



Conceptualising access in the direct-acting antiviral era: An integrated framework to inform research and practice in HCV care for people who inject drugs

Stine Bordier Høj^{a,*}, Brendan Jacka^{a,1}, Nanor Minoyan^{a,b,1}, Andreea Adelina Artenie^{a,b,1}, Julie Bruneau^{a,c,*}

^a Centre de Recherche du Centre Hospitalier de l'Université de Montréal (CRCHUM), 900 rue St-Denis, Montréal, Québec, H2X 0A9, Canada

^b École de Santé Publique de l'Université de Montréal, 7101 Avenue du Parc, Montréal, Québec, H3N 1X9, Canada

^c Département de Médecine Familiale et Médecine d'Urgence, Faculté de médecine, Université de Montréal, C.P. 6128, succursale Centre-ville, Montréal, Québec, H3C 3J7, Canada

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ABSTRACT

As direct-acting antiviral (DAA) therapy costs fall and eligibility criteria are relaxed, people who inject drugs (PWID) will increasingly become eligible for HCV treatment. Yet eligibility does not necessarily equate to access. Amidst efforts to expand treatment uptake in this population, we seek to synthesise and clarify the conceptual underpinnings of access to health care for PWID, with a view to informing research and practice.

Integrating dominant frameworks of health service utilisation, care seeking processes, and ecological perspectives on health promotion, we present a comprehensive theoretical framework to understand, investigate and intervene upon barriers and facilitators to HCV care for PWID. Built upon the concept of Candidacy, the framework describes access to care as a continually negotiated product of the alignment between individuals, health professionals, and health systems. Individuals must identify themselves as candidates for services and then work to stake this claim; health professionals serve as gatekeepers, adjudicating asserted candidacies within the context of localised operating conditions; and repeated interactions build experiential knowledge and patient-practitioner relationships, influencing identification and assertion of candidacy over time. These processes occur within a complex social ecology of interdependent individual, service, system, and policy factors, on which other established theories provide guidance.

There is a pressing need for a deliberate and nuanced theory of health care access to complement efforts to document the HCV 'cascade of care' among PWID. We offer this framework as an organising device for observational research, intervention, and implementation science to expand access to HCV care in this vulnerable population. Using practical examples from the HCV literature, we demonstrate its utility for specifying research questions and intervention targets across multiple levels of influence; describing and testing plausible effect mechanisms; and identifying potential threats to validity or barriers to research translation.

Introduction

Hepatitis C virus (HCV) infection represents a significant global public health concern, with an estimated 71 million people living with HCV in 2015 (Polaris Observatory HCV Collaborators, 2017). People who inject drugs (PWID) are a principal group at risk, with estimates that over half of all PWID have been exposed to the virus (Degenhardt et al., 2016, 2017). Highly effective and tolerable direct-acting antiviral

(DAA) therapies have transformed the landscape for HCV-infected patients and are a cornerstone of the World Health Organisation's (WHO) Global Viral Hepatitis Strategy, which targets an 80% reduction in new HCV infections and a 65% reduction in HCV-related mortality between 2015 and 2030 (World Health Organization, 2016). Mathematical modelling has driven a growing consensus that treatment scale-up is a cost-effective means to achieve substantial reductions in HCV incidence, prevalence, and burden among PWID, and is indispensable to

* Corresponding authors at: Centre de Recherche du Centre Hospitalier de l'Université de Montréal (CRCHUM), 900 rue St-Denis, Local R05.746, Montréal, Québec, H2X 0A9, Canada.

E-mail addresses: stine.hoj@umontreal.ca (S.B. Høj), julie.bruneau@umontreal.ca (J. Bruneau).

¹ These authors contributed equally to this work.

HCV elimination efforts (Pitcher, Borquez, Skaathun, & Martin, in press). Meanwhile, observational studies continue to document very low levels of treatment uptake in this population, raising concerns about how to achieve this in practice (Akyar et al., 2016; Alavi et al., 2015, 2014; Fraser et al., 2018; Hellard, Scott, Sacks-Davis, & Pedrana, 2018; Iversen et al., 2017; Mohamed et al., 2018; Negro & Maistat, 2017; Papatheodoridis, Tsochatzis, Hardtke, & Wedemeyer, 2014; Socías et al., 2018; Stephens, Young, & Havens, 2017; Wiessing et al., 2014; Young et al., 2018).

The “cascade of care” is a framework for describing, in visual form, the proportions of persons living with a particular condition that receive a standard of care, typically documenting progress through a sequential continuum of pertinent health services. An established tool in the fields of HIV, diabetes, and tuberculosis, the cascade also underpins the WHO Viral Hepatitis Strategy as a means to quantify uptake of essential services – including HCV testing, clinical follow-up, and treatment – and guide specific actions towards the 2030 elimination targets (Ali, Bullard, Gregg, & del Rio, 2014; Gardner, McLees, Steiner, del Rio, & Burman, 2011; Perlman, Jordan, & Nash, 2017; World Health Organization, 2016). This broadly standardised framework provides a clinically relevant means to measure and compare access to HCV care over time and in diverse populations, with uses documented in varied settings and groups (including PWID) in recent years (Cachay et al., 2014; Hochstatter et al., 2017; Iversen et al., 2017; Janjua et al., 2016; Maier, Ross, Chartier, Belperio, & Backus, 2015; Mohamed et al., 2018; Socías et al., 2015; Young et al., 2018; Zuckerman, Douglas, Nwosu, Choi, & Chastain, 2018). It bears numerous advantages for public health planning, including its utility for identifying key service gaps and intervention targets; defining quantitative metrics to monitor and evaluate treatment scale-up efforts; and generating input parameters for mathematical modelling (Perlman et al., 2017).

The cascade is, however, poorly suited to understanding determinants of service gaps in vulnerable populations and provides little insight into the mechanisms by which PWID enter, are retained in, and benefit from clinical care (Perlman et al., 2017). Others have warned that the cascade focuses attention primarily on clinical intervention levers, potentially de-emphasising the need to address structural- and individual-level factors outside the medical system, while also failing to document meaningful patient experiences and outcomes of treatment and cure (Harris & Rhodes, 2013; Henderson, Madden, & Kelsall, 2017; Janda & Mergenhagen, 2017; Madden, Hopwood, Neale, & Treloar, 2019; Mason et al., 2015; Perlman et al., 2017; Younossi, Birerdinc, & Henry, 2016). Meanwhile, studies characterising determinants of cascade gaps rarely elaborate the theoretical basis for their choice of study variables, resulting in inconsistent sets of explanatory factors. Moving forward, there is a need for an explicit and comprehensive theoretical framework of access to HCV care to guide treatment scale-up among PWID. Accordingly, this paper synthesises diverse theoretical perspectives on access to health care and presents an integrated framework to guide research and practice in HCV care for PWID.

