

Program Description of Central Outreach Wellness Center

Improving access to Hepatitis C Diagnosis and Treatment

by

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University of Pittsburgh, 2023

Abstract

Across Western Pennsylvania and much of the world, Hepatitis C continues to contribute to liver disease and related disorders of many persons. Groundbreaking progress has been made in available treatment methods; however, there is still much community work to be done to ensure that diagnosis and treatment intervention are equitably available. In response to this public health problem, many agencies, programs, and organizations are developing programs to engage impacted and at-risk communities in preventing and addressing HCV. One of these organizations located in Pittsburgh, Pennsylvania is the Central Outreach Wellness Center. Central Outreach focuses their work on populations that are affected by many disparities, including access to healthcare, socio-economic burdens, and stigma surrounding harm reduction methods. Many of these disparities are worsened or caused by the negative impacts of Hepatitis C. This paper is an analytical description of the efforts conducted by Central Outreach to mitigate the spread of Hepatitis C across Western Pennsylvania. To reach the World Health Organizations HCV global elimination plan for 2030, innovative methods conducted by Central Outreach and other leaders in HCV care, should be examined, replicated, and improved upon.

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1.0 Hepatitis C Background: Testing, Treatment, and Barriers

The diagnosis and treatment of the Hepatitis C virus (HCV) has advanced significantly since the virus was formally identified in the late 20th century (Pawlotsky et al., 2015). Currently, a simple finger prick test, known as an HCV antibody test, can be used to detect if an individual has been exposed to HCV. This will determine if an individual has ever created antibodies against HCV. Confirmatory Polymerase Chain Reaction blood tests will allow for the detection of the specific Hepatitis C genetic material. This will determine if an HCV is replicating in the individual's body. This streamlined combination of tests, in combination with modern antiviral medications known as Direct Acting Antivirals (DAAs), can cure more than 95% of people infected with Hepatitis C. Despite these advancements, globally there are still more than 60 million individuals living with a chronic Hepatitis C infection (WHO, 2022). The Centers for Disease Control and Prevention (CDC) estimates that in the US 4 in 10 people do not know they are infected with Hepatitis C (CDC, 2020). This is because many individuals who become infected with HCV experience acute infections resulting in minimal or no symptoms (CDC, 2020) and consequently often do not seek care because they are unaware that they are living with HCV. Individuals that do have symptoms can experience yellow skin or eyes, appetite suppression, nausea, vomiting, stomach pain, fever, dark urine, light-colored stool, joint pain, and fatigue (CDC, 2020). Individuals can go many years without having symptoms or feeling sick (CDC, 2020). Unfortunately, when individuals who are chronically infected with HCV begin experiencing symptoms, it is a sign of advanced liver disease, due to progression of HCV infection.

HCV is an enveloped RNA virus belonging to the family Flaviviridae and genus hepacivirus (Li et al., 2015). HCV genomic RNA is single stranded and has a positive polarity. All

this viral genetic information is packaged by a core protein that is enveloped by a lipid bilayer (Li et al., 2015). Along with two glycoproteins embedded in this bilayer, this forms the virion (Li et al., 2015). Variations within nucleotides found within the single strand of RNA, result in different genotypes of HCV (Li et al., 2015). Currently there are 8 different genotypes associated with HCV (Hedskog et al., 2019). Treatment methods will be discussed later in section 1.2.1.

The World Health Organization (WHO) estimates that high-burden regions such as the Eastern Mediterranean Region and European Region have around 12 million individuals currently living with HCV (WHO, 2022). Areas such as the South-East Asia Region and the Western Pacific Region have around 10 million individuals chronically infected. There are around 9 million individuals living with HCV in the African region, and about 5 million individuals living with HCV in the Americas. (WHO, 2022). Methods of transmission can occur by reusing or inadequately sterilizing medical equipment, transfusion of unscreened blood and blood products, or by sharing injection equipment. Less common methods of transmission can occur between mother and fetus and during sexual practices that lead to exposure to blood, like having multiple sexual partners and among men who have sex with men (WHO, 2022).

Within the United States, access to DAA HCV medications has improved but is still a major problem in many regions and communities. While recent US policy changes have improved access, other barriers such as cost of HCV medications and reaching priority populations continue to be significant barriers to diagnosis and treatment for individuals living with HCV (Nephew, 2022). In some states, barriers regarding Medicaid restrictions to treatment still exist. For example, in the state of Arkansas, treatment under Medicaid requires the individual be sober for a period of 6 months or enrolled in a drug rehabilitation program, obtain a fibrosis score of F3 or greater, and meet provider restrictions (State of Medicaid Access, 2023). A patient's fibrosis score is a

measurement of damage done to the liver by HCV (Nephew, 2022). The State of Pennsylvania only requires prior authorization for Hepatitis C Medications covered under Medicaid (State of Medicaid Access, 2023). Information regarding prior authorization and state-by-state coverage will be discussed below in section 1.1.1.

The severity of the substance use and misuse crisis in the United States has resulted in an increase of new cases of Hepatitis C infection particularly among individuals who inject drugs and share syringes. While living with substance use disorder, many individuals also come to be living with an undiagnosed HCV infection. Chronic HCV infection, combined with other limiting social factors, puts this community at a serious disadvantage for accessing treatment and diagnosis. This can result in a continuation of constant infection and reinfection of HCV, allowing it to remain constant within the population. Western Pennsylvania is no exception to this negative feedback loop. The opioid epidemic and the HCV pandemic have been circulating in small towns and major cities across the region for years. Regional hospitals and local organizations have attempted to reduce the rate of HCV transmission through a variety of programs as will be discussed in section 1.2 below.

1.1 Barriers

Although there have been major advancements in treatment options for Hepatitis C infection, globally there are around 58 million individuals living with a chronic Hepatitis C infection, and 1.5 million new infections occurring each year (WHO, 2022). In the United States, new cases of Hepatitis C are four times as high as they were 10 years ago (CDC, 2020). In Allegheny County alone, there are assumed to be over 1,000 expected and confirmed chronic Hep

C infections. It is also important to note that the COVID-19 pandemic disrupted important Hep C services across Allegheny County, resulting in a 40% decrease in reporting of new Hep C cases from 2019 to 2020 (White et al., 2022). Accordingly, the need for better access and a more feasible cascade of care for HCV services is not only needed but has grown in recent years among many individuals living with HCV in this region.

