



SIMPLIFYING MODELS OF CARE FOR TREATING HEPATITIS C IN PEOPLE WHO INJECT DRUGS

Viral hepatitis is a global public health threat, with the hepatitis C virus (HCV) responsible for an estimated 350 000 deaths and 9.7 million disability-adjusted life years (DALYs) in 2016.ⁱⁱⁱ Today, the unsafe injection of illicit drugs is a main driver of the global HCV epidemic.^{iii iv} It is estimated that 15.6 million people injected drugs globally in 2015,^v and that 6.1 million of them were living with HCV.^{vi} In 2016 WHO made the elimination of viral hepatitis as a public health threat by 2030 the overriding goal of its first global health sector strategy (GHSS) on viral hepatitis.⁷ The GHSS also established the ambitious targets of achieving an 80% reduction in HCV incidence and a 65% reduction in HCV mortality by 2030, as well as increasing the average number of sterile needles and syringes distributed to people who inject drugs (PWID) from 20 to 300 annually.

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In this review, we use *model of care* (MoC) to signify a setting-specific framework that outlines how to provide PWID with relevant services and interventions throughout the HCV cascade of care.

Although HCV became a highly curable disease with the introduction of direct-acting antiviral agents (DAAs), in most countries of the world, particularly low-income countries, access to DAAs and harm reduction services remains extremely limited^{8 9 10} and achieving the GHSS targets will require major expansion of both forms of access. That is because besides DAA therapy, which enables viral suppression, the most effective form of HCV prevention is harm reduction, including opioid substitution therapy (OST), needle and syringe exchange programmes (NSPs) and supervised injecting centres (SICs). The biggest obstacle to the scale-up of HCV services is affordability, particularly of treatment. Strategies that have proven successful in bringing DAA costs down to a fraction of the list price include directly negotiating with pharmaceutical companies, licensing generics and committing to scaling up treatment to secure bulk discounts and achieve economies of scale.¹¹

The World Health Organization (WHO) estimates that 80% of the people living with HCV have not been diagnosed.¹² For an MoC aimed at PWID, it begins with a concerted effort to test members of this hard-to-reach

population, using outreach to meet them where they are instead of waiting for them to show up in health care facilities and drug service facilities. Rapid testing has been shown to increase PWID coverage and referral rates significantly.¹³⁻¹⁵ Fortunately, because DAAs have few side-effects and can be administered orally, MoCs designed to optimise DAA delivery are much simpler than those designed for peg-interferon treatment, which requires more pre-treatment testing and intensive follow-up. Other elements that contribute to simplicity include effective linkage to care and the targeting and integration of services.¹⁶

It should be emphasised that HCV treatment should be offered based on clinical rather than social factors or injecting-related behaviours^{17 18} underlining the necessity of overcoming obstacles to HCV treatment delivery to PWID. Several studies demonstrate that HCV treatment achieves acceptable outcomes in active injectors, and outcomes that are just as good in people on OST as in people who do not inject drugs.¹⁹⁻²⁴



The following four key questions are critical to simplify models of care for treating hepatitis C in people who use drugs

Where to provide the services?

While a “one-stop shop” can be ideal, in that it provides PWID with continuity, it may be difficult to arrange financing for an integrated clinic offering a variety of health and social services in a system where funding comes from narrowly defined budgets. Moreover, clients often access services according to convenience, and providing services at a variety of sites may offer welcome flexibility.

Hospitals. For decades, hepatitis C has, as a rule, been managed by specialists in hospitals.^{25 26} As evidence became available on the effectiveness of HCV treatment in PWID and the need for tailored care pathways, new MoCs were developed. A systematic review of inpatient interferon treatment for PWID²⁷ found satisfactory results in the three studies analysing sustained virologic response (SVR), adherence and discontinuation,²⁸⁻³⁰ and in the three studies analysing reinfection.³¹⁻³³ While there appeared to be no clear advantage in providing treatment to PWID in hospitals instead of community-based settings,³⁴ most of the studies comparing HCV treatment in tertiary/specialist settings with community settings in another systematic review showed generally better uptake in the latter.³⁵ The main challenge is thus simplifying care at integrated centres and limiting the hospital role in HCV treatment. While hospital specialists may continue to play a key role in integrated HCV care for PWID, hospital referrals should ideally be necessary only in cases with severe complications, and the number of such cases is expected to decrease significantly as DAA therapy becomes more widespread. First, however, restrictions on DAA treatment in nonhospital settings³⁶ must be lifted to make such a shift possible.

Primary care facilities. The feasibility of successfully treating PWID receiving OST with interferon-based regimens has been broadly demonstrated in studies where well-trained general practitioners (GPs) work with nurses, social workers and other professionals in a primary care setting.³⁷⁻³⁹ This model can also benefit from telehealth technology.⁴⁰

The experience of Kirketon Road Centre in Sydney sheds light on the benefits of delivering DAA therapy in primary care. Among 72 marginalised PWID who started DAA therapy, 82% achieved SVR by week 12. Homelessness was a predictor of delayed SVR, but neither patterns of drug use nor treatment duration were associated with loss to follow-up.⁴¹ Multidisciplinary primary care facilities in the United States that provide training and support to professional staff have been found to provide high-quality assessment and treatment of PWID with HCV,⁴² but they are not yet a generalized reality⁴³ and further research is warranted on topics such as the impact of housing services on long-term outcomes.^{44 45}

