

BARRIERS TO HIV AND HCV SCREENING IN THE TRUST
BUPRENORPHINE CLINIC

A Thesis
Submitted to
the Temple University Graduate Board

In Partial Fulfillment
of the Requirements for the Degree
MASTER OF ARTS

by
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May 2021

Thesis Approvals:

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ABSTRACT

As the opioid epidemic continues in Philadelphia, buprenorphine clinics are becoming a necessary mainstay in treatment of these patients. HIV and HCV rates are rising throughout the city due to injection drug use, and buprenorphine clinics could be a bridge to therapy for these conditions as well.

This thesis explores the current data about HIV and HCV rates, their connection to injection drug use, and how these overlapping epidemics might be addressed in a comprehensive manner. Historical data, current trends, and first person reflections from clinicians in the TRUST buprenorphine clinic are used to inform our understanding of barriers to integrated screening and treatment. The thesis concludes with a discussion of a better integrated model of care.

ACKNOWLEDGMENTS

With special thanks to Dr. Nora Jones for mentorship and thesis advising, as well as Drs. Regina Jacob, Sam Stern and Paul Williams for their contributions to this thesis.

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CHAPTER 1: OVERLAPPING EPIDEMICS: WHY DOES IT MATTER?

Human immunodeficiency virus (HIV), Hepatitis C virus (HCV) and opioid use disorder (OUD) may seem like three isolated disease processes. However, due to overlapping social networks and associated patterns of transmission, physicians have begun to realize that these are concurrent disorders that will require collaborative treatment approaches. To quantify the scope of the issue, the National HIV Behavioral Surveillance Survey interviewed 628 people who inject drugs (PWID) in Philadelphia in 2018 and recently published their findings in March 2021. According to this most recent data, 89% inject drugs more than one time per day, with 31% sharing needles. While 72% of those interviewed tested negative for HIV within the past 21 months, 48% of women and 18% of men report exchanging sex for money or drugs, with only 20% of each of those groups reporting consistent condom use, putting them at significantly increased risk for contracting HIV and HCV (Dept of Public Health, 2021)

Importantly, 45% of those surveyed were in Kensington (Dept of Public Health, 2021) Kensington, a neighborhood located northeast of Temple University Hospital, is home to the cleanest and least expensive heroin and fentanyl along the northern seaboard, and thereby attracts not only Philadelphians struggling with substance use disorders, but travelers who find themselves attached to these opiates while passing through the area.

While the rate of HIV acquisition overall has decreased since the inception of syringe exchange programs in 1992, there has been a steady uptick in the rate of rise; between 2016 to 2019, there has been a 151% increase in new HIV diagnoses, from 33 to 83 new cases reported (Higgins et al, 2020). Rates of viral suppression also show

disparities, with persons who use IV drugs who are living with HIV showing a lower percentage of viral suppression among all of those living with HIV (Figure 1).

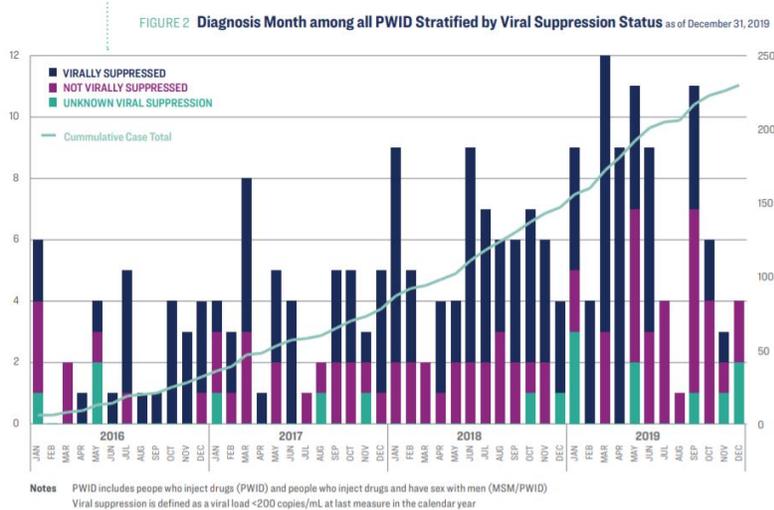


Figure 1: PWID With New HIV Diagnoses, Stratified By Viral Suppression Status. Blue is virally suppressed, pink is not virally suppressed green is unknown viral suppression. (<https://www.phila.gov/media/20201201082316/HIVReport-2019-final.pdf>)

Overdose deaths have skyrocketed in the same time- 1,150 people in Philadelphia died of an unintentional overdose in 2019 alone, with all but 164 deaths attributed to opioid use (Farley, 2020). The healthcare system, along with the city as a whole, continues to grapple with the effects of these concurring epidemics. In light of this, the Temple Recovery Using Scientific Treatments, or TRUST, clinic was established. Located 10 minutes away from the Kensington area, it serves as a clinic providing buprenorphine (hereafter referred to as suboxone) for opioid use disorder with innumerable benefits to patients struggling with OUD. Family physicians, internists and emergency medicine physicians staff this clinic that functions as a hub and spoke model, with the hub located in the family medicine clinic, and spokes including the Temple Internal Medicine Associates primary care clinic and the Begin the Turn mobile

suboxone van. Given the critical role this clinic plays in the health of the local North Philadelphia community, and this patient population's increased risk of contracting HIV and HCV, it seemed like an appropriate and ideal place to initiate screening.

