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UTILIZING A FORMATIVE PROGRAM EVALUATION APPROACH
AND AN APPLICATION OF GROUNDED THEORY TO
ASSESS A NOVEL HARM REDUCTION PROGRAM

A Capstone project submitted in partial fulfillment of the
requirements for the degree of Doctor of Public Health in the
College of Public Health
at the University of Kentucky

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2020

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College of Public Health
University of Kentucky

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Terms and Abbreviations

AETC: AIDS Education and Training Center
AIDS: Acquired Immunodeficiency Syndrome
CDC: Centers for Disease Control and Prevention
DPH: Department for Public Health
HAV: Hepatitis A Virus
HBV: Hepatitis B Virus
HCV: Hepatitis C Virus
HD: Health Department or District
HHS: US Department of Health and Human Services
HIV: Human Immunodeficiency Virus
HR: Harm Reduction
HRI: Harm Reduction Initiative
HRP: Harm Reduction Program
HRSA: Health Resources and Services Administration
IDU: Injection Drug Use
IVDU: Intravenous Drug Use
KADAP: Kentucky AIDS Drug Assistance Program
KDPH: Kentucky Department for Public Health
KIRP: KADAP Income Reinvestment Program
LHD: Local Health Department or District
MAT: Medication assisted treatment
MOUD: Medication for Opioid Use Disorder
NASTAD: National Alliance of State and Territorial AIDS Directors
NEP: Needle Exchange Program
NIDA: National Institute on Drug Abuse
NIH: National Institutes of Health
NSEP: Needle and Syringe Exchange Program
OPS: Overdose Prevention Site
PEP: Post Exposure Prophylaxis
PreP: Pre-exposure Prophylaxis
PWID: People Who Inject Drugs
PWUD: People Who Use Drugs
REDCap: Research Electronic Data Capture System
RRS: Risk Reduction Specialist
RW: Ryan White
RWHAP: Ryan White HIV/AIDS Program
SAMHSA: Substance Abuse and Mental Health Services Administration
SEP: Syringe Exchange Program
SSP: Syringe Services Program
TasP: Treatment as Prevention

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Executive Summary

This summary briefly outlines the methods, findings, and recommendations of formative program evaluation of the Harm Reduction Initiative (HRI). Formative program evaluation is conducted during development and early implementation to ensure a program is feasible, appropriate, and acceptable.¹ HRI, a program of KIRP, the Kentucky AIDS Drug Assistance (KADAP) Income Reinvestment Program, seeks to address some of the underlying causes of infectious disease vulnerability resulting from drug use by focusing on infectious disease testing and linkage to care among high risk individuals. The primary objective of the evaluation was to use a focused ethnographic field study approach to achieve the following aims:

1. Characterize the need for the program
2. Clarify the theory and logic of the program
3. Inform implementation
4. Improve the program where necessary

METHODS

Design. To conduct this formative evaluation, a focused ethnographic (FE) field study approach was used with the purpose of ascertaining, understanding, and describing the four categorical areas of formative program evaluation in the context of the Harm Reduction Initiative. The data collection activities included participant observation and semi-structured interviews.

Literature Review. A literature review to understand and characterize the need for the program and the activities that the program should offer was completed.

Setting & Participants. Primary participants included the HRI management team (program director, project director, medical director, strategist, program manager, fiscal director, DPH HRI clinical coordinator, and the director of evaluation and outcomes). Meeting observation and interviews took place at HRI offices on the University of Kentucky (UK) campus. In addition, two onsite meetings with local health department (LHD) personnel (public health directors, medical directors, nurses, and syringe service program (SSP)/Harm reduction workers) at the Clark County Health Department and the Lake Cumberland Health District office were observed.

Semi-structured interviews were used for theoretical sampling when clarification or elaboration was needed on topics discussed during meetings. The HRI project director participated in these interviews which took place primarily in her office on the UK campus.

Data Collection. Approximately 20 total hours of HRI management meeting observation was conducted between May and December 2019. Additionally, data

collection included two onsite meetings with LHD staff in the summer of 2019. Each of the two LHD meetings lasted approximately one and a half hours. Sixteen semi-structured face-to-face interviews of about 60 minutes each were completed with the project director.

Evaluation Tool Creation. To aid the analyses and illustrate the program need, theory, and implementation capacity, the researcher developed problem and solution trees, a stakeholder analysis matrix, a logic model, and a logframe matrix. These tools were produced from analysis and coding of data from meetings and interviews, as well as the literature review.

Data Analysis. This qualitative data analysis was guided by grounded theory (GT) methodology, which entails starting research without a principal theory already established, and utilizing inductive reasoning to develop a theory after data collection begins. All qualitative material gathered in this study (meeting observation and interviews) went through a systematic, three-step, manual coding process starting with open coding which was refined into axial coding by finding relationships in the data and finally emerging into selective coding by identifying core categories.

FINDINGS

Proactive. A literature review substantiated the needs identified by stakeholders within the state in regards to infectious disease consequences of drug use. It showed that the rates of HIV, HCV, and complications secondary to drug use and high-risk behaviors make Kentucky's population vulnerable to widespread and long-term, multi-generational consequences. Furthermore, it described the practices and policies that can mitigate the effects, such as harm reduction principles, along with infectious disease testing and linkage to care. The literature review laid out the landscape of causes and effects as illustrated in Problem and Solution Trees. This helps to better understand what the state is up against and how best to address the issues.

Local needs were assessed through a series of meetings with health department personnel. Needs identified by LHD staff included more staff, funding, a user-friendly, comprehensive data collection tool, and the capacity to access certain populations who cannot use syringe service programs (SSP). Some LHDs face opposition from law enforcement and local officials and expressed fear due to lack of information, training, and capacity to respond to potential outbreaks in their community.

Clarificative. A logic model and logframe matrix, tools that illustrate the program logic and theory in easy-to-understand depictions were developed for the HRI. They lay out the inputs (resources-staff and funding), outputs (testing/linkage to care), outcomes (goals), assumptions, and external factors associated with the

program as well as the logical progression from activities through output, results, and purpose, to the end goal of a reduced infectious disease burden in Kentucky.

Interactive. Aspects of HRI management, organization, and implementation strategy and practices were analyzed. A vital part of the program rollout was the development and improvement of the data collection tool, which is central to activity monitoring and goal evaluation. Additionally, managing the balance between state-wide standardization for quality assurance and local needs and nuances is critical for this innovative and much-needed program. HRI's ability to review and reflect upon circumstances and adapt where necessary was important for effectiveness and relevancy. It became apparent that outreach work would be a vital component to access those in most need. Additionally, due to HRI's setup and the fact that it is spread throughout the state, it will be a part of Kentucky's official plan to End the HIV Epidemic. HRI solicited input from SSP clients in order to implement practices that are appropriate for actual needs of consumers and took into account perspectives of health department and SSP staff to address concerns.

Monitoring. HRI management utilized frequent feedback from embedded staff to learn about and address issues. The core team has been shown to be highly responsive to staff needs. They have also leveraged existing strengths of employees while providing opportunities to support areas where improvement is needed. Furthermore, they continually look for ways to keep the program operating at the highest standard possible, including implementing a national Best Practices Evaluation Tool for all their sites. In addition, HRI management has been looking into and assessing the capacity of the state to provide data surveillance and outbreak response when needed. HRI is in ongoing conversations to support these efforts.

RECOMMENDATIONS

General Programmatic Issues. Findings suggest that HRI should remain in operation and expand to other areas of the state. Existing funds should continue to be used for this endeavor, as they are, to date, plentiful and versatile enough to allow the program to be effective. It may be beneficial to diversify funding to address gaps that arise due to non-allowable services (needles/syringes, HCV testing incentives).

HRI core staff should continue their management style of seeking out further expertise to fill gaps in understanding and ensure staff remain as competent as possible.

Management and embedded staff should continue to foster their consistent and rapid internal communication about happenings in their local areas. This essentially functions as a real-time alert system for important events, such as

potential outbreaks, mass overdose, which may indicate contaminated product in the area, or other sentinel events.

Additionally, long term goal targets may need to be further specified.

Service Expansion. Findings support continued capacity building for service expansion beyond SSPs to reach individuals with barriers that prevent them from physically coming to SSPs. County residents that cycle in and out of detention centers are a high-risk population and an easy point of access given they are a “captive audience”. Infectious disease testing, linkage to care, treatment initiation, medication assisted treatment (MAT), Pre-Exposure Prophylaxis (PreP), and vaccinations are services that could and should be offered in county detention centers.

Local Needs Assessment. Identifying local needs was essential in determining what relevant services should be offered by HRI. It is important that the program continue to assess local needs as they change over time, particularly if previously identified needs are being effectively addressed. Periodic local needs assessments should be built into program operations.

Consumer Input. Service provision should be informed by those who use the services. HRI should seek regular input from clients on the quality and value of services offered. Staff should continue to follow-up and check in with clients to evaluate their drug use practices to keep the offered services and activities as relevant as possible.

Furthermore, staff should assess challenges clients face accessing SSPs, getting tested, and engaging in care and find ways to address them. This will require accumulating knowledge of available, local resources. SSP clients have indicated housing instability, employment, and transportation are major issues they face. HRI needs to be positioned to take into account these structural vulnerabilities in order to adequately achieve program objectives.

Education/Advocacy. Findings further suggest that embedded HRI staff should advocate within their local communities to ensure that SSP best practices are implemented (i.e. needs-based syringe exchange). Furthermore, embedded HRI staff should continue to identify and advocate for SSPs in areas where they are needed but still lacking. The program should ensure adequate anti-stigma training including client-centered and recovery-positive language, to help reduce an unintentionally stigmatizing or unconsciously unwelcoming environment. HRI should continue to seek ways to address law enforcement interference in SSP operations. Progress has been made, but plans to implement an online educational series for law enforcement should go forward. Staff should seek further ways to engage local law enforcement. HRI should continue to collaborate with the state and other entities toward an adequate and robust data and surveillance system, as this is imperative to be able to identify and respond to

public health concerns. A last, more aspirational recommendation involves HRI advocating for and promoting the evidence-based harm reduction service of supervised injection facilities.

CONCLUSIONS

The purpose of this study was to conduct qualitative formative evaluation research on the Harm Reduction Initiative with the aim to identify the need for the program, clarify the program, inform implementation, and improve the program where necessary. The methodology and results revealed a program that was necessary, well thought out, carefully deployed, consistently checked for areas of improvement and success, and modified as necessary. This evaluation presented recommendations that are opportunities to further improve a well-structured program. In order to remain effective and relevant, services must be restructured when necessary to address real and current issues affecting individuals at any given time. In this regard, the Harm Reduction Initiative is as prepared as can be, as it has shown itself capable of the flexibility and adaptation necessary to continue vital services for communities in Kentucky.

1. INTRODUCTION

1.1 Background

Infectious disease vulnerability resulting from drug use, particularly through injection, has had vast and devastating consequences on communities in Kentucky and the state as a whole.²⁻⁶ The Harm Reduction Initiative (HRI), a program of KIRP, the Kentucky AIDS Drug Assistance (KADAP) Income Reinvestment Program, seeks to address some of the underlying causes of this costly burden. This innovative program focuses on infectious disease testing and linkage to care and was in the early stages of development and implementation at the time of this research. This study aims to conduct a formative program evaluation of the HRI. Formative program evaluation is conducted during development and early implementation to ensure a program is feasible, appropriate, and acceptable.¹

1.1.1 Program Description

The KIRP Harm Reduction Initiative came to be because of the intersection of need to reinvest program income funds and need to stem the infectious disease consequences of injection drug use in Kentucky. The conceptual impetus of KIRP is HIV prevention in high-risk populations, and the mission is to eliminate new HIV infections in the state by 1) providing comprehensive education and screening services to those at highest risk for HIV infection, and 2) linking identified HIV-positive persons into high-quality, state of

the art medical care and improving access to supportive services to ensure HIV-positive persons enjoy health and wellbeing (See Appendix A).

To accomplish this mission, stakeholders wanted to focus on prevention, education, treatment, and innovation. Therefore, four major areas of the program (See Figure 1.1) were set up:

1. Harm Reduction Initiative
2. Inter-Professional Health Education Collaborative
3. Prevention Care and Treatment Program
4. Innovative Pilot Programs

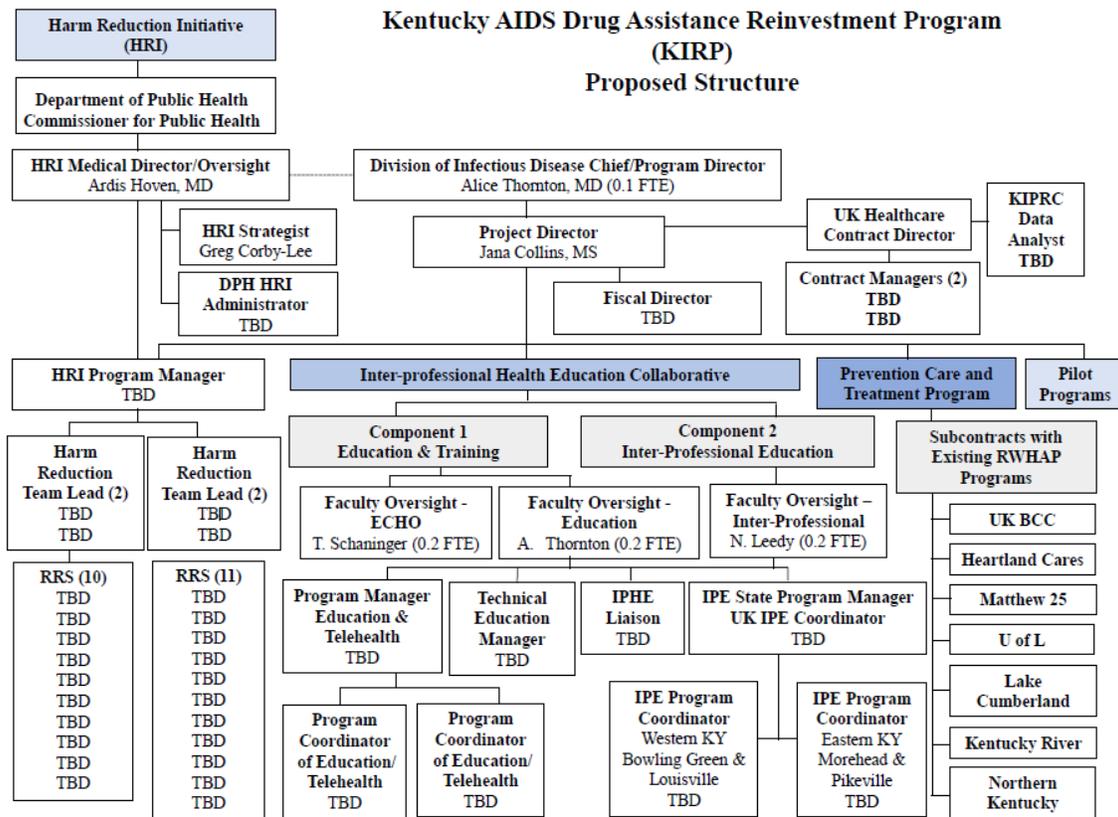
Figure 1.1: Kentucky AIDS Drug Assistance (KADAP) Income Reinvestment Program (KIRP) Pillars



Each pillar of KIRP was in various stages of development and implementation during the time of this study. The first area of KIRP, the Harm Reduction Initiative is the subject of and is discussed in detail and at length in

this report. The second, the Inter-Professional Health Education Collaborative will feature different components of education and training for providers and multi-disciplinary care teams. The Prevention Care and Treatment Program is designed to invest funds into existing Ryan White programs in the state. Those programs will use funds to address barriers their patients experience in order to improve outcomes. The last area reserves funds to be used for programs proposed from entities within the state that are designed to improve access and services in innovative ways (See Figure 1.2).

Figure 1.2:



The Harm Reduction Initiative (HRI) concept is designed to embed specially trained staff in local syringe service programs (SSP) in Kentucky, as well as infuse funds that may be used to ensure and improve testing provision and linkage to care. The idea is that local health departments (LHDs) where SSPs are located decide on what they need and want for their programs. They prepare and submit budget requests to HRI staff for review and approval. Thus, HRI exists to enhance capability of existing SSPs and focus on capacity building in local communities.

HRI funding originates from Ryan White Part B funds from the Health Resources and Services Administration (HRSA); therefore, all expenses must involve the prevention of HIV for people at highest risk of infection, and linkage to care for people with HIV. Of note, federal funding may not be used for the purchase of needles or syringes. This ban dates back to 1988 legislation sponsored by the late Senator Jesse Helms. The law states that officials may not use federal dollars to provide “individuals with hypodermic needles or syringes so that such individuals may use illegal drugs.”⁷ These funds may be used in other allowable areas (See Appendix B), however, to offset funds that LHD allocate to syringes and needles.

1.2 KIRP Program Origin

In March 2019, the concept for a new program, resulting from collaboration between the Kentucky Department for Public Health, the University of Kentucky HealthCare, and local health departments in Kentucky was

announced via a press conference in Northern Kentucky.⁸⁻¹¹ Northern Kentucky had been experiencing a cluster of HIV cases,¹² and thus, stakeholders felt it to be a fitting location to both unveil and begin implementation of the program, called The Kentucky AIDS Drug Assistance Program (KADAP) Income Reinvestment Program, or KIRP.

The Kentucky AIDS Drug Assistance Program or KADAP is a service under the Ryan White HIV/AIDS Program Part B grant.¹³ The Kentucky AIDS Drug Assistance Program Pharmacy located at the University of Kentucky receives 340B pricing for medications. The 340B Pricing Program is a federal program requiring pharmaceutical companies participating in Medicaid to provide certain drugs at reduced prices to healthcare providers who care for low-income populations.¹⁴ The ability to purchase medication for low prices combined with a higher post-Affordable Care Act insured patient rate, and thus more insurance reimbursement for medications, led to increased program income for KADAP. Program income must be reinvested according to allowable requirements of the Ryan White Program.

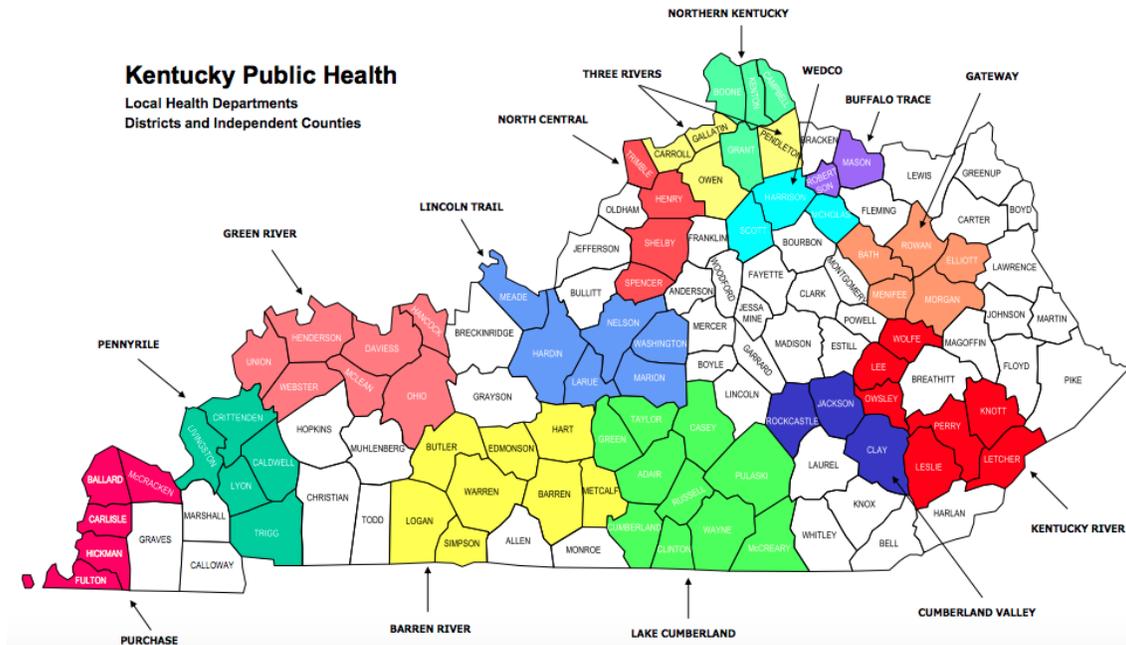
In April 2017, a Ryan White Part B site visit identified that changes needed to be made to how the program income funds were reinvested. University of Kentucky Healthcare became involved, and along with Kentucky Department for Public Health, sought to develop a program for fund reinvestment. They enlisted the help of the chief of the Division of Infectious Disease at the University of Kentucky who oversees the Ryan White program and the Research Protocol Manager for the University of Kentucky Ryan White Programs due to their

extensive Ryan White experience. After considerable research, meetings, brainstorming, and consultation, these individuals submitted proposals later in 2017. A meeting was held with the commissioner of the Kentucky Department for Public Health, and KIRP was eventually born.

1.2.1 Structure of Public Health in Kentucky

The structure of public health has bearing on how health policies and activities are handled in each state. Kentucky has a shared governance model between the state and local public health offices.¹⁵ Under the Cabinet for Health and Family Services, the Kentucky Department for Public Health's (KDPH) mission is to "improve the health and safety of people in Kentucky through prevention, promotion and protection".¹⁶ KDPH provides administrative guidance to local health departments (LHD) and relies on them to carry out lawfully required public health services in the state. Some LHDs are grouped into districts comprised of anywhere from two to ten counties. Seventy-three counties lie within fourteen grouped districts: Barren River, Buffalo Trace, Cumberland Valley, Gateway, Green River, Kentucky River, Lake Cumberland, Lincoln Trail, North Central, Northern Kentucky, Pennyrile, Purchase, Three Rivers, and WEDCO, and there are 47 standalone county health departments (See Figure 1.3).¹⁷

Figure 1.3:



(Kentucky CHFS 2017)

Each county has a local board of health, and districts will additionally have a district board of health. Boards of health assist in setting policy and priorities for their local area. Therefore, a district director will have to work with not only the district board but each individual county board as well.¹⁶ Each county has different political environments, rules, priorities, and perspectives. Moreover, each has unique requirements, challenges, and potential. This is of tremendous import for a statewide initiative attempting to tailor to local needs while still trying to keep a degree of uniformity in order to ensure a certain degree of standards and quality.

1.3 Formative Program Evaluation

KIRP was conceived out of a need for the state to address the crises of drug use and infectious disease, and it is necessary to evaluate this program in order to ascertain whether the resources are being used appropriately and most effectively.

Formative program evaluation is conducted prior to and during the development of a program, and it extends into the early implementation stage. Commonly, formative evaluation is described in four categories: proactive, clarificative, interactive, and monitoring.¹⁸ Other resources have described the four areas or stages as 1) exploration, 2) installation, 3) initial implementation, and 4) full implementation, but the two descriptions are essentially analogous.¹⁹ The function of formative evaluation is to first understand and clarify the need for the program (proactive), to describe and clarify the project (clarificative), to improve the program design after initial implementation (interactive), and to ensure that the project is being carried out as it should be (monitoring).¹⁸ Formative evaluation is largely conducted with the intent to improve the program, and this type of evaluation can also assess the readiness for summative evaluation.¹⁹

Formative program evaluation can be conducted using quantitative, qualitative, or a mixed methodology.²⁰ Qualitative data analysis is ideal for formative evaluation, as it is an exploratory process. There are activities that can be carried out to assess each category of evaluation (See Table 1.1). Literature reviews, stakeholder analyses, problem and solution tree analyses, and needs

assessments can be used to complete proactive evaluation. Various methods of laying out the program logic can clarify the program theory in the clarificative section. Interviews and reflection with subsequent adaptation are helpful for project improvement during interactive assessment, and further interviews and observation can be used during monitoring.¹⁸

The purpose of this study is to conduct qualitative formative evaluation research on the Harm Reduction Initiative with the aim to identify the need for the program, clarify the program, inform implementation, and improve the program where necessary. The KIRP Harm Reduction Initiative seeks to mitigate the crises of drug use and infectious disease burden on the state. The success or failure of the program has serious implications for the future health and economic status of Kentucky. Therefore, it is necessary to ensure this project is needed, is organized, is effective, is adaptable, is well-managed, and targets the correct populations. Formative evaluation permits the discovery of any problems and allows them to be worked out early in development and implementation.

Table 1.1: Categories of Formative Evaluation				
	Proactive	Clarificative	Interactive	Monitoring
When	Pre-project	Project development	Project implementation	Project implementation
Why	To understand or clarify the need for the project	To make clear the theory of change that the project is based on	To improve the project's design (continual improvement) as it is rolled out	To ensure that the project activities are being delivered efficiently and effectively
Examples	Literature Review Stakeholder Analysis Problem / Solution Tree Analysis Local Needs Assessment	LogFrame Matrix Program Logic	Interviews Project Reflection/ Adaptation	Observation Interviews
Adapted from: Sweeney & Pritchard 2010				

Formative program evaluation is important because it provides a basis for continuation or cessation of the program or certain activities, and it may be used to improve project activities. Well-conducted formative program evaluation informs decision-making and can lend support and credibility to projects. Formative research should be an essential and indispensable part of all program development.²⁰

With this in mind, the KIRP Harm Reduction Initiative, as a novel project, is well suited to and should undergo formative program evaluation in order to ensure it is doing what it should be doing and addressing serious needs in the state.

2. METHODOLOGY

2.1 Study Design

To conduct this formative evaluation, a focused ethnographic (FE) field study approach was used²¹⁻²⁴ with the purpose of ascertaining, understanding, and describing the four categorical areas of formative program evaluation in the context of the Harm Reduction Initiative. The data collection activities included participant observation and semi-structured interviews.

2.2 Literature Review Process

A literature review to understand and characterize the need for the program and the activities that the program should offer was completed. Early in planning the conceptual basis for the program, experts in infectious disease, public health, and other areas from Kentucky Department for Public Health and the University of Kentucky discussed the need for the program based on their knowledge and data at hand. This literature review serves to verify and corroborate what the program developers had determined to be the need for the program, and the appropriate services it should offer. A review of nearly 200 articles from peer-reviewed journals, online newspaper or media, and governmental and non-governmental organization websites was completed to characterize the program need and activities.

This literature review utilized InfoKat Discovery provided by University of Kentucky Libraries and the PubMed Database. Additionally, Google searches were performed to glean relevant information from websites of reputable

agencies such as the CDC, NIH, HRSA, NIDA, HHS, and SAMHSA or other organizations when needed. Search Terms included multiple variations of each topic or subject for a more thorough investigation. For example, “substance use”, “drug use”; “opioids”, and “addiction” were all searched. “Infectious disease” also included “HIV”, “hepatitis”, “endocarditis”, and others. “Harm reduction” was supplemented by “risk reduction”, and “syringe and needle exchange”. The terms “rural” and/or “Kentucky” were combined with many of the terms to provide a more nuanced and relevant picture of local information.

2.3 Setting

The setting for participant observation during meetings was the Harm Reduction Initiative Headquarters conference area on the University of Kentucky (UK) campus. Semi-structured interviews with the project director took place primarily in her office at UK’s medical center but occasionally were held in HRI headquarters as well.

Additionally, two meetings occurred onsite at local departments in the summer of 2019. One meeting with local health department personnel took place at the Clark County Health Department in Winchester and the other at the Lake Cumberland Health District office in Somerset, Kentucky.