Conceptualising access to care: a brief review of prior approaches

There exists no ‘gold standard’ definition of access to health care, which might be assessed in terms of service availability (the potential to obtain care); utilisation (the realisation of access through actual use); relevance and effectiveness (receiving the right service to achieve the best possible health outcome); and equity (achieving fairness or social justice in the mobilisation of resources) (Gulliford et al., 2002). These dimensions distinguish between potential and realised access, and between gaining access and achieving desired outcomes, where different dimensions may call for distinct applications, measures, and interventions (Gold, 1998). Notably, the cascade of care conceives access as service utilisation, whereas additional dimensions might be necessary to fully understand barriers to HCV elimination. For instance, analyses of service availability might highlight geographic inequalities in service

infrastructure (e.g. few DAA prescribers) and a focus on relevance might indicate whether those services adequately meet user needs (e.g. availability of primary care versus specialist prescribers). Here, we view access broadly as the opportunity to reach and obtain appropriate services when there is a need for care, with a focus on formal health services underpinning HCV treatment (Levesque, Harris, & Russell, 2013). We begin by briefly reviewing existing frameworks of health service utilisation, care-seeking processes, patient-provider fit, and ecological theories of health behaviour that can guide understanding of how and why this opportunity differs within or between populations. In the following section, we unite these perspectives with the HCV literature to present an Integrated Framework of access to HCV care for PWID.

An evolving behavioural model of health care utilisation

The Behavioural Model (BM) of Health Services Use is a widely-used framework of health care utilisation that has undergone numerous revisions since its introduction in the 1960s, including adaptation for use in vulnerable populations (BM-VP) (Andersen, 2008; Babitsch, Gohl, & von Lengerke, 2012; Gelberg, Andersen, & Leake, 2000). Fundamentally, it conceives health service use as a function of three domains: a predisposition to use services, factors that enable or impede service use, and a need for care, as recognised by the individual (perceived need) or health provider (evaluated need). The BM-VP revised and expanded the ‘traditional’ factors in each domain to include pertinent determinants of service use in vulnerable populations such as PWID. Among others, this revision stressed the importance of considering factors such as incarceration history, substance use, living conditions (predisposing), and social service resources (enabling). The model has since become a standard point of reference, providing the foundation for numerous studies of access to primary care, HCV and HIV services among PWID (Artenie et al., 2015; Bamvita et al., 2014; Frimpong, Guerrero, Kong, & Tsai, 2015; Mehta et al., 2008; Mlunde et al., 2016; Nambiar, Stoové, & Dietze, 2014; North et al., 2013; Nowgesic, Meili, Stack, & Myers, 2015; Skeer, Ladin, Wilkins, Landy, & Stopka, 2018; Sogarwal, Madge, Bishi, Woleng, & Garg, 2016). It is pertinent to note that the BM-VP positions process factors – which describe the ways in which access is realised – as key to patient satisfaction with services received. However, the model is not particularly well suited to document how process factors shape care trajectories, and these have scarcely been considered in its applications to HCV care.

Framing the dynamic, interactive and experiential process of health care seeking

In a 2005 review of frameworks for access to health care, Ricketts and Goldsmith (2005) described a body of research evolving in parallel with the BM that conceptualised access as the degree of fit between health care resources and potential users, where (mis)alignment between the parties may influence service utilisation, patient satisfaction, and provider practices (Penchansky & Thomas, 1981). Notably, distinct aspects of patient-provider fit may be more salient in particular segments of the population, resulting in differential effects on utilisation (Thomas & Penchansky, 1984). Ricketts and Goldsmith (2005) noted that this perspective was less frequently adopted than the BM in health care research, and called for increased attention to the dimensions of time, anticipation, experience, learning, and adaptation in models of access. Rather than viewing care-seeking as single, isolated event, they emphasised that “people have many opportunities to react to needs or perceived needs, and their reaction depends largely on how they anticipate the system will react to them, how much they trust the system, and how much benefit they feel they will derive” (Ricketts & Goldsmith, 2005, p.277). This perspective is arguably of vital importance to PWID, for whom wide-reaching stigma and marginalisation, and multiple competing needs, may inhibit care seeking regardless of perceived

need.

The Candidacy framework, which stems from a 2006 synthesis of literature on access to health care in socio-economically disadvantaged groups, subsequently reiterated the importance of patient-provider fit within a framework that places the dynamic, interactive and experiential process of seeking and attaining care at the centre of the analysis (Dixon-Woods et al., 2006). This framework describes access as a product of the alignment between individuals and health services and, in particular, the ways in which these parties jointly negotiate eligibility for health care. For the individual, accomplishing access to health care requires identifying oneself as a candidate for a service and performance of the work required to stake this claim, where the amount, difficulty, and complexity of that work may operate as barriers to receipt of care. Health professionals serve as gatekeepers to health services and adjudicate these statements of candidacy within the context of local operating conditions. Both parties seek to define the appropriate course of action, and their interactions shape help-seeking and health care access over time. Candidacy frames the health service “careers” of individuals (Ricketts & Goldsmith, 2005) as a series of repeated service use trajectories, evolving in a recursive manner throughout the life course (Mackenzie, Conway, Hastings, Munro, & O’Donnell, 2013, 2011). Prior experiences and knowledge of health systems, services and practitioners underpin the identification and assertion of future candidacies (Hunter et al., 2013), such that access difficulties influence responses to future illness episodes (Chase, Cleveland, Beatson, & Rousseau, 2017). The framework has been applied to understand access to health care, including HCV treatment, in vulnerable groups including PWID (Coupland & Maher, 2010), sex workers (Mastrocola, Taylor, & Chew-Graham, 2015), survivors of sex slavery (Dando, Brierley, Saunders, & Mackenzie, 2018), asylum seeker (Chase et al., 2017) and immigrant communities (Sweeney et al., 2015), and other groups (Koehn, 2009; Kovandžić et al., 2011; Mackenzie et al., 2011).