Multiple studies support that integrated, collaborative care for these concurrent epidemics among medical specialists, including primary care, addiction medicine, hepatology, infectious diseases and psychiatry, as well as social workers, case managers and community health workers, is key to maintaining patients within the care model to access the therapies they need (Rich et al, 2018). This thesis explores the ideal goal: to understand the current need for, and barriers to, HIV and HCV screening within Temple's own TRUST clinic, and how consistent screening and appropriate referral to treatment can be achieved to allow for the ideal continuum of care for this patient population.

Understanding The Terminology

The world of addiction medicine has its own language that is important to know to gain a complete understanding of this field. MAT (medication assisted therapy) is an umbrella term that refers to therapeutic modalities such as methadone, buprenorphine (or suboxone) and naltrexone, that allow patients a way to treat their opioid use disorder. These methods do not involve the painful process of detoxification, but instead still partially support the opioid receptor, allowing for an adjustment process for the patient that does not throw the body into acute drug withdrawal. All MAT clinics are not obligated to offer all three medical modalities- some may offer only methadone or only suboxone. Similarly, all medical doctors are not automatically certified to prescribe

methadone or suboxone. While opiates such as oxycodone and hydrocodone can be prescribed with an additional DEA license, a separate certification requiring eight hours of training is needed to be able to prescribe buprenorphine, which poses an additional, sometimes unforeseen, barrier to patient care.

As the opioid epidemic has progressively affected larger swaths of the country, health care providers have also recognized the role that stigmatizing language, such as “addict”, “user/abuser” or “junkie” can play on their interactions with patients, both among clinicians, and within the doctor-patient relationship (Biancarelli et al, 2019). To actively differentiate between ‘a diseased person’ and ‘a person carrying the diagnosis’, a new term Persons Who Inject Drugs (PWID) has become a more acceptable and empathetic term that forces the clinician to make that distinction in spoken and written language.

Within MAT clinics, urine drug screens (UDS) are used in an effort to maintain adherence to the methadone or suboxone being prescribed, and to test for other drug use simultaneously. Many clinics have a formal or informal cutoff, such that if you are found with non-MAT substances in your urine more than two or three times, you are discharged from their clinic. However, the more clinicians have come to understand about the nature of opioid use disorder, its triggers, the high rate of relapse, and the lack of added benefit by abruptly discontinuing MAT, the more they are reconsidering how they use the UDS in practice.

Current Understanding and Literature: HCV and HIV

HCV

Approximately 4 million Americans are currently or previously infected by HCV, with nearly 2.4 million with current chronic infection as of 2016 (Cournos, 2020). As of 2009, HCV was the number one cause of end stage liver disease in the United States, mainly because more than half of infected patients are unaware they are infected, (Norton et al, 2017; Cournos, 2020) leading to development of cirrhosis or hepatocellular carcinoma, both of which are the primary causes of need for liver transplant in the US today (Perlman et al, 2015).

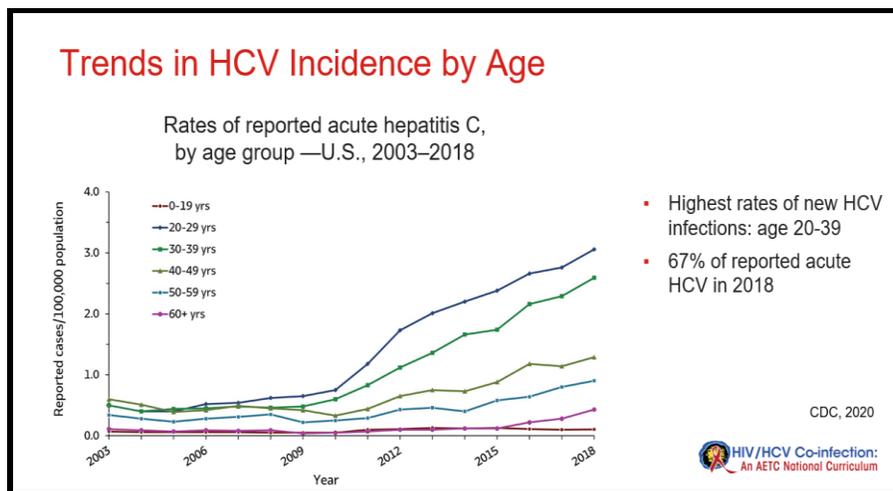


Figure 2: Trends in HCV Incidence by Age (<https://aidsetc.org/hivhcv/1/hiv-hcv-epidemiology>)