2.4 Participants

After being approached by the researcher with a request to complete formative program evaluation on the Harm Reduction Initiative, the KIRP project

director agreed to let the evaluation be done and to participate in evaluation activities (observation, interviews). The participants were the core HRI staff consisting of the program director, project director, medical director, strategist, program manager, fiscal director, DPH HRI clinical coordinator, and the director of evaluation and outcomes. Occasionally, others would attend, such a Risk Reduction Specialist (RRS) from a nearby county, the program manager of a KIRP-funded pilot program, or invited guests who had expertise to share with the HRI team.

The participants of the two onsite LHD meetings included public health directors, medical directors, nurses, and SSP/Harm reduction workers working in four local departments or districts, representing a total of 13 Kentucky counties.

In qualitative Grounded Theory (GT) methods, theoretical sampling is done when more information needs to be collected to clarify or refine ideas. Theoretical sampling deals with development of concepts and theories, and does not pertain to population representation or statistical generalizability.²⁵ In this study, semi-structured interviews were used for theoretical sampling when clarification or elaboration was needed on topics discussed during meetings.

The researcher was primarily an observer during the meetings. Clarifying questions served the purpose of helping participants develop the discussion at hand. Furthermore, while never having been employed by the KIRP program or HRI, the researcher was a staff member at a separate Ryan White-funded clinic at the time of data collection. The separate nature of funding and structure of the programs preempted a conflict of interest. Additionally, the Ryan White

experience allowed the researcher a fuller understanding of Ryan White program nuances.

2.5 Evaluation Tool Development

To aid the analyses and illustrate the program need, theory, and implementation capacity, the researcher developed several tools used in evaluation research, including problem and solution trees, a stakeholder analysis matrix, a logic model, and a logframe matrix. These tools were produced from analysis and coding of data from meetings and interviews, as well as the literature review.

Literature review and needs assessment discussions revealed the areas of focus for the problem and solution trees. To develop the HRI Stakeholder Analysis Matrix, basic data was filled in from information gleaned in management meetings but was largely completed from clarification questions asked during a semi-structured interview with the project director. Qualitative data coding revealed the resources and inputs, activities, outputs, outcomes, and other factors to construct the logic model as well as the activities, output, results, purpose, and goal details that allowed the HRI LogFrame Matrix to be created.

2.6 Data Collection

As is common in FE work, data was collected through participant observation.²³ The observations were comprised of meetings held by the KIRP/HRI core team. Approximately 20 hours of near weekly HRI management

meeting observation was conducted between May and December 2019. Additionally, data collection included two onsite meetings with local health department (LHD) staff that the researcher attended. As stated, these meetings were at the Clark County Health Department in Winchester and the Lake Cumberland Health District office in Somerset, Kentucky. Each of the two LHD meetings lasted approximately one and a half hours.

When clarification or elaboration was needed for ideas discussed in meetings, theoretical sampling in the form of semi-structured interviews with the project director occurred. Sixteen semi-structured face-to-face interviews of about 60 minutes each were completed.

Audio or visual recording was not feasible for this study. A laptop was used to take comprehensive and thorough field notes in real-time. Details on the participants' conversations as well as specifics on verbal and non-verbal interaction were documented. These comprehensive field notes were used for theoretical memoing²⁶ and eventual coding. Soon after meetings, field notes were edited and revised for accuracy.

The interview guide was simple and open-ended, which allowed new ideas to be brought up as a result of what the interviewee says. Not using a strictly structured interview set to restrict the scope of responses allowed themes to emerge naturally. The interview meetings with the project director began with a general prompt, "What's new?" or "How's it going?" and went from there. The project director openly spoke about the latest developments and any updates. For any clarification or elaboration needed, the questions beginning with the

phrases: “You mentioned...., can you tell me more about that?” or “Can you talk a little more about...?” were asked.

2.7 Data Analysis

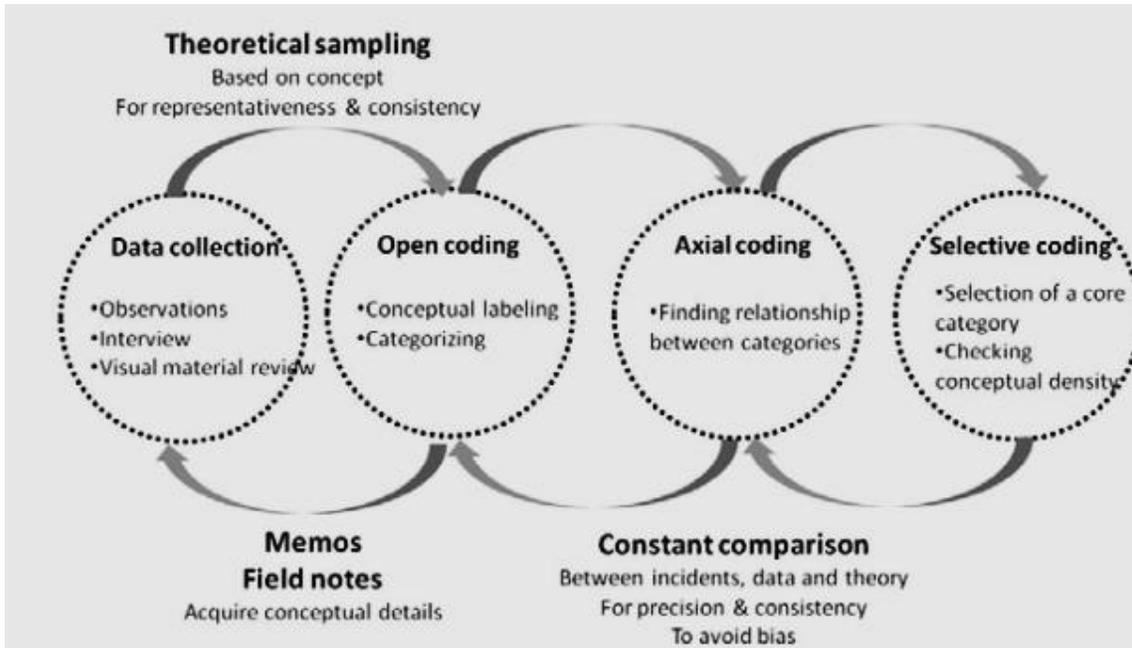
The data analysis was guided by grounded theory (GT) methodology. Grounded theory is a method for investigating a particular topic without a principal theory already established, thus it utilizes inductive reasoning. This way, a more “contextualized theory” may emerge from data collection.²⁷ A GT strategy allows for simultaneous data collection and analysis.²⁸ The examination of the data starts as soon as data gathering begins and helps to focus further collection. Instead of preconceived notions, natural themes surface and develop from the data.²⁵ GT may include qualitative or quantitative methods. In this study, a purely qualitative strategy was used.

In qualitative analysis, coding is a way for the data to be managed and organized.²⁸ It is how ideas and defined concepts are derived from raw data;²⁹ thus, it is essentially the transformation of data.²⁸ All qualitative material gathered in this study (meeting observation and interviews) went through a systematic manual coding process. Commonly in grounded theory methodology, the procedure for coding is structured into three processes (See Figure 2.1). The initial labeling of general concepts is called open coding. Refining the open coding categories by finding relationships is referred to as axial coding. Finally, selective coding involves identifying core categories.^{29,30} The codebook

development was guided by the formative program evaluation framework, existing literature, and the GT three-step coding system.^{29,30}

Figure 2.1:

Data Analysis Procedure Of Grounded Theory Method



(Cho & Lee 2014)

3. RESULTS

In this study, inductive coding was used to derive common themes. Thematic analysis was used to build concepts that described context, needs, barriers, facilitators, adaptation, and lessons learned. These processes yielded concepts that illustrated the categories of formative program evaluation: proactive, clarificative, interactive, and monitoring. Furthermore, to aid the analyses and illustrate the program need, theory, and implementation capacity, this researcher used collected data to develop several tools, including a stakeholder analysis matrix, problem and solution trees, logic model, and logframe matrix.

3.1 Proactive

The first step in formative program evaluation, proactive assessment, is completed in order to understand or clarify the need for the project.¹⁸ It happens early in program development and prior to full implementation. Literature review, problem/solution tree analysis, stakeholder analysis, and needs assessments may be conducted as part of proactive evaluation. These assessments help to reveal the context underlying program development.

3.1.1 Understanding the Need for the Program: Literature Review

A thorough review of current research revealed the context of the issues that affect the need for the program. This literature review did validate the circumstances that experts in infectious disease, public health, and other areas

from Kentucky Department for Public Health and the University of Kentucky had deemed necessitated the program and what the appropriate responses should be.

3.1.1.1 The Opioid Epidemic

For the past two decades, the United States has been experiencing a major public health crisis resulting from drug use.³¹ Opioid prescriptions quadrupled between 1999 and 2010.³² By the time efforts to decrease prescribing were put into place, many individuals had developed dependency and addiction, and subsequently, turned to other sources or substances when they could no longer obtain opioids through legal or legitimate prescriptions.³²⁻³⁵

Switching from oral opioid medications to heroin or other illicit drugs led to an increase in injection drug use.^{32,33,36} Data show that between 2002 and 2011, four out of five heroin users stated that their opioid use started with prescription opioid medication for pain.³² Those using opioids non-medically have a well-documented, increased likelihood of turning to injection as a method for consuming drugs and switching to heroin.³⁶⁻⁴⁰

Increased use of opioids and riskier routes of consumption have created a crisis of non-fatal overdoses and deaths due to overdose. Those who inject drugs have higher rates of preventable death⁴¹ with some data showing a risk nearly fifteen times that of the general population.⁴² Studies show that injection drug use is more likely to result in unintentional overdose, both fatal and non-fatal.^{31,36,37,43} In addition, the introduction of fentanyl to the drug supply has been especially

deadly.⁴⁴ Fentanyl, 50-100 more potent than morphine, is blamed for the rapid nature of overdose increases in the last decade.⁴⁵

Between 1999 and 2017, overdose mortality in the U.S. tripled.³¹ In 2016 alone, opioid-related deaths led to 1.7 million years of life lost.³¹ In 2017, this equated to 47,600 deaths.³² Since 1999, nearly half a million individual lives have been lost due to opioid overdose.³² Rates of overdose and mortality have been so significant, that an overall decline in life expectancy in the U.S. has been observed.³¹

Though disturbing trends are observed across all racial and ethnic groups, the opioid crisis has largely affected White Americans.³¹ It has been particularly devastating to many rural areas^{2,32,46-48} including Appalachia.^{3,49} Opiate prescribing in Kentucky is well above the national average (79.5 prescriptions per 100 person vs. 51.4).⁶ Kentucky also experiences more overdose deaths (27.9 per 100,000 vs. 21.7 nationally in 2017),⁶ recently claiming the unenviable spot of third in the nation for overdose mortality.⁵⁰ Additionally, Neonatal Abstinence Syndrome (NAS)/Neonatal Opioid Withdrawal Syndrome (NOWS) in Kentucky is more than three times the national rate: 7 cases per 1,000 hospital births nationally vs. 23.6 per 1,000 in Kentucky.⁶

This country and Kentucky and the surrounding area in particular,^{2,49,51} have experienced profound and devastating consequences from the opioid epidemic. Beyond overdose and mortality implications, opioid use, predominantly via injection, carries serious infectious disease risk.

3.1.1.1.1 Infectious Disease Implications

Drug use, particularly but not exclusively, from injecting behaviors such as sharing needles, carries a high risk of infectious disease transmission, predominantly HIV and Hepatitis C transmission.³⁶ However, other viral hepatitis infections, endocarditis, osteomyelitis, and various skin infections often occur.³² Frequent or unsterile injection increases the risk of blood-borne infections.⁵² Among people who inject drugs, one in three report using a syringe that had been used by another person.⁵² Furthermore, 43% of people who inject drugs (PWID) had given a syringe they used to someone else.⁵²

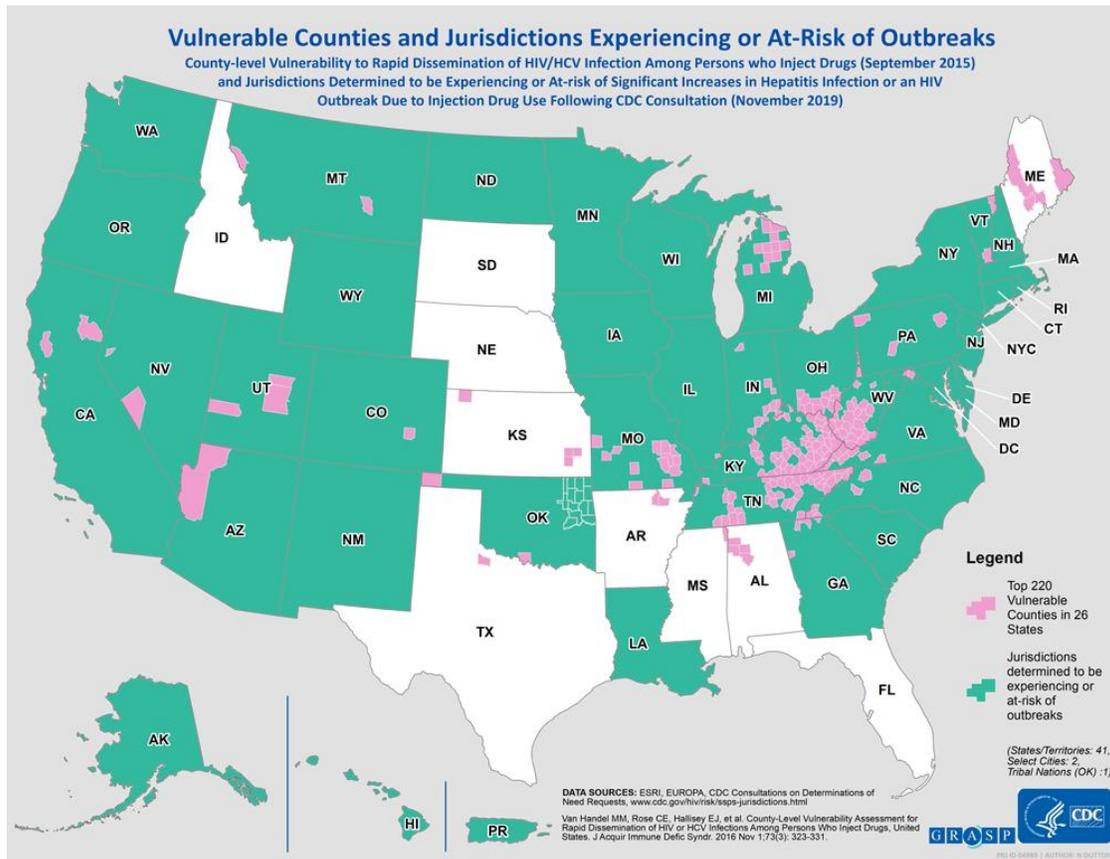
Research describes parallel epidemics of opioid abuse, unsterile injection drug use (IDU), and Hepatitis C Virus (HCV) infection.² In the United States, people who inject drugs account for 70 percent of new HCV infections and nine percent of HIV infections.⁵³ The opioid epidemic has caused a notable increase in HCV among pregnant women as well.⁵⁴ The number one cause of emergency room visits among PWID are infections of the skin and soft tissue.⁵⁵ Cellulitis and abscesses are common in this population and may cause more severe conditions such as gangrene or sepsis, which can lead to amputation or death.⁵⁵ Endocarditis, an infection within the heart chambers or valves, is highly associated with IDU; research has recommended hospitals and local health entities pay attention to rates of endocarditis in order to predict or determine IDU prevalence in the community.⁵⁶

Those in rural central Appalachia are experiencing disproportionate rates of infectious disease and its costs.⁴⁹ Between 2006 and 2012, this region saw a

364% increase in HCV infections among younger individuals.⁵⁷ Infectious disease consequences of the opioid epidemic have been particularly hard for rural areas as these areas had not previously had to deal with significant infectious disease events such as HIV outbreaks.³² These areas often do not have an adequate infrastructure in place to deal with such situations.³²

In March 2015, a public health emergency was declared as more than 200 residents of a small rural town of 4400 were diagnosed with HIV.³² The county had an HIV incidence of fewer than five cases in the preceding ten years.² This outbreak in the city of Austin in Scott County, Indiana was driven by the injection of prescription opioids.^{32,58} Additionally, the HCV coinfection rate during the outbreak was reported to be 92%.² This outbreak led to the realization that nightmare scenarios such as this are very real and even likely in many places far from urbanized areas that are the least prepared to respond to and mitigate such disasters. As a result, the CDC conducted a study to identify the areas that are similarly vulnerable to outbreaks.³² The study identified the 220 most vulnerable counties in the United States.² The majority are rural, and 54 of the 220 are in Kentucky (See Figure 3.1).²

Figure 3.1



Kentucky has a substantial infectious disease burden. From 2008-2015, Kentucky led the nation in new HCV cases.⁵⁹ Ninety-two percent of those cases were among people less than 50 years old (primarily ages 25-34), and the highest rates occurred in regions of Kentucky where IDU is most prevalent (Appalachia and Northern Kentucky).⁵⁹ Rural areas with historically low rates of HIV are now at an increased risk due to opioid and injection drug use.⁶⁰ In Kentucky, HIV infection among those who inject drugs is increasing in areas where sufficient testing was able to detect new positives.¹⁰ Northern Kentucky, an area comprised of Kenton, Boone, and Campbell counties just across the river

from Cincinnati, recently experienced an HIV cluster among the drug-using population^{12,61-63} where the HIV incidence increased by 48%.⁶⁴ Clusters were also uncovered just across the eastern border in West Virginia,⁶⁰ further increasing Kentucky residents' possible exposure points. Additionally, endocarditis has become so prevalent among PWID in Kentucky that local cardiothoracic surgeons are recognizing the need to address the larger determinants of health and not simply the immediate infection alone.⁵

Beyond the physical devastation inflicted through opioid and injection drug use and the resulting infectious disease morbidity and mortality, this epidemic has generated overwhelming economic damage as well.

3.1.1.1.2 Economic Repercussions

The opioid epidemic has caused tremendous and far-reaching economic distress. Low socio-economic status and unemployment are highly associated with substance use.⁵⁹ Increasing economic development can improve opportunities for employment which can help decrease substance use, however high rates of substance use create significant hurdles for stimulating economic development.³ White House economic advisors estimated that the opioid epidemic cost the country \$504 billion in 2015 alone.³

Untreated substance abuse is associated with loss of employment,⁴¹ and the overall human resources impact is substantial.⁶⁵ The viable US workforce has declined as a consequence of the opioid epidemic, which has hit adults of the prime working ages of 25-44 particularly hard.³ For example, the Pennsylvania

Chamber of commerce estimated that Pennsylvania's epidemic was responsible for 20% of the workforce decline for men and 25% of the workforce decline for women,³ and these same statistics have been found elsewhere in the country.⁶⁵ It is estimated that opioid addiction costs employers \$18 billion each year and an accumulated \$1 trillion between 2001 and 2017.⁶⁵

Rural poverty is increasing, and a shrinking middle class is correlated with higher rates of drug abuse.⁵ Appalachia is particularly economically depressed. The household income in the region is only 80% of the national average.³ All this compounds an already risky and unstable situation. Homelessness and housing instability, typically seen as urban issues, have been on the rise in rural areas largely due to increasing addiction.⁶⁶ A recent report cited that one in three rural Americans recognized homelessness as a problem in their community.⁶⁷ Additionally, 75% of those involved in the recent West Virginia HIV clusters identified as homeless or unstably housed.⁶⁸

Further economic consequences of the opioid epidemic include lost productivity and medical expenses^{36,69,70} with estimates of well over \$20-\$70 billion annually.^{33,69} Emergency department use and inpatient admissions have increased due to drug use³³ bringing with them astronomical financial charges. Hospital costs for Neonatal Abstinence Syndrome (NAS)/Neonatal Opioid Withdrawal Syndrome (NOWS) alone totaled over half a billion dollars in 2016.⁶

Such medical costs are untenable for individuals, families, and the communities where they live. The severe community economic strain and resulting social harms further victimize these regions and individuals who are

already in the throes of devastating illness. This creates a cyclical mire of stigma from poverty, disease, and addiction.

3.1.1.1.3 Stigma and the Social Construction of Populations

Stigma involves “labeling, stereotyping, social rejection, and exclusion, as well as the internalization of community attitudes in the form of shame”.⁷¹ Health related stigma is when an individual is “devalued, rejected, or excluded based on having a socially discredited health condition”.⁷² Though detrimental for care delivery and treatment outcome, even healthcare workers may espouse stigmatizing beliefs and language towards persons with substance use issues.⁷³ Stigma prevents individuals from pursuing substance use treatment, adhering to medication regimes, being tested for infectious disease, or seeking other care they need.^{71,72,74,75} To compound the problem, individuals often experience intersectional stigma, or the “convergence of multiple stigmatized identities”,⁷⁶ such as being poor and rural in addition to experiencing addiction and possible infectious consequences.

Stigmatized views towards groups of people lead to a social construction of these populations and their perceived political power (See Figure 3.2). This theory posits that these constructions influence agenda, tools, and rationale for policy. It helps explain why certain populations are seen more positively than others and what may facilitate policy passage or rejection. Social constructions become “embedded in policy” and further affect how the public regards particular populations.⁷⁷ In this model, deviants, including ‘addicts’, belong among highly

undesirable populations and have little to no political power. Public perception of these groups is extremely low, which eases and expedites approval of punitive, anti-drug policies.^{78,79}

Figure 3.2: Social Constructions and Political Power: Types of Target Populations

		Constructions	
		Positive	Negative
Power	Strong	<p><i>Advantaged</i> The elderly Business Veterans Scientists</p>	<p><i>Contenders</i> The rich Big unions Minorities Cultural elites Moral majority</p>
	Weak	<p><i>Dependents</i> Children Mothers Disabled</p>	<p><i>Deviants</i> Criminals Drug addicts Communists Flag burners Gangs</p>

(Schneider and Ingram 1993)

Justice-involved individuals when referred to as addicts, junkies, criminals, or deviants are cast in a negative light. These derogatory labels make it easy to disdain and dismiss them as deserving of punishment and undeserving of understanding and help. Programs such as syringe exchanges, for example, have always been controversial because they deal with injection drug use and disenfranchised populations.⁵⁸ Privilege and bias have long been used to shape substance use policies.⁸⁰

3.1.1.1.4 Implications of Negative Social Construction on Drug Policy

A population having little to no political power and a negative social construction carries important policy implications. Stigmatizing language influences how politicians and voters view the population. It is much more palatable for constituents to vote in and approve laws and regulations that are extremely and entirely punitive. Such policies allowed the opioid epidemic situation to progress to harrowing levels without significant, effective intervention. The opioid problem was seen as a criminal issue rather than a public health emergency for a long time. The advent of the War on Drugs in the 1970s and further criminalization of addiction during the 1980s led to the mass incarceration of individuals.^{78,79,81} The War on Drugs is “characterized by a moralistic and combative approach to drug use and users”.⁸⁰ During this time, funding for prevention was slashed, and resources for enforcement alone were ramped up.^{79,80}

When the extent of prescription opioid abuse was coming to light in the late 1990s and early 2000s, some lawsuits against pharmaceutical companies and other players were attempted early on, however, they were brought on the by wrong population of people: those without significant public presence or political sway (small town doctors, community advocates). Few substantial actions were taken until wealthy white people and celebrities started dying.³⁴ Prior to this, the only intervention was criminalization and incarceration without addiction support.⁸⁰ Resources for prevention programs and harm reduction strategies have long been controversial and unpopular because of the

populations involved.⁵⁸ Due to these circumstances, the harms of the prohibitionist policies have had profound legal consequences on millions of individuals and their communities.

3.1.1.1.5 Legal and Familial Implications

Mass incarceration of people who use drugs (PWUD) without addressing the underlying substance use issues has devastating effects. Untreated addiction damages not only individuals but also the communities where they live.

Untreated substance abuse often leads to incarceration.⁴¹ Those convicted of drug crimes represent 50% of federal prison populations.⁷⁹ A lack of treatment options has been cited for the large number of incarcerated due to substance use.⁸² Issues resulting from involvement with the justice system are extensive and long lasting. Disruption of stability and family dissolution are traumatic for adults and children alike. Growing up in a home with individuals experiencing substance use disorder makes children more likely to experience mental health issues, their own addiction, accidental poisoning, parental custody loss, and foster care involvement.⁸³ Having an incarcerated parent is equally traumatic.⁸⁴

Recently, Kentucky has ranked first or second nationally for percent of children with incarcerated parents.^{82,84} The percentage (15%) is nearly twice that of the national average (8%).⁸⁵ Subsequently, Kentucky is first in the nation for children who live with relatives. This is largely due to substance use and incarceration. Particularly concerning is the high rate of incarcerated females in Kentucky, many of whom are mothers.⁸²

The intergenerational effects and complex nature of the opioid epidemic paint a grim future for the country and the state if significant and effective steps are not taken to combat the detrimental consequences.

3.1.1.1.6 The Imperative Need to Address the Crisis

With such profound consequences affecting nearly every facet of family and community life, the need to address the epidemic is vital. As it reaches beyond any single domain into many sectors of society, it must be tackled from multiple levels. Comprehensive and evidence-based approaches have recommended responding in six important areas: leadership, partnership/collaboration, epidemiology/surveillance, education/prevention, treatment/recovery, and harm reduction/overdose prevention.⁸⁶ Coordinated efforts are necessary to be truly effective in mitigating harms. Even undertaking what may seem like only one facet of crisis, such as infectious disease prevention, actually requires actions in each of these areas. An HIV program director in West Virginia, who dealt with the HIV clusters found there, advises that both care and prevention continuums must be optimized in order to make a dent in the incidence and prevalence rates. This includes both the infected individuals as well as at-risk uninfected persons.⁶⁸

Infectious disease transmission resulting from the opioid epidemic is complex, and therefore has to be addressed in a comprehensive and practically effective manner. There are long-standing programs, as well as new initiatives that have been mobilized in an effort to prevent disease transmission.

3.1.1.2 Infectious Disease Prevention

The opioid and injection drug use crises have led to higher rates of infectious disease transmission and severe resulting consequences. HIV and Hepatitis C (HCV) are the two infectious diseases most associated with injection drug use (IDU).^{2,32,57,87,88} Existing mitigation efforts have been ramped up and new initiatives have begun in hopes of stemming the spread of these diseases.

3.1.1.2.1 Hepatitis C Virus

By the 1980s, Hepatitis C had been detected as a separate entity from Hepatitis A and B. After identification, sequencing, and antibody testing development, prevention efforts began including blood supply screening. Rapid spread of HCV had happened from the 1960s through the 1980s, and million Americans became infected including many who still do not know it today.⁸⁹ HCV can lead to cirrhosis and/or liver cancer; therefore, treatment is important. Early treatment research produced few viable options. It was not until the last five to ten years that safe, tolerable, and effective medications were available and accessible. While no vaccine exists, the infection is curable, and treatment options have vastly improved.⁸⁹ In fact, the CDC recently added viral hepatitis to its “list of winnable battles”.⁹⁰

3.1.1.2.2 HIV Initiatives

Due to concerns of increased vulnerability to HIV outbreaks in Kentucky and surrounding areas, particularly where poor and rural,² existing resources to prevent disease transmission are more important than ever. Additionally, new efforts are needed to address current gaps in care and resulting disparities in care and treatment.