Deconstructing the dimensions of patient-provider “fit”

The importance of patient-provider fit is implicit in the Candidacy framework, particularly through its attention to service navigability and permeability and the role of interpersonal interactions in determining access; for instance, services that do not fit user needs are likely to be difficult to navigate and use, and may be characterised by unpleasant social experiences. However, that framework does not deconstruct the interface between individuals and services in a way that enables a clear and comprehensive analysis of (mis)alignment. By contrast, Levesque et al.’s 2013 Patient-Centred Framework (PCF) specifically delineates five dimensions of paired demand-side and supply-side factors that jointly enable (or impede) the process of obtaining care (2013). For the individual, successful completion of a service trajectory requires abilities to perceive a need and to seek, reach, pay for, and engage in health care, with underlying determinants including health literacy (perceive), autonomy (seek), transport (reach), income (pay), and empowerment (engage). Corresponding dimensions at the level of services include approachability (ease of identification), acceptability to the patient population (e.g. socio-culturally), availability (physical presence, timeliness), affordability (including direct, indirect, and opportunity costs) and appropriateness (adequate services that meet client needs). The authors note the interdependence of these demand- and supply-side factors – for instance, the impact of an individual’s capacity to travel is dependent on service location, and vice versa – and highlight the importance of this for guiding policies that bridge gaps in patient ability. The PCF has been applied to understand the dimensions of access to injecting equipment for rural PWID (Fisher, Smith, Nairn, & Anderson, 2017). However, its representation of the process of obtaining care has been described as ‘too linear’ to adequately describe how PWID achieve HCV treatment within the context of broader life trajectories (Foley et al., 2016).

Ecological perspectives for the promotion of health care access

Ecological theories generally hold that organisms – whether individuals, organisations, or communities – do not exist or act in isolation. Rather, they are affected by forces internal and external to themselves, and seek to achieve a state of harmony by adapting to or modifying these environments (McLaren & Hawe, 2005). These theories describe how multilevel factors, from intrapersonal characteristics through to macro-social ideology, interact to determine health and behaviour (Golden & Earp, 2012; McLaren & Hawe, 2005; McLeroy, Bibeau, Steckler, & Glanz, 1988; Richard, Gauvin, & Raine, 2011; Stokols, Allen, & Bellingham, 1996). They expressly recognise that both individuals and health providers are embedded within larger geographic, economic, social, legal, and political systems, where unyielding environments and poor ecological ‘fit’ hamper the ability to act in accordance with personal or group goals (Stokols, Lejano, & Hipp, 2013). This perspective is essential to the study of health outcomes in vulnerable populations (Rhodes et al., 2012), and has been employed to explore factors associated with health care access among sex workers (Ma, Chan, & Loke, 2017), access to HIV services (Yakob & Ncama, 2016), and the risk environments for HIV (Baral, Logie, Grosso, Wirtz, & Beyrer, 2013) and drug-related harm (Rhodes, 2002). It may also be used to map potential influences on the configuration and behaviour of actors within health services, such as financing and payment mechanisms (Hennig-Schmidt, Selten, & Wiesen, 2011), administrative requirements (Landon, Wilson, & Cleary, 1998), socialised stereotypes or attitudes (Smedley, Stith, & Nelson, 2003), and public discourse shaping health policy and intervention (Wiley, 2016).

An integrated framework of access to HCV care for PWID

Syntheses of qualitative research reveal inadequate or negative health service encounters and social stigma as key elements of the lived experience of HCV and its treatment among PWID (Dowsett, Coward, Lorenzetti, MacKean, & Clement, 2017; Treloar & Rhodes, 2009). Because Dixon-Woods et al.’s (2006) Candidacy framework expressly theorises the intersubjective, experiential, and recursive nature of health service encounters as central to health service access in vulnerable populations, we employ this as the core basis for our Integrated Framework of access to HCV care for PWID (Fig. 1). The stages of negotiating candidacy for a particular health problem, represented by the six inner circles of the framework, include: (1) identifying oneself as a candidate for health care; (2) navigating the health system to identify appropriate services and (3) overcome barriers to service permeability; and (4) appearing at a service to assert one’s claim for (5) adjudication by the service provider, who may (6) offer treatment that is accepted, resisted, or refused by the candidate (Dixon-Woods et al., 2014). The cyclical nature of this process, reflecting both the temporal delineation of these stages and repeated journeys through the health services, is illustrated by arrows representing the dimension of time. The process of negotiating candidacy is nested within a multilevel hierarchy of influences, ranging in scope from (1) individual characteristics and resources to (2) attributes of services and (3) the broader meso- and macro-level context. Double-headed arrows traversing this hierarchy indicate the notions of ecological ‘fit’ and multilevel interactions emphasised by ecological theories. We further highlight Levesque et al.’s (Levesque et al., 2013) five dimensions of service accessibility and corresponding individual abilities to describe the interface between health systems and individuals/populations, and incorporate the BM’s delineation of predisposing, enabling and need factors as a useful structure for understanding potential mechanisms of influence for factors at each level (Andersen, 1995; Andersen, Davidson, & Baumeister, 2014; Gelberg et al., 2000). The following sections briefly describe the primary components of the framework, with selected illustrative examples from the HCV literature (summarised in Table 1).

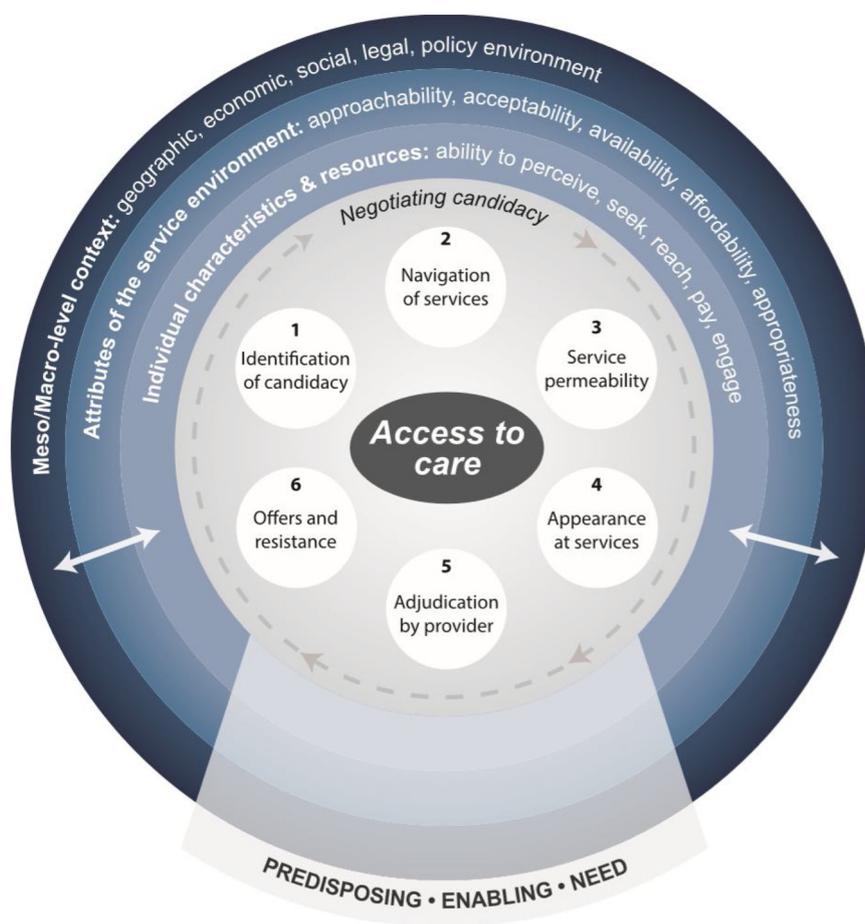


Fig. 1. Integrated framework of access to HCV care for people who inject drugs.