Incidence of HCV increased three-fold between the years of 2010-2015 (Figure 2), mainly due to injection drug use (Rich et al, 2018), with those ages 20 to 39 years driving the higher incidence of new HCV by 2018 (Cournos, 2020). These national numbers corroborate with Philadelphia’s numbers by 2019 as well (Dept of Public Health, 2021). By 2011, HCV-related deaths outnumbered HIV-related deaths, and the

mortality was projected to continue to climb. While older patients who were exposed to blood products before 1987, transplants before 1992, or current hemodialysis are likely candidates for HCV exposure, PWID are at higher risk of contracting HCV due to their riskier behaviors and HCV's ability to more efficiently transmit via non-sterile needle or syringe sharing behaviors compared to HIV (Cournos, 2020; Perlman et al, 2015). A 2018 national CDC survey found that 72% of new HCV cases were caused by IV drug use, and of the 54% who tested positive, 74% had active infection (Cournos, 2020) with 43-48% of PWID having HCV at some point in their lifetimes (Perlman et al, 2015). The second highest mode of transmission at 16% is sexual transmission via multiple partners, with particularly high rates of transmission in men who have sex with men (MSM) with HIV (Cournos, 2020). However, they are notably the least likely to be able to receive care for it; one study found that around 2007, <10% of PWID who presented to subspecialty clinics initiated antiviral therapy for HCV (Grebely et al, 2007). This statistic persists despite the fact that the newer direct-acting antiviral (DAA) therapies are combination oral medications with limited side effects and nearly no contraindications, but with exorbitant pricing that changes state to state and insurance to insurance, further emphasizing the multifactorial disparity of health care delivery in this population. Despite the possibility of using treatment as prevention, scaling this to a public health model has proven to be extremely challenging not only within the country, but internationally as well (Perlman et al, 2015).

Given these significant gaps in care, Norton et al (2017) examined the ability of a suboxone clinic in Bronx, NY to provide HCV treatment to completion for their patients. The Bronx population is comparable to the North Philadelphia population, given that

greater than 30% of the population lives under the federal poverty line, making the study particularly salient to this clinical question. In their retrospective cohort study, they asked whether or not maintenance in the suboxone clinic improved their adherence and completion of HCV care. Within their federally-qualified health center (FQHC), a clinical pharmacist would complete the intake of the patient and assign him or her to one of thirteen suboxone-prescribing physicians. They then retrospectively tracked whether the patients who received buprenorphine received HCV screening and treatment through a hepatology clinic located 5 miles away. The outcome of interest was whether or not patients were able to keep up with their suboxone care for greater than or equal to 6 months between January 2009 to January 2014.

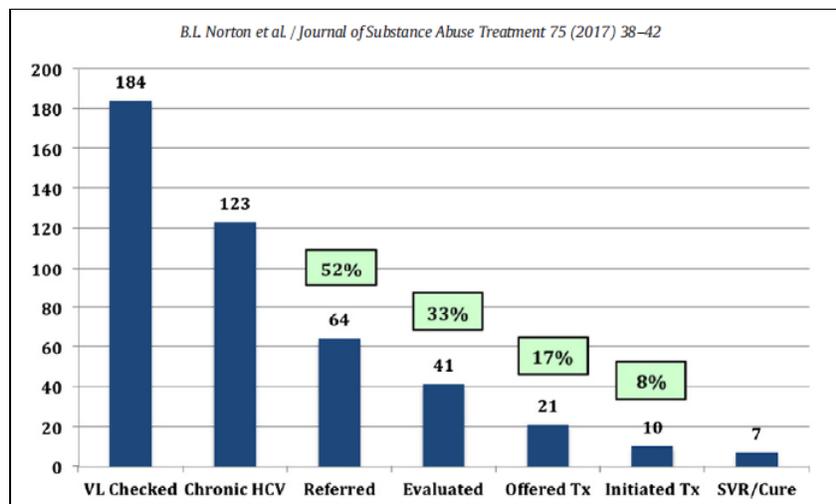


Figure 3: Dropoff Along HCV Care Continuum During Each Stage Of The Process ([https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5856469/#:~:text=The%20only%20patient%20characteristic%20associated,specific%20evaluation%20\(40.8%25%20vs.\)](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5856469/#:~:text=The%20only%20patient%20characteristic%20associated,specific%20evaluation%20(40.8%25%20vs.)))

Of the 390 patients who received suboxone, 93% were screened for HCV, and 53% tested for positive antibodies. Of those who screened positive, 96% had positive viral load testing consistent with chronic Hepatitis C infection. Of this group, 52% were

referred to Hepatology, 33% had an HCV evaluation, 8% initiated HCV therapy (10 patients), of whom 7 patients completed therapy to cure. This significant dropoff rate between screening and treatment is noted in other studies as well, which note that these incremental losses to follow-up at every step along the way, as seen in Figure 3, further contribute to the continued transmission of HCV (Perlman et al, 2015). The key, statistically significant patient characteristic associated with completion of HCV therapy was retention in suboxone therapy. This has been corroborated in other studies as well, which show that maintenance in a substance use disorder program is advantageous to completing therapy for HIV and HCV, independent of decreased substance use (Bini et al, 2011). Moreover, there is evidence that using treatment as prevention of spread of disease could work- if even 60% of patients were able to reach sustained virologic response (SVR), it would significantly drop the chronic prevalence of HCV in PWID, and thereby, transmission (Martin et al, 2015). While 62% of patients were retained in suboxone therapy, only half of those patients screened were offered HCV referral. This speaks to other barriers to care- is this due to the logistics of the hepatology clinic, or the need for multidisciplinary approaches to the issue, since 63% of the patient population is also dealing with concurrent mental health disorders?