3.1.1.2.2.1 Ryan White HIV/AIDS Program

Domestically, a key player in HIV care for the last three decades has been the Ryan White HIV/AIDS Program (RWHAP). Initially authorized and funded in 1990, the U.S. Department of Health & Human Services administers the RWHAP, which provides medical care, support services, and medications to persons living with HIV. The program serves more than half of individuals in the United States who have been diagnosed with HIV. Patients who receive services from Ryan White programs show better than average outcomes including 85.9% viral suppression compared to the national average of 59.8%.¹³

3.1.1.2.2.2 Ending the HIV Epidemic

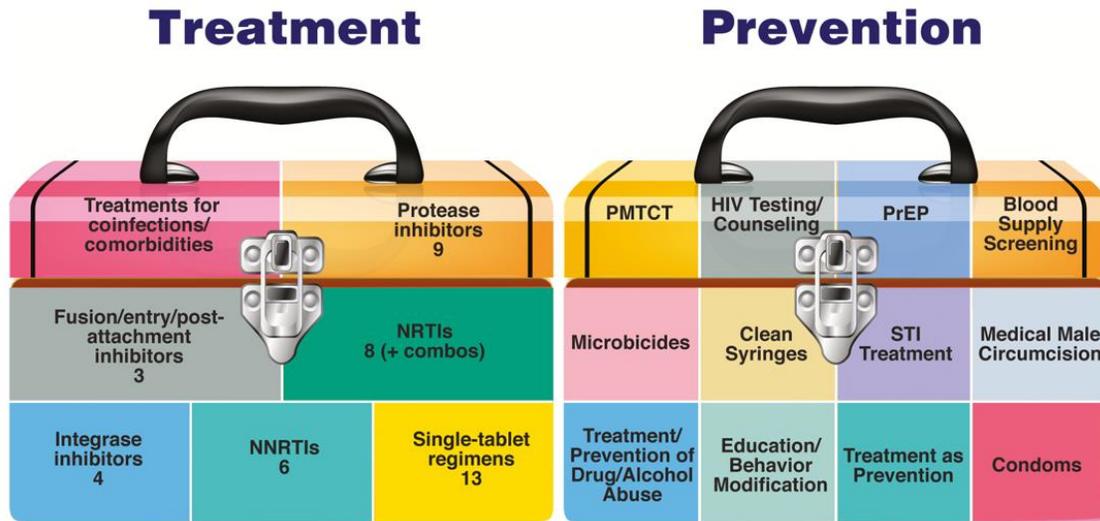
In the 2019 Presidential State of the Union Address, a new funding initiative to combat HIV was announced. *Ending the HIV Epidemic: A Plan for America* seeks to halt the HIV epidemic in the U.S. within ten years and will initially focus on areas where HIV infections are concentrated using four key strategies of diagnose, treat, prevent, and respond. It includes seven states, 48

counties, Washington D.C. and San Juan, Puerto Rico.⁹¹ Kentucky is among the seven targeted states and is in the midst of developing a plan for the funding and resources from this initiative.⁹²

3.1.1.2.3 HIV Treatment and Prevention Toolkits

The beginnings of the HIV epidemic in the 1980s are marked with devastating accounts of suffering and death due to reluctance and willful refusal by high-level entities to address the matter, often because of political posturing and perceived morality concerns.^{93,94} Nevertheless, decades of research since have led to various treatment and prevention options.⁹⁵ Despite the continued lack of a cure or vaccine, the available interventions offer effective tools with which to combat HIV infection (See Figure 3.3). These include medications for viral suppression, immune system optimization, and comorbidity management, as well as prevention practices such as testing and counseling, blood supply screening, sterile injecting equipment, pre- and post-exposure prophylaxis, condoms, STI treatment, mother-to-child transmission prevention, and treatment for drug and alcohol abuse, among others.⁹⁵ These tools for treatment and prevention have transitioned HIV from an acute, deadly infection to a chronic, manageable disease, making a profound difference in the lives of those affected by this virus.⁹⁵

Figure 3.3: HIV Treatment and Prevention Toolkits



(Eisinger, Folkers & Fauci 2019)

3.1.1.2.4 TasP: Treatment as Prevention

Early treatment options for HIV were only marginally effective, had serious toxic side effects, and led to a high likelihood of developing drug resistance.⁹⁶ Highly active antiretroviral therapy (HAART), introduced in 1996 was much safer and more successful as an HIV treatment. HAART works toward viral suppression, such that transmission of HIV is nearly impossible.⁹⁶ However, universal treatment was still not common practice until a Lancet article in 2006 made the novel and ambitious case for treating all diagnosed individuals.⁹⁷ Montaner et al posited that, “a prevention-centered approach would argue that treating 100% of HIV-infected individuals at once could greatly reduce HIV transmission”.⁹⁷ With this, the concept of “treatment as prevention” or TasP came to be.⁹⁸ In 2016, the model of Undetectable=Untransmittable or U=U became

popular for prevention promotion and important for testing, linkage to care, and adherence to treatment. U=U encourages patients to achieve and maintain viral suppression so that they are unable to pass the virus on to others.^{99,100} More recently, a new angle, V=V or Viremia=Vulnerability, illustrates how “uncontrolled viral load (viremia) leads to vulnerabilities physically, socially and emotionally”.¹⁰¹

About 40% of new HIV infections come from people who do not know they have HIV.¹⁰² In 2014, The Joint United Nations Programme on HIV/AIDS (UNAIDS) released an HIV treatment target strategy they called 90-90-90. The goal is for 90% of people living with HIV to know their status, 90% of those diagnosed to receive antiretroviral therapy, and 90% of those on ART to be virally suppressed.¹⁰³ This target was hoped to be reached by 2020, and while not met in this timeframe, such goals help push for testing, treatment, and ultimately prevention of new cases.

3.1.1.2.5 PreP: Pre-Exposure Prophylaxis

A boon for HIV prevention came in 2012 when the FDA approved the first medication, Truvada, for use as a pre-exposure prophylaxis for HIV.¹⁰⁴ Additionally, the FDA approved a second drug, Descovy, on October 3, 2019 for PreP use.¹⁰⁵ Medication taken as pre-exposure prophylaxis is highly successful in preventing the acquisition of HIV. Research has found either daily use or taken on demand to be 99% effective.⁹⁵ However, uptake has been slow, with misinformation, misconceptions, under-informed patients and providers, lack of access, and financial barriers abounding.¹⁰⁶⁻¹⁰⁸ PreP deserts, or areas where

providers are nonexistent or difficult to reach are common in the U.S.¹⁰⁹ PreP provider access issues, along with inability to pay for office visits, required laboratory tests, or the medication itself have been among the major barriers.^{110,111} Some public and private organizations have implemented programs to make PreP more accessible and affordable.^{91,112,113} PreP is one of the major strategy components of the “Prevent” arm in the Ending the HIV Epidemic plan.⁹¹ It has become increasingly apparent that the health benefits and cost effectiveness of PreP are instrumental in preventing the expensive and destructive transmission of this incurable infectious disease.^{91,95,113}

3.1.1.2.6 MAT: Medication-Assisted Treatment

Another way to prevent infectious disease transmission is through substance use treatment. Due to the overlap in the HCV, HIV, and opioid epidemics, substance use treatment providers can play a unique and vital role in mitigating infectious disease spread as well. The principles of substance use treatment, “harm reduction, screening and other prevention interventions, treatment initiation, and linkage to ongoing medical care” are in line with those of HIV and viral hepatitis care.⁵³

When prescribed in conjunction with other therapies (behavioral interventions, etc.), medications used in the treatment of opioid use, such as naltrexone, buprenorphine, and methadone, are classified as medication-assisted treatment or MAT.¹¹⁴ There are, unfortunately, addictions for which efficacious pharmacological treatment does not exist, such as cocaine and

methamphetamine.¹¹⁵ The National Institute on Drug Abuse (NIDA) agrees with the World Health Organization that long-acting medications such as buprenorphine and methadone are “essential medicines”.¹¹⁶ Treatment with these medications has shown to increase retention in care, decrease drug use, infectious disease transmission, and criminal activity, and improve social functioning.^{72,116-118} In particular, studies have shown that people with untreated opioid use disorder who are living with HIV and HCV are more likely to experience overdose and are often lost to follow up concerning their medical care. However, when they receive medications to treat their substance use, they are more engaged in their care, more adherent to HIV and HCV treatment, and more likely to achieve and sustain virologic suppression.¹¹⁹

While use of medications to treat opioid use disorder is effective and a critical part of helping to curb the opioid epidemic, there are significant issues with access to the medications as well as a shortage of providers who will prescribe and monitor patients’ treatment.^{120,121} Only around 10-30% of patients with an opioid use disorder ever receive medication to treat it.^{118,122} Other challenges include cost and insurance or regulatory restrictions, along with medical staff disapproval of this method of treatment.^{118,121} Criticism that MAT simply substitutes one drug for another still remains among providers.¹²³ However, chronic management of opioid use disorder with medication reduces morbidity and mortality and improves social functioning by addressing such issues as “unemployment, disrupted family relations, and involvement with the criminal justice system”.¹²⁴ Thus it may also be classified as part of another

concept that aids in the mitigation of infectious disease and substance use: harm reduction.

3.1.1.3 Harm Reduction

One major strategy for combatting the destruction caused by substance use is harm reduction. Also referred to by other names such as damage limitation or risk reduction, harm reduction is simply minimizing possible harms.¹²⁵ The principles of harm reduction may be applied to a wide array of issues such as sex work, eating disorders, or tobacco use.¹²⁶ When applied to substance use, harm reduction is characterized by ideas or interventions that reduce health risks when these risks are not able to be completely eliminated and also mitigates social and economic harm associated with high risk behaviors.¹²⁷ It turns the focus to the consequences of drug use rather than the drug use itself when individuals are unable to stop consumption of illicit substances, and it takes into account the needs of these individuals.¹²⁸

Harm reduction certainly has its critics. In the same way that some providers object to MAT, there are those who advocate for abstinence-only approaches, insisting that anything less encourages drug use.¹²⁶ However, one of the six principles of harm reduction is pragmatism, which asserts that substance use has been and will always be around regardless of policies or societal views, and therefore, everyone should operate from that mindset and provide services accordingly. The other principles are humanism, individualism, autonomy, incrementalism, and accountability without termination.¹²⁶ Humanism

is characterized by the belief that all individuals deserve dignity and respect. Individualism holds that each person possesses his or her own strengths and needs, and there is not a 'one size that fits all'. Furthermore, providers are there to educate and support, but the principle of autonomy emphasizes that the individual drives goal making, choices, and decisions and that both parties learn from each other. Incrementalism praises any positive movement however small and is flexible in the case of regression. The last principle of accountability without termination states that individuals are responsible for their choices and behaviors; however, they are not written off or discharged from services for failing to achieve goals.¹²⁶

With the advent of the AIDS epidemic, harm reduction became highly relevant not only for substance use but also for infectious disease transmission.¹²⁹ Syringe exchange programs (SEPs) have been in existence since the 1980s in places like Amsterdam, Australia, and the United Kingdom when AIDS began decimating communities, and no other practices or interventions were successful in reducing the spread of disease.¹²⁷ In the U.S., syringe exchange was initially informal and highly illegal. It was comprised of grassroots activists essentially handing out clean syringes in the street or distributing information about how to clean needles with bleach (including writing about it using "graffiti" in bathroom stalls where PWID were known to inject).¹³⁰⁻

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Due to a war on drugs mentality and zero tolerance stance, harm reduction was not officially condoned in the United States even while AIDS

ravaged communities of people who used drugs.¹²⁸ Politics and moral judgments aside, harm reduction practices including syringe service programs (SSPs) have been shown to be vastly effective.¹³³ According to the CDC, barring complete abstinence, the safest way to inject drugs is to use sterile equipment every time.¹³³ Decades of research demonstrates that SSPs are safe and not associated with increases in drug use or crime. In fact, SSP utilizers are more likely to enter treatment and stop illicit substance use. They are more likely to engage in primary care, which increases access to a myriad of preventative services, screening for serious conditions, and further opportunity for possible treatment including MAT. Additionally, SSPs facilitate the safe disposal of used injecting equipment, which reduces neighborhood litter and needlestick injuries. SSPs reduce overdose deaths when they provide overdose reversal drugs.¹³³

Comprehensive harm reduction and not simply provision of sterile syringes is the most effective means to prevent the spread of infectious disease. Comprehensive programs provide things like other injecting equipment and supplies (cookers, cotton, tourniquets) along with sharps containers for safe disposal, HIV and HCV testing, counseling, and linkage to care, access to overdose reversal drugs such as naloxone, referrals to substance use treatment and medical, mental health, and social services, education on overdose prevention and safer injection practices, pregnancy testing, contraception, and prenatal care, condoms, and vaccinations for Hepatitis A and B.^{68,133} Harm reduction is not only successful in reducing infectious disease transmission rates, it is cost effective. In fact, it has been described as, “cost effective in the short-

term and cost saving in the long term” with estimates of a \$100 to \$1000 cost per HIV infection averted and \$25,000-\$1.8 million in cost savings per averted HIV infection.¹²⁷ Additionally, the more comprehensive the program, the more cost-effective and cost-saving it is.¹³⁴ One study noted that a single infective endocarditis hospital admission (\$55,700-95,700) costs more than the entire, initial budget of one Cincinnati syringe exchange program (\$50,000).⁵⁶

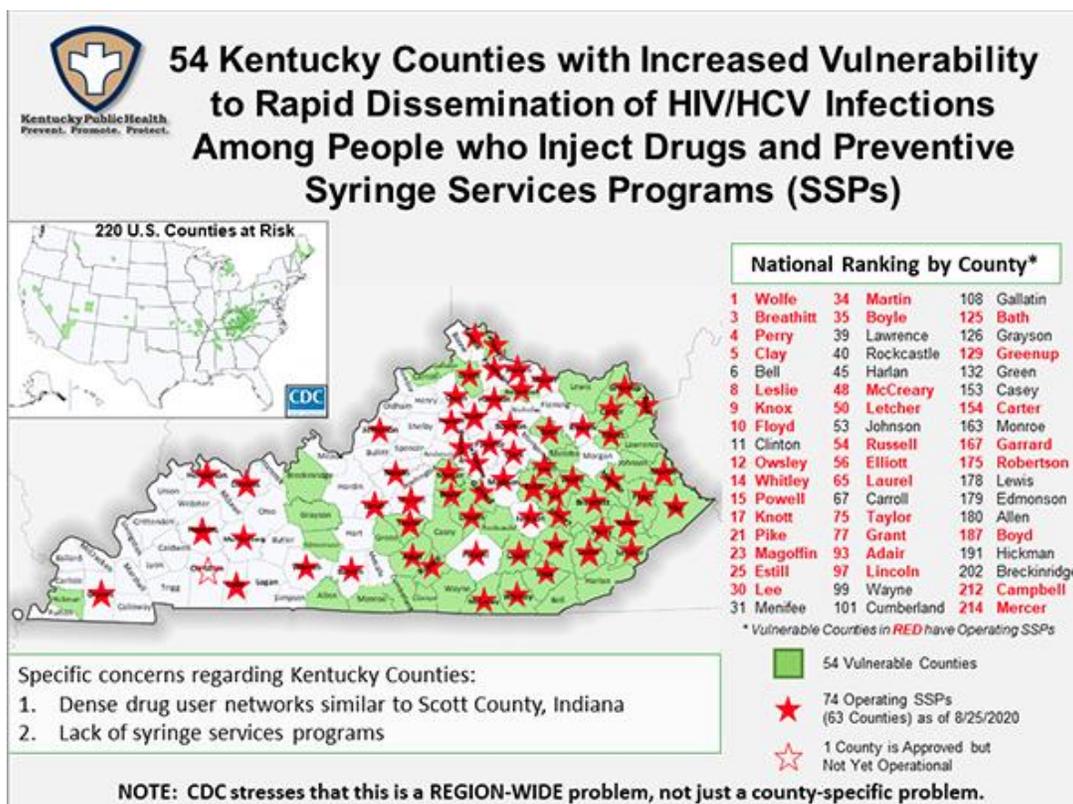
Their safety and effectiveness led SSPs to be included as one of the two major components (along with PreP) of the “Prevent” arm of the Ending the HIV Epidemic ten-year plan. Kentucky is a priority jurisdiction in Phase I of the plan because of its infectious disease transmission vulnerability and disproportionate HIV incidence in rural areas.⁹¹ Comprehensive harm reduction is more important than ever in Kentucky.

3.1.1.3.1 Harm Reduction in Kentucky

In March 2015, the same month that an official public health emergency was declared in nearby Scott County, Indiana,³² legislation was passed in Kentucky that made SSPs legally possible.⁵¹ While syringe exchange is now possible, opening a program requires multiple levels of local approval. The local county board of health, fiscal court, and city council must all express clear agreement.⁵¹ Advocates in Kentucky held town hall meetings, spoke at city council proceedings, and launched education campaigns to dispel myths and provide accurate data.⁵¹ By the end of that year, there were SEPs in three Kentucky counties. Within two years, 31 counties had functioning syringe

exchange programs, another five had gained all necessary local approval, and ten more were in the planning stages.⁵¹ By early 2019, 50 counties were operating nearly 60 programs. In mid-2020, 74 syringe exchange programs can be found across 63 Kentucky counties (See Figure 3.4).¹³⁵ The rapid and evidently successful nature of SSP start-ups in Kentucky belies the immense and challenging work that advocates went through in order to secure these victories. Opposition was seen from community members and elected officials alike in many areas.¹³⁶⁻¹⁴¹ Public health campaigners, both official and grass roots, fought hard and continue to fight as there are still many vulnerable areas in Kentucky without accessible harm reduction services.

Figure 3.4: Kentucky Syringe Services Programs



(Kentucky CHFS 2020)

Work continues in the state to combat the opioid epidemic. Kentucky has a Substance Use Disorder Workgroup that advocates a three-pronged approach to addressing the opioid epidemic in the state. Prevention, harm reduction, and treatment are the focus points.¹⁴² Since much of this work had never previously been done, initial work by the group centered on establishing baselines and gathering data in order to develop future goals.¹⁴² Progress has been made in the state, however reports still document pushback over acceptability of harm reduction. Furthermore, the unavailability of sufficient data, funding, and resources continues to be a challenge in Kentucky.¹⁴²

3.1.1.3.2 Harm Reduction Programs: Access to Populations with Barriers

Harm Reduction programs have a unique opportunity to touch portions of a population that otherwise rarely engage with service programs and providers. Highly prohibitionist, punitive drug policies have driven people who use drugs (PWUD) 'underground' and ensured that they would be hesitant to access any type of services for fear of harassment or arrest.¹⁴³ As such, this segment of the population is less likely to get tested for infectious disease or seek help for health complications. People who inject drugs (PWID) are among the least likely groups to get tested for HIV and are often not diagnosed until they have developed AIDS. This is called late diagnosis and is an indicator of much worse health outcomes including higher likelihood of treatment failure.¹⁴⁴⁻¹⁴⁶ Other facilities that

may have regular contact with this population, such as jails, do not typically provide comprehensive testing services, usually due to funding limits.¹⁴³

When deciding whether to get tested for infectious disease, PWUD face intersectional stigma not only from their drug use but also from potential positive test results. Therefore, it is a very difficult decision for these individuals to make. Having an environment that is open and hospitable without explicit or implicit disdain for their presence, allows PWUD peace of mind and safety to engage in screening and preventative services. Because of the nature and principles of harm reduction, personnel from these programs may be more likely to build rapport with PWUD.¹⁴⁷ This is accomplished through nonjudgmental and welcoming attitudes and through the use of non-stigmatizing or “recovery positive language”.^{148,149} In order to destigmatize addiction, resources such as the Recovery Research Institute’s Addictionary® asserts that a unified language is needed and provides an online reference of terms and phrases relevant to substance use and recovery. Different from typical reference books, the Addictionary puts a “stigma alert” on entries that are deemed harmful and provides a peer-reviewed citation for further information.¹⁵⁰

Harm reduction principles align with the belief that when individuals are assured of the appropriate resources and support and feel they are at a place where they can safely and realistically seek help for their addictions, they will. While not a tenant of harm reduction, places that offer harm reduction services provide a platform and safe space for PWUD to seek out and engage in treatment programs.¹²⁹

Harm reduction programs are a means to access and interact with populations that face significant barriers to care and services. The KIRP Harm Reduction Initiative (HRI) is designed to embed Harm Reduction Specialists in local SSPs in Kentucky. HRI, therefore, is posed to provide vital and unique opportunities to engage a high risk and elusive population. It should be noted that some advocates have recently pointed out that these populations should not be referred to as “hard-to-reach” since it is service providers who should be meeting these individuals where they are and that it is on providers to figure out better ways to serve these populations and not the other way around.

3.1.1.3.3 Importance of Evaluative Evidence

During creation and implementation of KIRP, multiple new SSPs were gaining approval and coming on board at a rather brisk rate. The last few years have been a time of rapid growth for SSPs in Kentucky as there has been much national and local attention on the injection drug epidemic and resulting issues. As the HRI strategist reiterated, in order to ensure sustainability, “we need to show that these programs are effective, and we need local proof to do that”. Local decision makers want to see results, and this is where robust program evaluation comes into play.

The CDC notes that community acceptance has a major impact on the success of SSPs.¹³³ In the midst of local support issues including law enforcement interference, community misperceptions, and misinformation campaigns, local evidence is key to sustaining high-quality, accessible services

for residents. As a cautionary tale, during early 2018 in West Virginia, in the middle of a raging opioid epidemic in highly vulnerable areas, the highest HCV rates in the country, and HIV cluster investigation,⁶⁰ an SSP was involuntarily compelled by “sociopolitical forces” to choose between shutting down or having to implement non-evidence based, harmful practices. They shut down in order to avoid not only subpar but potentially detrimental service provision. Less availability of quality harm reduction services led to increased vulnerability in the local area.¹⁵¹ More education, research, and dissemination of accurate information can help rectify misunderstandings and allay concerns that lead to misguided actions such as incapacitating SSP operations.¹⁵²

Most existing research on SSPs and harm reduction are from urban areas. Only recently has research on SSPs and harm reduction in rural areas started to be conducted. There are still insufficient studies and data from this perspective, however.^{70,151,153,154} Dynamics are different with unique challenges encountered in rural spaces; therefore research is needed from these areas.

Well-conducted research and convincing evidence can be a boon for policy change and pivotal for ensuring that best practices are implemented rather than capricious, arbitrary, and harmful policies based on whims or morality judgments.¹⁵² Therefore, evaluation of SSPs and other harm reduction programs is vital as this research assesses local needs, examines stakeholder roles, delves into the background and context of the problems at hand, and seeks to determine the most efficient and effective way to address them.

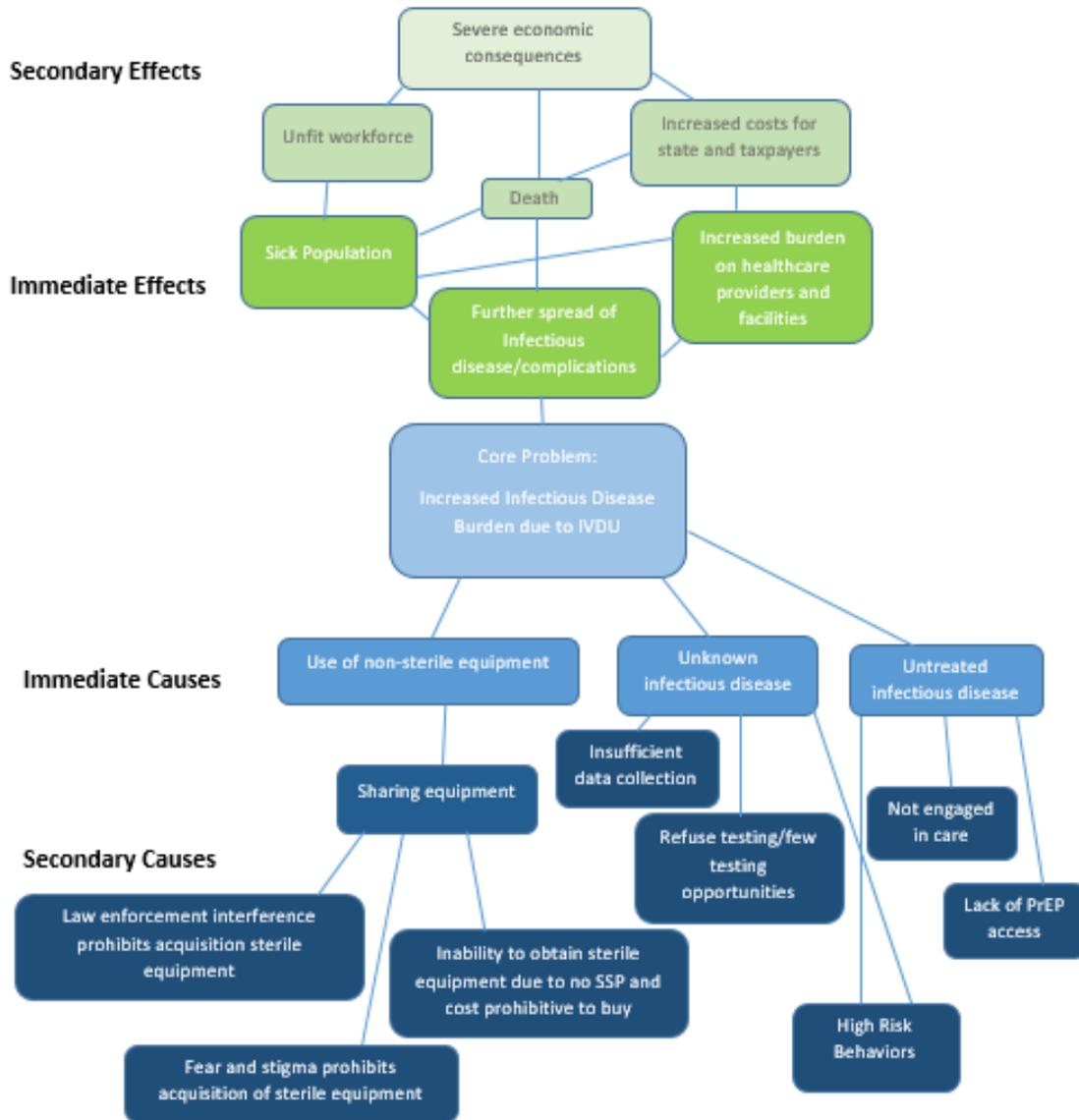
3.1.2 Problem/Solution Tree Analysis

The data aggregated from the literature review corroborating the need for the program as identified by early program developers was used to complete a Problem/Solution Tree Analysis in order to identify relevant causes and effects of the central problem that the Harm Reduction Initiative endeavors to address.

