



Promoting treatment for hepatitis C in people who inject drugs: A review of the barriers and opportunities

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ABSTRACT

Background: People who inject drugs (PWIDs) comprise a significant amount of the population who are also positive for hepatitis C virus (HCV) around the world. Even though there is evidence that patients who currently inject drugs do not display altered treatment adherence or medication effectiveness, health care providers are still hesitant to treat this patient population based on perceived threats and barriers.

Objectives: This literature review informs of the perceived barriers associated with PWID in receiving HCV treatment and supports recommendations to address these barriers.

Data sources: For this review, eight scholarly articles rated levels I A through II B using John Hopkins Evidence-Based Practicing ratings consisting of randomized controlled trials, systematic reviews, and meta-analyses were selected. Both qualitative and quantitative data contributed to identifying perceived barriers and suggested course of action that should be taken to increase HCV treatment uptake among PWID.

Conclusions: The three main perceived barriers are evidence of barriers to treatment in the PWID populations and include increased risk of reinfection, low adherence to treatment, and decreased response to treatment. Removal of these barriers by increasing education about HCV disease and treatment options to both patients and health care workers and changing current policy in health care settings to provide enhanced access to HCV treatment for PWID can promote an opportunity for successful treatment of these patients.

Implications for practice: There is a significant need for HCV treatment among PWID. Opportunities for successful treatment exist and should be adopted.

Keywords: Adherence; awareness; barriers; education; HCV; increase rates; PWID; recommendations; resources; treatment.

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Background

Hepatitis C virus (HCV) is the most common chronic bloodborne disease in the United States (Centers for Disease Control and Prevention [CDC], 2014). It was discovered 30 years ago in 1989 by scientists at the CDC and National Institutes of Health (NIH) (CDC, 2014). Hepatitis C virus is a RNA virus that affects the liver and causes progressive liver damage, which can result in liver cirrhosis and hepatocellular carcinoma (liver cancer) (Manns, et al., 2017). According to Arain and Robaeys (2014), in this decade, there is an expected increase for end-stage liver disease and hepatocellular carcinoma caused by HCV. On a global level, between 64 and 103 million people are chronically infected (Manns, et al., 2017). Hepatitis C virus affects more than 3 million people in the United States alone (Gilead, 2015), and it has been recognized as a leading cause of death from infectious disease, surpassing all other nationally notifiable infectious diseases combined (EndHepCSF, 2017). In highincome countries, such as the United States, 50-80% of people with HCV infection are people who inject drugs (PWIDs), both former and current users, and there is a global estimate that 10 million HCV antibody-positive people are also PWID (Grebely et al., 2015). It is especially important to treat this patient population for HCV because they carry a higher risk for spreading and transmitting infection rapidly due to their injection drug use. Although treatment of HCV has come a long way, including a cure with current

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pharmacotherapeutic drugs, there are still many barriers and challenges that are experienced by providers when trying to provide treatment to patients with active HCV, especially PWID. Even though PWID are the major source of transmission HCV infection, they had been excluded from antiviral treatments (Arain & Robaeys, 2014). Until recently, PWID have been denied access to treatment for HCV because of concerns about poor adherence, adverse events, and reinfection (Grebely et al., 2015). There is a large amount of successful HCV treatment studies among PWID that provide evidence in favor of treating this patient population (Grebely et al., 2015). Opioid substitution therapy (OST), like methadone, for active and former substance abusers is no longer contraindications for the receipt of HCV antiviral treatment (Arain & Robaevs, 2014). Rates of advanced liver disease complications, the associated health care costs, and liver-related morbidity and mortality among PWID rates continue to grow (Grebely et al., 2015). The initiation of HCV treatment in PWID is overall more cost effective and can prevent further liver-related mortality when treated in the early stages (EndHepCSF, 2017).

It should be noted that sustained viral response (SVR) is the key indicator of success in HCV treatment, which indicates the absence of the HCV 12 weeks after treatment completion (Porter, 2015).