Another meta-analysis looking into HCV seroconversion in PWID evaluated 28 studies to determine which type of clinical setting led to the best outcomes. The statistically and clinically significant changes only resulted from the clinics that offered both opioid replacement therapy as well as intensive HCV prevention programs. Opioid replacement programs or syringe exchange programs alone did not have the same rates of HCV seroconversion as the combined clinic, showing yet again that an integrated

approach to preventative care seems to be the most successful one for both individual patients and the public health model of decreasing transmission. In developed countries, the ability to integrate these services has also led to a greater time between starting to use IV drugs and acquiring HCV (Hagan et al, 2011).

HIV

While there are about 40,000 new cases of HIV per year and overall rates of HIV transmission and infection have decreased by about 7-8% in women, the rate of white PWID with new HIV infection rose by 51% between 2014 and 2018 (Cournos, 2020). Overall, the highest rates of transmission are still among black or Latinx MSM, likely because these two communities also overlap in their drug use and sexual behaviors and networks. HIV and HCV co-infection among PWID is between 50-90% (Rich et al, 2018) and between 60-80% in those living with HIV who use IV drugs (Cournos, 2020), since both can be transmitted by sharing needles, and access to safe syringe exchange sites might be limited or shrouded in the fear of stumbling upon the law enforcement system (Perlman et al, 2015). Just as in HCV, there is a distinct dropoff between linkage to care and retention in care from 81% to 43% (Higgins et al, 2020). As of 2017, about 1.2 million Americans were living with HIV, while 3.5 million lived with chronic HCV. 25% of those who live with HIV are co-infected with HCV, but this number increases drastically once IV drug use is taken into account- approximately 80% of patients who have HIV and inject drugs are coinfecting with HCV. This co-infection increases the mortality rate due to liver-related death for HIV patients by three times the average patient. Between 2012-2013, a randomized controlled trial was completed to test

acceptance of co-testing for HIV and HCV compared to testing for HIV alone in a population of 438 patients at the Jacobi Medical Center in Bronx, NY (Cowan et al, 2018). This study found that the rate of rejection of the HIV test did not change significantly based on the addition of the HCV test, which contributed to the practice of screening for both in the emergency department as a tool for identifying those who are at risk, especially since those with unstable housing are less likely to have a primary care doctor but could still benefit from screening in the ED (Cowan et al, 2018). However, early screening and treatment can act as a model for prevention of transmission. Due to relatively more expedited mortality risk of HIV compared to HCV, treatment of HIV is given precedence over HCV. Contrary to common belief, complete eradication of HIV within the population is not required to prevent transmission either. In an area with HIV prevalence of less than 5%, it was found that 10-20% of PWID still shared needles. By decreasing the seroprevalence, the risk of transmission dropped drastically, given sharing of needles tends to happen within the same stable social networks (Perlman et al, 2015).

Integrated Models of Care

As of 2016, 10-20% of heroin users had escalated to intravenous drug use, which has exacerbated all three epidemics of opioid use, HIV and HCV concurrently. Integrated care models are considered the ideal because they offer a multi-pronged approach to an otherwise cyclical problem. By treating the opioid use disorder with methadone or suboxone, the patient is less likely to contract HIV or HCV by seeking out IV drugs or associated needle sharing. Similarly, by treating the HIV or HCV, patients could prevent the transmission of HIV or HCV even if the other behaviors were to continue. By

addressing both sides of the issue, the models of treatment and prevention can be achieved.

The nexus of HIV, HCV, mental illness and substance use is considered a “syndemic” -conditions that not only co-exist, but feed into one another, creating a cyclical problem. As Reece et al (2014) note, from the perspective of HIV, simultaneous substance use has been linked to increased high risk sexual behavior, which increases viral loads and risk of HCV. Psychiatric comorbidities have also been linked to inability to adhere HAART for HIV, which worsens the cycle yet again (Reece et al, 2014) It has also been well-documented that providers tend to carry a bias that patients who inject drugs will be less likely to follow through with their care and that ongoing substance use will negate any care given. From the patient perspective, fear of being reported to the police or judgment about their continued use inhibits the individual’s ability to engage with care (Reece et al, 2014).

Rich et al (2018) assessed studies that had evaluated five types of treatment locations for such an integrated model of care, including three primary care clinics, six opioid treatment programs (specifically, methadone maintenance programs), five HIV clinics, two transitional clinics, and one community harm reduction program. They found that since patients came with physical complaints, such as abdominal pain, nausea or diarrhea, all of which are associated with withdrawal of opioids, primary care physicians had the opportunity to intervene. They were able to identify these patients as needing MAT and connect them with the right resources. Many had obtained the waiver to prescribe suboxone, and were thereby able to immediately engage their patients in care within their own clinic. The representative clinic among this group was a federally-

qualified health center (FQHC) primary care clinic affiliated with Montefiore Medical Center in Bronx, NY, with a sizable clinical population of about 9,000 patients per year. Their internists and clinical pharmacists worked hand-in-hand on the MAT component. Urine drug screens were only completed based on the doctors' discretion and clinical gestalt of the patient, and importantly, was not used as grounds to ask the patient to leave the practice if it resulted positive. Psychiatrists and HIV providers were housed within the same clinic, such that screening and treatment could be followed up consistently by the same care team. HCV care was also provided by clinicians who were able to care for both HCV and opioid use disorder. Notably, these patients were immediately plugged into the city's already-established Department of Health Hep C Coordinator program, which granted them access to care coordinators to assist with health insurance dilemmas and medication prior authorizations, health literacy and education regarding HCV therapies, and linkage of care between clinicians. The HIV component of this care is also grant-funded by the national Ryan White HIV/AIDS Program.