Due to limited symptoms associated with acute Hep C infection, many individuals do not seek care until the chronic stages of HCV infection have already been reached. This provides a clear rationale for routine testing and diagnosis of HCV during all stages of infection, but routine testing and other service delivery may not be feasible for a variety of reasons. For example, many of the individuals experiencing HCV infection are people who inject drugs (PWID) and experience many directly associated social deterrents for accessing care and treatment. These include poverty, insurance access, trust issues, need for childcare, poor transportation access to primary care and specialty treatment centers, and social stigma associated with one or more of these issues. Injection drug users may be involved with the justice system, which can also impair access to healthcare services. Of these commonly experienced barriers, lack of insurance, involvement with the justice system, and the use of injection drugs are issues with significantly high burdens.

1.1.1 Insurance and Costs

While more insurance companies have approved coverage for Hepatitis C treatment. However, some individuals struggle being approved for HCV medications (hcvguidelines.org., 2022). Currently, there are seven different FDA approved medications available for treatment of HCV (Nina Kim, & Spach, 2023). Not all medications are covered by Medicaid costs, but access is improving. A more detailed description of medications, and their Medicaid coverage status can

be found in Table 1. Medicaid is a heterogeneous mixture of insurance plans that receive the lowest price for HCV treatments through pharmaceutical manufacturers (hcvguidelines.org, 2022). This results in a mixture of costs dependent upon the details of the contracts negotiated with the medication manufacturers within that state (hcvguidelines.org, 2022). This means that there will be different uninsured out-of-pocket costs for each state. Because of the complex and often changing pricing associated with these drugs, Table 1 and this paper list medication prices obtained from the medication assistance site www.goodrx.com and the HCV nonprofit organization www.hcvguidelines.org as of April 2023.

It should be noted that not all U.S. states chose to undergo the Medicaid Part D expansion proposed by the Patient Protection and Affordable Care Act (ACA). This means that states who chose not to undergo the expansion have eliminated the benefits outlined above (hcvguidelines.org, 2022). Fortunately, as the price of HCV treatment has decreased over the years, states have loosened their Medicaid treatment restrictions, making treatment more accessible to individuals living with HCV in most states (hcvguidelines.org, 2022). However, in some states prior authorization from an individual insurance company is required to prescribe HCV medication (State of Medicaid Access, 2023). This means that individuals will encounter various levels of HCV medication access dependent upon which state their Medicaid Coverage operates in (State of Medicaid Access, 2023). For the purposes of this paper, where Pennsylvania is the primary focus, it should be noted that PA does require prior authorization before HCV medication can be prescribed (State of Medicaid Access, 2023).

Out-of-pocket costs for Hep C treatment can vary based on the state in which they are prescribed, and the specific medication needed. A more detailed representation of costs is included in Table 1. Due to reduced costs as mentioned above, insurance or out-of-pocket costs are less

problematic for those in need of these medications. For example, on one end of the price spectrum, Gilead offers an HCV medication known as Epclusa, which now retails at \$24,000 per month (Gilead Sciences, 2023). This is a significantly less expensive option than the other end of the spectrum where drugs like Gilead Science's Sovaldi retails for more than \$84,000 (Florko, 2022).

1.1.2 Hepatitis C and Persons Who Inject Drugs

Hepatitis C is one of the most common bloodborne infectious diseases in the United States (CDC, 2023). As noted above, HCV is primarily spread through injection drug use by sharing needles or other equipment that comes into contact with blood (CDC, 2023). Subsequently, PWID have the highest risk of HCV acquisition among all at-risk groups. This finding is noted by Centers for Disease Control and Prevention (CDC) reports, which state that “today most people are infected with HCV by sharing needles or other equipment to inject drugs” (CDC, 2020). If left untreated, which is more likely within this risk group due to the disproportionate experience of the other barriers described above, individuals will develop significant liver damage, including an increased risk of hepatocellular carcinoma (Smith, 2015). If treatment is delayed to the point of advanced fibrosis, an individual's period of infectiousness may be extended up to 30 years. (Smith, 2015). As mentioned previously, individuals that experience symptoms while chronically living with HCV are progressing towards advanced liver disease (CDC, 2020). In the past, PWID were often excluded from DAA trials due to their risk of reinfection (Norton, 2021). Today, the ease in restrictions, and importance in many global plans to eliminate HCV, have resulted in the prioritization of DAAs into treatment plans for individuals who inject drugs (Norton, 2021).

1.1.3 Hepatitis C and Men Who Have Sex With Men

Among other groups of individuals with an increased risk of HCV acquisition is men who have sex with men (MSM) (Tieu et al., 2018). There is a higher risk of acquiring HCV during receptive anal sex, especially during condomless sex, group sex, and sex with ulcerative STIs (Thompson et al., 2022). Within this community, comorbidities such as HIV, can also put an individual at a higher risk of acquiring HCV (Huang et al., 2023). A study conducted by Tieu et al found that MSM may be at a higher risk acquiring HCV especially if they have recently been diagnosed with an STI (Tieu et al., 2018). Due to this risk, it is recommended that MSM with recent history of an STI should be tested for HCV (Tieu et al., 2018). Information regarding STI status, and the risk associated with MSM can be obtained during risk-based screening efforts which will be discussed further in chapter 3.

1.1.4 Hepatitis C and Incarceration

Unfortunately, one of the many barriers that individuals may face while in recovery from substance use disorder are risks associated with incarceration. Activities or circumstances that an individual may experience while in the prison system may put them at a higher risk for Hep C infection as well, and many individuals may have HCV but only become diagnosed when they enter the justice system. Both these instances, however, mean that incarcerated individuals are at a higher risk of having or acquiring HCV than the public (Busschots et al., 2022). Risks in or related to incarceration include tattooing with unsterile equipment, sharing nail clippers, sharing needles, sharing toothbrushes, or sharing anything that could have been in contact with an

individual's blood who has HCV. A 2018 study estimates that PWID is associated with a 62% increase in risk of HCV acquisition during and after incarceration (Stone et al., 2018).

According to the Centers for Disease Control and Prevention, the most common way that individuals become infected with HCV is during injection drug use (CDC, 2023). Unfortunately, accidental use of equipment that contains blood with HCV in it continues to occur. This feedback loop contributes to and perpetuates the overall barriers that individuals who inject drugs *and* those who interact with the justice system experience.