Guidelines published by the American Association for the Study of Liver Disease, the Infectious Disease Society of America, the European Study for the Association of the Liver, the International Network for Hepatitis in Substance Abuse Users, and the World Health Organization all support and recommend treatment for HCV among PWID (Grebely et al., 2015). Even with the revised and updated guidelines, the initiation of treatment among PWID remains low (Grebely et al., 2015). According to Hutchinson, Bird, and Goldberg (2005), enhanced HCV assessment and treatment among PWID is necessary to decrease transmission and prevent further increases in HCV-related morbidity and mortality. The availability of effective, tolerable, and more simple interferon-free, direct-acting antivirals (DAAs) on the market improve the feasibility of treatment uptake among PWID (Dore & Feld, 2015).

Methods

A comprehensive review of the literature was completed between September and October 2018 using the following databases: Cochrane Library of Systematic Reviews, PubMed, CINAHL, Scopus, and DynaMed. Key words and freetext terms were entered into the above-stated databases in varying combinations. The search terms used were HCV, PWID, IVDA (IV drug abusers), hepatitis C, treatment, access, barriers, benefits, risks, challenges, efficacy, effectiveness, adherence, and initiating. The inclusion criterion were English-only articles, published between the years 2010 and 2018, participants may or may not be in methadone clinics, participants who were PWID, studies that included both male and female participants, and the use of HCV treatment that included newer DAAs. Following this search, articles that did not have a primary focus to identify the barriers and challenges to HCV treatment in PWID were excluded. The search process yielded a total of 504 articles. Eight articles met the above criteria and were selected for final review. Articles were evaluated for strength using the Johns Hopkins Nursing Evidence-Based Practice Research Evidence Appraisal Tool (Newhouse, Dearholt, Poe, Pugh, & White, 2007) and ranged from level I A to level II B (Appendix A, Supplemental Digital Content 1, http://links.lww.com/JAANP/A28).

Literature review

There are numerous barriers associated with the patient population of PWID receiving, adhering to, and responding well to HCV treatment, but much of the literature indicates that regardless of the perceived barriers, positive outcomes—from the initiation of treatment through and including cure from HCV—can be achieved in PWID. The review demonstrated a striking repetitive theme for perceived barriers, including risk of reinfection, adherence to treatment, and response to treatment.

Risk of reinfection

The notion that patients who are concurrently receiving drug addiction recovery treatment with HCV treatment may relapse into regular drug use is not only a fear of providers but also an identified fear and barrier from the health care system perspective (Hellard, Sacks-Davis, & Gold, 2009).

One of the predominant themes in the literature pointing to provider withholding of treatment is the concern regarding the risk of reinfection with patients who are concurrently infected and intravenous (IV) drug abusers. Hellard et al. (2009) express a continuing reluctance for clinicians to treat because there are the concerns of the risk of reinfection and high occurrence of alcohol abuse and of mental health issues, which would affect the overall compliance to the treatment regimen and the effectiveness. Despite a history of active or recent drug use, these factors do not compromise adherence, treatment completion, or SVR in the treatment of HCV among 1,268 PWID (Hellard et al., 2009). In the review of the available evidence, HCV treatment trials prescribing pegylated interferon plus ribavirin showed that the SVR rate among PWID was 54.3% compared with 54-63% among non-PWID, indicating that PWID should not be excluded from receiving treatment (Hellard et al., 2009). Based on a study of 76 PWID receiving HCV treatment, Gigi et al. (2007) concluded that 92% of the sample population attained virologic response at the end of treatment. These results indicate and support that active IV drug use does not interfere with HCV treatment adherence and attained SVR so long as there is close monitoring of the patient and adjunct psychological support with substance abuse treatment services. These methods

augment adherence to therapy and improve response rates as evidenced by an SVR of 92% (Gigi et al., 2007).

In 1997, the NIH recommended that patients who use illicit drugs not be offered HCV treatment until they have been sober for at least 6 months, and Edlin et al., (2001) found this policy to be unfair and discriminatory. Edlin et al., (2001) considered four possible reasons for why the policy was made: a) poor adherence to treatment regimens, b) side effects of the treatment, c) the risk of reinfection with HCV, and d) the lack of need to initiate treatment for HCV. It was concluded that patients who are actively injecting drugs and receiving effective HCV treatment can avoid reinfection using a new sterile syringe for each injection and not sharing equipment and needles with others and should not be disqualified from receiving HCV treatment despite active injection of drugs.