Results from studying the HIV clinics found that patients who were maintained on suboxone were much more likely to be given HAART for HIV and be maintained on it in the long-term, especially when care coordinators were available to assist with the logistical aspect of a patient's care. The HIV clinics also had psychiatrists and screening and treatment for HCV provided within the same clinic. In the methadone maintenance/opioid treatment programs, they found that patients who were HCV positive were more consistently able to reach sustained virologic response (SVR) than those who were not maintained on MAT. The same conclusion was derived from studies about the transitional clinics and community health programs. Transitional clinics, serving patients

after incarceration, found a sharp increase in untreated HIV and HCV rates. These patients also have disproportionately high rates of overdose deaths within days to weeks of leaving a correctional facility, as the body's tolerance for drugs goes unaccounted for, and the pre-incarceration dose might now lead to an overdose death. The important and recurrent thread through each type of clinic was that the clinics that had the most successful patient outcomes were due to a collaborative approach among the care teams, even if they were not physically located within the same office space (although that was the ideal model).

Important limitations to this study were recognized, which are worthwhile noting because these are inevitably the largest barriers to care. While 70% of primary care physicians agreed that they had an important role to play in medication-assisted therapy for patients struggling with addiction, less than 10% felt comfortable or qualified to prescribe MAT. Secondly, most of these clinics were affiliated with large academic centers, which provided them with financial and subspecialty resources that might not be available at other urban or rural community hospitals. Lastly, understanding the community is crucial in knowing how to serve it, and further study would be required to understand which of these types of clinics would be most amenable to serving the community in a comprehensive manner.

Why can't substance abuse programs, like MAT clinics, seem to consistently provide HIV, HCV and sexually transmitted infection (STI) care in this known high-risk population? Clinical and non-clinical faculty and program administrators from 319 programs across the country registered under the National Drug Abuse Treatment Clinical Trials Network (NIDA CTN) were surveyed between 2003-2005 for a

descriptive study that sought to answer this question. 84% of those asked to complete the survey responded, representing 269 of the 319 eligible programs. 78% were private, non-profit clinics, and 81-87% had outpatient outreach and support or resources. Overall, barriers to being able to deliver services for the three infection groups of HIV, HCV and sexually transmitted infections (STIs) were consistently noted across programs as being lack of funding (primarily), followed by health insurance coverage for both clinic reimbursement and patient benefits, acceptance of screening, and staff training. The single largest barrier identified by both program administrators and 2,100 surveyed clinicians was funding, followed by insurance benefits. More than half of the respondents also felt abstinence-only program funding would be better divested into funding for risk reduction for HIV, HCV and STIs. 98% of respondents felt treatment for these conditions would not distract or detract from their substance use treatment in any way, either on-site or via a linked referral program. Overall, not treating for these conditions was overwhelmingly seen as a ‘missed opportunity’ for significant risk reduction (Bini et al, 2011)

CHAPTER 2: KEY INFORMANT INTERVIEWS

The TRUST clinic is a suboxone clinic staffed by family medicine, emergency medicine, and internal medicine physicians. It is based on a hub-and-spoke model, such that the hub is housed in the family medicine clinic, and the internal medicine clinic and mobile suboxone vans act as spokes to this hub, without necessarily having direct connection to the hub. Despite the high risk nature of the intravenous drug use in this patient population and the rising rates of HIV and HCV in this community, screening for these conditions has not yet been implemented as part of the clinic protocol. I sought to understand the current functional model of the TRUST clinic, how screening might be implemented, and what the barriers to this screening have been thus far. I interviewed three key informants- internal medicine physicians who are now attending physicians in the TRUST clinic- to glean this information and get their insiders' perspective on the suboxone clinic. Drs. K, Dr. L, and Dr. M were interviewed individually over Zoom, and the recordings were manually transcribed. The analysis and summaries of their interviews follows.

All three physicians have been part of the TRUST clinic nearly since its founding three years ago, and all of them were invested in being a part of the suboxone clinic because of their interest in delivering more holistic health care either as outpatient clinicians (Drs. K, L) or general institutional need and seeing scope for ability to help (Dr. M). They recognized that they were seeing the effects of addiction and opioid use disorder in their practices, and wanted to be in a position to better serve this population. All three of them took personal time to complete the X-waiver 8 hour mandated training seminar to be able to become a suboxone prescriber, and one also shadowed a Temple

suboxone provider in clinic to get a better sense of what the clinic would be like. Per Dr. K, being a suboxone provider also provides a sense of “immediate tangible good” in a way that is not always experienced in patients with more chronic diseases like hypertension, diabetes or obesity. In serving these patients, these doctors were able to reconnect with their doctor-patient relationship and see the medications help turn their lives around to be in a more stable and safe place in their social environments and lives.

