

General Information

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Project Title:	Evaluation of a community-pharmacy program for medications to treat and prevent HCV, opioid use disorders, overdose, and HIV among HCV-infected PWID.
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Study Aims and Design

General Context / Purpose: *A general context for the study and the particular contributions of the project*

The opioid epidemic is a major public health crisis in the United States, leading to substantial morbidity and mortality related to the consequences of opioid use disorders and injection drug use, namely hepatitis C virus (HCV), HIV, and overdose. Yet, we are at a unique historical moment, as we possess effective medications that can improve and sustain the lives of people who inject drugs (PWID). Currently there are medications that can be prescribed to 1) cure HCV (directly-acting antivirals or DAAs), 2) prevent HIV infection (Pre-exposure Prophylaxis [PrEP]), and 3) treat/prevent overdose (naloxone and medications to treat OUD). Furthermore, there is an unprecedented opportunity to eliminate HCV, a disease that is transmitted through injecting drugs. However, achieving the goals of elimination will require better systems for allowing PWID access to medications to cure hepatitis C, as well as medications to prevent overdose and HIV. Pharmacists and community-pharmacy programs may be an innovative solution for this problem. Collaborative Drug Therapy Agreements (CDTAs) allow pharmacists to have authority to autonomously perform testing and prescribing and dispensing medications.

Aim(s): *The objective(s) of the analysis*

Aim 1: To conduct qualitative interviews with HCV-infected PWID to inform the development of a community-pharmacy program to expand access to medications to treat and prevent HCV, opioid use disorders, overdose, and HIV.

Aim 2: To pilot and evaluate a community-pharmacy program for medications to treat and prevent HCV, opioid use disorders, overdose, and HIV among HCV-infected PWID.

We will examine the following sub-aims:

1. The number/percent of participants who successfully link to the community pharmacy program and are seen for initial evaluation.

2. The number/percent who initiate medications for HCV.
3. Number/percent who receive other medications (naloxone, PrEP, and MOUD)
4. Baseline and 6-month follow-up substance use in past 30 days via modified Addiction Severity Index (ASI)
5. Baseline and 6-month follow-up the number of injecting episodes using shared needle/syringe within the past 30 days via the modified Risk Behaviors Survey (RBS)
6. Baseline and 6-month follow-up the number of episodes of unprotected vaginal or anal sex within the past 30 days via RBS
7. Self-reported participant Likert scale surveys of satisfaction and willingness to refer an injecting partner to the community pharmacy for treatment
8. The number/percent who complete treatment for HCV, defined as having received all planned medication doses.
9. SVR12 defined as undetectable HCV viral load at least 12-weeks post treatment completion

NOTE: This analysis plan does not include the data on injection network

Inclusion/Exclusion Criteria: *Defines the population to be analyzed. Describe criteria that were part of original data collection and additional criteria needed for this particular project.*

Inclusion criteria:

1. Age ≥ 18 years old
2. Injected any drug within the past 90 days (intravenous or intramuscular)
3. Tested positive for HCV (screening and/or confirmatory viral load) at a community testing site (syringe exchange programs, addiction treatment programs, homeless shelters, urban drop-in shelters and low-income housing sites)
4. HCV treatment naïve and not currently already receiving treatment
5. Willing to undergo evaluation for HCV at a community pharmacy

Exclusion criteria:

1. People who plan to leave the Seattle area within 6 months
2. Do not wish to be treated for their HCV infection
3. Are known to be pregnant
4. Report impending incarceration that would disrupt clinical care
5. Are not comfortable reading and speaking English
6. Report being HIV-positive
7. Report having end-stage renal disease or require dialysis treatments
8. Report prior enrolled in (i.e. completed at least the initial intake appointment) the Kelley-Ross pharmacy program for hepatitis C treatment ("One Step Hep C Free")

Data and Variables Needed for Analysis

Add rows to tables as needed

If a dataset or variable needs to be created / does not exist yet, you can note that here.

Variable Name	Definition	Variable type	Sub-aim #
m6hcvtxpharmd	Since our first visit, were you seen by the pharmacist (refer to them by name) for hepatitis C medications?	Yes/no	1
ehrtxkelleyross, ehrtxkrevaldoc (EHR)	Did this participant seek treatment through the KR community pharmacy program? (defined as presence of initial eval note by Kelley-Ross pharmacist)	Yes/no	1

Variable Name	Definition	Variable type	Sub-aim #
M6hcvpharmdmed	Since our first visit, did you take any medications to treat hepatitis C through the pharmacist (Kathleen)? This can mean that you took only one pill, some of the pills, or all of the pills you were prescribed.	yes/no	2
M6hcvpharmdmedcom pno	If no, why not?	Check all that apply	2
M6hcvothpromed	Since our first visit, did you take any medications to treat hepatitis C through the provider ? This can mean that you took only one pill, some of the pills, or all of the pills you were prescribed.	Yes/no	2
ehrtxinitiate (EHR)	Was treatment initiated? (Defined as meds were prescribed, regardless of showing up to receive)	Yes/no	2
ehrtxwhynotinitiated (EHR)	Why was treatment not initiated? (Response options: ppt determined not appropriate for tx, ppt verbalized not wanting tx, ppt never returned, ppt did not complete workup, other (check all that apply))	categorical	2
M6hcvpharmdmedper cent	On a scale of 0% to 100%, how much of your medication did you take? Where taking every pill would be 100%, taking half the pills would be 50% and not taking any pills would be 0%. If you are still in your hepatitis C treatment course, think about how much of the medications you should have taken to date.	Integer, 0-100	8

