical Trial to Study the Efficacy and Safety of the Combination Regimen of MK-5172/MK-8742 in Subjects who have Failed Prior Treatment with PEGylated Interferon and Ribavirin (P/R) with Chronic HCV GT1, GT4, GT5, and GT6 Infection 12.0424

Sub-Investigator **Protocol MK5172-017-00:** A Long-Term Follow-up Study to Evaluate the Durability of Virologic Response and/or Viral Resistance Patterns of Subjects with Chronic Hepatitis C Who Have Been Previously Treated with MK-5172 in a Prior Clinical Trial 12.0512

Sub-Investigator **MK5172-PN-003:** A Randomized, Active-Controlled, Dose-Ranging Estimation Study to Evaluate the Safety, Tolerability and Efficacy of Different Regimens of MD-5172 when Administered Concomitantly with Peginterferon alfa-2b and Ribavirin in Treatment-Naive Patients with Chronic Genotype 1 Hepatitis C Virus Infection 11.0301 (Completed)

Sub-Investigator **Novel Therapies for Alcoholic Hepatitis 12.0427**

Sub-Investigator **PO7755(MK-3034-040-01):** A Phase 3, Safety and Efficacy Study of Boceprevir/Peginterferon Alfa-2a/ribavirin in Chronic HCV Genotype 1 IL28B CC Subjects 12.0383 (Completed)

Sub-Investigator **Protocol 27018966IBS3001:** A Randomized, Double-blind, Placebo-controlled, Phase 3 Study to Evaluate the Efficacy, Safety, and Tolerability of JNJ-27018966 in the Treatment of Patients with Diarrhea-Predominant Irritable Bowel Syndrome 12.0226 (Completed)
Sub-Investigator Protocol ACT12688: A Randomized, Double-blind, Placebo-controlled, Multicenter Study Evaluating Efficacy and Safety of SAR339658 in Patients with Active Moderate to Severe Ulcerative Colitis (UC) 13.0339 (Completed)

Sub-Investigator Protocol IDN-6556-02 / A Placebo-Controlled, Multicenter, Double-Blind, Randomized, Pharmacokinetic and Pharmacodynamic Trial of IDN-6556 in Subjects with Acute-on-Chronic Liver Failure (Conatus) 13.0976 (Completed)

Sub-Investigator Protocol C13008: A Phase 3, Open-label Study to Determine the Long-Term Safety and Efficacy of Vedolizumab (MLN0002) in Patients with Ulcerative Colitis and Crohn’s Disease 08.0515

Sub-Investigator Protocol LUM001-201: A Phase 2, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate LUM001, an Apical Sodium-Dependent Bile Acid Transporter Inhibitor (ASBTi) in Combination with Ursodeoxycholic Acid (UDCA) in Patients with Primary Biliary Cirrhosis 13.0288 (Completed)

Sub-Investigator Merit-UC: Randomized, Double Blind, Prospective Trial Investigating the Efficacy of Methotrexate in Induction and Maintenance of Steroid Free Remission in Ulcerative Colitis (Methotrexate Response in Treatment of UC-Merit-UC) 12.0246

Sub-Investigator Protocol MK-3415A-002 (MODIFY II): A Phase III, Randomized, Double-Blind, Placebo-Controlled Study of the Efficacy, Safety, and Tolerability of a Single Infusion of MK-6072 (Human Monoclonal Antibody to C. difficile toxin B), and MK-3415A (Human Monoclonal Antibodies to C. difficile toxin A and B) in Patients Receiving Antibiotic Therapy for C. difficile Infection 12.0028 (Completed)

Sub-Investigator CLARITY-1: A Balanced, Randomized, Placebo-Controlled, Double-Blind Study of the Efficacy and Safety of AUT00063 Versus Placebo in Age-Related Hearing Loss 14.1295 (Completed)

Sub-Investigator Receptos Ulcerative Colitis Open Label Extension: A Phase 3, Multicenter, Open-Label Extension Trial of Oral RPC1063 as Therapy for Moderate to Severe Ulcerative Colitis 15.0688