1.2 Hepatitis C in Western PA

A county-level study conducted by Hall et al. in 2021 determined that rates of HCV infection have been increasing in counties across the United States. Counties experiencing an increase in HCV mortality lie within the areas surrounding New Orleans, Texas, Oklahoma, and the Appalachian region (Hall et al., 2021). Allegheny County and much of western Pennsylvania lies within the Appalachian region. From 2005 to 2017, HCV infection rates continued to fluctuate across the US as Direct Acting Antivirals (DAA) became available in 2011. Many counties experienced decreases in HCV mortality rates, while many of the counties located within the regions listed above continued to experience increasing HCV mortality rates. The main driver of HCV in these regions is due to injection drug use (IDU) among people who inject drugs (PWID). Much of the increasing HCV mortality within the Appalachian counties is associated with younger people, less than 40 years old (Hall et al., 2021). These areas and demographics are also known to be experiencing increases in injection drug use because of the ongoing opioid crisis.

Other bloodborne pathogens like HIV are important issues being addressed in many communities across Western PA. Many individuals are living with both HIV and HCV due to the shared transmission vector of injection drug use. This incidence data supports the argument that the opioid crisis has exacerbated HIV/HCV comorbidities within Western PA. A 2023 study conducted by Artenie et al. found that younger PWID are at a higher risk of HIV and HCV acquisition (Artenie et al. 2023). This is echoed by findings from the CDC, which state that HCV rates are rising most dramatically among younger adults aged 20-39 (CDC, 2020). This information only stresses the importance of screening for HIV and HCV in all individuals who are at risk.

1.2.1 Treatment of Hepatitis C

Thankfully, there are programs that exist to help individuals living with HCV. Costs associated with HCV treatment can be covered by the Ryan White AIDS Drug Assistance (RW ADAP) program if they are also living with HIV (HRSA, 2022). This program helps low-income individuals get access to pre-existing public health resources, such as FDA approved medications for HCV (HRSA, 2022). The RW ADAP program aims to specifically help people living with HIV (PLWH) attain medications for HIV treatment *and* a wide range of comorbidities, including HCV.

One of the most common direct acting antiviral drugs prescribed to individuals infected with HCV is glecaprevir/pibrentasvir, also known as Mavyret. This is the first pangenotypic NS3/4A protease inhibitor-NS5A combination medication. This means that Mavyret can work against all 6 genotypes of HCV, but it is important to note that another HCV medication may be prescribed to provide a more effective treatment for a specific genotype. This specific protease inhibitor effectively treats HCV by preventing the cleavage of the HCV polyprotein (Nina Kim, &

Spach, 2023). Individuals who have not experienced HCV treatment before are typically prescribed an 8-week regimen consisting of 56 tablets, each consisting of 100mg of glecaprevir and 40 mg of pibrentasvir. Individuals who have experienced HCV treatment before are typically prescribed an 8 to 16-week regimen consisting of 56 to 112 tablets (Nina Kim, & Spach, 2023).

The development of modern effective DAAs allows for providers and patients to collectively construct a care-plan that incorporates effective modern pharmaceuticals. Adherence to HCV medications is important to ensure that an individual achieves a sustained virologic response, meaning there is no detectable virus. The importance of this concept will be discussed in chapters 4, 5, and 6.

1.2.2 History of Treatment

Individuals older than 40 years typically experience a higher HCV death rate, at 9.77 per 100,000 persons, compared to individuals younger than 40 years, at 0.23 per 100,000 persons (Hall et al., 2021). Many of these individuals were born into the high burden birth cohort (born between 1945 and 1965) and are living undiagnosed with chronic hepatitis C infection. If left untreated, HCV causes progressive liver damage, leading to fibrosis of the liver, in some cases leading to the need for liver transplantation. Contemporary evaluations of effective HCV recommendations conclude that DAA regimens provide better cost effectiveness than liver transplant (hcvguidelines.org, 2022.) Many individuals in this cohort also experienced early iterations of Hepatitis C treatment, which was interferon treatment. This sometimes difficult or unpleasant treatment has resulted in reluctance of some older patients' acceptance of newer medications for Hepatitis C treatment, despite them being more effective and efficient in improving health outcomes and quality of life.

Historically, treatment plans for HCV consist of multiple steps, known as the HCV Care Cascade. This HCV care cascade begins with an individual initially seeking care for HCV symptoms, followed by diagnosis, referral to a specialist, evaluation for liver disease, prescribing treatment, then prevention. (Thomas, 2020). The largest gap in this care cascade is the diagnosis of HCV (Alshuwaykh et al., 2021). Today, this is still the care plan that is used by many healthcare institutions across the US. An article published in 2021 by Alshuwaykh et al states that this prevention and treatment model “evolved from the complexities of prior interferon-based therapies” (Alshuwaykh et al., 2021). As will be discussed in chapter 4, this is one of the many areas where CO operates differently from many other organizations.

Some experts argue that the future of HCV treatment involves the collaboration of multiple healthcare services immediately after diagnosis while also initiating risk-based screening efforts. This implementation approach is more common in countries that have developed a universal healthcare system. For example, as of 2021, Australia has managed to achieve a diagnosis rate of approximately 80%, after implementation of risk-based screening efforts (Alshuwaykh et al., 2021). The recent increase of HCV in younger individuals (18-40) due to the substance use pandemic has resulted in many institutions and even national governments releasing changes in screening recommendations for HCV (Alshuwaykh et al., 2021). For example, as of 2020, the official CDC guidelines for HCV screening include all individuals over the age of 18 at least once in their lifetime, as well as all pregnant people. It is also recommended that all individuals with risk factors be tested periodically while risk factors persist (CDC, 2023). It is imperative that guidelines, care plans, and staffing structure be continuously evaluated to ensure progress is being made to testing, diagnosis, and linkage to HCV treatment.

The ideal HCV care cascade would consist of implementing risk-based prevention and screening efforts within pre-existing public health infrastructure, such as primary care facilities, clinics, and within facilities that practice harm reduction methods. Shortening the number of steps within the HCV care cascade has been one of the issues that organizations are trying to improve. The remainder of this paper will discuss the methods that Central Outreach Wellness Center has taken towards shortening the HCV care cascade among individuals in Western Pennsylvania and Ohio.