They estimate that about 70% of patients were able to consistently attend their suboxone appointments in-person. Given the current telehealth model due to the COVID-19 pandemic, most feel they are able to reach 90-100% of their follow up patients. However, significant barriers continue to exist. Patients who walk in may not always have a reliable cell phone number that has paid service, which makes follow-up appointments, whether in-person or over the phone, incredibly difficult to coordinate or attend. The new patient visits are also particularly challenging since many of them are post-hospital discharge follow ups. These are patients who were started on suboxone during their hospital stay, and are being seen in the clinic for continuation of therapy within the first week of suboxone initiation. These patients tend to have the same social barriers as those who walk into the clinic- unstable housing situations, inability to obtain or use a telephone consistently, comorbid psychological issues and strained familial relationships which are amplified by drug use. Return to use is also a common reason why patients are unable to attend their appointments, and all the other social determinants of health increase the propensity of their no-show rate. While telehealth might be a sustainable model for follow up patients who do not have such barriers, all three clinicians agreed that a person’s physical presence allows for a better emotional

connection to be made, which fosters a better understanding of a change in attitude or circumstances in their lives, creating a stronger doctor-patient alliance that can have therapeutic benefits.

All three providers agreed that the suboxone clinic is the right location for HIV and HCV screening. While one felt this could be done during the intake visit, others felt that this could be better addressed at the second or third follow up appointment. Since many patients come to their first appointment already in withdrawal, they might not be in the frame of mind to have a conversation about HIV or HCV screening. Patients tend to be aware that their risk can be high, and in the physicians' experience, can be hesitant to pursue screening because of fear of the result. Moreover, screening may need to happen more than once, given that sexual activity with new partners and transactional sex work increases the risk of transmissible disease in this population.

The flow of the clinic is such that the patients sign in with a dedicated medical assistant (MA), who takes their vitals, collects their urine sample for a standard UDS, takes an initial history and reports their chief complaint as well. Previously, a social worker (SW) would be involved in speaking with the new patients on their first appointment, to discuss issues of housing and food insecurity, adverse childhood event (ACE) scores, and support groups located within the same clinic once a week. Due to COVID, this component with an in-person SW and support groups is currently on hold. After this intake process, they see the physician and leave with their prescription.

Barriers to being able to complete serum screening for HIV and HCV were identified as a series of factors. Due to the hub and spoke model, the TRUST clinic is no longer a singular clinic space in Jones Hall within which different clinicians rotate. The

internal medicine physicians now have half-days dedicated to patients requiring suboxone who are seen within the internal medicine clinic offices. Due to this split in location, there is a sense of not knowing who is specifically in charge to make practice-wide change, not only in relation to screening, but also in vaccinating patients with influenza or Hepatitis A shots. Secondly, there is no protocolized workflow for the MAs- should they draw labs on the initial encounter, is there enough time to do so, or should it be a phlebotomist? It is unclear if patients would be able or willing to go across the street to the main hospital to have these screening labs drawn, since this has not been offered in the past. One clinician (Dr. K) felt patients might not necessarily associate their suboxone provider as also taking care of issues such as HIV or HCV, and therefore might not be as prone to completing these labs. Clinicians' time is also a significant factor, since during an average four hour half-day in clinic, about 15 patients are scheduled. If all of these patients arrive for their appointments, time quickly runs too short to do more than checking on how they are faring with the suboxone, reviewing the results of the urine drug screen, and re-prescribing medication. Notably, new patient appointments are one hour long to allow more time to establish care, quantify their opiate use and the circumstances surrounding it, delve into their mental health and social stability, and prescribe a new medication. Some of these clinicians also discuss tobacco use disorder and cocaine use during these intake visits to try to better understand the scope of the addictive patterns that might need concurrent work.

The role of the urine drug screen was discussed, as it can truly shape the doctor-patient relationship and the propensity that a patient will return to the clinic consistently, which directly connects to the ability to screen them for HIV and HCV. Maintaining

clinic appointments and suboxone use would also hopefully help them avoid using further IV drugs, which would further decrease their likelihood for contracting one of these diseases. All three clinicians felt strongly that the use of the UDS should not be punitive, but an added tool to be able to open an honest dialogue with the patient. They make it clear to their patients that the purpose of the UDS is not to report them to the police, but to help the patient get to a healthier place. They expressed that they anticipate to see drugs result positive in the urine the first few times, and intermittently with relapse. If the urine tests positive for opiates, it opens up a conversation about return to use, triggers, and how to avoid them to try to improve on the journey to better health. Concurrent cocaine use is common, and is once again not judged punitively against the patient being able to receive suboxone. One clinician mentioned that seeing concurrent benzodiazepines in the UDS causes concern, because suboxone and benzodiazepines could be a hazardous and potentially lethal combination. They do look for suboxone in the urine- not seeing its presence is an indicator of possible relapse, and once again opens up a conversation about addiction and its triggers. Consistently not seeing suboxone in the urine becomes a concern of diversion, but the clinical context is always taken into account- is it being given away or sold to others, and if so, why? Has this patient presented with these behaviors in the past, or has something changed in their circumstances that might be either causing them to relapse, or necessitating that they sell the suboxone for money or food? Drs. K and L said it takes quite a bit to choose to dismiss a patient from the clinic, and they can each only remember about 1-2 cases of dismissals in their three years of experience.