Independent Assessor CONCERNT-HF: A Phase II, Randomized, Placebo-Controlled Study of the Safety, Feasibility, and Efficacy of Autologous Mesenchymal Stem Cells and c-kit+ Cardiac Stem Cells, Alone or in combination, Administered Transendocardially in Subjects with Ischemic Heart Failure 15.0733

Sub-Investigator Hep C with Simeprevir, Sofosbuvir, and Ribavirin: A Retrospective Review of the Treatment of Hepatitis C Virus Genotype 1 Patients with Simeprevir, Sofosbuvir, With and Without Ribavirin at University of Louisville/Jewish Hospital 14.1239

Sub-Investigator Protocol IDN-6556-07 (Conatus-POLT): A Multicenter, Double-
Blind, Randomized Trial of IDN-6556 in Subjects Who had Hepatitis C Virus (HCV) Reinfection and Liver Fibrosis or Cirrhosis Following Orthotopic Liver Transplantation for Chronic HCV Infection and Who Subsequently Achieved a Sustained Virologic Response Following anti-HCV Therapy 15.0242

Sub-Investigator GED-0301-CD-001 (Celgene Crohn’s) - A Randomized, Double-Blind, Multicenter Study To Explore The Effect Of Ged-0301 On Endoscopic And Clinical Outcomes In Subjects With Active Crohn’s Disease 15.0186

Sub-Investigator Protocol M13-740 / A Multicenter, Randomized, Double-Blind, Placebo-Controlled Study of ABT-494 for the Induction of Symptomatic and Endoscopic Remission in Subjects with Moderately to Severely Active Crohn’s Disease who have Inadequately Responded to or are Intolerant to Immunomodulators or Anti-TNF Therapy 15.0141

Sub-Investigator Novartis PBC: CLJN452X2201 A multi-part, randomized, double-blind, placebo-controlled study to assess the safety, tolerability, and efficacy of LJN452 in Patients with Primary Biliary Cirrhosis 15.0809

Sub-Investigator Xpert HCV VL Assay: Clinical Evaluation of the Xpert HCV VL Assay 15.0305 (Completed)

Sub-Investigator Protocol GA29144 Open-Label Crohn’s Disease: An Open-Label Extension and Safety Monitoring Study of Patients with Moderately to Severely Active Crohn’s Disease Previously Enrolled in the Etrolizumab Phase III 15.0375

Sub-Investigator Gilead 0102 Primary Sclerosing Cholangitis: GS-US-321-0102/A Phase 2b, Dose-ranging, Randomized, Double-Blind, Placebo-Controlled Trial Evaluating the Safety and Efficacy of GS-6624, a Monoclonal Antibody Against Lysyl Oxidase-Like 2 (LOXL2), in Subjects with Primary Sclerosing Cholangitis (PSC) 13.0517

Sub-Investigator Gilead 0105 Advanced Liver Fibrosis: GS-US-321-0105/A Phase 2b, Dose-Ranging, Randomized, Double-Blind, Placebo-Controlled Trial Evaluating the Safety and Efficacy of GS-6624, a Monoclonal Antibody Against Lysyl Oxidase-Like 2 (LOXL2), in Subjects with Advanced Liver Fibrosis but not Cirrhosis Secondary to Non-Alcoholic Steatohepatitis (NASH) 13.0518

Sub-Investigator Gilead 0106 Compensated Cirrhosis: GS-US-321-0106/A Phase 2b, Dose-Ranging, Randomized, Double-Blind, Placebo-Controlled Trial Evaluating the Safety and Efficacy of GS-6624, a Monoclonal Antibody Against Lysyl Oxidase-Like 2 (LOXL2), in Subjects with Compensated Cirrhosis Secondary to Non-Alcoholic Steatohepatitis (NASH) 13.0539