2.0 Central Outreach Wellness Center Background

Central Outreach Wellness Center (CO) is an organization dedicated to serving individuals from all backgrounds, specializing in LGBTQIA+ health. CO specializes in the prevention and treatment of sexually transmitted diseases, HIV testing and medications, PrEP services, transgender healthcare, Hepatitis C testing and treatment, mental health services, medical spa services, and medical marijuana services (Central Outreach, 2023). CO has Pennsylvania offices in Pittsburgh, Washington, Aliquippa, and Erie. Ohio locations include Cleveland Heights and Columbus (Central Outreach, 2023). Part of their HCV services include free mobile Hepatitis C testing at methadone, suboxone, pain management clinics, homeless shelters, and private homes throughout Western Pennsylvania and Ohio (Central Outreach, 2023). Lastly, in Pennsylvania and Ohio together CO has over 20 mobile sites that provide free onsite Hepatitis C rapid testing and blood draws for confirmatory testing (Central Outreach, 2023). The end-goal of this traveling clinic service is to eliminate the spread of Hepatitis C in western PA.

Central Outreach is a recipient of Ryan White Part B, Ryan White Emerging Communities, HOPWA, and MAI funding (JHF, 2023). This funding is received through Pennsylvania's Southwest regions fiscal agent, known as the Jewish Healthcare Foundation (JHF, 2023). Central Outreach also receives funding from other sources and structures that are not publicly disclosed.

Dr. Stacy Lane founded The Central Outreach Wellness Center, in 2015. Dr. Lane witnessed the crippling effect that the HIV pandemic had on individuals within her community and her own family (New Pittsburgh Courier, 2016). Dr. Lane has dedicated much of her life to serving individuals diagnosed with HIV/AIDS, those who are struggling with substance use disorder, comprehensive LGBTQIA+ healthcare, and transgender health services. Her compassion

and success in her field was cited as rationale for her receiving the Dignity and Respect Champion Award in 2016 (New Pittsburgh Courier, 2016). This award is granted by the Dignity and Respect Campaign, an organization working with partners throughout the US that is dedicated to “teaching individuals in organizations, communities, schools, and on sports teams to have respectful interactions, to build cultural awareness, and to find common ground with individuals who are different from themselves.” (Dignity & Respect Inc, 2019).

3.0 Current HCV Prevention and Treatment Practices

The ongoing public health HCV crisis has led to the continued transmission and occurrence of this disease despite being curable with new pharmaceutical treatment intervention. The effectiveness and efficiency of Central Outreach Wellness's program has proven that it is possible for program implementation across multiple regions. To assess the feasibility and effectiveness of Central Outreach's Hepatitis C treatment and diagnosis program, a brief review of recent literature regarding Hepatitis C programs was conducted.

The World Health Organization (WHO) has a goal to eradicate HCV as a public health threat by the year 2030. With few countries predicted to reach this target, experts are calling for action to increase access for individuals at risk (Di Marco et al., 2022). The most effective solution would involve wide-scale implementation of an effective HCV vaccine; however, no such strategy has been developed yet (Di Marco et al., 2022). For the time being, modern DAAs are the most effective form of treatment for HCV, and thus must be made more widely accessible (Di Marco et al., 2022).

The current HCV care cascade has evolved from a specialist-driven model resulting in few patients qualifying for treatment (Zuckerman et al., 2018). As a result of this shortcoming, experts now recommend a multidisciplinary approach to HCV care and treatment. An article published in 2018 states that involving a pharmacist care coordinator in contacting HCV+ individuals may help healthcare networks reduce the number of patients that are lost to care (Zuckerman et al., 2018). This pharmacist-led care plan could help individuals by beginning patient-education early, and by staying in contact with the individual throughout the treatment process (Zuckerman et al., 2018).

Risk-based screening efforts and peripheral medical centers should be used to reduce community transmission of HCV (Di Marco et al., 2022). Historically, provider specialists have been one of the only healthcare professionals creating care plans and educating individuals on HCV treatment and prevention (Di Marco et al., 2022). Expanding the allotment of individuals that can prescribe pangenotypic HCV medications and utilizing peripheral healthcare facilities, will improve access of effective treatment and prevention techniques to individuals at risk of, and living with HCV (Di Marco et al., 2022).

DAA's such as Mavyret show cure rates well above 90%) and suggest that to retain this cure rate, "highly motivated and well-informed patients" are required for cure rate success (Hajarizadeh et al., 2016.) Along these lines, it notes how important patient-education services are to overall program success. In addition to educating patients on the importance of adherence, a 2021 article by Alshuwaykh et al. states that the collaboration of multiple healthcare services and the implementation of risk-based screening will be the future of HCV treatment (Alshuwaykh et al., 2021). The article also suggests that point of care testing is imperative but remains a logistical challenge for many organizations. By reducing the number of steps in the cascade of care for an individual living with HCV, and by improving access to point of care testing, the article suggests that diagnosis of HCV could improve (Alshuwaykh et al., 2021). As the next chapter describes, Central Outreach has managed to simplify HCV diagnosis and treatment by offering services to "high-risk" populations, such as PWID and individuals who experience OUD, including in point of care encounters. Central Outreach also offers effective HCV prevention services to PWID. CO offers needle exchange services as well as linkage to care for individuals who may benefit from prescribed suboxone or methadone (Central Outreach, 2023).

4.0 Central Outreach Methods

Central Outreach Wellness Center has decades of experience supporting all communities including those of color, immigrants, transgender males and females, intersex, lesbian, gay, bisexual, down low (MSM), queer & questioning LGBTQIA+. Central Outreach also specializes in HIV/HEP C and Recovery health care and resources (Central Outreach, 2023). The mission of Central Outreach is focused on culturally competent care and committed to understanding what their patient's needs are and how they can be treated holistically.

This section will cover methods and techniques used by Central Outreach Wellness Center's Hepatitis C team. Some of the most effective measures that Central Outreach has taken include the following: funding, effective community outreach, education of safe practices regarding IV drug use, establishing care plans with patients, financial incentives for patients, effective marketing, connection to services, and having an active presence within the community. Of these, community outreach, staffing, and comprehensive healthcare services are Central Outreach's most engaging approaches while attempting to close the gaps within the HCV care cascade.