A meta-analysis performed by Hagan, Pouget, and Des Jarlais (2011) of 26 published and unpublished studies on behavioral interventions, substance-use treatment, syringe access, and syringe disinfection found that combination interventions, such as opioid agonist therapy (OAT), syringe-access programs, and syringe disinfection, can prevent reinfection among PWID. The most effective strategies were ones that combined substance-use treatment and support for safer injection practices. With multicomponent interventions, this meta-analysis shows that HCV infection and reinfection can be prevented in PWID.

Adherence to treatment

Another recurring theme in the literature for not initiating treatment was the fear that PWID will not adhere to their HCV treatment regimen. The Enhancing Treatment of Hepatitis C in Opioid Substitution Settings study (Grebely et al., 2016a) is a prospective cohort study that measured the treatment outcomes of adherence and SVR in 101 patients from six different OST clinics. The primary goal of this study was to estimate adherence and risk of reinfection, adherence to treatment, and response to treatment, and response to medication therapy for people living with chronic HCV who had a history of IV drug abuse. The secondary goal was to recognize predictors of positive HCV treatment response. Of the 101 patients who were treated for HCV, 36% (n = 37) had injected drugs within the past 6 months and 62% (n = 63) were receiving OST. The recent use of injection drugs at baseline did not affect achieving an SVR. The findings indicated that people with a history of IV drug use, or those receiving OST, with chronic HCV can achieve adherence and positive responses despite injecting drugs at baseline.

A randomized, placebo-controlled, double-blind trial conducted by Dore et al., (2016) was used to evaluate the drug elbasvir-grazoprevir (Zepatier) in treating HCV infection in PWID. In this study, a total of 301 treatment-naive patients diagnosed with chronic HCV, receiving OAT, received treatment with Zepatier lasting for 12 weeks. The findings strongly suggested that patients with HCV infection, receiving OAT, and treated with Zepatier had a high rate of achieving SVR (94%) regardless of on-going drug use, indicating that drug use at baseline does not affect adherence of HCV treatment.

Schutz et al. (2018) conducted an open-label, noninterventional, proof-of-concept, direct, observational study with 40 patients who had not been previously treated for their chronic HCV and were active PWID. The patients took their HCV antiviral medications under direct observation at an OAT clinic for the 8-week treatment period, along with receiving OAT. With the approach of treating patients under direct observation, excellent adherence was achieved, which was indicated by the 0.16% (95% confidence interval, 0.03–0.47) for missed doses during the 8-week treatment period. At the end of the study, 100% SVR was achieved. The results indicate that directly observed therapy (DOT) of chronic HCV is effective in PWID at risk for nonadherence.

Although DOT is well-known for its use in managing tuberculosis and HIV treatments, it may not be understood to be equally effective for HCV medication therapies as well. This study was designed to integrate DOT into the way treatment was administered for two specific reasons: first, to ensure that all drug therapies were fully received by each participant and second, because of its known effectiveness in improving successful outcomes in other medication protocols (i.e., for HIV/AIDS and TB). Although this project did not specifically identify studying successful patient outcomes due to DOT, anecdotally, it is fairly clear that the use of DOT in medication administration contributed to the successful HCV treatment outcomes in all of the project participants and therefore, had a direct positive correlation to treatment adherence in all patients.

In 2016, a series of studies called the Phase 3 ION studies were conducted as randomized, open-label trials that evaluated the drug ledipasvir/sofosbuvir (Harvoni) \pm ribavirin administered for 8, 12, or 24 weeks in 1,952 HCV Genotype 1 patients who were receiving (n = 70) and not receiving (n = 1882) OST. The findings revealed that OST and drug use during HCV treatment did not affect adherence to the medication regimen as evidenced by the high rate (94%) of SVR (sustained virologic response 12-weeks post treatment) attained (Grebely et al., 2016b).