M6hcvothpromedcom p	Have you completed your treatment regimen for hepatitis C(normally 8-12 weeks of daily medications)?	Yes/no	8
ehrtxiterrupt; ehrothxiterrupt (EHR)	Does the EHR text mention a treatment interruption?	Yes/no	8
ehrtxiterruptdays, ehrtxiterruptweek; ehrothxiterruptdays, ehrothxiterruptweek (EHR)	If yes, how many days? And at what week did the interruption occur?	Integer, -100, 1-12	8
ehrtxadherence (EHR)	Do the notes document non-adherence?	Yes/no	8
ehrtxdctx (EHR)	Did the provider pre-maturely discontinue treatment?	Yes/no	8
ehrrxreceived (EHR)	Did the participant ever pick-up/receive their medication from the pharmacist?	Yes/no	8
ehrrx1disptime (EHR)	Date of first medication dispensation	Date_mdy	8
ehrrx2actualdisptime (EHR)	Date of actual second medication dispensation	Date_mdy	8
ehrrx3actualdisptime (EHR)	Date of actual third medication dispensation	Date_mdy	8
m6hcvpharmdsrv12	Did you have a blood test to see if you were cured?	Yes/no	9
M6hcvothproccure	Has your provider told you that you are cured of hepatitis C?	Yes/no	9
m6hcvpharmdsrv12res ult	What were the results of that test?	Categorical	9
ehrlabavailable (EHR)	Are there post treatment HCV viral load lab results?	Yes/no	9
ehrlabresultdetect, ehrlabresultdetect2 (EHR)	Result (undetectable, detectable & quantifiable, detectable & unquantifiable)	Categorical	9

Descriptive/Other Variables of Interest (Baseline variables listed, 6-month follow-up variables start with "m6...":

Variable Name	Definition	Variable type	Sub-aim #
age	Age	continuous	NA
race	race	Categorical, nominal	NA

hispanic	Ethnicity/Hispanic/latinx	Yes/no	NA
gendid	Gender identity	Categorical, nominal	NA
Shstay	In the past 90 days, or since [des_neg90daycalc_2], where have you typically spent the night? *read options to participant, check all that apply	Discrete, check all that apply	NA
Shemploy	How would you describe your current employment status?	Categorical, nominal	NA
shinsur	Do you currently have health insurance or health care coverage?	Yes/no	NA
shinsurtype	What kind of health insurance or coverage do you currently have?	Categorical, nominal	NA
txsought	Prior to participating in this study, have you ever sought treatment for hepatitis C?	Yes/no	NA
othrxhivpos	have ever been told that you are HIV-positive?	Yes/no	NA
othrxnalox	Do you currently have Naloxone (i.e. Narcan), a medication to treat an overdose? It can be either on you right now, or at the place where you stay.	Yes/no	3
othrxoudrx	In the past 12 months, since [des_neg1yearcalc], which of these medications have you been prescribed and used as directed?	Categorical, nominal	3
Othrprepuse, or othrxprepnnow	Have you ever used PrEP? Or taking now?	Yes/no	3
*asi...	Variables for ASI substance use and injection drug use	ASI past 30 days Route Number of days	4
hivdayshare	How many times did you use a cooker/cotton/rinse water that had been used by another person who injects in the last 30 days?	Discrete, count between 0-30	5
hivshareafter	How many times did you share your works (needle/syringes) with somebody else after you used it in the last 30 days?	Discrete, count between 0-30	5
Hivinsertvagcond Hivinsertanalcond Hivreceptvagcond hivreceptanalcond	Episodes of sex without condom	Discrete, count between 0-30	6
M6pnexpplan	My navigator and I developed a plan for hepatitis C treatment.	Categorical, ordinal	7
M6pnexpunderstand	My navigator and I understand each other.	Categorical, ordinal	7
M6pnexpchange	We have established a good understanding of the kind of changes that would be good for me.	Categorical, ordinal	7

M6pnexpefficient	I believe the time my navigator and I are spending together is spent efficiently.	Categorical, ordinal	7
M6pnexpaccomp	My navigator understands what I am trying to accomplish.	Categorical, ordinal	7
M6pharmdexp	I had a positive experience with the pharmacist who saw me for hepatitis C.	Categorical, ordinal	7
M6pharmdexprecom	I would recommend the pharmacist to other people I know who inject drugs.	Categorical, ordinal	7
m6pharmdexpquest	The pharmacist addressed the healthcare concerns and questions that I brought up during our visit(s).	Categorical, ordinal	7
m6pharmdexphelp	The pharmacist was able to help me with the services I was seeking.	Categorical, ordinal	7
m6pharmdexpunderstand	The pharmacists were understanding of the difficulties I face trying to access healthcare.	Categorical, ordinal	7
m6pharmdexpwelcome	I felt welcomed in the setting where I saw the pharmacist.	Categorical, ordinal	7

Analytic Plan

Descriptive Analyses

First we will calculate participant demographic and HCV treatment characteristics using their baseline survey data (see Table 1). Then Compare participant opioid use disorder (OUD) and PrEP medications, injection drug use practices, and HIV risk behavior characteristics at baseline and final visit (Table 2). Figure 1 shows a Diagram of participant progress from pre-enrollment to end of treatment. Figures 2 and 3 are stacked bar charts showing the participant responses on pharmacist care and patient navigator satisfaction Likert scale survey questions at the final visit.

Inferential Analyses

McNemar's exact test for matched pairs or t-test to test for associations or difference in means between baseline and final visit (table 2).