The theme of stigma came up multiple times in the interview with Dr. L, and united much of the discussions with the other two doctors. It was noted that stigma works along multiple levels concurrently- there is fear of judgment in seeking help for their substance use from the patient's perspective, and there can be a judgment or bias against the series of life decisions that led to this point in the patient's life from the doctor's perspective, which can undoubtedly interfere with the therapeutic relationship. Lastly, state, federal and health care policies add another layer of stigma by making it exceedingly difficult to get pregnant patients suboxone or allow physicians to be waived to prescribe suboxone. If we can prescribe oxycodone with our DEA license, why do we need a separate waiver to prescribe suboxone, and who stands to gain from that? Moreover, mental health is also a stigmatized issue, and many patients have comorbid psychiatric disease, making it even more difficult to ensure continuity of care both within suboxone and psychiatry clinics. The internal referral system to psychiatry is also not possible, since they do not accept dual-diagnosis patients, further compounding the problem. In an effort to reduce stigma in the next generation of physicians, Dr. M was keen on having learners be a part of the clinic process. Medical students and residents who had a chance to witness the humanity of these patients, who are working hard to change their lives, are less likely to be stigmatized against them or to prematurely judge these patients, and this was seen as a sustainable way to bridge the divide.

But all three clinicians felt this is the part of the job they loved- creating these relationships and reaching out to the community to try to help people is truly what they are all passionate about and makes the job, regardless of the number and scope of barriers, worth it. All of this speaks to the lengths to which physicians are willing to go to

not only engage patients, but maintain them, within the practice to continue to be successful on suboxone. This speaks to its unique ability to foster the type of relationship that can allow for screening and healthier behaviors in the future.

The Ideal Clinic

The question was posed to the key informants: what would you envision your ideal suboxone clinic to be, if funding were no object? One clinician felt that the process of the initial visit itself needed to be reconstructed, such that patients who are initiating suboxone for the first time are able to be a part of an overnight observation unit or urgent care facility. This would allow patients to avoid enduring prolonged withdrawal symptoms while collecting their suboxone prescription for the first time, give physicians a chance to more quickly address increased dosing needs in the first 24 hours, and give clinicians the opportunity to have a longer conversation with the patient about their previous substance use, goals for moving forward, and permission to screen for HIV and HCV.

All three clinicians agreed that the ideal model would include decreasing barriers to physicians ability to care for these patients. While the training for the X waiver is valuable, this same information can be better disseminated in training programs that don't involve a completely separate license to prescribe suboxone. Similarly, two of the clinicians felt this practice should be integrated into primary care entirely- just as internists are able to prescribe antihypertensives and diabetes medications, treatment of opioid use disorder should be integrated into their practice such that it becomes a part of general practice, instead of a separate clinic entirely. This would also allow for a broader

and more longitudinal conversation about comorbid conditions such as HIV and HCV, smoother transitions of care into referral programs via hepatology, infectious diseases, and psychiatry, and internal referral sources for issues of housing and food insecurity. Such a system would allow for continuity of care, with the goal of closing the gap on the dropoff rates of suboxone use, and HIV and HCV care coordination that have been seen across the country in PWID.

Begin the Turn: The Mobile Unit Model

The Begin the Turn mobile suboxone unit was founded approximately one and a half years ago, and Dr. M has been involved with it since its inception. Two street corners, F and Allegheny and Ruth and Somerset, were chosen based on geospatial mapping of the highest rates of overdose deaths in the area to directly care for this population. The van hosts a team of physicians, counselors, and outreach workers who care for patients as they come to the van. There are no structured appointments- people arrive when their medication runs out or if an issue comes up, which is ideal for this primarily unhoused population. A UDS can be completed in the bathroom at the back of the van. Paper charts are used for these visits, while the Pennsylvania Drug Monitoring Program (PDMP) can be accessed over the phone by each clinician. Importantly, grant funding is provided by the Center for Urban Bioethics, which can cover patient's prescriptions, as well as the overhead expenses of the van, since each individual visit is not billed as an office visit either. This model does an incredible job serving the population, however, it would be difficult to integrate a screening model for HIV and HCV within this structure. It would require a way to order the studies and have them

drawn on the van with either a nurse or phlebotomist, an associated lab to run the samples, and a clinician to provide counseling for results and next steps to care. It would also require a reliable phone number through which to reach the patient, which is particularly difficult to obtain in the population of patients that primarily use the van as their clinic source, since many of these patients are living in temporary housing, in a shelter, or on the streets. While this might be the target population for intervention, given likely higher rates of infection, high risk behavior and therefore transmissibility, the current focus remains on improving the clinic model to accommodate HIV and HCV screening, since much of the infrastructure to pursue this already exists in that setting.