The ACTIVATE study (Cunningham et al., 2017) was a directly observed study of 93 patients. Of these 93 participants, 59% had recently injected drugs (within the past month), 77% were receiving OST, and 56% injected drugs during therapy. Of the patients who completed treatment, there was no association between recent injection of drug use at baseline or during treatment that affected adherence to the medication regimen and the overall treatment outcome. A total of 95% of the patients attained an SVR. The findings of this study indicate that there was a high adherence to the HCV drug treatment regimen among the patients who were injecting drugs during the therapy and/or were receiving OST.

Response to treatment

The third perceived barrier highlighted in the literature was the idea that response to treatment in PWID would be

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significantly reduced compared with those who are not PWID. Aspinall et al. (2013) conducted a systematic review of people who are actively injecting drugs and treated for HCV. A search for primary articles and conference abstracts examining HCV treatment outcomes in PWID was done using the databases of Medline, Embase, and Cochrane between the years 2002 and January 2012. Ten primary articles and one conference abstract were reviewed, and after evaluating SVR, adherence, discontinuation, and reinfection rates among PWID from these studies, the pooled adherence rate was 82%, and the pooled risk for reinfection was 2.4 per 100 person-years, indicating that the HCV treatment outcomes were generally supportive of a positive outcome (Aspinall et al., 2013). These data support the current guidelines that PWID should not be excluded from treatment for HCV.

Eckhardt, Scherer, Winkelstein, Marks, and Edlin (2018) conducted a direct observational study of 53 participants who were active PWID, and as part of the study, the participants were to receive HCV treatment in a community-based harm reduction facility in Washington that also had a syringe services program. Medication for HCV was dispensed to the patients at the clinic through DOT. Of the 53 participants, 48 had an undetectable HCV RNA 12 weeks after completing treatment (SVR, 91%), indicating a high success rate for the cure of HCV. Based on the findings, it is evident that a highly significant response rate to HCV treatment can be achieved regardless of concurrent IV drug use and likely in conjunction with a syringe/needle exchange program.

Other barriers

Patient barriers. During this review, barriers from the patient perspective were also uncovered and have significance in the overall success of treatment of PWID. One of the commonly identified barriers from the patient's perspective were lack of knowledge of HCV disease (low perceived need for treatment) and of HCV treatment (fears of financial costs and side effects of medication regimen) (Patel et al., 2018). Other barriers were fear of stigmatization and judgment from providers, difficulty in access to medications, lack of access to social support (social worker and peer support groups), and fear of intolerable side effects of the HCV medication regimen (Patel, et al., 2018).

Results

In reviewing the available literature for PWID and HCV treatment, it was evident that there are three key beliefs from the provider perspective that act as barriers to the implementation and maintenance of treatment. Although these concerns may be perceived as impediments, the evidence clearly supports both the initiation and continuation of HCV treatment in PWID and its success in curing HCV in that population. Furthermore, the literature demonstrates a high SVR and adherence rate in PWID who are offered treatment. While treating this population, it is also conceivable to intervene with other community health promotion models, such as syringe programs, increased health education, and the building of trust and minimization of stigma for both health care providers and patients.

Recommendations

One of the key recommendations to facilitating HCV treatment in PWID is to promote and provide education to both patients and providers. This can help reduce stigmatization and judgment, and further aid in increasing knowledge and awareness of the HCV disease and its treatment options. Health care systems can then be equipped to make systematic modifications by developing current policies and procedures that better facilitate HCV treatment among PWID despite perceived hindrances to effective treatment (Harris & Rhodes, 2013).

Another strategy recommended by Zeremski et al. (2013) to help with HCV treatment adherence would be to have patients become stable with drug substitution therapy (methadone maintenance therapy) before beginning their HCV treatment to help promote treatment adherence. Methadone maintenance therapy programs have been successful in linking PWID to health and support services, like social workers and primary care providers, by promoting regular access to care (Zeremski et al., 2013). Methadone maintenance therapy offers the benefits of daily DOT by way of window dosing, which also promotes treatment adherence.