4.1 Community Outreach

Central Outreach Wellness Center is heavily involved in community outreach. Their presence can be seen at different events all over the Pittsburgh region and other regions where their clinics operate as well. A passionate staff and administrative team hold information booths to

increase the organization's visibility during many of the city-wide celebrations throughout the year (Central Outreach, 2023). For example, during the month of June Pittsburgh and many of the surrounding towns and communities hold pride events. Central Outreach always participates in these events throughout the region and is ready to test on-site any individuals who request testing for HCV, HIV, and other STIs (Central Outreach, 2023). By celebrating with local communities, Central Outreach creates and maintains an effective message and credibility within Pittsburgh and surrounding communities. Central Outreach has also made their STI, HCV, and HIV services completely mobile. By providing point of care testing at convenient locations, as well as celebratory events such as a pride event, Central Outreach's presence is accessible for all individuals within the areas they serve.

Central Outreach Wellness Center has developed a methodology of community engagement that allows for their continued success. The headquarters of Central Outreach Wellness Center is located right in the heart of Pittsburgh's North Shore, just north of downtown. This is a convenient location for clients with easy access by bus/metro, on foot, or by car. Central Outreach Wellness Center can project and maintain their presence in the community with their marketing team, whose focus is to create consistent and ongoing outreach and messaging in print media, social media, and other advertising content (Central Outreach, 2023).

If an individual decides to seek care at the Pittsburgh location of Central Outreach, they will see that the building is decorated by local artists from the queer, OUD, and PWID communities. The art on the walls clearly presents a sex-positive, identity-positive, shame-free environment where individuals can feel welcome to regularly return to seek care. This is a form of outreach as well, as it conveys unmistakably affirming and welcoming messaging and imagery to all who enter or pass by. Similar art and themes are incorporated in numerous ways in all CO

locations throughout their other onsite Pennsylvania locations in Washington, Aliquippa, and Erie, as well as their two Ohio locations in Cleveland Heights and Columbus (Central Outreach, 2023).

4.2 Staffing of Central Outreach Wellness Center

Central Outreach makes sure to include individuals from all backgrounds, race, and sexual orientations within their staff. Their mission involves providing culturally competent care to all the communities and individuals served by their clinics; accordingly, their staffing draws from and represents these communities as well (Central Outreach, 2023). CO prides itself in employing individuals from the LGBTQIA+ community, individuals that have experienced OUD or IDU, individuals that identify as transgender, non-binary, and people of many other backgrounds as well. Central Outreach is heavily staffed by nurse practitioners who are supported by qualified physicians specializing in clinical care (Central Outreach, 2023). Many of the nurse practitioners employed by CO work remotely and take phone calls from mobile clinics. Importantly, this remote work includes the ability to quickly initiate prior authorization for insurance companies. This remote process expedites the HCV care cascade, shortening the period that an individual otherwise may have encountered at a different patient care facility.

The mobile Hepatitis C team that Central Outreach has developed offers free mobile HCV, HIV, and STI testing at harm reduction facilities, suboxone/methadone clinics, pain management clinics, homeless shelters, community events and celebrations (as discussed above) and even private homes upon request (Central Outreach, 2023). This methodology also shortens the length of the HCV care cascade by providing individuals with convenient and quick testing services. If an individual tests positive for HCV or HIV from a rapid test, all personnel are trained medical

assistants able to perform venous blood draws onsite (Central Outreach, 2023). Should a positive confirmatory test occur, patients are then able to create an individualized care plan over the phone with a nurse practitioner.

4.3 Overall Services Provided at Central Outreach

Central Outreach provides more than point-of-care testing and HCV, HIV, and STI testing services. They are a fully operating primary care provider. In addition to primary care, Central Outreach provides a variety of healthcare services including HIV and PrEP services, STI testing, transgender healthcare, hormone therapy, Hepatitis C testing and treatment, mental health services, and medical marijuana services (Central Outreach, 2023). Central Outreach also offers prescription mailing services, such as PREP2ME and HEPCMYWAY (Central Outreach, 2023). Central Outreach also offers harm reduction services, such as suboxone and needle exchange programs (Central Outreach, 2023). These services help connect individuals to care by effectively mailing medications that effectively prevent and treat disease. As noted above, Central Outreach also advertises that they are supportive of individuals most likely to have encountered social or even health system marginalization, including people of color, LGBTQIA+ individuals, and PWID (Central Outreach, 2023). Along with staffing, this step taken by central outreach allows patients to receive care safely and comfortably within an organization that values their sense of belonging.

4.4 Hepatitis C Services

Central Outreach's scope extends past the urban community of Downtown Pittsburgh, offering their mobile Hep C services to individuals across Pennsylvania and into Ohio. The education mobile units provide is focused primarily on bloodborne pathogen transmission such as Hepatitis C and HIV, along with STIs. All employees must administer patient-education services before and after rapid Hep C testing, diagnosis, and treatment. Their presentation begins with simple background information that explains how bloodborne pathogens and STIs are transmitted and acquired. This background information is followed by explaining techniques and recommendations regarding bloodborne pathogen prevention. Examples would include sharing nail clippers, injection equipment, toothbrushes, snorting equipment, razors, personal care products, tattooing with unsterile equipment, and using anything that could potentially have blood with Hepatitis C on it (Central Outreach, 2023). Central Outreach employees give all clients the opportunity to ask any questions they may have regarding transmission of a bloodborne pathogen or their health. While this service does conduct home visits, their primary function is to educate, diagnose, and treat individuals within treatment centers, halfway houses, suboxone/methadone clinics, as well as inpatient correction facilities (Central Outreach, 2023).

As stated previously, once blood draws are conducted nurse practitioners create patient-centered care plans that educate the patient on their infection/disease status and can be conducted over the phone. If medication is required, nurse practitioners begin any prior authorization procedures, and Central Outreach Pharmacies mails prescribed medications to the individual. If a patient cannot undergo a blood draw at that time, a member of the Hep C team can conduct a home visit to collect blood from an individual at their earliest convenience.

This process combines multiple steps of the original HCV care cascade, including the patient's initial engagement in care, diagnosis, confirmatory testing, and referral to a specialist. Central Outreach also offers services that prevent the spread of HCV. Examples include but are not limited to needle exchange services, HCV education, and advertisements to raise awareness for HCV (Central Outreach, 2023). The prescription step of the cascade is also simplified/made more convenient as well, as patients can choose to have their medications shipped directly to their homes. This staffing structure and mobile clinic services have effectively shortened the HCV care cascade to two encounters: the event in which patient is tested and then taking the treatment as prescribed.