Conducting a Problem/Solution Tree Analysis seeks to reveal the context beyond the problem and further understand how to more adequately identify areas to tackle. This information is then laid out in a graphical depiction resembling a tree with branches (effects) and its roots (causes).¹⁸

3.1.2.1 HRI Problem Tree

Figure 3.5: HRI Problem Tree



The core problem identified was Kentucky’s increased burden of infectious disease due to injection drug use. As was discussed in planning meetings and similarly in the Literature Review, this burden includes HIV, Hepatitis A, B, and C, and injection-associated infections such as endocarditis, osteomyelitis, and skin

abscesses. Due to biological mechanisms and disease pathogenesis, the immediate effect of increased rates of infectious disease is the further, exponential spread of disease and the resulting complications. Increased incidence results in a sick population as well as higher burdens on healthcare facilities and providers. Healthcare providers must deal with the physical burden of both higher volumes of patients and an intensified severity of health complications for these patients. Furthermore, the fiscal impact is enormous. Healthcare facilities are dealing with large numbers of indigent patients with high acuity. Without adequate resources to fully deal with the problems at hand, much less the underlying cause of disease and infections, facilities are unable to prevent further usage of emergency departments and inpatient admissions. Kentucky, a state with fully expanded Medicaid and a population of 4.4 million, has nearly 1.4 million residents who depend on this insurance for healthcare coverage.¹⁵⁵ Needless to say, the financial cost to the state government, and thus Kentucky taxpayers, is massive. Additionally, high numbers of deaths have been occurring not solely due to disease and disease complications but to overdose. Death, beyond the devastating emotional impact, is very costly not only to families but local communities where municipal resources are needed when morbidity and mortality occurs locally. Reduced numbers of residents and residents who are incapacitated because of addiction, illness, and disability create issues maintaining a fit and reliable workforce. Companies looking for areas to expand and build businesses will not locate to an area with an unstable or unfit workforce. Companies already located in the areas may move. Such

closures result in job loss and subsequent financial hardship on families and communities. Severe economic consequences result in areas that suffer from workforce problems and untenable financial burdens. These effects are seen graphically depicted in the top half of the Problem Tree (See Figure 3.5).

The immediate causes of increased infectious disease burden due to injection drug use are the use of non-sterile equipment, undiagnosed disease, and untreated disease. Individuals who inject drugs sometimes share equipment if they are not able to obtain their own sterile injecting supplies. Reasons for not being able to obtain supplies for personal use include the physical absence of this equipment in the areas where they live because there is no accessible SSP. It may be cost prohibitive to purchase them from pharmacies and stores. Furthermore, even if there is a local SSP, law enforcement interference may prevent residents from getting supplies and carrying them on their person. Paraphernalia laws have resulted in harassment and arrest of individuals using SSPs. This discourages residents from returning to the SSPs. In addition, potentially one of the most salient reasons preventing PWID from obtaining sterile equipment is stigma. Fear, both perceived and realized, is a debilitating influence on whether PWID will go out of their way to procure sterile injecting equipment.

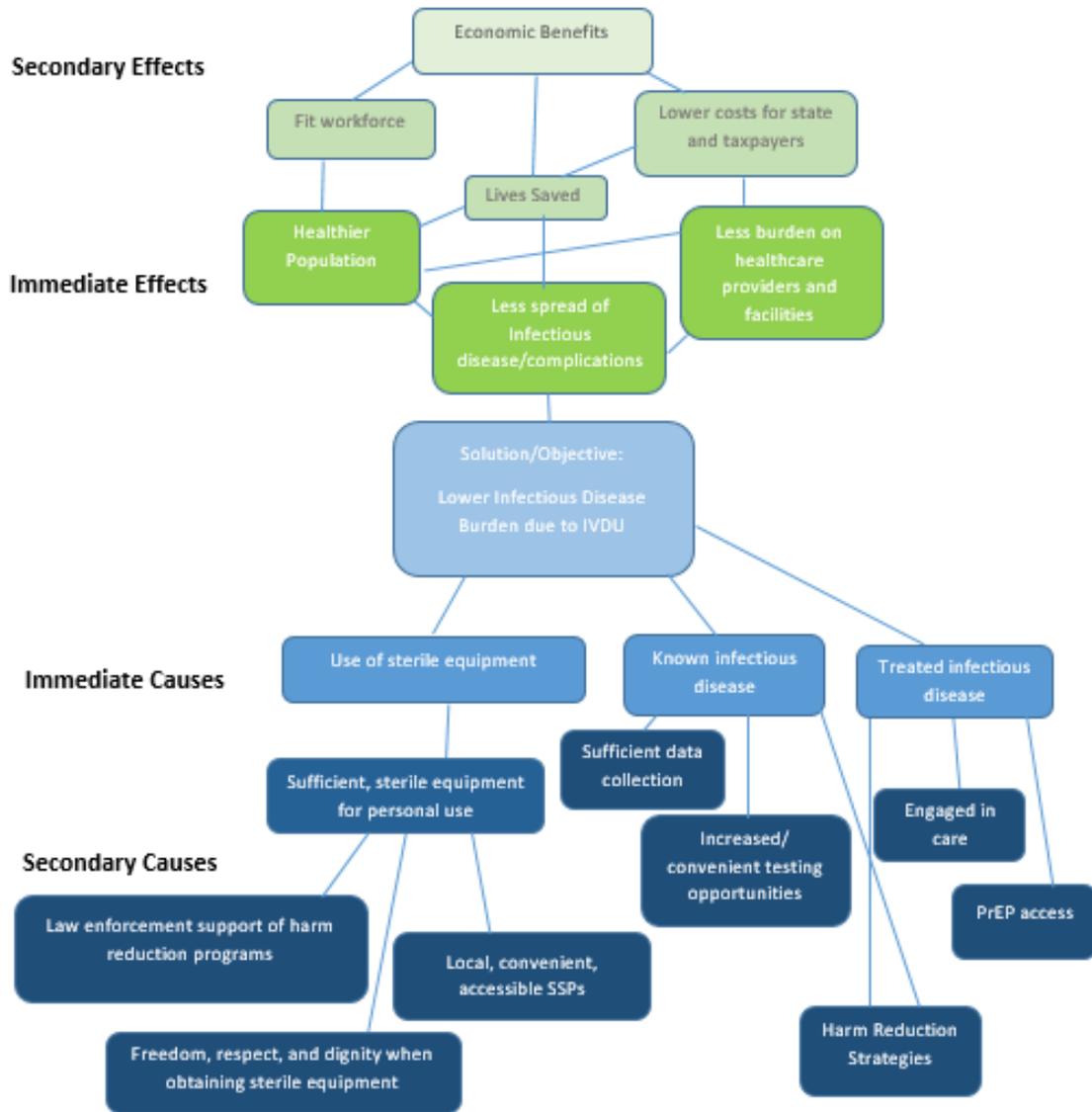
Combined with continued high-risk behaviors, two major factors contributing to the spread of infectious disease are undiagnosed cases and known cases that remain untreated. Unknown disease in the population will spread uncontrolled. Pockets of disease will remain undiscovered if there are not

opportunities for testing available or if individuals decline testing. Undiagnosed individuals in the population mean that disease surveillance is inaccurate and unable to identify clusters and thus respond accordingly. Outbreaks will occur and worsen without intervention. For diagnosed individuals not engaged in care, significant risk for further disease transmission remains. Treatment as Prevention drastically reduces this risk. Furthermore, it was noted that a major reason for HIV incidence is the lack of access to Pre-Exposure Prophylaxis.

3.1.2.2 HRI Solution Tree

After a thorough Problem Tree Analysis, evaluators create a Solution Tree (also known as an Objective Tree) by reversing the Cause-Effect areas to reveal the means-end relationships.¹⁸ Solution Trees highlight key points to address and ways to address them.

Figure 3.6: HRI Solution Tree



Thus, in the HRI Solution Tree (See Figure 3.6), the central objective becomes “Lower infectious disease burden due to IVDU”. The immediate effect of less infectious disease in the population is less spread of infections to others resulting in a healthier population. Healthier populations utilize less emergent and

costly healthcare, thereby saving money for individuals, families, and state agencies and organizations. Less disease means less death from disease and resulting complications. A fitter, healthier workforce provides deep economic benefits for communities and the state.

In the 'roots' section, the causes of lower infectious disease burden are use of sterile injection equipment, diagnosed cases, and treated disease. Law enforcement support of harm reduction programs, accessible SSPs, and a destigmatized process all lead to sufficient, sterile equipment use for injection. Adequate data surveillance and ample testing opportunities ensure that pockets of disease are uncovered before widespread outbreaks occur. Engagement in care and treatment and plentiful PreP access will keep the community viral load levels suppressed. Harm reduction strategies keep further disease from ramping up and spreading.

Problem and Solution Trees are one way to put the landscape into perspective and identify areas for intervention targeting. With this laid out, it is important to consider the entities relevant and integral to the program and their role in it.

3.1.3 Stakeholder Analysis

In formative evaluation, it is important to identify relevant stakeholders.¹⁸ Often, three broad categories of stakeholders are discussed: those affected, those involved in operations, and those who will use the evaluation results.¹⁵⁶ In this study, those affected include the clients of SSPs, the local communities, and

health departments. Those involved in operations are staff of local health departments, SSPs, and harm reduction programs, as well as the KIRP staff. The Kentucky Department for Public Health, KIRP, and LHD management may use the evaluation results.

For a more thorough look at the stakeholders and an efficient way to identify and clarify the context surrounding various stakeholders, a Stakeholder Analysis Matrix may be completed. This document lists the stakeholder, explains their stake in this issue, describes how they may help the project be successful, and discusses level of engagement along with possible conflict among stakeholders.¹⁸ The HRI Stakeholder Analysis Matrix is a comprehensive listing of affected entities (See Table 3.1). This information was gleaned from planning meeting observations and reviewed and refined during project director interviews.

Table 3.1: HRI Stakeholder Analysis Matrix

ORGANIZATION NAME: KIRP Harm Reduction Initiative

STAKEHOLDER	STAKE IN THE ISSUE	HOW CAN THEY HELP THE PROJECT BE SUCCESSFUL	HOW SHOULD THEY BE ENGAGED
Name & brief description	What is of interest to them, what do they want to see happen, how are they affected, how motivated are they etc.?	What skills, attributes do they have to bring to the project?	What level of engagement do you need to consider, and what processes of engagement would suit? Are there conflicts amongst some stakeholders?
KIRP/HRI Management Staff (University of Kentucky-based)	Create, Implement, Monitor, Oversee program Very motivated to see program be successful	Years working in SSP/HR Medical expertise Management experience Evaluation knowledge	Highly engaged- actively working on development, implementation, evaluation of program

Embedded HRI Staff [RRS/ Associates/ etc.]	Motivated to do their job well/ be successful	Local geographical placement Likely from local community- inside knowledge/background	Highly engaged- doing on-the-ground work directly with clients and working with LHD/CBO
Kentucky Department for Public Health [Commissioner, staff]	Funding oversight Motivated to see improvement in poor state statistics Also political motivation	Political authority Funding authority	Need to be engaged enough to be aware of services in order to avoid duplicative efforts. DPH HRI Administrator is in place for this. May be conflict between HRI mgmt staff and DPH due unforeseen or unavoidable delays in implementation.
Local Health Department Staff/ Management	Recipients of funding/staff; will improve their capacity to offer services Some staff may or may not be motivated (varying levels)	Local knowledge Rapport with local community Established site/services	Need to be highly engaged in order to work closely with HRI on-site staff daily. Potential for conflict if LHD wants to use staff/funds for duties outside the scope of agreed-upon or allowable services
Staff/ Management of other Community Based Organizations where HRI staff will work	Recipients of funding/staff; will improve their capacity to offer services Some staff may or may not be motivated (varying levels)	Local knowledge Rapport with local community Established site/services	Need to be highly engaged in order to work closely with HRI on-site staff daily. Potential for conflict if CBO wants to use staff/funds for duties outside the scope of agreed-upon or allowable services
Clients of SSPs and CBOs where HRI staff will be	Recipients of services Varying levels of motivation- may not be motivated at all or may be highly motivated	Lived experience Potential to offer insight to improve program services and delivery	Engagement/input may be helpful during various phases of implementation and evaluation; but not all May require high level of effort to engage due to barriers
Local communities at-large	Services are being provided within the community Clients may be from local community or coming in from neighboring communities	Local knowledge Relationships	Potential for a great deal of conflict or for support Need to be engaged/educated

Local Government Officials/Law Enforcement	<p>Clients of HRI services may be seen as criminals/undesirable/undeserving to local officials; may be against SSPs</p> <p>Officials may be able to offer support for services, SSPs, treatment, etc.</p>	<p>Local authority</p> <p>Local knowledge Relationships</p>	<p>Potential for a great deal of conflict or for support</p> <p>Need to be engaged/educated</p>
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It is important to have a more contextualized understanding of the entities involved in programming, just as it is imperative to understand and appreciate the complexity of the environment within which a program will be developed and implemented. A Local Needs Assessment is one way to more fully discern this environment.

3.1.4 Local Needs Assessment

For the HRI planning team, a vital component of the program is that it has the capacity to address local needs and take local opinions and values into consideration. Therefore, the program is set up in such a way that the staff hear firsthand and are responsive to local needs. HRI administrative staff reached out to local health departments and districts, both those with SSPs and without, in order to set up meetings to introduce the new program and offer its services. HRI staff traveled around the state to meet with public health personnel at or near their counties. Between December 5, 2018 and August 29, 2019, HRI held meetings at which 44 health departments and districts that cover 79 counties were represented. KIRP staff met with LHD representatives on-site at the local facilities. One, or frequently, more than one health department or district was

represented at each meeting. Often, neighboring departments drove in to attend in order to reduce the amount of travel for program staff.

At the meetings, KIRP staff explained the reason for the program and what it could offer. They subsequently engaged in substantial dialog with attendees regarding their local needs and harm reduction and testing ideas. Beyond explaining KIRP and the Harm Reduction Initiative to health department staff, these meetings essentially functioned as focus groups that elicited an assessment of community needs surrounding drug use and local public health capacity and challenges. HD representatives were readily able to identify needs and possibilities for the resources that KIRP could provide. Valuable information and insights were gleaned as these representatives had real “boots on the ground” experience in their communities. These focus groups revealed that each area had their unique challenges, but common themes also emerged.

3.1.4.1 Common Themes

Data reduction in the form of open, axial, and selective coding was completed on the qualitative data gathered from meetings with LHDs. This allowed the information to be organized and focused into meaningful themes (See Table 3.2). The core categories that emerged were 1) needs or what HD programs are lacking in order to ensure well-run and effective harm reduction programs and 2) barriers that prevent adequate and effective programming.

Table 3.2: Local Needs Assessment Coding		
Open Coding (Initial concepts and categories)	Axial (Refined concepts and categories)	Selective Coding (Core Categories)
<ul style="list-style-type: none"> -Not enough hours of operation due to limited staff -Cannot do much ID testing due to limited money to buy tests and supplies 	Underfunded/ Understaffed	Needs: What is lacking for well-run, effective program
<p>Some individuals will not come into SSP</p> <ul style="list-style-type: none"> -May not have transportation; SSP location may not be accessible (at least one is right down the road from the police department) -There are known local “hot spots” for drug use 	Need mobile units/ability to help hard-to-reach populations	
<ul style="list-style-type: none"> -Hard to keep track of supplies, testing information due to non-user-friendly data collection system -Unable to get data from state due to insufficient surveillance, bureaucracy -Unable to monitor & evaluation program due to insufficient data 	Lack of Data (local and state)	
<ul style="list-style-type: none"> -So many local individuals are cycling in and out of county jails (due to drug use). These are high-risk individuals. Jails do not have sufficient resources or will to provide testing and linkage to care services -Many LHDs do not have permission or resources to regularly provide these services to incarcerated individuals -LHD staff expressed great interest in providing these services in jails -Incarcerated/formerly incarcerated individuals have expressed great interest in having these services available to them and taking part in them 	Lack of services for Incarcerated/formerly incarcerated individuals creates a public health threat	

<p>LHD representatives spoke at length of extent of pushback SSPs and SSP clients get from law enforcement</p> <p>-LHD staff said police from a county where there is no SSP wait at the border of the neighboring county with an SSP on the days/times they know the SSP is open in order to stop vehicles coming from the SSP</p> <p>-Staff at one county SSP state they advise their clients to hide the supplies received from SSP because staff know that local law enforcement are aggressively opposed to SSP</p> <p>-SSP staff have advised clients to use children's metal lunchboxes or similar item as a sharps container so cops are less suspecting</p>	<p>Law Enforcement Interference</p>	<p>Barriers to effective program</p>
<p>LHD staff stated some of their local officials deny there is a drug problem in their county, therefore oppose SSPs</p> <p>-LHD staff member spoke of introducing overdose maps to visually show one dimension of the local drug problem</p> <p>-One county has harm reduction program without needle exchange and keep inviting local officials and law enforcement to community forums, but they do not attend and will not engage in dialog with harm reduction advocates</p>	<p>Local Official Opposition</p>	
<p>LHD staff expressed a fear of "HIV" coming to their community. One nurse stated she would not know what to do for the patient. She had no idea where to refer the patient for care.</p> <p>-Another stated that her colleague had tested a patient and the result was positive. The staff member was so distraught that she could not even speak to the patient.</p> <p>-Staff expressed fear of outbreak (such as Scott Co Indiana). Stated they know that locally they do not have the capacity to respond and do not believe the state does either.</p>	<p>Fear/lack of information: outbreak without capacity to respond on local or state level</p>	

Within the “needs” category, insufficient funding, staff, and resources were pervasive, recurring themes. These shortages prevented SSPs from offering ample or convenient operational hours and left very little, if any, capacity for infectious disease testing onsite. LHDs also stated that they know there are portions of high-risk populations who will not come to SSP for various reasons. LHDs conveyed interest in mobile units and resources for outreach to service local ‘hot spots’ for drug use.

Also in the “needs” category, the lack of data was discussed. A need expressed by LHDs/SSPs was a user-friendly data collection tool that could also function as a way to pull data for their own evaluative purposes. They must report certain information to the state, but have significant issues getting data back from the state. This was one of the most voiced and prevalent issues mentioned by LHD representatives.

Additionally, LHDs articulated an imperative need for services for incarcerated and formerly incarcerated residents in their local communities. There is a large number of individuals cycling in and out of detention centers due to drug use. These individuals are at a high risk for infectious disease acquisition and transmission. LHDs state that local jails need testing and linkage to care services. LHD representatives indicated that they would be happy to provide these services onsite in the jails if they had the resources and permission. The representatives stated that jails are a good place to target testing and vaccination provision since, as one SSP representative said, this is “literally a captive audience”. Furthermore, they stated that inmates really wanted and appreciated

the services offered onsite by LHDs. Several sites mentioned that they have used small grants or other limited funding they have scraped together to provide some services at their local jails with great success.

The second major category to emerge was that of barriers encountered by LHDs and their SSPs. The most voiced concern in this area was interference from law enforcement. Representatives spoke about law enforcement waiting at the county line or down the road from the SSPs in order to stop clients traveling from SSP sites. One county said they explicitly told their clients to hide the supplies they get from the SSP because they know the local police are aggressively opposed to syringe exchange. Others advise clients to use children's metal lunchboxes or other nondescript items as sharps containers so that law enforcement will be less suspicious.

An additional impediment is opposition from local government officials. LHDs said that they have heard their local officials deny that there is a drug problem in their area. One HD representative spoke about introducing overdose maps to visually show that there is in fact a problem. One representative from a county that did not have an operating SSP stated that they (the local Harm Reduction advocates) keep inviting local officials and law enforcement to community education forums, but the officials do not attend and will not engage with them.

A third barrier was that of fear resulting from a lack of information and education. LHD staff voiced fear of an HIV outbreak knowing they have very limited capacity to respond. One HD nurse who works in an SSP stated they are

very worried about “HIV coming to their community”. She said they need a framework or work plan in place for when “HIV hits”. She stated they do not currently have a strategy. Additionally, the state does not have the capacity to handle an increase in diagnoses.

Having solicited needs, concerns, challenges, ideas, and plans from local public health staff, HRI set out to further design and implement a program that is responsive to local needs.

3.2 Clarificative

In this study, data was gathered and analyzed to form a contextualized landscape of program need, development and implementation. Grounded Theory guided qualitative coding of the results of the next three categories of formative program evaluation, clarificative, interactive, and monitoring, can be seen in Table 3.4.

The second category in formative evaluation is the clarificative category. The goal of this category is to describe the program and the theory behind it. Tools commonly used in planning, development, and evaluation may be used. A Logic Model and Logical Framework Approach Matrix were constructed from the relevant data collected for this step of the evaluation.

3.2.1 Developing Goals

In the evolution of program development, once the program and project directors, medical director, and HRI strategist were on board, regular meetings

continued to further develop and implement the components of the Harm Reductive Initiative. The core team grew as new staff were hired: a program manager, a fiscal director, a DPH HRI clinical coordinator (also called HRI DPH administrator), and a director of evaluation and outcomes. The next important step was to establish objectives and goals to guide program activities toward targets. Objective and goal development are key steps to position a program for success and effective evaluation. The first iterations of goal brainstorming by HRI staff were referred to as “moonshots” as they were ambitious targets. Preliminary discussion of potential objectives for the Harm Reduction Initiative produced ideas that the staff would further examine:

- HIV status awareness for PWID increases
- Linkages to HIV/HCV treatment
- Kentucky’s HCV state ranking drops from X to Y
- Overdose rates drop
- Reduction in syringe litter
- Increase MAT and substance use treatment

HRI staff held a meeting in August 2019 dedicated to discussing program goals, how to quantify them, and how to measure the success of program activities. HRI administrative staff decided against setting test quotas for the first year. The first year objectives would concentrate on setting up staff and beginning to offer services. Furthermore, the goals set during this time would apply to clients encountered within SSPs only and not outreach activities since it was not yet clear which counties would have the capacity to perform outreach. This is all dependent on a particular site’s hours of operation and how busy they are during operation. It may not be possible for a Risk Reduction Specialist

(RRS) in a particular county to be away from the SSP for long. It was decided that at the end of the current fiscal year, HRI core staff would assess each county and available local HRI staff to determine who will be able to perform outreach activities. This will also be dependent on available opportunities within the community. For example, counties with college campuses or numerous faith-based organizations may have ample places in which to carry out outreach activities. It is expected that upon starting employment, RRSs will explore the possibilities for outreach in their areas, but there is no expectation that activities will be undertaken at that time.

Measurable goals that were discussed and established were organized into three categories. Short, intermediate, and long-term targets were laid out along with the time frame for completion and assessment.

3.2.1.1 Short Term

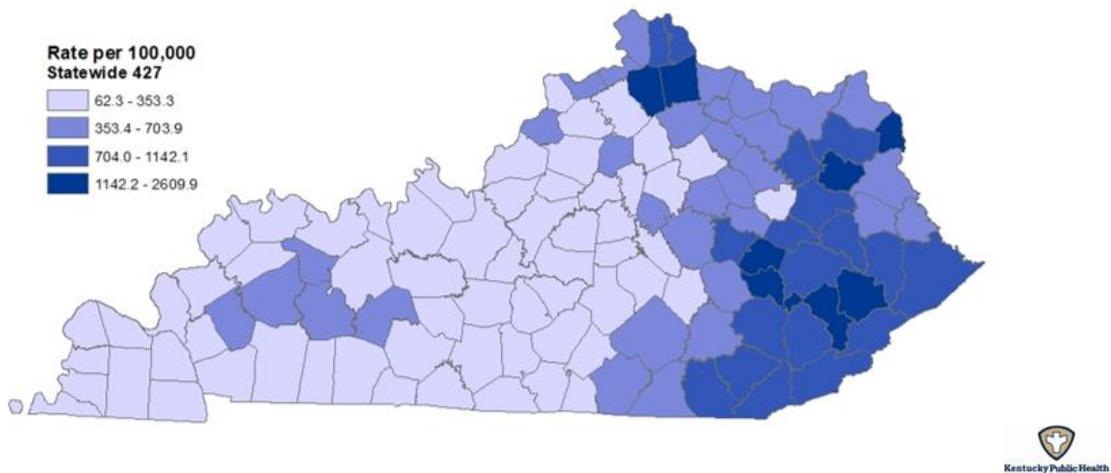
- Recognizing high risk/vulnerable populations
- Timeframe: (Fiscal year) July 1, 2019-June 30, 2020

Goal discussions first included how the program would recognize vulnerable populations and who to define as high-risk. It was noted that the vulnerable expose others who are not classified as high risk, thus the infectious disease implications are far-reaching. The KIRP program director mentioned the story of a woman in an Eastern Kentucky county who was recently diagnosed with HIV after her newborn baby became very ill and tested positive. The women had been in a monogamous relationship. Her partner, unbeknownst to her, was high-risk and HIV-positive. The HRI medical director noted, "This is not the Kentucky

of 20 years ago”. Many programs are using CDC vulnerable county data² (Refer to Figure 3.1) to set standards for high-risk areas, however HRI staff pointed out that the data is now old, and furthermore, by using more local data, they could define a more expanded base. The HRI medical director believed the Hepatitis C rate to be an adequate marker of HIV risk due to similarities in risk factors and modes of transmission. HRI decided to deem each county Tier 1, 2, 3, or 4 based on HCV rate information from the Kentucky Department for Public Health (See Figure 3.7). The objective established was to embed RRSs in 100% of Tier 1 and 2 counties, which have the highest HCV rates. Tier 3 counties would be targeted for an at least 75% HRI presence and 50% in Tier 4 counties.

Figure 3.7:

Positive Confirmatory Hepatitis C Virus Results by County, January 2017 – June 2019



From: KDPH

Shortly after this goal discussion, HRI staff learned that results from a new vulnerability study conducted by the state of Kentucky would soon be released by

DPH. Staff decided that this local and more recent data would be used to assign tiers to counties. They stated that they anticipated these results would add some counties to the HRI list that were not there before. Consequently, this goal will be more fully assessed after the release of the report.

3.2.1.2 Intermediate Term

- Focus on Testing
- Timeframe: 12 months after local HRI staff begin employment

Intermediate goals center on testing and linkage to care. HRI would like 25% of all clients encountered in SSPs to be tested for HIV regardless of if or how they use drugs. Additionally, in order to target higher risk and more vulnerable individuals, they want 50% of PWID tested. HRI would like a minimum of 25% of clients to get tested at least twice a year. Staff noted that local RRSs must build trust and rapport to convince these individuals to be tested. The timeline for intermediate goals will vary by site. Dates depend on when local HRI staff began employment.

The REDcap data collection tool can keep track of the number of tests performed. Additionally, local staff will have this information completed on quarterly report forms (Refer to Appendix F). The availability and reliability of baseline data, however, is questionable. HRI staff will only have access to tests done at LHDs and not elsewhere in the community. The director of evaluation and outcomes will look into getting access to state data, though this is typically a

cumbersome process. The difficulty in retrieving data from the state was a complaint frequently voiced by LHDs.

In order to assess whether the appropriate participants are being targeted, HRI will look at the positivity rate of testing. The positivity rate is the proportion of tested individuals with positive results. A low positivity rate means that the wrong people (i.e. low risk) are being tested. Thus, resources are not being targeted appropriately. The HRI project director believes the CDC overall HIV positivity rate goal is 1%. Therefore, HRI set their goal higher since they are targeting high-risk individuals. They will start with a 2% goal and review to potentially reassess after some time. The goal for the HCV positivity rate for the first year is 10%. HCV has a much higher prevalence than HIV. HRI staff report that the University of Kentucky emergency department universal testing rate is 11%, therefore, they feel that a 10% rate is realistic.

Linkage to care for individuals testing positive is the next priority. To align with 90/90/90 treatment targets,¹⁰³ the HRI goal is to connect 90% of those testing positive for HIV to care. For those testing positive for HCV, the goal is to link 50% to care. For the Madison County syphilis testing pilot project, 100% of positives will be linked to care. RRSs will refer patients to care for any positive tests. This means that RRSs will need to be familiar with local resources in order to know where and how to refer.