Negotiating candidacy for HCV care

Identification of candidacy reflects the process by which individuals come to view themselves as legitimate candidates for health services, including how they recognise a need for medical attention. HCV diagnosis is a clear prerequisite to identify as a candidate for treatment. However, for PWID, normalisation of HCV within the community, a lack of symptoms, insufficient post-diagnosis counselling, poor understanding of treatment options, and competing needs may impede identification of candidacy among those aware of their infection (Dowsett et al., 2017; Grebely et al., 2008; Jordan et al., 2013; Lally, Montstream-Quas, Tanaka, Tedeschi, & Morrow, 2008; Madden, Hopwood, Neale, & Treloar, 2018; Mah et al., 2017; Mehta et al., 2008; Morris et al., 2019; Skeer et al., 2018; Swan et al., 2010; Treloar, Hull, Dore, & Grebely, 2012; Treloar et al., 2016a, 2016b; Treloar & Rhodes, 2009; Valerio et al., 2018; Whiteley, Whittaker, Elliott, & Cunningham-Burley, 2018; Wright et al., in press; Zeremski et al., 2014). Conversely, becoming symptomatic, access to trusted medical providers, and a feeling of responsibility or support towards/from social ties may motivate PWID to seek HCV information and care (Falade-Nwulia et al., 2019; Fortier et al., 2015; Harris, Rhodes, & Martin, 2013; Swan et al., 2010).

Navigation of services denotes the capacity to reach appropriate services, requiring an awareness of suitable sources of care and an ability to mobilise practical resources and overcome opportunity costs to care seeking. For PWID, inadequate counselling and referrals accompanying HCV diagnosis, fragmented care systems, and an uneven geographic distribution of services can compound practical barriers such as a lack of access to transport, internet/phone, or childcare (Dowsett et al., 2017; Harris & Rhodes, 2013; Holt et al., 2007; Jordan

et al., 2013; Lally et al., 2008; Lang et al., 2013; Madden et al., 2018b; McGowan & Fried, 2012; Neale, Tompkins, & Sheard, 2008; Skeer et al., 2018; Skinner, Cote, & Khan, 2018; Stephens et al., 2017; Swan et al., 2010). **Service permeability** reflects the ease with which a service is accessible to a given population, and incorporates both explicit and implicit gatekeeping. Explicit gatekeeping requirements, including a need to make and keep appointments, obtain referrals, complete necessary forms, and pay for services, can impede entry into care; particularly among individuals with inadequate health insurance (McGowan & Fried, 2012; Neale et al., 2008; North, Devereaux, Pollio, Hong, & Jain, 2014; O'Donnell, Tierney, O'Carroll, Nurse, & MacFarlane, 2016; Stephens et al., 2017; Zuckerman et al., 2018). Many HCV treatment settings are poorly adapted to PWID populations, with the experience and expectation of stigma or discrimination making health services – particularly tertiary care settings – potentially hostile, uninviting, and implicitly impermeable environments (Brener, Horwitz, von Hippel, Bryant, & Treloar, 2015; Bruggmann & Litwin, 2013; Dowsett et al., 2017; Harris, 2005; Harris et al., 2013; Henderson et al., 2017; Paquette, Syvertsen, & Pollini, 2018; Souliotis, Agapidaki, Papageorgiou, Voudouri, & Contiades, 2017; Treloar, Rance, Yates, & Mao, 2016). By contrast, familiar low-threshold services such as needle-syringe programs and supervised injection facilities can play an important role in fostering trust and mediating access to health care (McNeil & Small, 2014). Numerous published intervention studies have successfully improved the navigability and permeability of HCV care for PWID through implementation of integrated/collocated, community-based and multidisciplinary care models, patient navigation and peer support programs, and telemedicine approaches, with results suggesting enhanced levels of linkage to care and treatment (Bajis et al., 2017; Bruggmann & Litwin, 2013; Crawford & Bath, 2013; Day et al.,

Table 1
Components of the integrated framework: selected examples relating to HCV care and treatment among people who inject drugs.