Independent Assessor Heartmate III (MOMENTUM 3): Multi-Center Study of MagLev Technology in Patients Undergoing MCS Therapy with Heartmate 3 15.0347
Sub-Investigator Protocol CNTO1275UCO3001 (UNIFI): A Phase 3, Randomized, Double-blind, Placebo-controlled, Parallel-group, Multicenter Protocol to Evaluate the Safety and Efficacy of Ustekinumab Induction and Maintenance Therapy in Subjects with Moderately to Severely Active Ulcerative Colitis 15.0638

Independent Assessor SENECA: A Phase I, First-in-Human, Multicenter, Randomized, Double-Blinded, Placebo-Controlled Study of the Safety and Efficacy of Allogenic Mesenchymal Stem Cells in Cancer Survivors with Anthracycline-Induced Cardiomyopathy 15.0928

Sub-Investigator PERSEUS Tobira: A Phase 2 Proof of Concept Study Investigating the Preliminary Efficacy and Safety of Cenicriviroc in Adult Subjects with Primary Sclerosing Cholangitis (PSC) 16.0015

Sub-Investigator Roche GA28951: An Open-Label Extension and Safety Monitoring Study of Moderate to Severe Ulcerative Colitis Patients Previously Enrolled in Etrolizumab Phase III Studies 14.0533


Sub-Investigator Protocol 747-302 (Intercept PBC): A Phase 3b, Double-Blind, Randomized, Placebo-Controlled, Multicenter Study Evaluating the Effect of Obetacholic Acid on Clinical Outcomes in Subjects with Primary Biliary Cirrhosis 14.1228

Sub-Investigator Protocol 747-303 (Intercept NASH): A Phase 3, Double-Blind, Randomized, Long-Term, Placebo-Controlled, Multicenter Study Evaluating the Safety and Efficacy of Obetacholic Acid in Subjects with Nonalcoholic Steatohepatitis (NASH) 15.0879

Sub-Investigator Protocol APD334-003 Arena Ulcerative Colitis: A Phase 2, Randomized, Double-Blind, Placebo-Controlled, Parallel Group, Multi-Center Study to Investigate the Safety and Efficacy of APD334 in Patients with Moderately to Severely Active Ulcerative Colitis 15.0696 (Completed)

Sub-Investigator Protocol CC-10004-UC-001 Celgene Ulcerative Colitis: A Phase 2, randomized, placebo-controlled, multicenter study to investigate the efficacy and safety of apremilast (CC-10004) for treatment of subjects with active ulcerative colitis 14.1249

Sub-Investigator Protocol GA28948: Phase III, Randomized, Double-Blind, Double-Dummy, Placebo-Controlled, Multicenter Study to Evaluate the Efficacy (Induction of Remission) and Safety of Etrolizumab Compared with Adalimumab and Placebo in Patients with Moderate to Severe Ulcerative Colitis Who Are Naïve to TNF Inhibitors 14.0881
Sub-Investigator Protocol GA28950: Phase III, Double-Blind, Placebo-Controlled, Multicenter Study of the Efficacy and Safety of Etrolizumab During Induction and Maintenance in Patients with Moderate to Severe Ulcerative Colitis Who Are Refractor or Intolerant of TNF Inhibitors 14.0220

Sub-Investigator Protocol GA29144: A Phase III, Randomized, Double-Blind, Placebo-Controlled, Multicenter Study to Evaluate the Efficacy and Safety of Etrolizumab as an Induction and Maintenance Treatment for Patients with Moderately to Severely Active Crohn’s Disease 15.0252

Sub-Investigator Protocol GS-US-326-1100 (Gilead UC): A Combined Phase 2/3, Double-Blind, Randomized, Placebo-Controlled, Induction and Maintenance Study Evaluating the Safety and Efficacy of GS-5745 in Subjects with Moderately to Severely Active Ulcerative Colitis 15.0904

Sub-Investigator and Coordinator Protocol IDN-6556-10 (Conatus Cirrhosis): A Multicenter, Double-Blind, Placebo Controlled Study to Evaluate the Safety, Tolerability and Efficacy of IDN-6556 in Subjects with Liver Cirrhosis 14.0613 (Completed)