HRI chose to define linkage to care as a completed referral as the patient keeping the first referral appointment. At that point, HRI will drop out and cease tracking the patient. There are issues regarding how to keep track of referrals

and appointments. As of the end of 2019, this situation was still fluid, but brainstormed solutions included assigning team leads to make follow-up calls, utilizing an anticipated hepatitis grant which would hire navigators, and/or utilizing linkage navigators for HIV that would be funded through Part B rebate dollars. Patients would also need to sign Release of Information forms to give HRI staff permission to follow up on appointments.

3.2.1.3 Long term

- Universal Testing, PreP Access
- Time Frame: Varies

HRI laid out several longer-term initiatives they felt were important to address. The timeframe for most of these goals is 12-24 months after local HRI staff begin employment. Again, dates and timelines will vary by site as staff were hired at different times.

It has been the HRI medical director's firm and passionate belief that HIV care should to be integrated into general medicine. She asserts that healthcare practice should mainstream concepts around HIV testing and care. To this end, the HRI would like to pursue several initiatives to improve this area.

3.2.1.3.1 Emergency Department HIV Testing

HRI core staff envision that KIRP could be an instigator of pushing universal HIV testing in emergency departments. Additionally, the program could work to stimulate the infrastructure for testing in urgent treatment and walk-in

clinics. The staff noted that PWID are often high-utilizers of emergency and urgent services, thus these facilities are good opportunities to reach these populations. Currently, whether a particular hospital or clinic performs universal HIV testing depends on individual institutional regulations.

HRI management decided that embedded HRI staff will make in-person educational contact with at least three unique facilities in their county or area. They will target ER managers or nurse managers. RRSs will also explain that they are available to ERs to test or deliver results and link to care.

3.2.1.2.2 Testing in MAT Programs

Additionally, universal HIV testing should be occurring in Medication-Assisted Treatment (MAT) programs. The HRI medical director asserted that these facilities are not testing enough even though they have been advised to. It is uncertain how consistent they are. She noted that it often depends on economics. HRI core staff emphasized that RRSs could test at MAT programs, however, they were unsure as to the best way to connect with these programs. The good ones are likely testing already, but HRI staff noted that some MAT programs are erratic, “fly-by-night” types of facilities. It was decided that the HRI DPH clinical coordinator would speak to KORE (Kentucky Opioid Response Effort) representatives to see the best way to go about this. HRI management staff decided that MAT programs can be included in the three unique facility contact goal.

3.2.1.3.3 PreP Access

The “dream” of the HRI core staff is to get LHDs to become PreP providers since there are currently very few. This vision is a much longer 5-10 year goal and involves considerable educational components. This would include reviewing core services guides for LHDs, highlighting the fact that APRNs can prescribe under their own licenses, and hosting educational opportunities such as webinars and/or in-person trainings. Currently, Christian County is piloting a PreP-prescribing program. The more immediate goal for embedded HRI staff is to identify at least three unique prescribers in their area who are interested in prescribing PreP and begin education with them. The end goal is to have at least one provider who prescribes PreP in each area in the state.

3.2.2 Logic Model

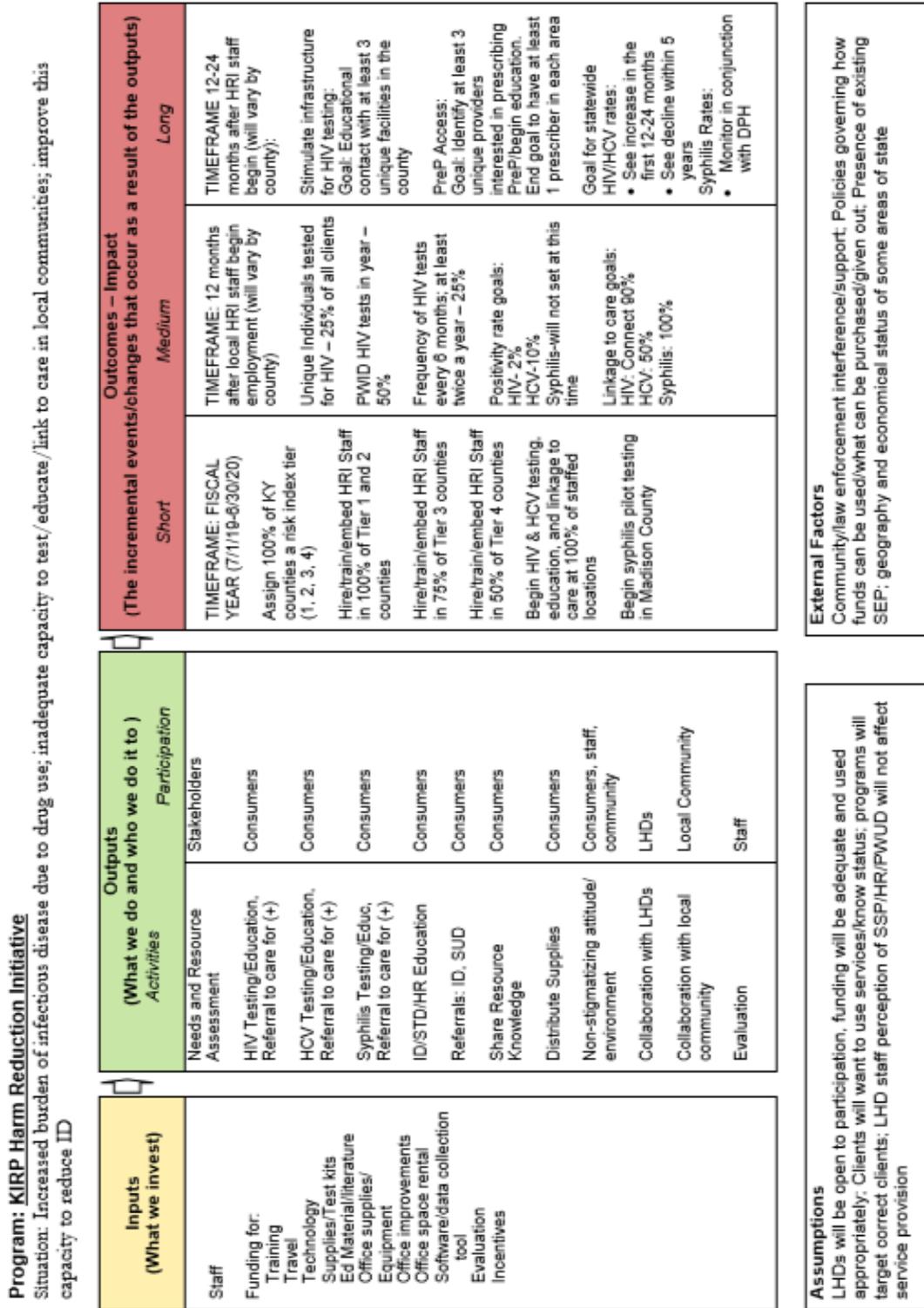
Each of these established goals can be seen in the HRI Logic Model (See Figure 3.8). A logic model lays out the underlying theory of the program. It links outcomes with activities and processes.¹⁵⁷ It is a clear, visual way to depict program features. The logic model for the Harm Reduction Initiative was developed with information from HRI meetings and interviews.

First, inputs are listed. For HRI, these include funding for staff, training, travel, technology, supplies and test kits, educational materials and literature, office supplies and equipment, office improvements, office space rental, data collection program, and incentives.

Next, outputs including activities and the recipients of the services are recorded. All testing, education, supplies, and linkage to care activities are for SSP clients. HRI staff and stakeholders will utilize needs assessment and evaluation results. The collaboration with HRI is advantageous for LHDs and the local community. Everyone involved benefits from an informed, non-judgmental environment that does not foment stigma. On the far right of the logic model, outcome performance measures are indicated. The short, intermediate, and long-term goals can be seen.

Lying outside the inputs, outputs, and impact assessment are critical assumptions and external factors. Program evaluation measures can be put into place to gauge the extent to which assumptions and external factors impact the program. Assumptions in this Logic Model include: 1) local health department and districts will be open to participation, 2) funding will be adequate and used appropriately, 3) clients will want to use SSP services and know their disease status, 4) program will target the correct populations, and 5) staff biases will not affect service provision. External factors include either support or interference from the community and law enforcement, existing policies, and the geographical and socio-economic status of the area.

Figure 3.8 Harm Reduction Initiative Logic Model



3.2.3 Logical Framework Approach Matrix

A Logical Framework Approach Matrix, or Logframe Matrix, is another way to conceptualize aspects of a program, similar to a logic model but with a different approach and layout. A LogFrame Matrix outlines features that lead to the achievement of program goals (See Figure 3.9).¹⁸

Figure 3.9: LogFrame Matrix

OBJECTIVES	INDICATOR	DATA SOURCE	ASSUMPTION
Goal (or long term outcome)			
Purpose (or intermediate outcome)			○
Results (or immediate outcome of the project)			○
Output Tangible products or services that are to be delivered to achieve the purpose			○
Activities The key activities required to produce each output			○ <i>And this holds true...</i>

The LogFrame Matrix stems from a Logical Framework or LogFrame Approach used in project planning. A LogFrame Approach starts with a stakeholder analysis and a problem/solution tree analysis. The matrix is read from the bottom up. The first column characterizes the logical progression from activities to outcomes that should occur. The second and third columns indicate a

measure of whether the first column was achieved and how you know. The assumptions represent potential risk that should be carefully considered. If all goes well on the first row, then you successfully progress to the next step above.¹⁸ The LogFrame Matrix for the Harm Reduction Initiative can be seen in Table 3.3.

Table 3.3: Harm Reduction Initiative LogFrame Matrix			
Objectives	Indicator	Data Source	Assumption/Risk
Goal	Reduction in Kentucky's infectious disease burden	REDCap, State data	
Purpose	Increase in linkage to care	Partners (DIS, HCV navigators); follow up w/RW programs, LHDs, other ID providers	Referrals are completed and clients engage in treatment
Results	Increase in high-risk positives identified	Quarterly Reports; REDCap data	Those identified will successfully be referred to care
Output	Tests performed	Quarterly Reports; REDCap data	Target population is being reached
Activities	Personnel, training, equipment, supplies	HRI core staff records	Sites will be fully staffed, trained, and resourced in order to carry out duties

3.2.4 Diffusion of Program Awareness

Advertising the program adequately was an important step to ensure the greatest reach, utilization, and effectiveness. HRI core staff has engaged in various methods to disseminate program information. They completed numerous direct contacts in the form of phone calls, emails, and face-to-face encounters

with health department directors, community organizations, and other relevant stakeholders throughout the state. The press conference in Northern Kentucky in March 2019 resulted in online and print news articles and social media attention.⁸⁻¹¹ Beyond individual meetings with LHDs and the initial press conference, HRI co-hosted and presented at the Kentucky Harm Reduction Summit in April 2019. It also leads both in-person and webinar-based AIDS Education Training Center (AETC) conferences. HRI core staff have attended and continue to attend various other conferences and events throughout the state to increase diffusion of HRI program awareness and encourage uptake and engagement in the program.

3.3 Interactive

Interactive evaluation is carried out during early implementation and is used to improve the design of a program.¹⁸ Evaluation during implementation seeks to reveal the lessons that emerge at this time and can be used to modify processes early on. In this study, meetings with staff and open-ended interviews when needed allowed relevant information and issues to surface naturally.

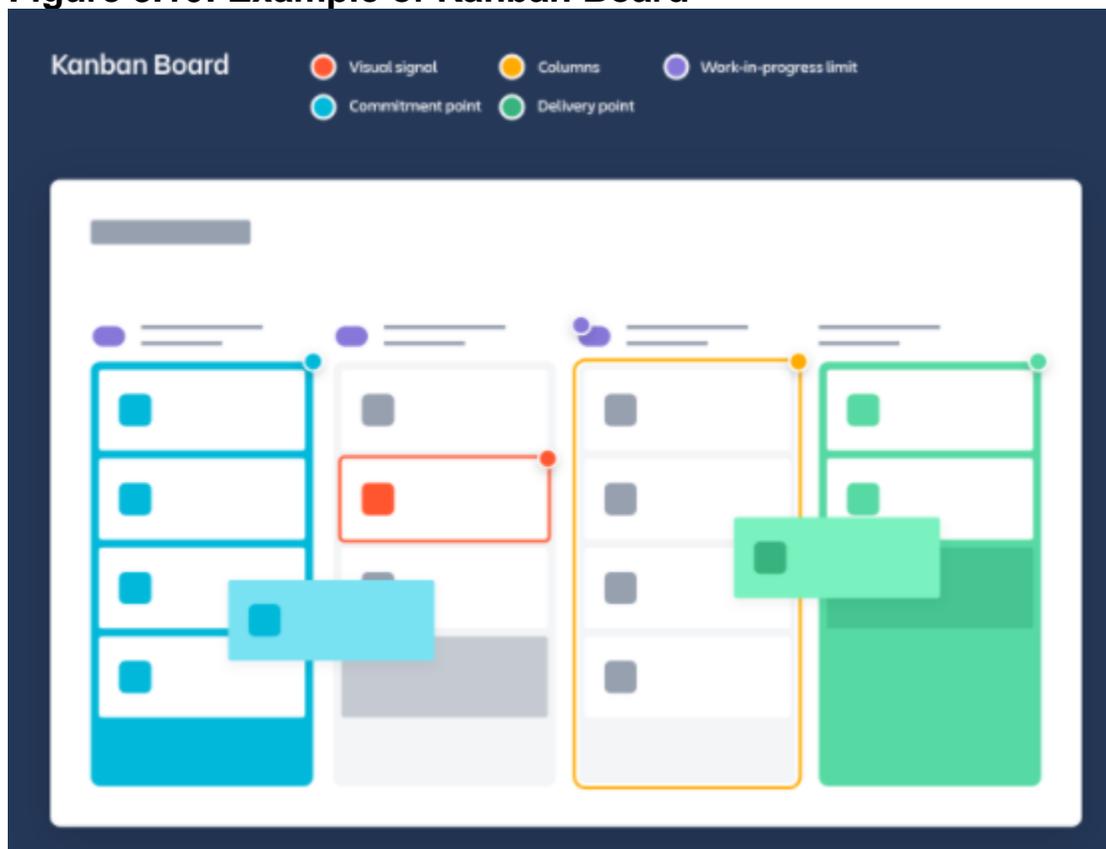
3.3.1 Organization, Development & Implementation Strategy

Throughout meeting observation and interviews, themes emerged that illustrated program strategy with respect to its organization, development, and implementation.

The staff consistently sought out advice, guidance, and expertise on topics so that they would be optimally informed for decision-making. Though there were decades of infectious disease, harm reduction, and grant management experience represented on the team, they did not presume to know exactly what to do all time. When new topics or issues arose, they pursued information, paid attention, sought to understand, and took more informed action. This was observed when the core team invited a professor to share her recent research studying local SSPs and when they had a software developer in to explain the options available for data collection tools.

For the program to work well, the staff must be highly organized. Special meetings were dedicated to deciding how program processes and implementation would be tracked. For logistical support of a large and complex program, a Kanban system was employed. Kanban is a system originally used in manufacturing and designed for workflow management. It has been developed into software that keeps track of and visually follows the progress of program development and implementation (See Figure 3.10).¹⁵⁸ The online Kanban system keeps track of each LHD contact and meeting, budget requests received and approved, position postings, hiring, and more.

Figure 3.10: Example of Kanban Board



Prior to HRI, the capacity of organizations (SSPs and others) to provide testing and linkage to care was extremely limited. As illustrated on the Problem/Solution Tree Analysis, HRI focuses on the right side causes (testing opportunities, data collection, linkage to and engagement in care), but builds capacity for left side causes (sterile injection equipment provision, reduction in fear, stigma, and interference). For embedded staff in counties with no SSPs, one of their job duties will include advocacy for setting up syringe exchange programs as well as outreach. The Harm Reduction Initiative is limited from a funding perspective in that it must operate within federal Ryan White program guidelines (See Appendix B).¹³ HRI is not able to purchase syringes, cookers, or

other equipment legally deemed to be 'paraphernalia'. Program activities and supplies are also subject to local laws and regulations.

One of the main objectives of the Harm Reduction Initiative is to hire local Risk Reduction Specialists to be embedded into local syringe exchange programs, harm reduction programs without syringe exchanges, and other community based organizations. Under the original conception, LHDs would essentially write their own job descriptions for the positions they desire at their facility. Although these positions would be paid through the University of Kentucky and receive UK benefits, they will be locally selected and stationed. Furthermore, there will be local oversight. Positions are posted via the University of Kentucky Human Resources website (See Appendix D). The project director shares the link with the respective health department director who then advertises via their email lists, social media pages, websites, and any other venues they deem appropriate.

Besides staff, allowable costs include supplies (other than injecting equipment), travel, training, HIV and HCV tests, outreach and education materials, client incentives, and office space rent. Each Risk Reduction Specialist position includes an annual budget of up to \$242,402 (See Appendix E). Each staff member hired will undergo several trainings including UK New Staff Orientations; Harm Reduction Navigator training, and training on HIV, HCV, and syphilis testing.

HRI's focus is on infectious disease testing. Due to the nature of its funding, HIV is the main emphasis. However, HCV, being so highly co-

diagnosed, is an important indicator in HIV risk. Furthermore, it was decided that HRI would conduct syphilis testing in addition to HIV and HCV because there was a new, rapid syphilis test available, and rates of syphilis in Kentucky were rising. This is concerning for HIV prevention because syphilis is associated with increased risk for contracting HIV, according to DPH and HRI medical staff. The new syphilis test will be piloted in Madison County, the first HRI county to fully come on board. Once the Department for Public Health determines how positive syphilis referrals will affect their workflow and if they have the capacity to handle all the positives, it will be decided whether to roll out rapid syphilis testing in other counties.

The management team decided that for ongoing evaluative measures, quarterly reports will be completed from each site. These reports would include summaries of relevant areas such as successes, barriers, and a data table with the number of tests, distribution of supplies, referrals to care, and a brief narrative of activities (See Appendix F). HRI administrative staff will review data on a regular basis to assess effectiveness.

Beyond the periodic information on program activities, considering the major focus of the initiative is infectious disease screening and linkage to care, real-time tracking for testing is essential. In order to have meaningful data, designing an adequate, useful, and user-friendly collection tool was critical. Being able to document program activities and progress toward target goals is among the most fundamental requirements for assessing program success.

3.3.2 Data Collection Tool

One of the early priorities was devising a way to capture and measure services and outcomes in order to keep operations on track and evaluate success. HRI staff and relevant stakeholders spent significant time discussing data and data collection. In order to set and measure goals and objectives, relevant and appropriate data must be collected in a way that allows for meaningful analysis and demonstrates targeted outcomes.

The team discussed that current state-level data on the true incidence and positivity rates for HIV and HCV are not accurate, if they exist at all. Thus, if data collection is done right, HRI could potentially become a starting place for this kind of data in the state. It was noted that with more than fifty possible sites and more individual staff members collecting data, uniformity is vital in order to allow statistical analysis.

HRI staff strove to put emphasis on local input and feedback in all areas. In developing a new data collection system, it was suggested that a survey be sent out to all the health departments and SSPs in the state with the new proposed client questions to elicit thoughts and any additional information that may be helpful. Mention was made that if possible, client feedback would be useful. It is unknown if actual clients have ever been consulted in the formation of Kentucky SSP data questions and procedures.

3.3.2.1 REDCap

An existing data collection system created and advocated for by the DPH (REDCap) was largely found by SSP staff to be non-user-friendly, and therefore, not generally used appropriately, if at all, in individual SSPs. One LHD representative described REDCap: “It’s difficult, and it’s difficult”. Another SSP representative said that it is “important to be able to pull data in minutes, not days” to show stakeholders. As it was, the intake and testing questions in REDCap were cumbersome, out of order, difficult to maneuver through, and hard to complete in their entirety, thus they rarely ever were. The data pulled from the platform was abysmal when HRI began to look into it.

A consultation was held with a software developer to discuss the possibility of creating a program from scratch that meets the exact specifications of the HRI and SSP staff in a user and client-friendly way. Meanwhile, the HRI strategist and the director of evaluation and outcomes held a meeting with state employees to discuss the limitations of REDCap. It was agreed that REDCap would be modified.

In the improved version, there were collapsible sections that were grouped in an order that made sense. It was user-friendly and not time consuming as it was appropriately shortened without sacrificing necessary data. It was also decided that pop-up alerts were needed to inform staff when a client was due for testing. A webinar for a small test group of users to pilot the new version was held on July 22, 2019. However, several glitches and errors were encountered, and the webinar was set to be rescheduled and attempted again at a later date

after some modifications could be made. After several iterations of the system, the current version went live on September 2, 2019. The first round of data was reviewed the first week of October 2019.

3.3.3 State-Wide Standardization and Local Decision-Making

Due to the structure of Public Health in Kentucky and state regulations, each site within each health department or district is different and has its own needs and distinctions. Allowing for local decision-making presents both advantages and challenges. Ensuring standardization while still addressing individual site nuances requires a delicate balance. This makes implementation difficult, as each process will look a little different. The mantra, heard many times over during meetings is, “If you’ve seen one health department, you’ve seen one.” Often, the single commonality will be these HRI positions, which afford an opportunity for some standardization in order to implement best practices while still keeping local needs in the forefront.

3.3.4 Challenge of Innovative Programming

Being a completely innovative program, there were no existing plans, policies, or procedures in place when stakeholders set out to develop KIRP. Everything had to be built from the ground up. In doing so, they kept in mind the tenuousness of the situation. HRI staff knew that once the initial RRSs started in the field, there would be unforeseen issues that arise and many challenges. The management staff was prepared for this. Therefore, when an issue has surfaced,

the team has not yielded to chaos or panic resulting in hasty decisions. The staff discusses the issue to decide upon a plan of action. Then the project director writes up a preliminary draft of a policy, which she sends out to RRSs in the field to review. Feedback from the field staff is incorporated when applicable and appropriate.

Administrative staff members are also open to realizing and utilizing strengths of staff and the existing syringe service or harm reduction programs. For example, HRI identified that Madison County was strong in the area of policy and procedure development and had a robust set of policies and procedures for their programming. Therefore, HRI has solicited and utilized their assistance in building HRI policies. Additionally, at the time, both Christian and Bell Counties lacked syringe exchange programs, and local HRI staff were working to get approval for one. The staff members from each county began communicating with each other to share advice and help each other with lessons learned.

With new staff and an infusion of funding, SSPs and harm reduction programs have the freedom to innovate and explore options that were previously unavailable due to restrictions of personnel and money. This ability is novel. The project director stated that “go-getters” are needed in each county to fully utilize and realize the potential that each program has. She states that the innovation that local HRI staff bring to each SSP or harm reduction program will ultimately dictate what happens and how successful the program is.

HRI management staff wants to use what is essentially peer-pressure to push RRSs to be innovative and achieve. Embedded staff communicate with

each other extensively through email lists, meetings, and other venues. They share challenges, ideas, and new things they are doing. Management hopes that this constant encouragement and reminder of what is possible will prevent underperformance or complacency in embedded staff.

3.3.5 Review, Reflection, and Adaptation

For any program, particularly new ones, challenges to implementation and sustainability require adaptation. During the interactive stage of evaluation, early implementers are studied to assess what the barriers and facilitators are; what conditions make it harder or easier to carry out activities.¹⁵⁹ These discussions occurred during HRI meetings and interviews.

In the course of creating and implementing local-need-specific programming state-wide, all within federal guidelines, the team unsurprisingly encountered numerous challenges. The complexity of working with several distinct entities creates multiple layers of bureaucracy and so-called 'red tape'. Each step of the way takes time, and a hold-up in one area will affect each successive step. These delays created frustration for some partners 'higher up' the chain. While there were no official timelines set ahead of time, some entities, particularly those who may have political constituencies, had expectations for more prompt results. One area of delay stemmed from the legal and contracting nuances required for approval and implementation. The main point of contact for contracting was out on leave before new contract management positions were filled, and this slowed things down significantly.

Additionally, a changeover of public health commissioner in the midst of development planning created some interruption. This required that new relationships, understandings, and expectations be established mid-way through. While not a major impediment, it did generate more work for HRI staff, which shifted their focus from other tasks that could be done.

From the time budget requests from LHDs started rolling in, the HRI organizational chart was in a constant state of flux. It was changed to adapt to the actual, unexpected needs rather than the initial, estimated ones. KIRP has had to be versatile in this regard. The original thought was that four Team Leads and 21 Risk Reduction Specialists would be needed in the state. These estimates were based on the days and hours that existing SSPs were operating at that time. Meeting with LHDs, however, HRI staff learned that those limited days and times were a function of insufficient manpower and resources. SSPs wanted and recognized the need for increased operating hours but had simply been unable to make it happen due to budget restrictions. Therefore, after accounting for more operational days and increased hours, it was found that much more personnel were needed. As of August 2020, HRI has hired 50 staff in 40 counties. This includes twice as many team leads (eight vs. four) and other staff (42 vs. 21) as was anticipated, and hiring is not complete. Not all of the available KIRP funding was budgeted at the beginning, and that has been a pivotal factor in being able to amend and expand areas of HRI based on local needs.

The hiring process presented major obstacles. While a certain degree of complexity was anticipated, hiring turned out to be “surprisingly” complicated according to the HRI project director. Working with the Human Resources department of a very large organization came with its own challenges. Further, finding the right personnel in local areas sometimes took several postings and re-postings. Often, a LHD had a candidate in mind, either from previous internships or other experiences. Matching available job descriptions with preferred candidates proved to be a difficulty that caused considerable delays in some areas. In the case of Northern Kentucky, for example, which was supposed to be the first area to come onboard, it took numerous postings, rewording/reworking positions, and a full year (June 2019-June 2020) to finally get fully staffed.

Due to the difficulty in matching known candidates with job positions, new categories of positions were created. Instead of just Risk Reduction Specialists (RRS), a Risk Reduction Associate position was made available. This post requires less education and experience and allowed some LHDs to hire individuals they could not get approved for the RRS position. The local offices decide which positions they would like and can mix and match, as they deem necessary.

The employment application system used by the University of Kentucky is particular and strict. Without prior experience and employment history worded just right, it was not recognized by the system. An estimated 75% of applicants had to go back into their applications and reword their experience and employment histories. They had to use different language in order to get hired

and paid commensurate with their actual experience. Even when the years or months of experience were counted appropriately, the salary offers were often not fair, in the eyes of HRI management. For example, 100 months versus 200 months of experience yielded the same salary offer.

After the hiring process, employee management was another area that had to be figured out. The logistics of supervision are tricky because embedded staff are technically UK employees, however the HRI core team knew that day-to-day management should be handled locally. This includes time schedules and vacations or leave requests, among other issues. Policies for the division of supervision were developed with LHD staff and written up.

Rolling out training for all staff was challenging. The HRI project director said that if she could do something differently, she would roll out hiring regionally. What happened was that different staff from all over the state came on board at the same time and the logistics of getting them all to a training was difficult and sometimes impossible due to travel. It would have been easier to schedule trainings by region. Lessons from this experience were applied almost immediately. Due to this experience, the Kentucky Finding Cases program, one of KIRP's funded innovative, pilot programs, was rolled out differently (regionally rather than statewide) in order to onboard staff in a simpler and more cost-effective manner. Overall, the HRI team was able to review and reflect upon issues in real-time as they arose, and they used the program flexibility to adapt and improve as necessary.