Candidacy	Barriers	Facilitators	Interventions
Identification of candidacy	<p>Competing social, health, or life needs</p> <p>Lack of HCV disease and treatment knowledge, insufficient post-diagnosis counselling</p> <p>Perception of HCV as benign and negative treatment perceptions (e.g. fear of side effects)</p> <p><i>Sources and suggested reading:</i> (Dowsett et al., 2017; Falade-Nwulia et al., 2019; Foley et al., 2016; Grebely et al., 2008; Harris et al., 2013; Jordan et al., 2013; Lally et al., 2008; Madden et al., 2018b; Mah et al., 2017; Morris et al., 2019; Skeer et al., 2010; Swan et al., 2010; Treloar et al., 2012, 2016a, 2016b; Treloar & Rhodes, 2009; Valerio et al., 2018; Whiteley et al., 2018; Zeremski et al., 2014).</p>	<p>HCV diagnosis, onset of symptoms</p> <p>Social support and responsibility, e.g. from/ towards romantic partners, friends, family</p> <p>Trust, rapport and continuity of care with health professionals</p>	<p>Rapid antibody/RNA testing in diverse settings</p> <p>HCV education and outreach for PWID, including comprehensive post-test counselling</p> <p>Enhanced peer-based recruitment and targeted community outreach</p>
Navigation and permeability of services	<p>Financial barriers, lack of practical resources, opportunity costs (e.g. income generation)</p> <p>Fragmented service provision, poor follow-up, diagnosis without referral to appropriate services</p> <p>Referral and appointment requirements, expectations of stigma & discrimination</p> <p><i>Sources and suggested reading:</i> (Bajis et al., 2017; Brenner et al., 2013; Bruggmann & Litwin, 2013; Crawford & Bath, 2013; Day et al., 2019; Dowsett et al., 2017; Foley et al., 2016; Gonzalez et al., 2017; Harris, 2005; Harris & Rhodes, 2013; Henderson et al., 2017; Holt et al., 2007; Jordan et al., 2013; Lally et al., 2008; Lang et al., 2013; Madden et al., 2018b; McGowan & Fried, 2012; McNeil & Small, 2014; Morgan et al., 2015; Neale et al., 2008; North et al., 2014; O'Donnell et al., 2016; Paquette et al., 2018; Roncero et al., 2018; Skeer et al., 2018; Skinner et al., 2018; Souliotis et al., 2017; Stephens et al., 2017; Swan et al., 2010; Treloar, Rance, & Backmund, 2013; Treloar et al., 2016a, 2016b; Wright et al., in press; Zuckerman et al., 2018)</p>	<p>Adequate health insurance, peer/social support, internet access</p> <p>Personalised and flexible healthcare, e.g. appointment times adapted to PWID schedules</p> <p>Enabling and familiar service environments including trust as a critical feature</p>	<p>Integrated multidisciplinary services addressing substance use, mental health, infectious disease</p> <p>Facilitated referral and appointment scheduling, including peer navigation programs</p> <p>Mobile clinics and telemedicine</p>
Asserting candidacy and adjudication by professionals	<p>Patient perceives communication issues, lack of physician knowledge, mismanaged care</p> <p>Provider lack understanding of PWID lived experience, or negative views of PWID</p> <p>Provider concerns about treatment cost, adherence, reinfection risk</p> <p><i>Sources and suggested reading:</i> (Dowsett et al., 2017; Lang et al., 2013; North et al., 2014; O'Donnell et al., 2016; Sublette et al., 2010; Zickmund et al., 2004)</p>	<p>Health literacy and support from peers/social workers/advocates when accessing care</p> <p>Continuity of care, individualised clinical information and messaging</p> <p>Provider motivation to treat PWID: education, encouragement and mobilisation in DAA era</p>	<p>Clinical HCV treatment guidelines, continuing medical education and sensitivity training</p> <p>Broad DAA prescriber base, including primary care providers, to provide greater patient choice</p>
Offers and resistance	<p>Patient concern about treatment (e.g. side effects) and scepticism towards DAA therapy claims</p> <p>Perceived lack of medical urgency or desire to defer treatment until abstinent from drugs</p> <p><i>Sources and suggested reading:</i> (Madden et al., 2018b; Richmond et al., 2018; Whiteley et al., 2018; Wright et al., in press)</p>	<p>Contact with trusted physicians - knowledgeable and experienced in HCV treatment - and peers who have completed DAA therapy</p> <p>Understanding consequences of untreated HCV, treatment options & possibility of retreatment</p>	<p>Biopsychosocial peer-driven approaches to improve treatment engagement</p> <p>Simplified and flexible DAA treatment models that do not interfere with other priorities</p>
Ecological	<p>Predisposing</p> <p>Age, gender, race, education, employment</p> <p>HCV knowledge</p> <p>Internalised stigma and shame</p> <p><i>Sources and suggested reading:</i> (Alavi et al., 2014; Barocas et al., 2014; Beaulieu et al., 2018; Bird et al., 2018; Butler et al., 2015; Charlebois et al., 2012; Fortier et al., 2015; Harris & Rhodes, 2013; Iversen et al., 2014; Janda & Mergenhagen, 2017; Mah et al., 2017; Makarenko et al., in press; Mehta et al., 2008; Øvrehus et al., 2019; Socías et al., 2019; Sogawal et al., 2016; Ti et al., 2018; Treloar et al., 2011; Treloar et al., 2012; Treloar et al., 2016a, 2016b; Young et al., 2018; Zeremski et al., 2014)</p>	<p>Enabling</p> <p>Insurance, transport, incarceration (+), competing needs, unstable housing, stimulant use (-)</p> <p>Regular source of care, enrolment in OAT</p> <p>Social support, social functioning</p>	<p>Need</p> <p>Diagnosis received, illness & treatment perception</p> <p>Experienced symptoms and liver health</p>
Individual characteristics & resources	<p>Age, gender, race, education, employment</p> <p>HCV knowledge</p> <p>Internalised stigma and shame</p> <p><i>Sources and suggested reading:</i> (Alavi et al., 2014; Barocas et al., 2014; Beaulieu et al., 2018; Bird et al., 2018; Butler et al., 2015; Charlebois et al., 2012; Fortier et al., 2015; Harris & Rhodes, 2013; Iversen et al., 2014; Janda & Mergenhagen, 2017; Mah et al., 2017; Makarenko et al., in press; Mehta et al., 2008; Øvrehus et al., 2019; Socías et al., 2019; Sogawal et al., 2016; Ti et al., 2018; Treloar et al., 2011; Treloar et al., 2012; Treloar et al., 2016a, 2016b; Young et al., 2018; Zeremski et al., 2014)</p>	<p>Enabling</p> <p>Insurance, transport, incarceration (+), competing needs, unstable housing, stimulant use (-)</p> <p>Regular source of care, enrolment in OAT</p> <p>Social support, social functioning</p>	<p>Need</p> <p>Diagnosis received, illness & treatment perception</p> <p>Experienced symptoms and liver health</p>

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Table 1 (continued)

Ecological	Predisposing	Enabling	Need
Attributes of the service environment	Funding, physical space, staffing/workload issues Institutional culture (e.g. attitudes towards PWID), physician experience/interest in HCV Proportion of HCV-infected patients <i>Sources and suggested reading:</i> (Brener et al., 2019, 2017; Cheallagh et al., 2016; Grebely et al., 2019; Richmond & Wallace, 2018; Rogal et al., 2017; Sublette et al., 2017)	Collocated services for comorbid conditions (e.g. HIV, substance use, mental health) HCV training, guidelines, continuing education; local “champions” to motivate action Service autonomy and context (e.g. privately owned vs public vs prison) Geographic context and configuration of services cf. population Availability of local HCV elimination “champions” Government-backed, coordinated and invested HCV action plans Health insurance, service funding structure State of the economy and health systems funding <i>Sources and suggested reading:</i> (DeBeck et al., 2017; Grebely et al., 2017; Hutchison et al., 2015; Kapadia et al., 2018; Lancaster et al., 2018, 2016; Nasrullah et al., 2017; Ooka et al., 2017; Richmond & Wallace, 2018; Scott et al., 2018)	Size of patient population affected by HCV
Meso/Macro-level context	DAA reimbursement conditions (liver health, prescriber base, drug or alcohol use) Regional commitment (financial, ideological) to elimination targets Social norms around HCV (PWID vs. broader population) Public discourse around illicit drug use, media coverage Criminalisation and punishment of drug use <i>Sources and suggested reading:</i> (DeBeck et al., 2017; Grebely et al., 2017; Hutchison et al., 2015; Kapadia et al., 2018; Lancaster et al., 2018, 2016; Nasrullah et al., 2017; Ooka et al., 2017; Richmond & Wallace, 2018; Scott et al., 2018)	Prevalence of competing/syndemic needs (e.g. overdose)	

2019; Gonzalez, Fierer, & Talal, 2017; Meyer et al., 2015; Morgan, Lee, & Sebar, 2015; Roncero et al., 2018; Tait et al., 2017; Treloar et al., 2015; Wade, Veronese, Hellard, & Doyle, 2016).