The findings of Lok et al. (2017) strongly support that when treatment is initiated with new, safer, and more effective DAA treatment regimens, which are highly tolerated (due to a low side effect profile) and efficacious (due to their short treatment duration, oral route, and have been formulated to facilitate adherence), patient adherence and overall response rates to treatment are increased.

According to Grebely et al. (2015), sterile drug injecting equipment to decrease rates of HCV transmission and reinfection is highly recommended and has been shown effective in decreasing the rates of transmission and reinfection. Eckhardt, Marks, and Edlin (2017) stated that needle syringe programs have been shown to be effective in achieving SVR12 and strongly support decreasing reinfection rates among this patient population.

Patel et al. (2018) found that willingness to participate in and adhere to HCV treatment increased when the duration of therapy decreased (8–12 weeks with Mavyret vs. 24–48 weeks with interferon). With this, there was a higher perceived efficacy. It was also revealed that patients preferred daily visits to a clinic for HCV treatment rather than being prescribed a month's supply of take-home medication (Patel et al., 2018).

There are a number of leading organizations that provide valuable information and resources on HCV screening, treatment, management, cure, and costs (**Table 1**).

In many communities, there may be opportunities for funding and grant opportunities to aid with the initiation

Table 1. Available guidelines and resources for hepatitis C treatment		
Organization	Web site Address	Resources
CDC	https://www.cdc.gov/hepatitis/hcv/ management.htm	Patient education materials, provider resources, treatment guidelines and algorithms, recommendations for testing, managing, treating, curing, and preventing reinfection HCV.
WHO	https://www.who.int/hepatitis/ publications/hepatitis-c-guidelines/ en/	Patient education materials, provider resources, treatment guidelines and algorithms, recommendations for testing, managing, treating, curing, and preventing reinfection HCV.
AASLD and IDSA	https://www.hcvguidelines.org	Patient education materials, provider resources, medication costs, treatment guidelines and algorithms, recommendations for testing, managing, treating, curing, and preventing reinfection of HCV.
San Francisco Hepatitis C Task Force	http://sfhepc.org/wp-content/ uploads/2015/11/SFHCTF_Action_ Recommendations.pdf	Recommended screening and treatment protocols specifically for SF from 2010.
Hepatitis C State of Medicaid Access	https://stateofhepc.org/resources/	Information on demographics of the current state of Medicaid access to HCV treatment.

Note: AASLD = American Association for the Study of Liver Disease; CDC = Centers for Disease Control and Prevention; HCV = hepatitis C virus; IDSA = Infectious Disease Society of America; WHO = World Health Organization.

of HCV treatment programs. The funding could come from the level of the local department of health or national organizations, like the National Viral Hepatitis Roundtable and Health Resources and Services Administration, to support treatment of HCV.

Conclusion

For providers who treat PWID, there may be perceived difficulties in initiating HCV treatment, but when PWID patients are presented with the opportunity to be treated for HCV with an adequate amount of resources, such as syringe exchange services and clinics that offer DOT, uptake of treatment is high, indicating that this patient population is very suitable for receiving HCV treatment. The number of PWID who are assessed and treated for HCV is increasing, making it extremely vital to understand the various barriers that PWID experience in achieving successful outcomes and to adopt systematic processes to better facilitate HCV treatment for this patient population. It is important that access be provided for this patient population because maximizing treatment for PWID can be an effective preventative measure for decreasing transmission and mortality associated with the long-term consequences of HCV.

Implications for Practice

To improve the delivery of HCV-related health care services, Arain and Robaeys (2014) recommend removing stigmatization through implementing peer support and group treatments, along with having more involvement by nurse educators and practitioners. There is hesitancy among providers to treat HCV in PWID due to the fear of reinfection, but there is strong data that support to prevent the spread of HCV in the community. Recent or active PWID should be eligible candidates to receive HCV treatment (Arain & Robaeys, 2014). Grebely et al. (2015) confirmed that access to social work and social support services, and peer-based support should be included in the clinical management and treatment of HCV among PWID. In turn, these recommendations in change of practice will promote increased seeking of treatment, initiation, adherence, and response to HCV treatment by PWID.

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