3.3.6 Harm Reduction Beyond Syringe Service Programs

During the course of program development and early implementation, staff realized that some of the most vulnerable areas do not have SSPs or any form of harm reduction program. Therefore, there is a vital need for HRI presence in these places. Additionally, even in counties with such programs, many high-risk individuals do not utilize the onsite services. To address these needs, outreach became a necessary part of embedded staff job duties.

Mobile units were requested by several counties and were provided by HRI. Other promising outreach venues are community-based organizations (CBOs). Local HRI staff have been exploring possibilities. Madison County decided to test out renting space within a free clinic in the community. Facilities such as shelters and food pantries may be other options. Partnering with CBOs is cheaper and safer than mobile units, and also faster to get under contract from a logistic standpoint.

Outreach work beyond SSPs brings a myriad of logistical and evaluation issues with which to deal. It is imperative to keep track of where all testing is completed in order to evaluate whether it is an effective place to test. Again, the positivity rates will be reviewed, and if they are too low, it is an indication that staff may need to move to a new location. Thus, it is important to have a place to document the testing location during data collection. Talks were underway about whether there should be a separate section in REDCap for outreach at non-SSP sites. Also, there will be a separate evaluation plan for outreach locations, but it will be similar in that there will still be a quarterly report, with subsequent quarters

compared. It was noted that staff will need time to build rapport with community in outreach locations. Additionally, some counties may eventually be able to offer syringe exchange in these locations if they prove to be highly effective areas in which to connect with high-risk clients. In this way, these locations may also be a helpful strategy for LHDs that have issues integrating harm reduction services onsite at LHDs.

Some counties wrote jail outreach into their HRI plans. Because the Health Resources and Services Administration (HRSA) recently changed the rules on allowing Ryan White funded services in jails, HRI may be a big help in allowing local programs to make an impact on incarcerated populations. Testing supplies purchased with HRI funds may be used for testing and education to incarcerated individuals. Theoretically, embedded staff are able to go into jails as long as the jail gives approval. As of December 2019, HRI was working with the Ryan White project officer to get official approval for staff to go into jails.

3.3.7 State Plan for Ending the HIV Epidemic

Since Kentucky is one of the priority jurisdictions for the Ending the HIV Epidemic (EHE) initiative, the state has been devising a plan. HRI has been a major stakeholder, working with other entities on this plan. The four pillars of the program are diagnose, treat, prevent, and respond. At the state level, there has been much discussion on how to respond to outbreaks such as the one in Scott County, Indiana or ones that nearby HIV clusters may foreshadow. Knowing that the state has very limited resources, all potential, available assets are being

evaluated. HRI will play a significant role in the state's EHE strategy. Response plans are being written to mobilize local HRI staff and/or deploy staff to the county where an outbreak is occurring in the case that one does. The HRI set up gives a good framework for response.

3.3.8 SSP CLIENT EXPERIENCES

Although it is a Best Practice,^{133,160} in reality, SSP operation is often not informed by those who use the services. The HRI DPH administrator carried out a series of interviews with clients of SSPs around the state during August 2019, in order to solicit information from individuals who have been utilizing the services.¹⁶¹ The administrator is a former DPH employee familiar with the inner workings and felt that client voices are not always well represented in program development and improvement. For HRI, being familiar with the context of a client's drug use is essential for informing the types of services and supplies that need to be available at SSPs and harm reduction programs. The administrator was surprised by the uniqueness of each client's situation and the differences found among the various counties, populations, and programs. He learned that there are no experts on drug use experience except for the clients themselves and that expertise only extends to their own individual reality and not anyone else's. Nonetheless, common themes did emerge in the course of these discussions.

During the interviews, he asked about drug use including the drug(s) of choice, frequency and route of consumption, fentanyl, and overdose experience,

as well as barriers and challenges clients face. Many clients were very open about their experiences and shared information readily. Early on in the interview process, valuable information and suggestions surfaced that led to changes in program operations. For example, the information that the consumption of methamphetamines causes the blood to thicken came up. This makes it difficult to get a good sample when testing for infectious disease. Therefore, programs were given approval to buy water bottles and snacks in order to mitigate this issue.

For the most part, injecting seems to be the most common way to consume drugs in these areas. Even meth is no longer smoked. Clients stated that everyone 'shoots it up' now because it 'hits harder' and produces a better high. One exception was a county where clients said that everyone there is still using Percocet because there is a doctor who is selling them locally, and he makes 'a killing' doing it. The Percocet is crushed and snorted. Therefore, in this area SSP education should include safer snorting information and ideally, safer snorting kits.

Clients spoke about side effects and characteristics of their drug use. They stated that certain drugs induce a voracious sexual appetite, thus they engage in frequent sexual acts while under the influence. This is particularly concerning for infectious disease transmission and stresses the importance of family planning for women. Client experiences with fentanyl were discussed as well. They stated that fentanyl is everywhere, and since it speeds up the high, clients must buy more drugs and use more often. This leads to a high frequency

of injecting. Therefore, in SSPs where there is a limit on the number of syringes that can be given, it will likely not be enough. The Best Practice is a needs-based model.

Most participants reported prior overdoses. In fact, an overdose occurred while the HRI DPH administrator was onsite interviewing. Some clients reported having naloxone, and some used with other people around as an overdose safeguard, but many did not.

The HRI DPH Administrator asked clients about their history of getting tested for infectious disease. Most had been tested for HCV or simply assumed they must have it. There was a very fatalistic mindset when it came to HCV, however, no one wanted to talk about HIV, as there is still so much stigma surrounding it in many areas, particularly rural ones. This is important for the health educators and risk reduction specialists at SSPs. One SSP used to do HIV testing one day a month only, but now offers it every day since the HRI staff was hired. When it was held one day per month, no one showed up for testing, largely due to stigma since everyone knew those were HIV testing days.

While mainly using now to prevent dopesickness and to be able to function, many clients stated that they initially used drugs as a way of self-medicating. Clients spoke of difficult childhoods and various types of trauma they had experienced throughout their lives. One client stated, "It takes away the pain". Another stated it was to lessen their stress.

The HRI DPH administrator asked clients why others they know do not use SSPs. Their answers included not wanting their names in a system, being

afraid of law enforcement, being too high to come in, having a day job that conflicts with SSP hours of operation, fear of losing their job, being embarrassed, and lack of transportation. Common challenges they reported facing were living situations (often homeless or precariously housed, frequent eviction), employment, and transportation issues.

Understanding client situations, experiences, challenges, and motivations is an important dimension. It is critical for program development, implementation, and monitoring that staff have a contextualized understanding of the target population in order to have the most effective program that does the right things (provides relevant and necessary services) and identifies and reaches the right people (those at most risk). In addition, the HRI core team knew they needed to have a grasp of the environment and mindset of LHDs and other sites where they wished to embed HRI staff in order to market the program to them and organize the services accordingly.

3.3.9 Local Health Department Staff Perspectives

Some important assumptions in the program logic are that local staff will be open to HRI participation and that staff viewpoints, beliefs, and perspectives will not negatively affect service provision. For HRI management, interactions with and anecdotes about LHD staff revealed some insight into these assumptions.

Early on, when HRI staff first started meeting with local health departments, one HRI staff member noted that program was initially met with

uncertainty because LHDs were used to the state “taking things away from them” due to budget restraints, policy changes, or resource reallocation. However, by the end of each meeting, the KIRP staff stated that LHD personnel felt like it was “Christmas in July”. The LHDs were able to see that there were many resources offered with very few strings attached. The initial hesitancy and skepticism were quickly and easily assuaged.

Another issue encountered was that local staff had varying opinions on SSPs, harm reduction, and SSP clients. When health departments first started offering harm reduction services, some veteran HD staff felt like those services were taking away from what they thought local health departments were supposed to be doing, such as reproductive health services for women and preventative health for children. However, with the passing of the Affordable Care Act and expanded insurance coverage, patients had more options and were able to access those services elsewhere. Many people have primary care providers for the first time in their lives and do not have to rely on local health departments for their care.

Additionally, it was found that some LHD staff had negative perceptions of people who use drugs (PWUD), sometimes referring to them as “those people”. Some staff did not agree with the concept or provision of harm reduction services. Anecdotally, it was felt that these negative perceptions espoused by staff were affecting service provision and the way SSP clients were being treated. Some LHD staff had been working at HDs since before SSP or harm reduction work began and were asked to engage in harm reduction work despite

their opposition to it. However, to keep their job, it was something these staff felt they were forced to do despite the fact that they “didn’t sign up for it”. In cases where staff felt this way, HRI was particularly needed and welcomed as those staff members no longer had to engage in services that they did not agree with. Now, it is a win-win situation with HRI providing the resources for new, dedicated staff that are passionate about harm reduction and the clients who use the services. Those staffing SSPs are now people who specifically want to do that work versus people who are ‘forced’ to do that work.

There were existing staff at some SSPs who were very passionate about their client population. Some were peers and some simply had compassion and empathy for their clients. These staff were pivotal in offering insight and suggestions for program development and improvement. They were quick to point out barriers they knew their clients faced and helpful ideas for ways SSPs can best serve the community. For example, they knew many of their clients deal with food insecurity and often come hungry. Many suggested food assistance and being able to keep snacks on hand. These staff were familiar with their communities and were able to point out places where outreach and mobile units could reach others in need. These staff were also familiar with the health status of those they serve, such as the uptick in syphilis cases locally. This trend was also being seen in state-wide data and was one reason why rapid syphilis testing is being explored. These staff members were vital to SSPs before HRI and continue to be now.

3.4 Monitoring

After initial implementation, monitoring occurs in order to ensure that program activities are being carried out faithfully and competently.¹⁸ Observation and follow-up interviews are ways to evaluate the program well into implementation.

3.4.1 Monitoring: Ongoing Activities

In order to maintain relevancy and sustainability, ongoing monitoring of programs must take place. HRI management frequently solicits feedback from embedded staff and is highly responsive to expressed needs. This was illustrated early on when core staff responded to voiced concerns by putting an extensive amount of time and effort into making an adequate data collection tool a priority and a reality. The KIRP project director states that data was one of the leading complaints they have received from the field. Both the hassle of inputting and recording SSP data in a non-user-friendly system and the inaccessibility of data from the state were concerns that SSPs had. After the revamped REDCap came out and local HRI staff were hired, more sites began using the system. HRI is still working to convince others to adopt REDCap in their practice.

Through use of a more uniform system, HRI and individual SSPs can access their data easily and immediately. The management staff will continue to have regular data meetings to review the previous month's REDCap data. In this way, monitoring of program activities is consistent. In addition to REDCap data review, quarterly reports and frequent discussions with local staff occur.

Management wants to keep staff at different locations communicating with each other, sharing challenges and successes.

There has been an ongoing conversation surrounding whether completely integrated services or separate, defined hours for syringe exchange at local health departments is better. In general, the best practice is to have integrated services, and around one-quarter of programs in Kentucky are integrated. However, sometimes the SSP client may not want to be in with the general population. Clients have stated that patients in the LHD for medical or other services know or assume the reason that the clients are there, and it contributes to an atmosphere of stigma. In these cases, the clients prefer separate hours or a separate area for exchange services. KIRP has found that the setup of the LHD affects which model works better. HRI will attempt to look for ways to address stigma through education and anti-stigma campaigns. Mobile units allow a separate, safe place so that PWID do not have to go LHDs to access SSPs. The staff, both management and embedded, continue to seek ways to improve the program in any way they can.

3.4.2 Best Practices Evaluation Tool

In 2019, the National Alliance of State and Territorial AIDS Directors (NASTAD) developed a Program Evaluation Tool for the CDC that measures an organization's level of Best Practices as applied to SSPs.¹⁶² Its design is based on a Stages of Change Model. It includes five stages ranging from "Not a current practice and not yet in discussions to change" to "Consistently employ this policy or practice" (See Appendix G). With the aim to reach the highest level of national

best practices standards possible, Harm Reduction Initiative staff chose to incorporate the tool into their work. Though some sites will never reach full potential on this scale due to restrictions of local regulations, it gives HRI administration an idea of the direction in which a program is heading. For baseline data, they decided that embedded HRI staff will complete the survey when they first begin working at their site and will reassess annually. The KIRP director of evaluation and outcomes digitized the survey tool into an online form with a link to be sent via email to RRSs to fill out (See Figure 3.11). In this way, real time data may be captured without the need to input or compile further data. This online evaluation form was piloted with the first RRS who came on board and was revised based on recommended changes and further discussion. One major change was the addition of a comments box after every question. The RRS wanted the opportunity to explain the situation with respect to each individual question. HRI administrative staff decided that this would be valuable, qualitative data that can be used to inform possible change and see where more attention or resources are needed.

Figure 3.11: HRI Adaptation of NASTAD Program Evaluation Tool (page 1)

Harm Reduction Program Evaluation Form

Kentucky Income Reinvestment Program (KIRP) – Harm Reduction initiative (HRI)

Health Department / Health District

Your answer

Syringe Exchange Program/Harm Reduction Program Site:

Your answer

Person Completing the Form:

Your answer

Date
MM DD YYYY
_ / _ / 2019

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3.4.3 Further Concerns, Future Issues

There are intended outcomes of the Harm Reduction Initiative, that, for now, will remain unmeasured: lower substance use disorder (SUD) rate, decrease in overdose incidence and death, decrease in syringe litter, increase in community support for harm reduction programs, and lower rates of stigma in communities and healthcare facilities. As the initiative grows and local programs

gain capacity, HRI will look at adjusting targets and adding goals for official measurement.

Over the past few years, there has finally been an influx of funding and resources into the state to address the opioid epidemic. One potential issue of the many public health and grant-funded programs aimed at combatting drug use issues is whether the HRI impact evaluation results will be confounded by other programs' activities. HRI management staff believes this is probably not going to be a problem as each program is largely measuring different things. For example, the Healing Communities program is focused on overdose and overdose death prevention¹⁶³ and others on HCV elimination.¹⁶⁴ Some state programs are looking at substance abuse and mental health treatment services.¹⁶⁵ HRI will be focusing on HIV rates and linkage to care. Furthermore, one of the functions of the HRI DPH administrator is to monitor other programs operating in the state in order to prevent duplicative efforts.

If HRI program activities are done well and carried out to the fullest extent possible, an initial increase in HIV cases is expected as previously undiagnosed individuals learn their status. The state is currently not prepared for an increased population of newly diagnosed. At the time data was being gathered for this study, disease intervention specialist (DIS) work was almost non-existent for new HIV cases. It was still somewhat robust for syphilis, however, so HRI felt comfortable piloting rapid syphilis testing. Investigative and contact tracing work for both HIV and HCV is a challenge that is on the radar of both local and state entities.

3.4.4 Data, Surveillance, and Response Capacity of the State

The current capacity of the state frequently came up in conversation during meetings and interviews. Data infrastructure at the state level is suboptimal and continues to be a limiting factor in programs and activities that require robust surveillance. Furthermore, it was generally agreed upon by the various stakeholders that the state had limited capacity to detect and respond to potential infectious disease health threats. Due to the inadequate data collection and surveillance, the identification of problem areas or clusters of infectious disease is delayed and restricted. For example, local entities recently found a potential HIV cluster in one Kentucky health district, but the state could not determine the origin. Local public health officials theorized it could have originated from a nearby military base. Cases such as these are noticed locally but not caught by the state surveillance system. Likewise, Ryan White clinics were anecdotally seeing unprecedented increases in newly diagnosed HIV patients whose risk factor was injection drug use well before the state could respond or preempt further infections by offering assistance to local entities. It was years later before any meaningful funding or response materialized, and this was largely from federal channels.

It is imperative to know and understand the capacity of state-level offices to respond to emerging public health crises. When insufficiencies are found, programs can help fill in the gaps. How KIRP can assist the state in data, surveillance, and response is an ongoing conversation. As HRI is more fully

implemented and increases in strength and efficiency, the core team hopes that HRI data can help provide an infrastructure in the state for improved data and surveillance and lead to more reliable estimates. They continue to work toward this goal.

In addition to state-level deficiencies, gaps exist on a community and institutional level. Even when an adequate level of testing and positivity rates is achieved, there are challenges that will be faced by embedded HRI staff and clients alike. HRI will have to provide linkage to care. As is, there are limited options for referring patients to treatment for HIV, HCV, PreP, and substance use. Clients face barriers in accessing services due to limited availability particularly in rural areas, provider shortages and lack of training in existing providers, issues of discrimination, and insufficient cultural competence when working with special populations such as sexual minorities.

Other areas of KIRP are designed to work on many of those issues, including provider education to both increase the quality and number of providers offering treatment for relevant conditions and decrease stigma, unconscious or conscious bias, and assumptions or misunderstandings frequently held regarding various patient populations.

Additionally, taking into account the numerous, adamant concerns of LHD staff and SSP clients regarding law enforcement interference, there are plans to address misconceptions and bias in police agencies. The AIDS Education & Training Center (AETC), another Ryan White and KIRP founded program, plans to launch education for law enforcement in the future. A recent study on barriers

to using new needles in Rural Appalachia found that the most frequently reported barrier was law enforcement. The researchers suggested reframing education, engagement, and advocacy efforts to align goals with the occupational safety of law enforcement in the hope of improving police perception of SSPs.⁴⁹

Something HRI is excited about is the hiring of a retired police officer who understands the importance and necessity of harm reduction services for the SSP in one rural Kentucky county.¹⁶⁶ This individual is helping the core team to better understand the law enforcement perspective, and he has been speaking to his acquaintances still in law enforcement to engage and educate them on harm reduction as well.

3.4.5 Comprehensive Approach

The HRI, having been thoroughly considered, organized, and appropriately laid out, was well situated for implementation. The program addresses all six areas that an adequately comprehensive approach to the opioid crisis should include: leadership; partnership/collaboration, epidemiology/surveillance; education/prevention, treatment/recovery, and harm reduction/overdose prevention.⁸⁶ The Harm Reduction Initiative works in collaboration with the top public health leadership in Kentucky, partners with LHDs and other organizations throughout the state, places high priority on and builds capacity for adequate data collection leading to improved surveillance, focuses on educating and screening individuals for prevention of morbidity, assists and advocates for referrals to treatment and recovery, and emphasizes

harm reduction including supplies provision and information on overdose prevention.

Overall, clarificative, interactive, and monitoring evaluation of the HRI reveal a strongly developed, thoughtfully implemented program that is continuously monitored for quality and improvement. It is poised to provide a needed service with good results and, in fact, is already seeing progress and opportunities for even greater success.

Table 3.4: Clarificative, Interactive, & Monitoring Data Coding		
Open Coding (Initial concepts and categories)	Axial (Refined concepts and categories)	Selective Coding- Core Categories
-Multiple meetings to refine iterations of what HRI should accomplish -How and what to measure to determine success -Determining motivated yet achievable standards	Establishing Goals/ Objectives	Clarificative (Development Process)
-Press conference -Press Releases/news media -Presented HRI at 2019 Harm Reduction Summit -BLOCK HIV/HCV 2019 -AETC Conferences -Personal Contact	Dissemination/ diffusion of program awareness	
-Logic model development: establishing/identifying inputs, outputs, outcomes, assumptions, external factors -LogFrame Matrix completed- activities, output, results, purpose, goal; determining process, progress toward goal	Program Description	
-Did not budget all funding initially; left room for expansion based on needs -HRI is responsive to funding other allowable areas in order to offset cost of syringes or any non-allowable injection supplies	Using flexibility to address funding limitations	Interactive (Early implementation)
-Poor existing data collection tool -Challenge of uniformity for reporting/data collection from different sites with different practices/systems -Funding limitations (RW allowable only)	Limitations	
-Bureaucracy/Red tape leading to delays (contracts) -State leadership changes -Issues with data collection system	Challenges	

<ul style="list-style-type: none"> -Data collection tool revamped -Input from tool users sought before, during, and after improvements -Need to establish reliable baseline data 	Data Collection/Surveillance	
<ul style="list-style-type: none"> -Interviewing SSP clients -Utilization of NASTAD Best Practices Evaluation Tool -Seeks to address problems laid out in Problem Tree Analysis 	Ensuring evidence-based/best practices	
<ul style="list-style-type: none"> -Figuring out structure of employee management: local vs. UK -Regular meetings -Organization: Gantt chart/Kanban system -Reporting requirements for local sites -HRI staff review data on regular basis 	Logistic Concerns	
<ul style="list-style-type: none"> -Team represents diverse and relevant knowledge and experience -Seeks out further information/expertise on topics they believe to be important to program (Invited prof to share research on SSP/PWUD, Spoke to software developer for data collection tool options) -They do not assume they have all the answers, thus refuse to listen to others -Interviews with PWUD at SSPs -Input sought from SSP staff on data collection needs -Feedback is solicited from HRI staff in the field regarding any new policies and procedures. 	Core staff behavior that leads to success	
<ul style="list-style-type: none"> -Organizational chart expansion; many more staff than anticipated needed -Added additional positions to accommodate different educational levels - Flexibility with funding for allowable services in order to offset SSPs' costs for non-allowable items 	Adaptations Made After Review/ Reflection	
<ul style="list-style-type: none"> -Positivity rate will be the testing metric used to ensure high risk individuals are being targeted -SSP staff realized there were many high risk individuals in the community not utilizing SSPs, therefore, mobile units, outreach, and services offered at other CBOs were set up. -Working with Ryan White project officer to get approval to go into jails -Ongoing conversations about integrated vs. separate hours for SSP at LHDs 	Ensuring Target Populations are reached	
<ul style="list-style-type: none"> -Bureaucracy/Red tape leading to delays (contracts) -Completely novel program- developing everything from the ground up -Hiring "surprisingly" complicated -Training roll out was challenging; would do differently if could -Balance between standardization and diverse local needs 	Challenges	

<ul style="list-style-type: none"> -Ensure all hired staff are fully trained -Supplies purchased with HRI funds may be used in jails -Assisting with state Ending the HIV Epidemic plan 	Ensuring resources/ needs met	
<ul style="list-style-type: none"> -Initial skepticism of KIRP -Opinions on harm reduction -Bias towards PWUD -Staff passionate about this population/helping others 	LHD/SSP Staff Perceptions	
<ul style="list-style-type: none"> -Interviews with SSP clients revealed information, concerns helpful for improvement of service provision -Drug use, overdose, trauma, infectious disease testing, barriers/challenges 	Target Population Perspectives	
<ul style="list-style-type: none"> -HRI Management is highly responsive to expressed needs -Regular reporting required from HRI SSP staff -Quarterly staff meetings -Encourage HRI staff from different counties to communicate/collaborate with each other (staff meetings, email lists, etc.) -Feedback solicited from HRI staff in the field for new policies and procedures -NASTAD SSP Best Practices Tool -HRI meets all 6 requirements of a comprehensive response 	Ensuring ongoing quality	Monitoring (Ongoing)
<ul style="list-style-type: none"> -Intended and Unintended consequences -State capacity: ability to follow-up/deal with positive cases; data infrastructure -Community/institutional capacity to handle new diagnoses -Accurate impact results -Ongoing conversations about integrated vs. separate hours for SSP at LHDs -Education for law enforcement 	Ongoing/Future Concerns	

4. DISCUSSION

4.1 Findings and Implications

Formative program evaluation provided an efficient framework in which to assess the KIRP Harm Reduction Initiative. Being in its development infancy and, soon after, initial stages of implementation, the program was a prime candidate for this type of evaluation. Furthermore, Grounded Theory principles allowed answers to relevant evaluation questions to arise fully and naturally, as often happens in qualitative research. More contextualized dimensions are uncovered that may have otherwise been overlooked in a traditional, quantitative survey or interview. Evaluation results from the four formative categories, proactive, clarificative, interactive, and monitoring, are presented here.

4.1.1 Proactive

Proactive research seeks to understand or clarify the need for a project. A literature review substantiated the identified needs within the state in regards to infectious disease consequences of drug use. It also helped to lay out the landscape of causes and effects in order to better understand what the state is up against and how best to address the issues. This was illustrated in Problem and Solution Trees. Stakeholder Analysis assessed those involved and connected to the program.

The rates of HIV, HCV, and complications secondary to drug use (sepsis, abscesses, osteomyelitis, and endocarditis) and high-risk behaviors make Kentucky's population vulnerable to widespread and long-term consequences

that can devastate generations of its residents. There are practices and policies that can mitigate the effects, such as harm reduction principles, along with infectious disease testing and linkage to care. Medication for treatment, cures, and prophylaxis exist to control the spread of disease.

In assessing local needs, health department personnel described the situations within their area and barriers they face. Staff and funding are limited to non-existent for certain programs. They have issues collecting and submitting data to the state due to cumbersome and outdated tools, they do not have access to sufficient surveillance data with which to effectively monitor their public health status, and they have difficulty reaching and providing services for certain populations due to immense barriers faced by those individuals, including incarceration. Local public health staff also often face opposition from law enforcement and governmental officials in their area when trying to provide care and services to PWUD, especially harm reduction services. LHD personnel also expressed fear due to lack of information, training, and capacity to respond to potential outbreaks in their community.

4.1.2 Clarificative

The objective of the clarificative category of formative program evaluation is to make the theory of change that the project is based on clear. Tools such as logic models and LogFrame Matrices lay out the program logic and theory in easy to understand depictions. These tools were developed for the HRI and lay out the inputs, outputs, outcomes, assumptions, and external factors associated

with the program as well as the logical progression from activities through output, results, and purpose, to the end goal.

4.1.3 Interactive

Interactive assessment occurs early in implementation and is used to improve the program's design. Aspects of HRI management, organization, and implementation strategy and practices were analyzed. A vital part of the program rollout was the development and improvement of the data collection tool which is central to activity monitoring and goal evaluation. Additionally, managing the balance between state-wide standardization for quality assurance and local needs and nuances is critical for this innovative and much-needed program. HRI's ability to review and reflect upon circumstances and adapt where necessary was important for effectiveness and relevancy. It became apparent that outreach work would be a vital component to access those in most need. Additionally, due to HRI's setup and the fact that it is spread throughout the state, it will be a part of Kentucky's official plan to End the HIV Epidemic. HRI solicited input from SSP clients in order to implement practices that are appropriate for actual needs of consumers and took into account perspectives of HD and SSP staff to address concerns.

4.1.4 Monitoring

Further into implementation, monitoring evaluation is used to ensure that activities are being delivered efficiently and effectively. HRI management utilized

frequent feedback from embedded staff to learn about and address issues. The core team has been shown to be highly responsive to staff needs. They have also leveraged existing strengths of employees while providing opportunities to support areas where improvement is needed. Furthermore, they continually look for ways to keep the program operating at the highest standard possible. They have implemented a national Best Practices Evaluation Tool for all their sites. In addition, HRI management has been looking into and assessing the capacity of the state to provide data surveillance and outbreak response when needed. HRI is in ongoing conversations to support these efforts.

4.1.5 Overall

The methodology and results revealed a program that was necessary, well thought out, carefully deployed, consistently checked for areas of improvement and success, and modified as necessary. Such study of public health programs is fundamental to ensure effectiveness and continued relevance in a time and place where public health programming and funding is scarce and often threatened.