Appearing at health services involves asserting one’s claim for medical attention, requiring an ability to coherently articulate the issue (s) for which help is sought and engage in an effective dialogue about potential treatment options. Unfortunately, members of marginalised groups often report poor communication with health providers, with the social distance between parties impeding engagement and collaboration around health (O’Donnell et al., 2016). This is true for many people living with HCV, who have described feeling mistreated, ignored, misinformed, misunderstood, or patronised by providers; lacking confidence in their physicians’ competence related to HCV; and receiving too much, too little, or conflicting information about HCV and HCV treatment (Dowsett et al., 2017; North et al., 2014; Sublette, Smith, George, McCaffery, & Douglas, 2017; Swan et al., 2010; Zickmund, Hillis, Barnett, Ippolito, & LaBrecque, 2004). For some this is a deciding factor in their disengagement from HCV care (North et al., 2014). Meanwhile, service providers have acknowledged feeling inadequately educated and uncomfortable dealing with the complex needs of PWID (Lang et al., 2013) and lacking time to suitably deliver HCV messages to patients with low health literacy (Sublette et al., 2017).

Adjudication refers to the judgements and decisions of health professionals that allow or inhibit continued progression through the HCV cascade. Here, we distinguish formal definitions of treatment candidacy (clinical indication/eligibility, closely related but not identical to adjudication) from the broader notion of ‘candidacy for health services’ depicted in this framework (Dixon-Woods et al., 2006; Stepanova & Younossi, 2015; Stepanova, Kanwal, El-Serag, & Younossi, 2011). Adjudication decisions are likely to reflect a combination of clinical guidelines and the knowledge, experience, and preferences of health providers, and may be particularly sensitive to local operating conditions. For instance, although clinical guidelines recommend treating HCV in all PWID without pre-screening for illicit drug or alcohol use (American Association for the Study of Liver Diseases, 2018; European Association for The Study of The Liver, 2018; Shah et al., 2018), some physicians are reticent to prescribe DAA therapy to individuals with active substance use, citing treatment cost, adherence, and risk of reinfection as important factors in treatment decisions (Asher et al., 2016; Rogal et al., 2017). Adjudication also occurs at higher levels of the HCV treatment ecology, with dispensation closely tied to local resourcing and prioritisation of publicly funded treatment to specific groups such as individuals with advanced liver disease or those who abstain from using drugs (Marshall et al., 2016, 2018; Ooka, Connolly, & Lim, 2017).

Finally, **offers and resistance** recognises that non-utilisation of services does not necessarily reflect non-offer. PWID may refuse or defer HCV treatment, perhaps due to a perceived lack of medical urgency, fear of side effects, or competing priorities, or because the treatment offer does not meet their needs (e.g. carries a requirement for abstinence from drugs or alcohol) (Madden et al., 2018b; Mehta et al., 2008; Moirand, Bilodeau, Brisette, & Bruneau, 2007; Richmond & Wallace, 2018; Richmond et al., 2018; Wright et al., in press). Of note, recent studies suggest that concerns about side effects associated with interferon treatment persist in the DAA era (Richmond & Wallace, 2018; Whiteley et al., 2018). This suggests a need to consider the experiential and social construction of biomedical reality in key risk groups such as PWID (Carrier, Laplante, & Bruneau, 2005) and a role for peer educators in helping to shift lagging perceptions (Richmond et al., 2018).

The recursive nature of candidacy for HCV care

The framework’s temporal dimension captures the **recursive nature of candidacy**, whereby experiences accumulated through prior

health service trajectories (or learned vicariously through the experiences of others) influence identification and assertion of future candidacies. For simplicity of presentation, this process is not included in Table 1. However, we note its consistency with the findings of numerous studies of HCV care in PWID, which have tied widespread experiences of stigmatisation and discrimination in health services to the receipt of inadequate care (Brener et al., 2015; Harris, 2005; Harris, Albers, & Swan, 2015; Harris & Rhodes, 2013; Harris et al., 2013; Lang et al., 2013; Treloar & Rhodes, 2009; Zickmund et al., 2004). These experiences are internalised, shape expectations of future treatment, reinforce mistrust in health services, and can drive avoidance and delays in care seeking (Biancarelli et al., 2019, 2749). Yet the recursive nature of candidacy cuts both ways; other studies have demonstrated that continuity, familiarity and trust in health providers can foster greater engagement in HCV care among PWID (Swan et al., 2010). Moreover, achieving HCV cure can aid in recovery from internalised stigma and shame (Batchelder, Peyser, Nahvi, Arnsten, & Litwin, 2015), in some but not all cases (Harris, 2017), which may have a positive impact on future self-care and care seeking.

The ecological context of candidacy for HCV care

The ecological aspect of our Integrated Framework draws attention to a wide-ranging set of multilevel factors that interact to influence the process of negotiating candidacy for HCV care. It serves to guide understanding of the distinct access barriers faced by diverse subpopulations of PWID, for whom these factors differ, while maintaining a focus on care-seeking processes as the mechanism by which characteristics of people and settings affect treatment uptake. Distinguishing between predisposing, enabling, and need factors at the levels of individuals, services, and meso/macro contexts (see Table 1) may help to further isolate and clarify these effect mechanisms. Importantly, the impact of the various factors described here may differ across candidacy stages and/or steps in the HCV cascade.