Once treatment is completed, an individual must complete follow-up blood work to ensure they no longer have HCV. This is referred to as a Test of Cure (TOC). This TOC must be performed to ensure that an individual is no longer infected with HCV, and that they do not need to take another course of prescribed HCV medication. This TOC is important for a patient's health, Central Outreach and reporting records, and data collection. Unfortunately, many individuals fail to complete a TOC, resulting in a lack of accurate data to determine how many individuals have been cured. This issue will be discussed further in the discussion.

5.0 Discussion

As described above, HCV experts stress the importance of patient education, community engagement, and screening individuals based on risk of HCV infection. For years, Central Outreach has grown in a region dominated by several well-established healthcare networks. A numerical representation of the amount of testing conducted by the organization within nine months can be seen in Figure 2 and Table 2. Central Outreach contributes to this level of success with their community-centered approach. Across Pittsburgh, you can see signs and advertisements pertaining to the high-quality patient-focused care that can be obtained at any of central outreach's facilities, and the chapter above enumerated many ways in which Central Outreach seeks to build and maintain community engagement. By establishing a community based, patient focused approach, Central Outreach has managed to spread their services across Western Pennsylvania and parts of Ohio reaching patients untreated by other networks or healthcare providers.

Education has been a primary step in prevention and elimination of Hepatitis C from Western Pennsylvania since Central Outreach began. Employees of the mobile HCV clinic begin each visit by presenting effective harm-reduction techniques and bloodborne pathogen information, followed by rapid HCV antibody tests. By valuing patient education, Central Outreach has been able to steadily increase the number of individuals tested each year. This trend is borne out in the detailed visualization of their tests conducted and test results over the years in Figure 3.

Figure 3 is a representation of how many individuals were tested for HCV between the years 2017 and 2022. Central Outreach's Hep C team was established in 2017, and data regarding the number of individuals that tested negative or positive were collected since then. Whether or

not an individual knew that they were positive for HCV was also collected. The number of individuals being tested has increased every year, but data regarding an individual's HCV status after completion of prescribed medications is still lacking, as will be discussed in the next chapter.

The effective use of modern DAA's allows for individuals to be cured entirely from their Hepatitis C infection. This once-small organization has been able to take the lead in Hepatitis C treatment in the region; they claim that they are the number one curer of Hepatitis C in the entire country (Central Outreach, 2023). Although the only source of this claim is from Central Outreach itself, further national testing data and research, including confirmation from pharmaceutical companies, would allow this claim to potentially be verified. It is important to note that determination of whether a patient has been cured of HCV is determined by whether the individual has a Sustained Virologic Response (SVR) 12 weeks after treatment has concluded. This means that after the prescribed medication has been completed a TOC blood draw will determine if there is any detectable virus left in the body to result in an infection (Nina Kim, & Spach, 2023). It can be seen in Figure 3 and Table 3 that the number of known positive cases continues to increase every year. This number is lower than recorded but is not reflected in the data because individuals may have completed their prescribed medication and never returned to complete their TOC. To address this issue, Central Outreach has resorted to offering incentives for completion of the test of cure after the prescribed medication is completed. Incentives consist of a \$25.00 gift card to a local grocery store chain. However, establishing contact with patients that may have already been cured of their hepatitis C infection can prove to be difficult. For example, when individuals fill out paperwork to receive the medication, they are required to list an address, emergency contact, and preferred method of contact. By the time that this information is needed to contact the patient at the end of a long treatment regimen, much of this information may have changed, making it

difficult or in some cases impossible to track down the individual. The reality of this problem can be observed in Figure 1 and Table 4.

Table 4 consists of data collected by an individual tasked with contacting and scheduling follow up bloodwork for individuals who should have completed their prescribed HCV medications. The issue regarding contacting patients can be visualized in Figure 1, as establishing contact with individuals based off information collected with initial intake forms can be difficult. Unfortunately, 40 out of 69 individuals were not able to be reached. Contact was established with 21 individuals' total; however, one individual had already received follow-up bloodwork, while seven individuals agreed to receive their follow-up blood work.

Overall, by reducing the number of steps within the cascade of care for individuals living with HCV, and by focusing screening efforts on risk-based screening, Central Outreach has been able to test over 4000 patients, over a five-year period. This can be seen in Figure 2 and Figure 3

As previously mentioned, Figure 3 consists of the number of individuals tested for HCV over a five-year period. Figure 2 visualizes the data that was collected from Table 2, which consists of the total number of HCV consults for the year 2022. Table 2 and Figure 3 also consists of information regarding if the data was collected during a home visit, or a clinic visit. The data suggests that the majority of HCV consults occur at clinic visits.

This effective methodology has allowed Central Outreach to shorten the HCV care cascade to two steps, resulting in expediting the delivery of HCV medications. Central Outreach continues to be an effective leader in HCV engagement and treatment by valuing employee-led patient education, funding community centered approaches, and by continuing to work to shorten the length of the HCV care cascade.

6.0 Conclusions/Recommendations

HCV is a blood-borne virus that is contracted primarily through direct contact with blood already containing HCV. Fortunately, there are a variety of FDA medications approved for the treatment of HCV infection. Specific medications are prescribed depending upon the specific genotype of HCV virus; however, pangenotypic medications such as Mavyret are normally prescribed. While medications remain effective, access to diagnosis and treatment remains an issue. Central Outreach Wellness Center is a regional organization located in Western PA that focuses on delivering culturally competent care to individuals living with HCV and comorbid diseases. Their community centered, patient centered approach has resulted in testing over 4,000 individuals since 2017.

Central Outreach has proven to be a significant curer of HCV in western PA as well as Ohio. By focusing screening methodologies on risk-based criteria and providing mobile services for HCV, CO has proven to be a known, reliable resource for the LGBTQIA+ community, communities of color, PWID, and other individuals who are or may be living with HCV.

Every year, individuals suffer from chronic Hepatitis C infection, and many succumb to liver failure related to this curable disease. To implement effective public health measures, organizations must make diagnoses and treatments more accessible. The brief state-of-the-field summary regarding HCV diagnosis and treatment suggests that risk-based screening may currently be the best approach to establishing the most efficient HCV programs. It has also been suggested that if an organization is able to reduce the number of steps within the HCV care cascade adherence to treatment may improve. Given that Central Outreach is succeeding in both these best practice recommendations and have the data to support their success, major health organizations in Western

Pennsylvania may benefit from examining the successes of the program and methods set forth by Central Outreach.