4.1.6 Policy and Management Implications

Investigators argue that research evidence has a potentially significant impact on policy change. They state that advocates should incorporate such evidence into efforts to establish public health programs.¹⁵² Opponents often use (or misuse) data in opposition of certain policies, particularly controversial ones

such as SSPs. However, public health professionals may miss opportunities by not using research to counterbalance erroneous or misleading claims.¹⁵²

We have seen the implications for policies that allow or prohibit syringe exchange and other harm reduction services. Syringe exchange was illegal in Indiana when the Scott County outbreak occurred. It worsened significantly before emergency orders finally allowed SSPs to operate.⁵⁸ We also know after three decades of documented research that SSPs reduce infectious disease transmission, do not increase crime or drug use, and lead to less syringe litter in the community.¹³³

State and local infectious disease testing policies play a crucial role when it comes to detecting and mitigating outbreaks. Funding and data collection are pivotal factors in these policies. Proper and adequate surveillance must be in place to ensure that disease clusters do not turn into the next epidemic.

Management practices of harm reduction programs lead to either efficacy or failure, which shapes the public perception of these programs. This perception will determine the support or opposition for the continuance of such programs or expansion of services. With fierce competition for scarce public health dollars, assumptions of efficacy are not sufficient,¹⁶⁷ and success must be shown through evaluation.

4.1.7 Utilization-Focused Evaluation

The target of good evaluation should be effective utilization.¹⁶⁸ The results of this study are intended to be used by the HRI management staff to continue

improvement activities and strive for the highest-quality and most relevant programming possible. This report and all findings will be shared with the core KIRP staff. The evaluator will be available for any questions or clarification the staff may need.

4.2 Limitations

For this project, several strategies sometimes employed in qualitative analysis were not feasible including peer collaboration in data collection and coding. Video or audio recording was not possible, therefore meetings and interviews were not transcribed verbatim, and coding was done manually. Though detailed field notes were taken, it is possible that some items were missed during meetings. Furthermore, with more time and manpower to make it feasible, in-depth interviewing of additional HRI team members may have added to the research.

4.3 Recommendations

This section of the report provides recommendations for the program, based on the information collected and analyzed. Some represent intense, long-term commitments; others are far simpler and less time-involved. These recommendations are not ordered by priority or feasibility. They are largely designed to evoke a broader conversation among stakeholders to work toward achieving KIRP's highest potential. The recommendations are grouped by:

General Programmatic Issues, Service Expansion, Local Needs Assessment, Client Input, and Education/Advocacy.

4.3.1 General Programmatic Issues

Based on the real and critical needs identified, and the established capability of this program to address them, HRI should remain in operation and expand to other areas of the state. Existing funds should continue to be used for this endeavor, as they are, to date, plentiful and versatile enough to allow the program to be effective. One caveat is that it may be beneficial to supplement with some additional non-Ryan White funding to address gaps that arise due to non-allowable services (needles/syringes, HCV testing incentives).

HRI core staff should continue their management style of seeking out further expertise and knowledge when presented with new situations as it ensures any gaps in understanding are filled and that the staff become and remain as competent as possible. This will ensure they stay up to date on current or evolving trends and they are able to make the most informed decisions possible.

In the absence of real-time surveillance data in the state, management and embedded staff should continue to foster their consistent and instantaneous internal communication about happenings in their local areas as a way of forming a real-time alert system for important events, such as potential outbreaks, mass overdose, which may indicate contaminated product in the area, or other sentinel events.

Part of KIRP's mission is to eliminate HIV infections in the state, and in terms of goal setting, a general statement of an anticipated decline of HIV and Hepatitis C rates within five years has been put forth. A discussion on whether to set specific targets for the rate declines may need to occur. This will likely be predicated on the ability to establish an adequate data and surveillance infrastructure which can produce accurate baseline figures. A practical and functional action would be to align goals with national strategies such as those from the Ending the HIV Epidemic and National Viral Hepatitis Action Plan.

4.3.2 Service Expansion

LHD staff acknowledged that there are high-risk populations who do not access SSPs. HRI should continue to build capacity for expanding services beyond SSPs to reach individuals with barriers that prevent them from physically coming to these programs.

The lack of services or access to jails was a highly voiced concern given the sheer numbers of county residents that cycle in and out of detention centers on a regular basis. This is a high-risk population and an easy point of access given they are a "captive audience". Infectious disease testing, linkage to care, treatment initiation, MAT, PreP, and vaccinations are services that could and should be offered in county detention centers.

4.3.3 Local Needs Assessment

Identifying local needs was essential in determining what relevant services should be offered by HRI. It is important that the program continue to assess local needs as they change over time, particularly if previously identified needs are being effectively addressed. Periodic local needs assessments should be built into program operations.

4.3.4 Consumer Input

Service provision should be informed by those who use the services. HRI should seek regular input from clients on the quality and value of services offered. Staff should continue to follow-up and check in with SSP/HRP clients to evaluate their drug use status, practices, routes of consumption, and type of substances consumed in order to keep the existing services and activities as relevant as possible.

Furthermore, beyond inquiring about drug use behavior, staff should ask about challenges clients face accessing SSPs, getting tested, and engaging in care. Find out what the barriers are when clients or those they know are not able to use SSPs. Then, look for ways to address the issues. This will require accumulating knowledge of not just local medical referral locations but social service agencies as well. SSP clients have indicated housing instability, employment, and transportation are major issues they face. This will affect their ability to get tested, linked to care, and engage in treatment options. HRI needs

to be positioned to take into account these structural vulnerabilities in order to adequately achieve their objectives.

4.3.5 Education/Advocacy

Embedded HRI staff should advocate within their local communities to ensure that SSP best practices can be implemented; including needs based exchange for needles and syringes instead of one-for-one. This will also allow secondary exchanging to be possible, thereby indirectly accessing individuals who do not physically come to the SSP. Furthermore, embedded HRI staff should continue to identify and advocate for SSPs/HRPs in areas where they are needed but still lacking.

Discussions with some LHD staff prior to HRI embedding staff revealed that some local employees espoused negative and stigmatizing views towards PWUD and harm reduction practices. In addition to hiring the right staff, HRI should ensure adequate training on anti-stigma topics including client-centered and recovery-positive language, to help reduce an unintentionally stigmatizing or unconsciously biased environment.

Since it was such a heavily voiced local concern, HRI should continue to seek ways to address law enforcement interference in SSP operations. Progress has been made with the hiring of former law enforcement personnel. KIRP plans to implement an AETC educational series for law enforcement should go forward. Staff should seek further ways to engage local law enforcement.

HRI should continue to collaborate with the state and other entities toward an adequate and robust data and surveillance system, as this is imperative to be able to identify and respond to public health concerns.

A last, more aspirational recommendation will likely involve state-level authorization and will depend upon the national climate at the time. HRI can be helpful in advocating for and promoting supervised injection facilities. Lessons learned from embracing and encouraging SSPs can be applied to the current debate over these sites. Supervised injection facilities, also called overdose prevention sites, harm reduction sites, safe injection facilities, or safe consumption sites, are secure and hygienic spaces where individuals can bring and inject their substances under medical supervision.¹⁶⁹⁻¹⁷¹ Among advocates, the preferred name is often overdose prevention site (OPS) as it draws attention to the primary reason for the facilities (to reduce overdose mortality), and it is less stigmatizing.¹⁷¹

Although common in Canada, Australia, and Europe, there has not been a sanctioned site opened in the United States. Organizations in several states (California, Colorado, Washington, Oregon, New York, Missouri, Wisconsin, Maine, Vermont, Massachusetts, and Maryland) have considered, attempted, or come close to opening one only to be blocked by threatened or actual legal action.¹⁷⁰⁻¹⁷² At the end of 2019, a federal judge ruled that a Philadelphia organization's plans to go ahead with an OPS was not against the law.¹⁷² The organization is based in the neighborhood with the highest overdose mortality in the city with highest overdose mortality among all large cities in the U.S.¹⁷¹ A

peer-reviewed and published research study found that 90% of neighborhood residents and more than 60% of local business owners were in favor of the site opening.¹⁷¹

The American Medical Association and other health organizations are in favor of OPS.¹⁷⁰ Recently released research on an unnamed, unsanctioned site in the U.S. shows no overdose deaths from more than 10,000 injection events.¹⁷³ Studies of sites elsewhere in the world illustrate their efficacy in the prevention of overdose, infectious disease, and mortality.^{169,170,174} They have been shown to reduce the incidence of public injecting and subsequent syringe litter in the community.¹⁷⁰ Like SSPs, these sites also increase the likelihood that clients seek and enter addiction treatment and help them access needed health and social services.^{170,173}

Despite the myriad of research studies touting the social and health benefits of such facilities, morality opinions and misconceptions keep laws and regulations in place that discourage the opening of these facilities.¹⁷⁰ Sooner rather than later society should embrace evidence-based practices that save lives and give individuals suffering from addiction the opportunity to overcome or cope with major obstacles they face. We know that the causes of such afflictions are deep and multifaceted, and while we find ways to address those, we need measures to keep people alive, safe, and able to take advantage of second chances.

4.4 Conclusions

COVID-19 with its sudden, massive, and unprecedented effects has upset all areas of life, and public health capacity in particular has been shocked and overwhelmed. Many personnel and vast resources have been redirected to fight the most pressing health concerns at hand. People who inject drugs are particularly vulnerable to other outbreaks because of a myriad of risk factors including comorbidities, homelessness and housing instability, and stigmatization, among others.¹⁷⁵ Testing for infectious disease has decreased.¹⁷⁶ For those working in harm reduction and infectious disease prevention, there are fears that recent progress made could be entirely wiped out.¹⁷⁶ On the other hand, this pandemic experience may teach us lessons applicable to various areas of public health. Real-time data and surveillance that is useful for near immediate decision-making and mitigation efforts has been one of the hallmarks of COVID-19 monitoring. “Within a few weeks from the time the first cases were diagnosed in Wuhan, China, anyone with an Internet connection could monitor the spread and effects of COVID-19. More importantly, elected leaders, scientists, and health care workers can see these data and use them to inform their responses and their choices of interventions in real time.”¹⁷⁷ Additionally, this pandemic could lead to more robust disease investigation and contact tracing work for other infectious diseases, as novel methods have emerged in many countries.¹⁷⁸⁻¹⁸⁰ This unprecedented occurrence will impact HRI operations and may affect its ability to achieve its goals. Conversely, necessity may force further creative modification to meet challenges head on. Perhaps the major

lesson learned is that program flexibility and adaptation are more important than ever.

Kentucky is a predominantly white state¹⁸¹ and the opioid and injection drug use crisis is often characterized as an issue largely affecting white populations. However, communities of color have been disproportionately affected in a variety of ways.^{182,183} Communities of color are overrepresented in rates and complications of HIV¹⁸⁴ and viral hepatitis.¹⁸⁵ The public health inequities among communities of color and lack of attention to the issue have long been concerning, particularly considering intersectional stigma and discrimination,^{76,186-189} as well as structural vulnerabilities.^{190,191} Kentucky does not have an insignificant population of people of color, and that proportion is not decreasing.¹⁸¹ During the course of meetings and interviews, discussion regarding communities of color did not occur. The fact that it did not come up in conversation may or may not indicate an oversight. However, it is necessary to purposefully ensure that these populations are not being overlooked. These considerations are important for outreach, staff hiring, and service provision, particularly in light of historic mistrust of medical and other institutions among communities of color.¹⁹²⁻¹⁹⁷

Research as well as SSP client interviews that HRI conducted reveal the extent that the drug use crisis is an epidemic of despair.^{161,198-200} In interviews and conversation, Kentucky SSP clients regularly stated that they used drugs to self-medicate for emotional pain and trauma. Additionally, many stated that there is nothing else for them to do, citing local areas that are so economically and

socially depressed.¹⁶¹ There is a great need for larger scale, systemic changes which must address the underlying determinants of health: the economy, poverty, childhood experiences, and social and environmental injustice, all of which foment and feed into causes of the epidemic.²⁰⁰⁻²⁰²

In the meantime, public health systems are actively working to do what they can to mitigate symptoms of the drug use epidemic while simultaneously attempting the daunting task of tackling larger solutions to underlying causes. While it is good and necessary that funding is being allocated towards the deadly and costly consequences of existing addiction, a major shift in national policy and perspective is needed to prevent addiction altogether. Actions required include legislation strengthening social safety net systems, early childhood education, youth programming, and criminal justice reform, as well as deep-rooted and far-reaching interventions to address growing wealth inequality.^{201,203-206} Until this radical shift happens, harm reduction is saving lives and giving people the possibility of a future.

The KIRP Harm Reduction Initiative was conceived out of a need for Kentucky to address the crises of drug use and infectious disease, and it was necessary to evaluate this program in order to ascertain whether the resources are being used appropriately and most effectively. The purpose of this study was to conduct qualitative formative evaluation research on the Harm Reduction Initiative with the aim to identify the need for the program, clarify the program, inform implementation, and improve the program where necessary. The success or failure of the program has serious implications for the future health and

economic status of Kentucky. Therefore, we must assess whether this program operates at the highest standards, quality, and relevancy.

As discussed, the Harm Reduction Initiative identified actual, pressing needs within the state, and importantly, within local jurisdictions and created an adequate framework to carry out appropriate local-level activities to address those needs. Additionally, this evaluation has presented recommendations that are opportunities to further improve a well-structured program. In program management, flexibility, adaptation, and growth are important. In order to remain effective and relevant, services must be restructured when necessary to address real and current issues affecting individuals at any given time. In this regard, the Harm Reduction Initiative is as prepared as can be, as it has shown itself capable of the flexibility and adaptation necessary to continue vital services for communities in Kentucky.

APPENDIX A: KIRP One-Page Information Handout

Ryan White HIV/AIDS Program Part B Kentucky AIDS Drug Assistance (KADAP) Income Reinvestment Program (KIRP) 																						
<p>Vision: Enhance the health, safety, and wellbeing of all people in the Commonwealth of Kentucky by addressing high-risk behaviors, providing comprehensive education, and expanding state of the art medical care for persons living with HIV.</p> <p>The Mission of the KIRP is to eliminate new HIV infections in the state of Kentucky by:</p> <ul style="list-style-type: none"> • Providing comprehensive education and screening services to those at highest risk for HIV infection • Linking identified persons living with HIV (PLWH) into high-quality state of the art medical care and improving access to supportive services to ensure HIV positive persons enjoy health and wellbeing • Educating current health care providers and students in training to address the substance abuse disorders and the mental health issues that hinder the provision of effective HIV and Hepatitis C medical care 																						
Objectives																						
Harm Reduction Initiative (HRI) 	Inter Professional Health Education Collaborative (IPHEC)	Prevention Care and Treatment Program (PCTP)																				
Strategies																						
<p>Embed Risk Reduction screening and education in collaboration with Harm Reduction Programs (HRP) throughout the Commonwealth of Kentucky.</p> <p>The Harm Reduction Team Leaders and Risk Reduction Specialists will distribute prevention supplies and education materials to at-risk persons visiting HRPs and provide warm hand off and distribute contact information to programs providing services for HIV and Hepatitis C medical care, as well as mental health and substance abuse counseling.</p>	<p>Component 1 - Section II b(i): Collaborate with Kentucky's AIDS Education and Training Center (AETC) and Project ECHO (Extension for Community Healthcare Outcomes) to expand Comprehensive HIV, Hepatitis C, Substance Abuse, and Mental Health Education for Health Care Providers serving the Commonwealth of Kentucky.</p> <p>Component 2 - Section II b(ii): Integrate Inter-Professional Education (IPE) programs in the multidisciplinary care programs (medical, nursing, social work, dental) at the University of Kentucky, University of Louisville, University of Pikeville, Morehead State University, Northern Kentucky University, and Western Kentucky University and to include strategies to address HIV, Hepatitis C, Substance Abuse, and Mental Health issues prevalent throughout the state.</p>	<p>Invest KIRP funds into Existing Ryan White funded agencies to enhance the HIV Care Program's ability to address co-occurring Hepatitis B and C, as well as substance abuse and mental health issues impacting health outcomes and HIV transmission risks. Funds will be distributed based on regional HIV prevalence.</p> <table border="1"> <thead> <tr> <th>Site</th> <th>% Living w/ HIV</th> </tr> </thead> <tbody> <tr> <td>Heartland Care</td> <td>5%</td> </tr> <tr> <td>Matthew 25</td> <td>10%</td> </tr> <tr> <td>U of L - 550</td> <td>47%</td> </tr> <tr> <td>Lake Cumberland</td> <td>4%</td> </tr> <tr> <td>Kentucky River</td> <td>1%</td> </tr> <tr> <td>Northern KY</td> <td>9%</td> </tr> <tr> <td>UK - HCC</td> <td>24%</td> </tr> <tr> <td>Graves County</td> <td><1%</td> </tr> <tr> <td>Todd County</td> <td><1%</td> </tr> </tbody> </table>	Site	% Living w/ HIV	Heartland Care	5%	Matthew 25	10%	U of L - 550	47%	Lake Cumberland	4%	Kentucky River	1%	Northern KY	9%	UK - HCC	24%	Graves County	<1%	Todd County	<1%
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Action Plan																						
<ul style="list-style-type: none"> • Hire a Medical Director, an HRI Strategist, and a Clinical Consultant working under the direction of the Commissioner of Health for the Kentucky Department of Public Health to provide oversight of the HRI • Hire a Program Manager and 4+ Harm Reduction Team Leads to oversee the integration of Risk Reduction Services into the HRM and provide oversight of 21+ Risk Reduction Specialists (RRS) • Hire 21+ RRS to provide screening, comprehensive education, and linkage to care through the HRP for persons at highest risk for contracting and transmitting HIV and Hepatitis C • Distribute prevention supplies and education materials to at-risk persons visiting HRPs • Provide warm hand off and distribute contact information to programs providing services for HIV and Hepatitis C medical care, as well as mental health and substance abuse counseling 	<p>Component 1</p> <ul style="list-style-type: none"> • Offer regularly scheduled education sessions across multiple disciplines (medical, nursing, social work, dental) addressing HIV, Hepatitis C, Substance Abuse Treatment, and Mental Health Issues • Offer 2-3 Annual Statewide Conferences specific to the needs of medical providers, nurses, and social workers in addressing HIV, Hepatitis C, Substance Abuse Treatment, and Mental Health Issues • Provide a continuous learning system via specialist mentoring via an ECHO like model of education and care management for HIV, Hepatitis C, Substance Abuse Treatment, and PrEP <p>Component 2</p> <ul style="list-style-type: none"> • Hire one Program Manager and two program coordinators to expand the IPE program to students attending programs throughout Kentucky universities. • Identify expert faculty at each institution to mentor students enrolled in medical, nursing, social work, and dental colleges/programs • Provide annual IPE curriculum to train medical, nursing, social work, and dental students in the Commonwealth to address HIV, Hepatitis C, Substance Abuse, and Mental Health Issues 	<p>Collaborate with Ryan White HIV/AIDS Program (RWHP) Part B, C, D, and F funded agencies through the Commonwealth to:</p> <ul style="list-style-type: none"> • Address needs identified by each program based on the barriers of the specific patient populations served • Integrate mental health, Hepatitis C and substance abuse services into existing HIV services to address high-risk behaviors 																				
<p>Innovative Pilot Programs: The KIRP will invest funds in Pilot Programs to fund innovative projects throughout the state to uniquely address access to care and supportive services for PLWH and those at highest risk.</p>																						
<p>Administration: Project Oversight and Fiscal Integrity will be managed by 1 Project Director, 1 Fiscal Director, a UK Health Care Contract Director and 2 Contract Managers. The KIRP will also hire a Director of Evaluation and Outcomes and a Data Analyst in collaboration with the Kentucky Injury Prevention and Research Center (KIPRC) to provide data collection, analysis, continuous quality management, as well as and program evaluation and reporting to the Health Resource Services Administration (HRSA) and the Kentucky DPH.</p>																						

APPENDIX B: Ryan White Allowable Services

Kentucky AIDS Drug Assistance (KADAP) Income Reinvestment Program (KIRP) Harm Reduction Initiative - Allowable Services

United States Department of Health and Human Services (HHS) & Health Resources Services Administration (HRSA)

Through the Kentucky AIDS Drug Assistance Program (KADAP) Income Reinvestment Program (KIRP) the University of Kentucky and Kentucky Department of Public Health propose to embed Risk Reduction Screening and Education in collaboration with Harm Reduction Programs (HRP) throughout the Commonwealth of Kentucky.

The KIRP proposes to:

- Hire a Medical Director, a Harm Reduction Strategist, and a Clinical Coordinator, working under the direction of the Commissioner of the Kentucky Department of Public Health, to provide oversight and promote the initiatives of the HRI.
- Hire A Program Manager and four (4) Harm Reduction Team Leaders to oversee the integration of risk reduction services into harm reduction programs throughout the Commonwealth of Kentucky and to provide oversight of 21 Risk Reduction Specialists (RRS)
- Hire twenty-one (21) RRS that will be embedded into harm reduction programs through the state to provide screening, comprehensive education, and linkage to care for persons at highest risk for contracting and transmitting HIV and Hepatitis C.

The RRS will distribute prevention supplies and education materials to at-risk persons visiting HRPs and provide a warm hand off and/or distribute contact information to programs providing services for HIV and Hepatitis C medical care, as well as mental health and substance abuse counseling. The KIRP is funded by program income generated by the Ryan White HIV/AIDS Program (RWHAP) Part B KADAP program. As such the KIRP is subject to the legislative and programmatic guidelines of the RWHAP. This document combines guidance from multiple resources to define the allowable services for the KIRP HRI program. All excerpts are in italics for emphasis.

HRSA/HHS Guidance

In 2016 the HIV/AIDS Bureau of the Health Resources and Services Administrative released (updated in October 2018) Policy Clarification Notice 16-02 (also referred to as PCN 16-02) which defines all allowable Ryan White Services. (Ryan White HIV/AIDS Program Services: Eligible Individuals & Allowable Uses of Funds – Policy Clarification Notice https://hab.hrsa.gov/sites/default/files/hab/program-grants-management/ServiceCategoryPCN_16-02Final.pdf). This document defines three service categories (Early Intervention Services, Outreach services, and Health Education and Risk Reduction) which can be provided to persons who are at high risk for contracting/transmitting HIV/AIDS. These service categories will serve as the guiding service categories for the HRI. Excerpts below:

“Early Intervention Services (EIS) (page 10)

Description: The RWHAP legislation defines EIS for Parts A, B, and C. See § 2651(e) of the Public Health Service Act.

Program Guidance: *The elements of EIS often overlap with other service category descriptions; however, EIS is the combination of such services rather than a stand-alone service. HRSA RWHAP Part recipients should be aware of programmatic expectations that stipulate the allocation of funds into specific service categories.*

- *HRSA RWHAP Parts A and B EIS services must include the following four components:*
 - *Targeted HIV testing to help the unaware learn of their HIV status and receive referral to HIV care and treatment services if found to be living with HIV*
 - *Recipients must coordinate these testing services with other HIV prevention and testing programs to avoid duplication of efforts*
 - *HIV testing paid for by EIS cannot supplant testing efforts paid for by other sources*
 - *Referral services to improve HIV care and treatment services at key points of entry*
 - *Access and linkage to HIV care and treatment services such as HIV Outpatient/Ambulatory Health Services, Medical Case Management, and Substance Abuse Care*
 - *Outreach Services and Health Education/Risk Reduction related to HIV diagnosis*

- *HRSA RWHAP Part C EIS services must include the following four components:*
 - *Counseling individuals with respect to HIV*
 - *High risk targeted HIV testing (confirmation and diagnosis of the extent of immune deficiency)*
 - *Recipients must coordinate these testing services under HRSA RWHAP Part C EIS with other HIV prevention and testing programs to avoid duplication of efforts*
 - *The HIV testing services supported by HRSA RWHAP Part C EIS funds cannot supplant testing efforts covered by other sources*
 - *Referral and linkage to care of PLWH to Outpatient/Ambulatory Health Services, Medical Case Management, Substance Abuse Care, and other services as part of a comprehensive care system including a system for tracking and monitoring referrals*
 - *Other clinical and diagnostic services related to HIV diagnosis”*

“Outreach Services (page 22)

Description:

The Outreach Services category has as its principal purpose identifying PLWH who either do not know their HIV status, or who know their status but are not currently in care. As such, Outreach Services provide the following activities: 1) identification of people who do not know their HIV status and/or 2) linkage or re-engagement of PLWH who know their status into HRSA RWHAP services, including provision of information about health care coverage options.

Because Outreach Services are often provided to people who do not know their HIV status, some activities within this service category will likely reach people who are HIV negative. When these activities identify someone living with HIV, eligible clients should be linked to HRSA RWHAP services.

Outreach Services must:

- 1) *use data to target populations and places that have a high probability of reaching PLWH who*
 - a. *have never been tested and are undiagnosed*
 - b. *have been tested, diagnosed as HIV positive, but have not received their test results,*
or

- c. *have been tested, know their HIV positive status, but are not in medical care;*
- 2) *be conducted at times and in places where there is a high probability that PLWH will be identified; and*
- 3) *be delivered in coordination with local and state HIV prevention outreach programs to avoid duplication of effort.*

Outreach Services may be provided through community and public awareness activities (e.g., posters, flyers, billboards, social media, TV or radio announcements) that meet the requirements above and include explicit and clear links to and information about available HRSA RWHAP services. Ultimately, HIV-negative people may receive Outreach Services and should be referred to risk reduction activities. When these activities identify someone living with HIV, eligible clients should be linked to HRSA RWHAP services.

Program Guidance:

Outreach Services provided to an individual or in small group settings cannot be delivered anonymously, as some information is needed to facilitate any necessary follow-up and care. Outreach Services must not include outreach activities that exclusively promote HIV prevention education. Recipients and subrecipients may use Outreach Services funds for HIV testing when HRSA RWHAP resources are available and where the testing would not supplant other existing funding.

Outreach Services, as described here, replaces PCN 12-01.

“Health Education/Risk Reduction (page 18)

Description: Health Education/Risk Reduction is the provision of education to clients living with HIV about HIV transmission and how to reduce the risk of HIV transmission. It includes sharing information about medical and psychosocial support services and counseling with clients to improve their health status.

Topics covered may include:

- *Education on risk reduction strategies to reduce transmission such as preexposure prophylaxis (PrEP) for clients’ partners and treatment as prevention*
- *Education on health care coverage options (e.g., qualified health plans through the Marketplace, Medicaid coverage, Medicare coverage)*
- *Health literacy*
- *Treatment adherence education*

Program Guidance: Health Education/Risk Reduction services cannot be delivered anonymously. See also Early Intervention Services”

Ryan White Guidance on Pre-Exposure Prophylaxis (PrEP) and Needle Exchange

PrEP – What is allowed?

In the 2017 Ryan White Part C Notice of Funding Opportunity (NOFO) the guidance states that PrEP and NPEP are generally unallowable expenditures:

“In addition to the general funding restrictions included in Section 4.1.iv of the [SF-424 Application Guide](#), funds under this announcement may not be used for the following purposes...

- *PrEP or nPEP medications or medical services.*

As outlined in the June 22, 2016 RWHAP and PrEP program letter, the RWHAP legislation provides grant funds to be used for the care and treatment of PLWH, thus prohibiting the use of RWHAP funds for PrEP medications or related medical services, such as physician visits and laboratory costs. However, RWHAP Part C recipients and subrecipients may provide prevention counseling and information, which should be part of a comprehensive PrEP program."