Individual characteristics and resources influence a person's ability or likelihood to perceive a need and to seek, reach, pay for, and engage in care, thereby acting as determinants to one or several stages of negotiating candidacy. For example, enrolment in opioid agonist therapy (OAT) has been associated with greater HCV knowledge (Treloar et al., 2012) and greater likelihood of HCV testing (Butler et al., 2015; Øvrehus, Nielsen, Hansen, Holm, & Christensen, 2019), linkage to care (Ti et al., 2018; Young et al., 2018), and treatment uptake among PWID (Makarenko et al., in press; Socías et al., 2019). Coupled with studies noting greater engagement in HCV care among HIV-seropositive PWID (Beaulieu et al., 2018; Socías et al., 2019) and PWID who have a primary care provider (Barocas et al., 2014; Makarenko et al., in press), these findings reinforce the recursive nature of candidacy and the enabling role of ancillary service use. Conversely, the lack of suitable pharmacological treatment options for stimulant users may limit points of entry to HCV care for this group (Bird, Socías, & Ti, 2018; Butler et al., 2015; Høj, Minoyan, Artenie, Grebely, & Bruneau, 2018). Markers of social vulnerability such as lower education and unemployment have been associated with lower HCV knowledge (Mah et al., 2017; Treloar et al., 2011; Treloar et al., 2012) and a reduced likelihood of HCV testing among PWID (Barocas et al., 2014; Sogarwal et al., 2016), suggesting a lower predisposition to identify as a candidate for HCV care. Meanwhile, cocaine use, alcohol use, and unstable housing have been associated with lower odds of initiating and completing HCV treatment (Alavi et al., 2014; Harris & Rhodes, 2013; Janda & Mergenhagen, 2017; Mehta et al., 2008; Socías et al., 2019), even in the context of a community-based HCV treatment program for marginalized patients (Charlebois, Lee, Cooper, Mason, & Powis, 2012), emphasizing the important role of competing needs and priorities in the navigation of services. Finally, non-modifiable factors such as Indigenous ethnicity have been associated with lower HCV treatment uptake among PWID (Alavi et al., 2014; Socías et al., 2019) and likely

act as markers for a variety of enduring, intersecting, and omnipotent barriers to care (e.g. racial discrimination, historical trauma, compounding stigmas) that act throughout the entire process of negotiating candidacy (Brener et al., 2016; Fayed et al., 2018; Goodman et al., 2017; Ross, Dion, Cantinotti, Collin-Vézina, & Paquette, 2015; Treloar et al., 2016a, b).

Attributes of the service environment are implicit in procedural elements of the candidacy framework, particularly those relating to **service navigation and permeability**. Evidently, greater service approachability (through promotion and outreach), acceptability (of professional values, norms, culture), availability (suitable geographic locations, opening hours, appointment mechanisms), affordability (including direct, indirect, and opportunity costs), and appropriateness (including technical and interpersonal quality, coordination, and continuity of care) are likely to increase the ease with which PWID can navigate and permeate health services. As depicted in Table 1, higher-order predisposing, enabling, and need factors might further influence the extent to which services can adapt to support HCV elimination. For example, a lack of time and resources may prevent practitioners from participating in HCV education initiatives (Cheallaigh et al., 2017) or acting as prescribers of DAA therapy (Rogal et al., 2017), particularly in practices with large patient loads, few HCV-infected clients, and a lack of support services for substance use and mental health comorbidities (Falade-Nwulia et al., 2016). Local “champions” with an understanding of these practical realities may therefore play a crucial role in motivating, supporting, or coordinating action and, subsequently, expanding the availability and variety of DAA prescribers (Richmond & Wallace, 2018). With regards to providing an acceptable and appropriate treatment environment, attitudes towards PWID and concerns about their possible behaviour were identified as key predictors of discrimination by health care workers (Brener et al., 2019). These are amenable to change through online education (Brener, Cama, Hull, & Treloar, 2017), but short appointments (reflecting underlying reimbursement mechanisms) still limit practitioners' ability to tailor HCV messaging to patients with low health literacy (Sublette et al., 2017). Meanwhile, many OAT prescribers – a key group for integrated models of HCV care targeting opioid users – perceive their competency to treat HCV to be low, reflecting a lack of formal training and experience with this condition (Grebely et al., 2019).

Finally, **meso- and macro level contexts** include the range of geographic, economic, social, legal, and policy factors that define a particular environment and interact to influence the organisation of services and the lives of individuals. We present meso- and macro-contexts together for simplicity, but note that pertinent distinctions may exist across levels; for instance, social norms within the community of PWID may differ from those of the broader regional community, while regional (e.g. state or provincial) health policies may differ within a broader national context. Overall, these factors are important for determining the generalisability of study findings and programmatic successes to other contexts, and for identifying barriers to effective knowledge translation in the community. Examples include variation in service infrastructure between urban and rural areas, as reflected in HIV and HCV treatment gaps (Lopes, Eron, Mugavero, Miller, & Napravnik, 2017; MacKenzie et al., 2017; Schafer et al., 2017; Scott et al., 2018); local restrictions on reimbursement for DAA therapy, which directly impact treatment eligibility (Kapadia, Jeng, Schackman, & Bao, 2018; Marshall et al., 2016, 2018; Ooka et al., 2017); the presence of government-backed, coordinated and invested HCV action plans, which support changes in the service landscape (Hutchinson et al., 2015; Nasrullah, Sergeenko, Gamkrelidze, & Averhoff, 2017; Richmond & Wallace, 2018); the role of the media in shaping public discourse around illicit drug use, perceptions of deservedness, and ultimately, public policy (Lancaster, Hughes, Spicer, Matthew-Simmons, & Dillon, 2011; Wiley, 2016); and the criminalisation of drug use, which effectively criminalises the lives of PWID, fosters stigma, and impedes access to essential treatment and prevention services (DeBeck

et al., 2017; Grebely, Dore, Morin, Rockstroh, & Klein, 2017; Hughes & Stevens, 2010).

Possible applications of the integrated framework

As a complement to the cascade of care, this framework is intended to orient both research and practice to better understand, investigate, and intervene upon modifiable barriers and facilitators to HCV care. In research, it may serve to guide study questions or hypotheses; identify potential quantitative explanatory or confounding variables; provide a structure for the systematic reduction and analysis of qualitative data; and guide the interpretation of study findings or the organisation of research syntheses (Curtis & Drennan, 2013; Dixon-Woods, 2011; Gale, Heath, Cameron, Rashid, & Redwood, 2013; Issel, 2018; MacFarlane & O'Reilly-de Brún, 2012). Paired with the care cascade, the framework may be particularly beneficial in mixed-method designs (where qualitative research serves to either refine quantitative research questions or explain quantitative associations) seeking to broaden and contextualise our understanding of the complex multilevel influences on access to care (Rhodes et al., 2012). The framework can also contribute to intervention mapping by helping to specify which determinants of access should be targeted; the change process by which the intervention is expected to improve outcomes; and how local environmental conditions might support or negate intervention effectiveness (Bartholomew, Parcel, & Kok, 1998; Des Jarlais, Lyles, Crepaz, & Group, 2004; Issel, 2018).