Issues are still prevalent within the cascade of care involving HCV, as confirmatory testing and a SVR should be measured upon completion of HCV medication. Unfortunately, many individuals are unable to be contacted afterwards. To be sure that individuals are completing their prescribed medications, Central Outreach must be able to obtain a test of cure from these individuals. While current employees attempt to track down individuals that have completed the prescribed course of medications, this method is not completely successful. In the future, employing more individuals to track down and schedule tests of cure for patients may be needed, and additional methods to entice individuals to schedule this test of cure may need to be explored. To benefit the overall health of the public, organizations must make treatment and confirmation of cure for curable diseases like HCV more accessible, including following the example being set by Central Outreach.

7.0 Implications for Public Health Research and Practice

Hepatitis C is a significant global burden that affects more than 60 million individuals, especially in younger PWID, individuals involved with the justice system, and among men who have sex with men. The World Health Organization has a goal set to eliminate HCV by the year 2030. To reach this goal, organizations should take necessary steps to shorten the length of HCV care cascade, and especially prevention efforts. Risk-based screening efforts should be practiced in HCV programs and primary care settings to identify any increased risks of HCV acquisition. To ensure that individuals complete their prescribed medications, and are practicing prevention techniques, further resources such as increased incentives and staffing may be needed to remain in regular contact with individuals.

Currently, there is no effective HCV vaccine, but further research regarding vaccine development should still be explored. Until then, the dissemination of the model utilized by Central Outreach should be conducted to ensure organizations are able to reach individuals who could benefit from HCV care. Examples would include the mention of Central Outreach practices in academic articles, policy briefs, and during conferences or presentations. Organizations could also benefit from staff training practices set forth by Central Outreach. Staffing components such as culturally competent care, heavy usage of nurse practitioners, as well as hiring of individuals with diverse characteristics such as having a history of OUD. Other recommendations would include increasing the over amount of funding to organizations that offer HCV care. This would provide organizations with the proper funding needed to provide effective HCV services, and important educational services such as harm reduction techniques and prevention education. Funding could

also allow for development of effective programs to diagnose and treat HCV, such as the mobile HCV service development conducted by Central Outreach Wellness Center.

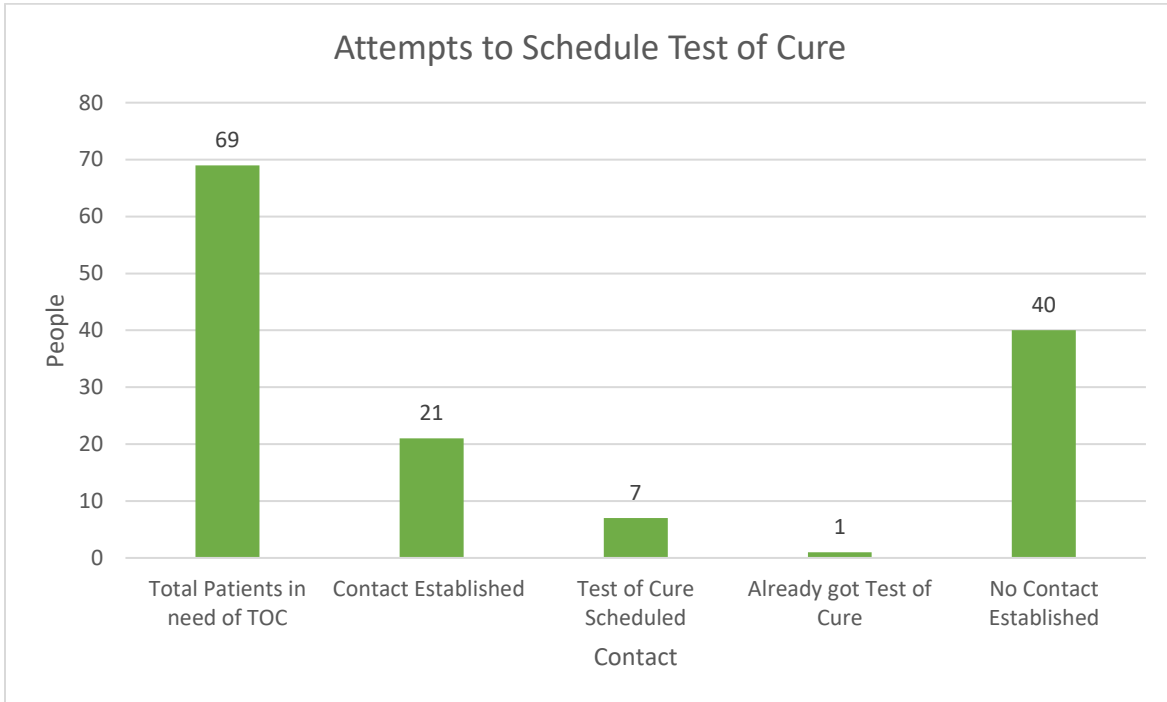


Figure 1. Attempts to Schedule Test of Cure for Individuals Who Should Have Completed HCV Treatment