CHAPTER 3: ETHICS, CONCLUSIONS AND FUTURE DIRECTIONS

To Screen or Not to Screen- the Ethical Outlook

Throughout this exploration of the screening process, it has become clear there are multiple barriers to patients accessing care. This brought up an ethical dilemma- is it better to screen a patient even if they are unable to access treatment due to social barriers, or is it better not to screen, since the treatment outcome might not be achievable in PWID? There are multiple ethical frameworks within which to consider this question. In the consequentialist model, under which utilitarianism falls, it could be argued that the utility of the outcome of treatment to cure for HIV or HCV is either diminished or indeterminate, since the act of screening does not guarantee completion of treatment. Without this guarantee, one could argue that the process of screening is not utilitarian- since it cannot be guaranteed for all, it cannot be seen as an ethical benefit, since it does not maximize its intended outcome.

Deontological, or Kantian, theory takes on a much more narrow approach to any individual's role in moral decision-making. Even in the agency-centered deontological theory, if a person is not overtly intending to or acting in a harmful manner, then blame cannot be rested on that individual or system. However, the entire model is based solely on the morality of the action alone, that the morality inspires a sense of duty within the person taking the action, and requires that the morality of that action be universally applicable in all scenarios. However, deontological theory makes room for intention, with good will being the ultimate moral duty. In this sense, the screening program would follow this paradigm.

This is where urban bioethics takes a unique approach that is more patient-centered. Due to its foundation in contextualization, urban bioethics takes into account the patient's capacity and agency in his or her own care. Systemic changes that are made, via screening or treatment, should therefore center the patient's ability to engage with the system. The important note about this structure is that the outcome does not have to be immediate, such that if the result of the screening test will help at a future time, it is still an avenue for furthering the patient's agency in their own care, and a worthwhile and ethically-sound outcome.

Conclusions and Future Directions

The literature and the key informant interviews both express the importance of an integrated model of care. As we compare our TRUST clinic to some of the studied integrated models of care we find that we have fewer suboxone-providing clinicians (Bronx 1 of 13 physicians, here 1 of 6, not all scheduled at same time), and a less consistent referral system to specialized care. While serum screening studies can be conducted relatively easily by either adding a nurse or phlebotomist to the team or offering lab prescriptions at an established lab, the ability to take action on the results of those screening studies would need to be established from the start- otherwise, the goal of completing the screening test itself is futile.

The studied models had established points of referral within their institutions, such that referrals to hepatology and psychiatry were simple. Within our system, there seem to be issues with both. While hepatology can take patients, they hesitate to start those with substance use disorders on direct antivirals for HCV treatment, although the

national guidelines recommend treatment and data shows no contraindication (AASLD, 2019). However, this is not isolated to our hepatology clinic. 88% of states have substance use as exclusion criteria for therapy, with 50% of those requiring abstinence from use to qualify for therapy, despite the lack of contraindication to initiation of HCV therapy. Studies have also shown that systemic viral response (SVR) rates, the marker of cure in HCV, in PWID are comparable to the general population, disproving the notion that these patients are unable to successfully adhere to care once plugged into the system (Martin et al, 2015)

The psychiatry department is excellent in cognitive behavioral therapy, however they do not accept dual diagnosis patients. Those with substance use disorder and concurrent depression, anxiety, PTSD, bipolar disorder or schizophrenia are therefore automatically disqualified from engaging with this practice, and need to find mental health resources elsewhere in the city. These barriers cause fragmentation of care, which would affect a patient with stable housing and reliable engagement with health care, and unfortunately exacerbates the situation for those whose lives are many times already in relative disarray.

The integrated models were also plugged into well-established city or state-level public health programs, such as Department of Health Care Coordination programs, that allow case workers to follow patients to help establish care at specialists' clinics. Although the TRUST clinic received a generous grant of \$1 million In July 2018 from the state of PA as part of the Pennsylvania Coordinated Medication-Assisted Treatment Program (PAC-MAT), it remains to be seen whether this is adequate to also start and sustain an HIV and HCV screening and referral model in the long-term.

Each component of this process, from the ability to expand suboxone prescriptions to all of primary care, to finding the right moment and funding to provide screening tests and referral to create a continuum of care, increases the agency of the individual patient in their own care. The use of the UDS as a trust and rapport-building model is admirable and should be continued for the same reason. It fosters a sense of security within the healthcare environment, and gives the patient the agency and capacity to engage with their care, which achieves the urban bioethical model of care for this community.

What would we want to ask patients?

Future studies should include patient interviews to gain a more nuanced understanding of how the outpatient medical model can better serve their needs. First, it would be important to establish who they trust most within the practice, because this will allow for an open conversation about every aspect of their care, from relapse and sexual activity, to housing insecurity and associated domestic issues. The next step would be to further explore how social barriers or concurrent mental illness play a role in their ability to engage with their care. While we have seen this from the provider's perspective, it will be equally important to note how the patient experiences this, and what they identify as the most helpful possible intervention. It will also be important to note what their hesitations might be about screening- due to fear of results, treatment, implications for their lives- so these can be addressed during visits, or public health initiatives can be better targeted to address these fears such that more patients are prone to engage with their care.

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