Discussion and conclusion

Recent years have seen great strides to document the HCV cascade of care in diverse settings and populations, providing useful benchmarks to guide and monitor the rollout of DAA therapies. Yet the cascade framework remains conspicuously detached from the contextual realities facing vulnerable populations such as PWID, and is liable to produce an oversimplified understanding of health care access. As 'easy to reach' individuals are treated, the quest to identify and engage the marginalised will require a thorough understanding of the role of process, individual, provider, and contextual factors shaping health care access, including how they interact to present or impede opportunities for care. Drawing from established models of access to health care, developed and/or adapted for vulnerable populations throughout the past fifty years, we have presented a comprehensive integrated framework of access to HCV care and treatment for PWID.

Based in the concept of Candidacy (Dixon-Woods et al., 2006), this framework highlights the procedural aspects of accessing health services and the importance of patient-provider alignment throughout the various phases of care seeking. It stresses the experiential, interactive, and dynamic nature of negotiating access to care, highlighting the ways in which prior service experiences shape perceptions of legitimacy in health care seeking and the destructive influence of ongoing access barriers, stigma, and discrimination. It also draws attention to "gatekeepers" and "guides" as key mediators of service trajectories, and underscores the importance of positive therapeutic relationships and patient-centred health care approaches that respect patients' values, preferences and needs, and prioritise coordination, integration and continuity of care (Lambert et al., 1997).

Barriers to optimal service use can arise at multiple levels. Where the original Candidacy framework was lacking in its conceptualisation of individual and contextual influences on access to care (Mackenzie et al., 2013), our framework integrates ecological theories of health promotion (to frame and identify relevant multilevel determinants), specific dimensions of the interface between individual abilities and service characteristics (based on frameworks making visible the role of patient-provider fit) (Levesque et al., 2013; Penchansky & Thomas, 1981), and the mechanistic structure of the Behavioural Model of Health Services Use (Andersen, 1995; Gelberg et al., 2000) (to

distinguish between predisposing, enabling, and need-related determinants). Ecological frameworks force us to consider the balance of individual and communal responsibility for health service access, emphasising the political, cultural, and geographic barriers that hamper – or necessitate – innovative interventions to reduce population health disparities (Wiley, 2016). Our framework stresses the importance of environmental supports to (a) achieve adequate program implementation, effectiveness, and sustainability at the level of services and (b) effect behavioural change at the level of individuals (McLeroy et al., 1988). It also suggests that interventions will not be equally effective for all individuals or groups, calling for tailored interventions that enhance the fit between people, services, and policy environments (Stokols, 2000).

Our framework demands that health systems themselves empower and enable PWID to care for their health (Richard et al., 2011; Ziglio, Simpson, & Tsouros, 2011), and suggests that innovative models of care might be evaluated not only for their impact on HCV suppression or liver health, but also health, social, and service access outcomes more broadly (Mason et al., 2015). Streamlined, low-monitoring treatment models focused on biomedical outcomes risk leaving patients feeling isolated and unsupported (Henderson et al., 2017; Whiteley, Whittaker, Elliott, & Cunningham-Burley, 2016), with the institutional trivialisation of HCV (Treloar & Rhodes, 2009) and "a one-dimensional focus on the liver" (Harris, 2005, p.5) thought to negatively influence engagement in care. Without prioritising the patient experience, efforts to expand treatment access might fail to capitalise on opportunities to engage PWID in transformative therapeutic episodes or relationships (Batchelder et al., 2015; Harris & Rhodes, 2018; Harris, 2017). This is not reflected in HCV care cascades, and we should be wary of 'counting what is measured' at the expense of 'measuring what counts'. A groundswell of work in patient reported outcome and experience measures presents an opportunity to routinely quantify outcomes that matter to PWID – such as improved health-related quality of life and psychosocial functioning – and to document areas in which services are failing the people they are supposed to serve (Goutzamanis, Doyle, Higgs, & Hellard, 2019; Madden, Hopwood, Neale, & Treloar, 2018; Pourmarzi et al., 2019; Stepanova et al., 2017; Weldring & Smith, 2013). Qualitative data are also crucial for understanding the complex social structural dynamics underpinning cascade gaps and might be employed more systematically in the evaluation of new models of care (Lewin, Glenton, & Oxman, 2009; Rhodes et al., 2012).

Other fields have highlighted the inadequacy of disease-specific models for identifying the consequences of adverse social arrangements, which organise people's lives in ways that potentially influence a broad array of health-related outcomes (Aneshensel, 2005). In seeking examples to describe our framework, overarching themes of stigma and discrimination, negative health care experiences, the importance of continuity of care, and the relative prioritisation of HCV within the lives of PWID were strongly evident (Dowsett et al., 2017; Roy, Nonn, Haley, & Cox, 2007; Skeer et al., 2018; Treloar & Rhodes, 2009). Efforts to improve care processes and reduce structural vulnerability will likely be necessary to improve outcomes related not only to HCV, but other health conditions (e.g. substance dependence, HIV, mental health problems) and their social determinants (e.g. housing, social support, legal problems) (Marmot, Friel, Bell, Houweling, & Taylor, 2008; Perlman & Jordan, 2018; Reece et al., 2014; Rhodes et al., 2012; Wang et al., 2016). We therefore emphasise the need to consider how seemingly unrelated service trajectories might influence the identification and assertion of candidacy for HCV care, and the generalisability of this framework to other conditions affecting PWID. In particular, the framework may be highly applicable to understanding access to care for other chronic or relapsing conditions, particularly those characterised by repeated service trajectories, such as substance use disorders.

Finally, we note that many examples employed in this paper hail from the pre-DAA era. Further work is required to improve our understanding of access to care in the context of modern DAA therapies,

and to validate and refine the framework in this context (Noar & Zimmerman, 2005).

Declaration of interest

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CRediT authorship contribution statement

Stine Bordier Høj: Conceptualization, Investigation, Writing - original draft, Writing - review & editing, Visualization. **Brendan Jacka:** Conceptualization, Investigation, Writing - review & editing. **Nanor Minoyan:** Conceptualization, Investigation, Writing - review & editing. **Andrea Adelina Artenie:** Conceptualization, Investigation, Writing - review & editing. **Julie Bruneau:** Conceptualization, Writing - review & editing, Supervision.

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