The letter referenced above states that RWHAP funds can be used to support PrEP and nPEP services specifically citing Health Education and Risk Reduction Counseling and Target HIV Testing (as detailed in PCN 16-02). An excerpt of this letter is below; this letter can be found at: https://hab.hrsa.gov/sites/default/files/hab/Global/prepletter062216_0.pdf

"The RWHAP legislation provides grant funds to be used for care and treatment of people diagnosed with HIV, thus prohibiting the use of RWHAP funds for PrEP medications and the related medical services such as physician visits and laboratory costs. The RWHAP legislation does, however, allow RWHAP recipients and providers to provide services such as risk reduction counseling and targeted testing which should be part of a comprehensive PrEP program. We encourage RWHAP recipients and providers to reference HAB guidance and discuss allowable uses of RWHAP funds and any applicable limitation with their Project Officers."

Federal Funds Could be Used For:
Risk Reduction Counseling
Targeted Testing"

Needle Exchange – What is allowed?

In the 2017 Ryan White Part C Notice of Funding Opportunity (NOFO) the guidance also states that the purchase of sterile needles and syringes is not allowed:

"In addition to the general funding restrictions included in Section 4.1.iv of the SF-424 Application Guide, funds under this announcement may not be used for the following purposes ...

- *Purchase of sterile needles or syringes for the purposes of hypodermic injection of any illegal drug.*
Some aspects of Syringe Services Programs are allowable with HRSA's prior approval and in compliance with HHS and HRSA policy (see: <https://www.aids.gov/federal-resources/policies/syringe-services-programs/>)"

As referenced in the NOFO, HRSA has provided specific guidance as it relates to the needle exchange programs. An excerpt of related information is below, the letter can be found at: <https://www.hiv.gov/sites/default/files/hhs-ssp-hrsa-guidance.pdf>

"Federal funds may not be used to purchase sterile needles or syringes for the purpose of injecting illegal drugs. However, federal funds may be used to support various components of SSPs as

outlined in the *Department of Health and Human Services Implementation Guidance to Support Certain Components of Syringe Services Programs, 2016* (see <https://www.aids.gov/pdf/hhs-ssp-guidance.pdf>).

The following conditions must be met when federal funds are used for SSP.

- 1. The applicable state, local, territorial, or tribal health department must determine, in consultation with the Centers for Disease Control and Prevention (CDC), that the jurisdiction in which federal funds will be used for SSP is experiencing or is at risk of experiencing a significant increase in hepatitis or HIV infections due to injection drug use.*
- 2. SSPs must adhere to federal, state and local laws, regulations, and other requirements related to such programs or services.*

Process for HRSA recipients to use HRSA funding to support SSPs: *HRSA recipients must obtain prior approval for use of HRSA funding to support SSPs.*

Required documentation:

In accordance with Department of Health and Human Services Implementation Guidance to Support Certain Components of Syringe Services Programs, 2016, HRSA recipients that wish to use new or existing HRSA funds for SSPs are required to obtain the following documents:

- the CDC notification to the applicable state, local, territorial, or tribal health department that the evidence submitted by the health department is sufficient to demonstrate that the jurisdiction is experiencing, or is at risk for, a significant increase in hepatitis infections or an HIV outbreak due to injection drug use; and*
- a certification in the form of a letter signed by the Health Officer from the state, local, territorial, or tribal health department that such program is operating in accordance with applicable law.*

Approval process

HRSA recipients must contact the corresponding HRSA project officer or contract officer, as applicable for the grant, cooperative agreement, or contract, to discuss their interest in using HRSA funds for SSPs. Requests to use HRSA funds for SSPs will require electronic submission of the required documentation described above. Recipients that wish to reallocate existing HRSA funding to support SSPs must follow standard procedures established for the awarded grant, cooperative agreement, or contract. Following submission of required documentation and HRSA approval, as applicable, funds may be reallocated starting in Fiscal Year (FY) 2016, and may continue in future FYs unless otherwise indicated. The HRSA project officer or contract officer will instruct the HRSA recipient of any additional requirements to implement use of HRSA funds for SSPs under the grant, cooperative agreement, or contract.

Future Plans

Beginning in FY 2017 and thereafter, HRSA FOAs will identify whether the programs funded under the FOA or contract will permit support of SSPs, including criteria for eligibility and any budgetary or programmatic requirements."

In this letter the HHS Guidance on Syringe Exchange Program is referenced. An excerpt of allowable federally funded services is below, the full document can be found at:

<https://www.hiv.gov/sites/default/files/hhs-ssp-guidance.pdf>

"Funds may be used to support various components of SSPs⁴ including, but not necessarily limited to, the following:

- Personnel (e.g., program staff, as well as staff for planning, monitoring, evaluation, and quality assurance);*
- Supplies, exclusive of needles/syringes and devices solely used in the preparation of substances for illicit drug injection, e.g., cookers;*
- Testing kits for HCV and HIV;*
- Syringe disposal services (e.g., contract or other arrangement for disposal of biohazardous material);*
- Navigation services to ensure linkage to HIV and viral hepatitis prevention, treatment and care services, including antiretroviral therapy for HCV and HIV, PrEP, PEP, prevention of mother to child transmission and partner services; HAV and HBV vaccination, substance use disorder treatment, recovery support services and medical and mental health services;*
- Provision of naloxone to reverse opioid overdoses;*
- Educational materials, including information about safer injection practices, overdose prevention and reversing a opioid overdose with naloxone, HIV and viral hepatitis prevention, treatment and care services, and mental health and substance use disorder treatment including medication-assisted treatment and recovery support services;*
- Condoms to reduce sexual risk of sexual transmission of HIV, viral hepatitis, and other STDs;*
- Communication and outreach activities; and*
- Planning and evaluation activities."*

Based on these documents and guidelines the KIRP will focus on services that fall within the following RWHAP allowable service categories: Early Intervention Services, Outreach Services, and Health Education and Risk Reduction and are identified as allowable in the associated letters and guidance. These identified service categories are centered on identifying persons living with HIV and reconnecting PLWH who know their status by engaging them in ongoing medical care. Through these centralized services the HRI will address impacting co-morbidities and co-occurring conditions such as Hepatitis C, substance abuse, and mental health.

Information as compiled by Jana D. Collins, MS – University of Kentucky

APPENDIX C: HRI Informational Handout

HARM REDUCTION INITIATIVE (HRI)



FUNDING

The Harm Reduction Initiative (HRI) is being supported by income funds generated by the Commonwealth's Ryan White HIV/AIDS Program - Kentucky AIDS Drug Assistance Program (KADAP) through a contract with the University of Kentucky's outpatient pharmacy program. As program income of the federal Ryan White HIV/AIDS Legislative program, these funds must be reinvested back into initiatives and programs that are designed to provide services to low-income individuals living with HIV and/or persons who are at high risk for contracting/transmitting HIV/AIDS through the Commonwealth.

The KADAP Income Reinvestment Program (KIRP) is a collaborative effort, through a Memorandum of Understanding, between the Kentucky Department for Public Health (DPH) and the University of Kentucky (UK) to invest these funds into initiatives that will enhance the health, safety, and wellbeing of all people in the Commonwealth of Kentucky by addressing high-risk behaviors, providing comprehensive education, and expanding state of the art medical care for persons living with HIV.

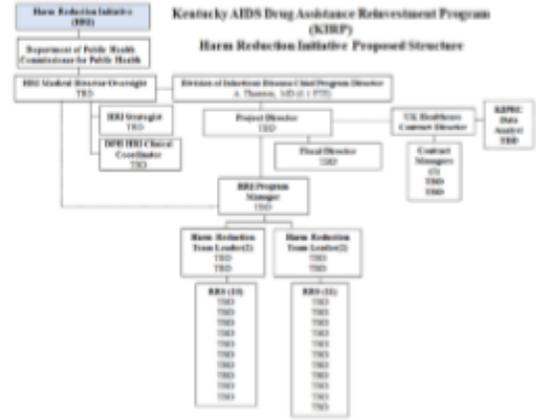
The Mission of the KIRP is to eliminate new HIV infections in the state of Kentucky by:

- Providing comprehensive education and screening services to those at highest risk for HIV infection
- Linking identified HIV-Positive persons into high-quality state of the art medical care and improving access to supportive services to ensure HIV positive persons enjoy health and wellbeing

STRATEGIES

The HRI will consist of:

- A Medical Director, a Harm Reduction Strategist, and a Clinical Coordinator, working under the direction of the Commissioner of DPH, to provide oversight and promote the initiatives of the HRI.
- A Program Manager and four (4) Harm Reduction Team Leaders to oversee the integration of risk reduction services into harm reduction programs throughout the Commonwealth of Kentucky and to provide oversight of 21 Risk Reduction Specialists (RRS)
- Twenty-one (21) RRS that will be embedded into harm reduction programs through the state to provide screening, comprehensive education, and linkage to care for persons at highest risk for contracting and transmitting HIV and Hepatitis C. The RRS will distribute prevention supplies and education materials to at-risk persons visiting HRPs and provide a warm hand off and/or distribute contact information to programs providing services for HIV and Hepatitis C medical care, as well as mental health and substance abuse counseling.



Kentucky AIDS Drug Assistance Reinvestment Program (KIRP)
Harm Reduction Initiative Proposed Structure

ACTION PLAN

- The KIRP will hire and support the salary and benefits of all HRI program staff through UK who will provide training, staff development, supervision, and program oversight.
- While HRI program staff will be fully supported by the DPH/UK collaboration, the KIRP initiative is designed to dually integrate these positions into the established harm reduction programs and to operate as key staff in implementing the missions and goals of the harm reduction programs. The KIRP will work closely with the local health departments to hire candidates that meet the needs of the KIRP program and the existing harm reduction programs.
- The KIRP will fund: office space, travel for the program staff to high risk locations; office supplies (laptop/desktop/printer), prevention supplies (condoms, lubricant, fitpacks sharps boxes, wound care supplies); HIV & Hepatitis C test kits; outreach brochures, posters, and cards; patient education materials; participant incentives (\$10 gift cards); and naloxone.

HRI Job Descriptions & Structure
<p>HRI Medical Director – Dr. Ardis Hoven</p> <ul style="list-style-type: none"> • Provide Oversight of the HRI Initiative; report to the DPH Commissioner the activities of the HRI • Provide expert guidance on harm reduction services and the impact on infectious disease acquisition and transmission • Oversee the integration of HRI initiatives into Harm Reduction Programs throughout the Commonwealth
<p>HRI Strategist – Greg Corby-Lee</p> <ul style="list-style-type: none"> • Serve as a liaison between the HRI/KIRP, DPH, and the syringe access/and harm reduction programs throughout the state • Collaborate with health departments, community based organizations, and AIDS service organizations to integrate health education and harm reduction services into outreach programs for persons impacted by the opioid epidemic and at high risk for being infected or transmitting HIV/Hepatitis C • Facilitate trainings for RRS to ensure they are equipped to address individual and systemic barriers to mental health, substance abuse, behavioral health, and ongoing medical care
<p>DPH HRI Clinical Coordinator – TBD</p> <ul style="list-style-type: none"> • Report to the HRI Medical Director of the Harm Reduction Initiative (KIRP) and collaborate with the HRI Strategist to ensure KIRP-HRI activities expand current harm reduction program activities and do not duplicate current efforts • Ensure and educate the KIRP program and HRI staff of DPH initiatives and activities that impact the KIRP • Facilitate collaboration and communication with all branches in DPH around HRI to assist with the integration of DPH and KIRP activities. Serve as a resource to the KIRP in identifying gaps in prevention and outreach
<p>HRI Program Manager – TBD</p> <ul style="list-style-type: none"> • Collaborate with the KIRP Director, HRI Medical Director, and HRI Strategist to plan and implement the HRI program's strategic plan, goals and objectives, and establish and facilitate program policies, procedures, protocols • Develop HRI quality assurance initiative and monitor the program's progress with identified goals and targets • Serve as a liaison between the HRI program staff and local Health Departments and state/community agencies • Coordinate budget development and monitor expenditures in concert with program goals and objectives. • Prepare reports, narrative, and proposals to federal and state stakeholders • Monitor integrity of collected data collected and ensure the program is meeting HRSA/HAB performance measures. • Recruit, hire, supervise, train, and evaluate assigned personnel including, 4 Harm Reduction Team Leaders (directly) and 21 RRS (indirectly) and coordinates coverage of Health Education and Risk Reduction counseling services • Facilitate monthly full staff meetings and individual consultations; coordinate training and continuing education opportunities • Establish a referral system with community resources with health care and social services providers
<p>Harm Reduction Team Leader – TBD</p> <ul style="list-style-type: none"> • Supervise, train, evaluate and support 4-6 RRSs embedded in harm reduction/needle exchange programs • Serve as the first contact for the RRSs, provide individual consultations to discuss difficult clients/cases • Coordinate coverage of Health Education and Risk Reduction counseling in concert with syringe exchange program hours • Ensure that the RRS attend mandatory continuing education programs and trainings related to interventions and strategies • Maintain appropriate program documentation on unique program services and reporting statistics and regularly evaluate case notes and data entry of RRS, providing additional training on quality as needed. • Assist in data collection/entry into reporting database and in preparing performance reports and narratives • Provide Risk Reduction services described below in the field for 10-12 hours per week.
<p>Risk Reduction Specialist (RRS) – TBD</p> <ul style="list-style-type: none"> • Provide targeted HIV and Hepatitis C testing and counseling to persons presenting for services at the harm reduction (HRP)/syringe exchange (SEP) programs to help the unaware learn of their HIV status • Assess individual risk; refer persons found to be HIV positive to care and treatment services • Provide information about medical and psychosocial support services and counseling to improve the client's health status on educational topics and risk reduction strategies to reduce transmission of HIV, Hepatitis C, and other STIs • Provide information related to preexposure prophylaxis (PrEP) for clients' partners and treatment as prevention • Provide harm reduction and provide counseling to clients to improve their health literacy, increase retention in medical care, and improve treatment adherence to achieve better health outcomes. • Distribute patient education materials (pamphlets and books) as well as risk reduction supplies (sharps containers and condoms) to persons at high risk for contracting or transmitting HIV. • Facilitate support groups as indicated by needs of the population served. Attend and actively participate in mandatory continuing education programs and trainings related to required interventions and strategies. • Coordinate services with CDC prevention specialists and linkage navigators throughout the defined service area and will refer persons found to be positive for HIV or Hepatitis C to medical care and treatment services at key points of entry for Outpatient/Ambulatory Health Services, Medical Case Management, Mental Health and Substance Abuse Services.

APPENDIX D: HRI Position Posting Example

Health Education Coordinator Assoc/UKHC

Posting Details

Posting Details

Job Title	Health Education Coordinator Assoc/UKHC
Requisition Number	RE20525
Working Title	Risk Reduction Specialist Associate
Department Name	H5000: CHANDLER - RETAIL PHARMACY
Work Location	Bracken County
Grade Level	08
Salary Range	\$17.32-27.24/hour
Type of Position	Staff
Position Time Status	Full-Time
Required Education	MS
Click here for more information about equivalencies:	http://www.uky.edu/hr/employment/working-uk/equivalencies
Required Related Experience	1 yr
Required License/Registration /Certification	None
Physical Requirements	This position will require driving between multiple HRI sites over a defined service area in Bracken County, Kentucky.
Shift	Shift is dependent on HRI/SEP program hours, generally Monday – Friday 8:00 am – 4:30 pm (40 hours per week); additional evenings and weekends.
Job Summary	This position will be embedded in a Harm Reduction Program at the Bracken County Health Department and will serve as a Risk Reduction Specialist Associate. This position will provide targeted HIV and Hepatitis C testing and counseling to persons presenting for services at the harm reduction programs to help the unaware learn of their status. This position will refer persons found to be positive for HIV or Hepatitis C to medical care and treatment services at key points of entry for Outpatient/Ambulatory Health Services, Medical Case Management, Mental Health and Substance Abuse Services. This position will provide interventions and educational information to persons at high-risk for contracting or transmitting HIV on how to reduce the risk of HIV transmission and will work with individuals to assess individual risk needs and connecting them to appropriate resources as needed. This position will provide information about medical and psychosocial support services and counseling to improve the participants health status. Educational topics covered to include: risk reduction strategies to reduce transmission including comprehensive HIV, Hepatitis C, and STI prevention counseling, preexposure prophylaxis (PrEP) for clients' partners and treatment as prevention and harm reduction. This position will provide tools to clients to improve their health literacy, increase retention in medical care, and improve treatment adherence to achieve better health outcomes. This position is distribute patient education materials (pamphlets and books) as well as risk reduction supplies (sharps containers and condoms) to persons at high risk for contracting or transmitting HIV. The Risk Reduction Specialists will represent the HRI program within the local health department and assist in collaborations and strategic

	<p>planning.</p> <p>This position is part of the Harm Reduction Initiative and will be funded by the the Kentucky AIDS Drug Assistance Program (KADAP) income Reinvestment Program (KIRP). This position is currently funded through June 30, 2020 and will require travel in a defined service area within the Commonwealth of Kentucky, specifically for the Bracken County Health Department and related Service Area.</p>
Skills / Knowledge / Abilities	The ideal candidate will have extensive knowledge of and experience using Microsoft Windows, including the Office applications Word, Excel, Access, and Outlook.
Does this position have supervisory responsibilities?	No
Preferred Education/Experience	Bachelor's degree in Health Education, Social Work, Social Services or Human Development highly preferred.
Deadline to Apply	10/13/2019
University Community of Inclusion	<p>The University of Kentucky is committed to a diverse and inclusive workforce by ensuring all our students, faculty, and staff work in an environment of openness and acceptance. We strive to foster a community where people of all backgrounds, identities, and perspectives can feel secure and welcome. We also value the well-being of each of our employees and are dedicated to creating a healthy place to work, learn and live. In the interest of maintaining a safe and healthy environment for our students, employees, patients and visitors the University of Kentucky is a Tobacco & Drug Free campus.</p> <p>As an Equal Opportunity Employer, we strongly encourage veterans, individuals with disabilities, women, and all minorities to consider our employment opportunities.</p> <p>Any candidate offered a position may be required to pass pre-employment screenings as mandated by University of Kentucky Human Resources. These screenings may include a national background check and/or drug screen.</p>

Posting Specific Questions

Required fields are indicated with an asterisk (*).

1. * Please describe your experience providing health education counseling.
(Open Ended Question)
2. * Please describe your experience working with persons with a substance abuse disorder.
(Open Ended Question)
3. * Describe an encounter when you assisted a difficult or disgruntled client.
(Open Ended Question)
4. * Please describe any training/certifications you have completed for health education or behavioral modification interventions.
(Open Ended Question)
5. * This position requires driving to various locations in the state of Kentucky. Are you aware of this requirement?
 - Yes
 - No
6. * This position requires working evenings, nights and/or weekends per departmental needs. Are you aware of this requirement?
 - Yes
 - No
7. * University of Kentucky HealthCare seeks to attract, develop and retain highly skilled and competent employees, to provide the best experience for every patient, every time. If selected for a position, do you agree to abide by the UK HealthCare Values of diversity, innovation, respect, compassion, and teamwork?
 - Yes
 - No
8. * University of Kentucky HealthCare recognizes a set of values that guide us in our daily interactions. By applying for a position within UK Healthcare, you are indicating your commitment and expressing your agreement to our five values. These values are diversity, innovation, respect, compassion, and teamwork. Please choose one of the UK Healthcare values and

give a specific example when you exhibited this quality in your professional experience.

(Open Ended Question)

9. * Where did you first see this position advertised other than on UK's online employment system?

- InsideHigherEd.com
- HigherEdJobs.com
- Diverseeducation.com (Diverse Issues in Higher Education)
- HERCjobs.org (Higher Education Recruitment Consortium)
- InsightIntoDiversity.com
- Latinosinhighered.com
- HospitalCareers.com
- Indeed.com
- LinkedIn.com
- Institute for Diversity in Health Management
- A Colleague, Friend and/or Family Member
- None of the Above

Applicant Documents

Required Documents

Optional Documents

1. Resume
2. Cover Letter

APPENDIX E:

Harm Reduction Initiative

Line Item Budget and Budget Justification per Risk Reduction Specialist

Line Item	Total Project Costs
Personnel	
Risk Reduction Specialist – 1.00 FTE	\$ 55,109
Subtotal Personnel	\$ 55,109
Fringe Benefits	
Fringe Benefits	\$ 21,610
Salary & Fringe	\$ 76,719
Travel	
Local Travel for Risk Reduction Counselor to High Risk Locations	\$ 2,834
Subtotal Travel	\$ 2,834
Supplies	
Office Supplies	\$ 100
Color Printers	\$ 900
Desktop/Laptops	\$ 1,400
Prevention Supplies	\$ 10,943
HIV Test Kits	\$ 26,000
Hepatitis C Test Kits	\$ 26,000
Outreach brochures, posters, cards	\$ 6,951
Patient Education - books and Pamphlets	\$ 7,800
Subtotal Supplies	\$ 77,708
Other Non-Personnel	
Participant Incentives	\$ 13,000
Subtotal Other Non-Personnel	\$ 13,000
Occupancy	
Office Space for Risk Reduction Specialist	\$ 8,250
Subtotal Occupancy	\$ 8,250
Total Direct Expenses	\$ 178,511
F&A Rate	\$ 60,694
TOTAL BUDGET	\$ 242,402

Budget Justification Narrative - The Budget Justification reflects the proposed expenditures for the Harm Reduction Initiative and is based on the program, space and supply needs of one Risk Reduction Specialist (RRS) embedded in a Harm Reduction Program. This amount per RRS could be increased based on regional needs. This proposal is based on the assumption that while implementing services in a Harm Reduction Program an RRS will provide an average of 5 encounters per day for a total of 1,300 encounters per year.

Personnel (Less Fringes) **\$55,109**

Risk Reduction Specialist-RRS (1.0 FTE), TBD (\$55,109 x 1.0 FTE) The RRS will provide outreach and deliver risk reduction education and screening for persons at high risk for contracting and transmitting HIV, Hepatitis C, and STDs. This position will provide risk reduction supplies (condoms/lubricant) and patient education materials in coordination with the state sponsored needle exchange program. This position will assist clients in navigating services to ensure linkage to needed services such as: HIV and viral hepatitis prevention, treatment and care services; medical care associated with PrEP and/or post exposure prophylaxis (PEP); Hepatitis A & B vaccinations; substance use disorder treatment; recovery support services and mental health services. This position will collaborate with statewide Linkage Coordinators, Ryan White Part B Medical Case Managers, and Ryan White Part C/D programs to link HIV positive persons into care.

Fringe Benefits	\$21,610
Fringe benefits for retirement, social security, and other fringe for employees at 20.2%, including Social Security (7.65%), retirement (10%), and other benefits (3.6%). Health insurance rates for the university are: \$6,000 employee only; \$9,540 Employee + Spouse; \$7,908 Employee + Children; and \$11,232 employee + family. Current budget is built on employee plus family.	
Travel	\$2,834
Local travel will include travel of the RRS assuming one 100-mile round trip per week to provide off-site testing in a designated high risk area. 100 miles x .0545 cents/mile x 52 trips = \$2,834	
Supplies	\$80,094
<u>Office Supplies (\$100)</u> : Office Supplies are estimated at \$100/person and include: Copier/Printer Toner, Paper, folders, and other miscellaneous office supplies (pens, tape, paper clips, etc.).	
<u>Printer (\$900)</u> – one color printer will be purchased for the Risk Reduction staff.	
<u>Program Desktop/Laptops (\$1,400)</u> - to be used by Risk Reduction Program staff to facilitate data entry to address reporting requirements, and facilitate communication with program and collaborating staff. Specifications: Dell Latitude E6320 12.3 HD Laptop= \$1400 x 1= \$1,400	
<u>Prevention Supplies (\$10,943)</u> – Prevention supplies (condoms and lube) to be distributed during each testing encounter 20 condoms/8 lube per encounter x 1300 encounters.	
Condoms - LifeStyles Assorted 1008/case = \$108/case x 26 cases = \$2,808	
Lube 1800/Case = \$378/case x 8 cases = \$3,024	
FitPacks Sharps Container (100/case) = \$182/case x 13 = \$2,366	
Wound Care Supplies (band-aids, gauze sponges, triple antibiotic ointment, alcohol prep pads, fentanyl test strips) \$183 x 15 = \$2,745	
<u>HIV Test Kits (\$23,614)</u> – HIV testing for persons at high-risk for acquiring HIV, assuming each RRS will test 1300 individuals/year. HIV Test Kits \$500/case – 25 kits/case x 52 cases = \$26,000	
<u>Hepatitis C Test Kits (\$26,000)</u> - Hepatitis C rapid test kits for persons at high-risk for acquiring Hepatitis, assuming each RRS will test 1300 individuals/year. \$2,000/case –100 test kits/case x 13 cases = \$26,000.	
<u>Outreach Supplies (\$6,951)</u> – to be used as a tool to link at-risk persons to the Risk Reduction program. Brochures and contact cards will also be created to connect persons to HIV, Hepatitis C, PrEP Substance Abuse, and Mental health services. <i>Brochures: \$6,300 for 10,000 brochures (color/double sided 0.63/each) Posters: \$251 posters x 100 (color 12x18 - \$2.51/each) Business Cards: \$400 for 10,000 business cards (500 = \$20)</i>	
<u>Patient Education Materials (\$7,800)</u> - funds will be used to purchase pamphlets, brochures, and books (HIV/AIDS, Hepatitis C, Substance Abuse, mental health, PREP and co-morbidities) to be offered to clients during each encounter - \$6/encounter x 1300 encounters	
Other Non-Personal	\$13,000
<u>Patient Incentives (\$13,000)</u> : Funds will be used to provide incentives to persons participating in the Risk Reduction program and presenting for HIV, Hepatitis C, and STD screening and risk education. Incentives are budgeted at \$10/encounter x 1300 encounters.	
Occupancy	\$8,250
<u>Office Space</u> for Risk Reduction Counselor, Data Analyst, and Program Supervisor	
Office space assumes: 150 sq. feet/office x 1 personnel x \$55 /sq. foot/year = \$8,250	
Facilities & Administration (Indirects)	\$61,505
Per our institution's federally negotiated facilities and administrative (F&A) rate agreement, costs at a rate of 34% should be recovered for this project which equals \$61,505.	

APPENDIX G: NASTAD Program Evaluation Tool

Best practice	Not a current practice and not yet in discussions to change	In early discussions to implement this practice or policy	Will make this change imminently	Employ this policy or practice but not consistently	Consistently employ this policy or practice
Needs-based syringe and equipment distribution policy					
Provision of high-quality, non-retractable syringes of a type preferred by participants and in varying sizes					
Safe disposal on-site					
An official secondary syringe exchange program, including training and supervision of secondary exchangers					
Financial compensation for secondary exchangers (i.e. stipend or incentive)					
Naloxone distribution and training freely available to all SSP participants					
A comprehensive, well-enforced bathroom safety policy					
Active consultation with program participants around service design and changing trends in community needs (e.g. through focus groups, interviews, committee membership, surveys, informal conversations) as an iterative means of evaluating program effectiveness					
Program design based on published evidence and/or results of a local needs assessment					
Minimal data collection during each encounter (i.e., only number of people coming in, syringes distributed, naloxone kits distributed, people participant is exchanging for; maybe one or two other things if non-invasive and truly needed)					
No requirement for provision of information or participation in research in exchange for access of sterile injection equipment					
SSP employees include people with lived experience					
Partnerships with community agencies to support community pickup of syringe litter (whether directly by the SSP or through advocacy)					
Protocols to minimize potential harm to participants resulting from interactions between the SSP and law enforcement, ICE, and/or child protective services					
Existing relationship with legal counsel willing to provide aid to the program when needed, either pro bono or via an affordable retainer					
Diverse funding streams that provide some consistency and security for services					

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