Sub-Investigator and Coordinator Protocol IDN-6556-02 (Conatus): A Placebo-Controlled, Multicenter, Double-Blind, Randomized, Pharmacokinetic and Pharmacodynamic Trial of IDN-6556 in Subjects with Acute-on-Chronic Liver Failure 13.0976 (Completed)

Sub-Investigator RPC01-301 (Receptos 3101 UC): A Phase 3, Multicenter, Randomized, Double-blind, Placebo-controlled Trial of Oral RPC1063 as Induction and Maintenance Therapy for Moderate to Severe Ulcerative Colitis 15.0586

Sub-Investigator Protocol BAY 86-9766: A prospective, single-arm, multicenter, uncontrolled, open-label Phase II trial of refametinib (BAY 86-9766) in patients with RAS mutant Hepatocellular Carcinoma (HCC) 13.0432 (Completed)

Sub-Investigator PF-05285401: A Phase 2 Randomized, Double-Blind, Placebo-Controlled, Parallel Group, Multi-center Study to Investigate the Safety and Efficacy of MultiStem (PF-05285401) in Subjects with Moderate to Severe Ulcerative Colitis 10.0594 (Completed)


Sub-Investigator Protocol LTS12593 (Sanofi Extension): A multicenter single-arm open-label extension study evaluating the long-term safety and tolerability of SAR339658 in patients with Ulcerative Colitis (UC) 13.0875 (Completed)
Sub-Investigator Protocol D5170C00002 (MedImmune Crohn’s): Phase 2b Double-blind, Multi-dose, Placebo-controlled Study to Evaluate the Efficacy and Safety of MEDI2070 in Subjects with Moderate to Severe Crohn’s Disease Who Have Failed or Are Intolerant to Anti-tumor Necrosis Factor-alpha Therapy 16.0093

Sub-Investigator Protocol IDN-6556-12 (Conatus NASH): A Multicenter, Randomized, Double-blind, Placebo-Controlled Trial of Emricasan (IDN-6556), an Oral Caspase Inhibitor, in Subjects with Non-alcoholic Steatohepatitis (NASH) Fibrosis 16.0115

Sub-Investigator PIONEER-CD: A Randomized, Double-Blind, Placebo-Controlled Trial to Evaluate the Effectiveness of a Nutritional Intervention in Improving the Intestinal Mucosal Health Status in Subjects with Crohn’s Disease (CD) Receiving Induction Anti-TNF Therapy 16.0616

Sub-Investigator GFT505-315-1 (GENFIT NASH): A Multicenter, Randomized, Double-blind, Placebo-Controlled Phase III Study to Evaluate the Efficacy and Safety of Elafibranor in Patients with Nonalcoholic Steatohepatitis (NASH) and fibrosis 16.0637

Sub-Investigator Protocol SHP626-201 (Shire NASH): A Phase 2 Double-Blind, Randomized, Placebo-controlled, Dose-finding Study to Evaluate the Safety, Tolerability and Efficacy of Volixibat Potassium, an Apical Sodium-Dependent Bile Acid Transporter Inhibitor (ASBTi) in Adults with Nonalcoholic Steatohepatitis 16.0666

Sub-Investigator Protocol GS-US-366-1992: A Phase 3b Randomized, Open-label, Controlled Study of the Efficacy, Safety and Tolerability of 12 Weeks of Ledipasvir/Sofosbuvir (LDV/SOF) Treatment for HIV/HCV Co infected Subjects who Switch to Elvitegravir/Cobicistat/Emtricitabine/Tenofovir Alafenamide (E/C/F/TAF) or Emtricitabine/Rilpivirine/Tenofovir Alafenamide (F/R/TAF) prior to LDV/SOF HCV Treatment, the HIV/HCV Co-STARs study (Co-infection treatment with Single Tablet Antiviral Regimens) 16.0799

SERVICE


River TaeKwonDo, Black Belt and Instructor, 5th Dan, 1999-Present.

LICENSURE/Maiden name: Barbra A. Peper
CREDENTIALINGFormer name: Barbra A. Goshko (2005-2015)
DETAILSLegal name: Barbra A. Cave