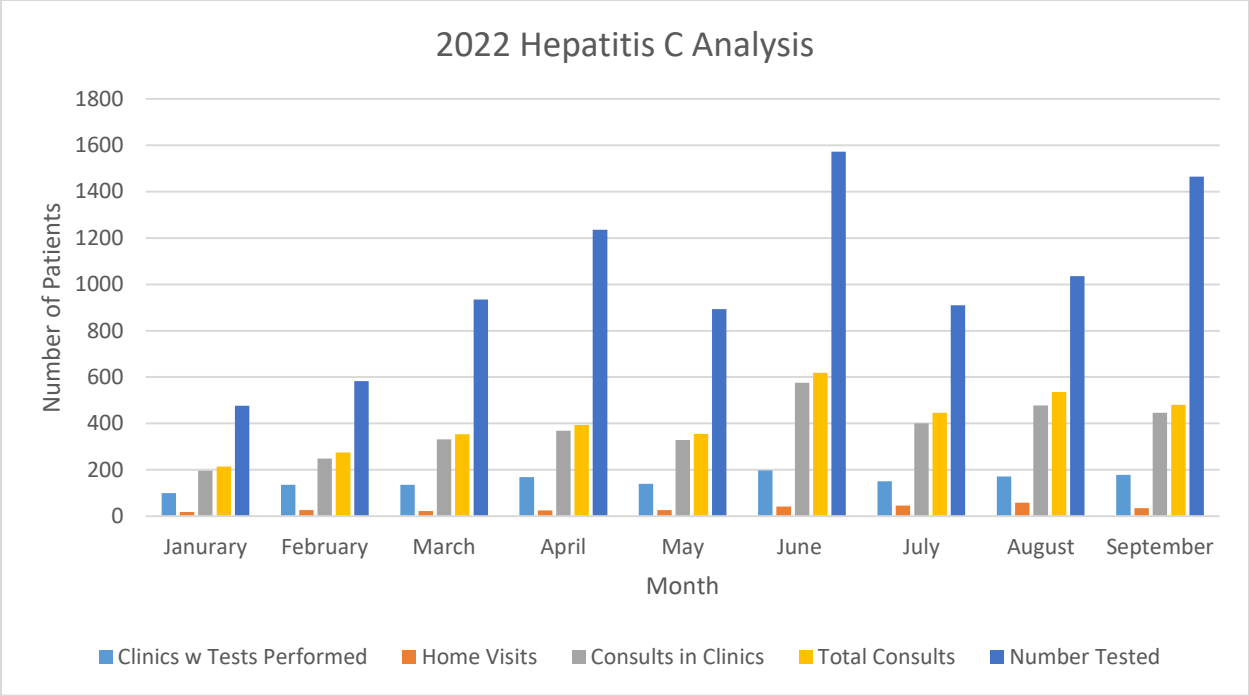


Figure 2. 2022 Trends of Consults Completed for Hepatitic C Care

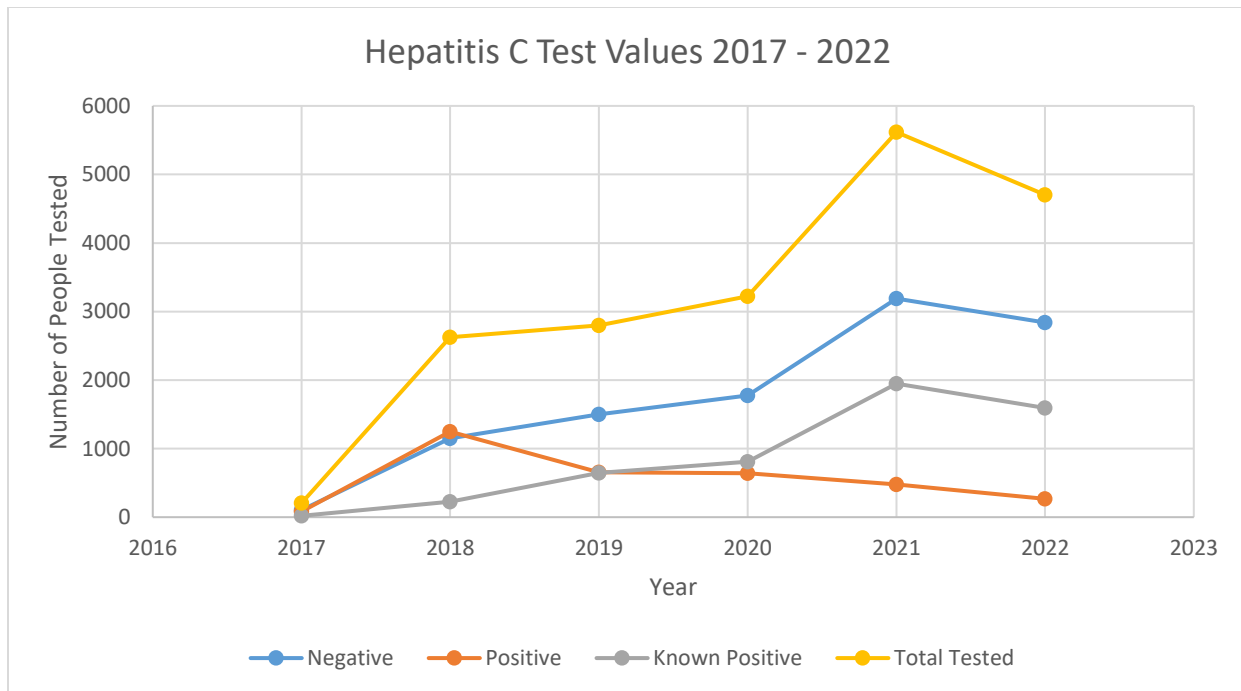


Figure 3. Hepatitis C Diagnosis Trends for 2017 to 2022

Table 1. FDA Hepatitis C Treatment Costs and Coverage

Medication	Estimated Uninsured Costs / Month	Medicaid Coverage?	Estimated Post-Deductible Costs	Percentage of Medicare Plans that Cover Medication
Ribavirin	\$2,400	Yes	\$0.00 - \$8.00	99%
Epclusa	\$24,000	State plan dependent	\$85.00 - \$9,600.00	42%
Harvoni	\$14,000	No	\$103.00 - \$14,000	N/A
Mavyret	\$27,000	Yes	\$39.00 - \$15,180.00	64%
Sovaldi	\$32,000	No	\$334.00 - \$32,200.00	N/A

Vosevi	\$25,000	Yes	\$216.00 - \$977.00	93%
Zepatier	\$8,000	No	\$267.00 - \$8,372	N/A

Table 2. Hepatitis C Testing Analysis for 2022

2022 Hepatitis C Testing Analysis					
	Clinics w Tests Performed	Home Visits	Consults in Clinics	Total Consults	Number Tested
January	100	18	196	214	476
February	135	26	249	275	583
March	135	22	332	354	934
April	169	25	369	394	1235
May	139	26	329	355	893
June	198	42	576	618	1573
July	150	45	401	446	910
August	171	58	478	536	1036
September	178	34	446	480	1464

Table 3. Hepatitis C Test Results for 2017 to 2022

Hepatitis C Test Results Positive and Negative Values 2017 - 2022						
	2017	2018	2019	2020	2021	2022
Negative	103	1151	1499	1774	3189	2842
Positive	82	1248	654	642	480	267
Known Positive	20	226	646	808	1948	1593
Total Tested	205	2625	2799	3224	5617	4702

Table 4. Call Log Data for Test of Cure Services

Call Log Data	
Total Patients in need of TOC	69
Contact Established	21
Test of Cure Scheduled	7
Already got Test of Cure	1
No Contact Established	40

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