It is unclear if shifting from an MoC relying on infectious disease doctors working in primary care settings to an integrated-care pathway led by GPs can be both effective and cost-effective. GPs are still prohibited from prescribing DAAs in most countries,⁴⁶ or are limited to delegated prescribing, but in countries where they may prescribe freely, such as Australia, the proportion of DAAs they prescribe is high.⁴⁷



Community health centres. These community-based facilities are not fully integrated into the health care system. The term is used here for centres whose primary focus is *not* drug addiction. There are several examples of community health centre MoCs from the interferon era. In 2001–2005, the overall SVR for a Canadian treatment cohort, most of them PWID, was 61%, which was comparable to outcomes from contemporaneous randomised controlled trials.⁴⁸

In one systematic review of community-based HCV treatment, most studies were undertaken at OST facilities, but none assessed DAA delivery in the community setting.⁴⁹ Studies in Toronto⁵⁰ and Philadelphia⁵¹ provide evidence of the effectiveness of community-based MoCs involving OST and DAAs, and a project in Brighton shows promising preliminary results.⁵² A Melbourne trial is comparing a control group treated with DAAs and followed at the tertiary level with an intervention group treated and followed at community health centres.⁵³

Addiction centres and harm reduction centres (HRCs). Addiction centres include drug treatment centres, primary addiction care units and facilities providing services to help PWID cope with medical and psychological issues related to addiction. *HRCs* include OST facilities, NSPs and SICs; many incorporate peer-based services with medical support.

A Danish project has provided important evidence of DAA therapy being used in addiction centres affiliated with hospital infectious disease departments. Preliminary results show that PWID can be tested and treated outside of hospitals, using specialists who prescribe DAAs without ever seeing the patient in person.^{54 55} In an East London study, 83 of the PWID attending an outreach clinic, where a consultant hepatologist and a nurse reviewed client cases, expressed interest in receiving antiviral therapy, and 58 completed treatment. Compliance was greater than 80%; homelessness, active drug injection and pre-treatment antidepressant therapy were *not* associated with noncompliance.⁵⁶ In a more recent ETHOS study, 24% of 415 PWID were treated with interferon-based regimes; of them, 62% were receiving OST. Among the treated PWID, adherence was 86% and SVR 74%.⁵⁷ Studies of OST cohorts in Norway⁵⁸ and Ireland⁵⁹ show similarly encouraging results.

NSPs too have been shown to be effective and cost-effective in preventing both HIV⁶⁰ and HCV transmission among PWID.^{61 62} They are essential for optimising linkage to care and testing, especially among young PWID,⁶³ and can also serve as a venue for HCV treatment. A large Australian study of PWID attending NSPs in 1999–2011 found that the proportion treated for HCV increased over time, although overall numbers never exceeded 10%.⁶⁴

There is also evidence for the effectiveness of SICs in preventing HCV and other blood-borne infections and avoiding other serious medical complications.^{65 66} Assessment for liver disease has proven suitable in this setting.^{67 68} However, we found no studies assessing implementation of HCV treatment pathways through SICs. Moreover, models involving SICs, such as the “service model” used by the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA), rarely address HCV.⁶⁹ Basic work is thus still needed to reconceptualise the role of SICs within the HCV cascade.

Prisons. PWID form a large proportion of the prison population.⁷⁰ A study involving 3126 HCV-infected individuals incarcerated in the United States showed that rates of linkage to care and treatment for adults



were very low, with just 18% being evaluated for initiation of treatment while incarcerated, and a mere 10% initiating DAAs.⁷¹ The high burden of HCV infection in prisons, together with the presence of other conditions such as HIV infection, HBV infection or drug use, creates a syndemic cluster that is difficult to address. On the other hand, surveillance and movement restrictions allow for straightforward implementation of diagnostic and therapeutic strategies. For instance, a recent modelling study concluded that incarceration contributes a 28% risk of HCV transmission among PWID in Scotland but scaling up HCV treatment to 80% of chronically infected PWID with sufficiently long sentences (>16 weeks) upon entrance to prison was able to reduce both the incidence and prevalence of HCV by 46%.⁷² Offering prisoners HCV services upon intake is quite rare, however. Another recent study using a prevention benefit analysis concluded that increasing HCV testing in United Kingdom prisons is marginally cost-effective compared to current voluntary risk-based testing, but it could be highly cost-effective if DAAs are broadly prescribed and PWID treatment rates increased.⁷³ Similar conclusions were drawn from a similar United States study.⁷⁴ Other authors have demonstrated that scaling up harm reduction services is a prerequisite to effectively tackling HCV, HIV and drug epidemics in prisons.⁷⁵ Another challenge is ensuring prisoners uninterrupted treatment upon release.

A systematic review of the effectiveness of MoCs for HCV in European prisons found that seven studies utilising second-generation DAAs in France, Italy and Spain achieved SVR rates of 85% to 98%, and one study that switched from interferon therapy to DAA therapy increased SVR rates from 62%–68% to 90%–98%.⁷⁶ A Spanish study demonstrated that HCV elimination is possible in a prison setting. Using a test-and-treat strategy, the prison tested 99.5% of its inmates, treated all who were infected and would be incarcerated more than 30 days, established a teleconsultation programme for those who were released, and achieved SVR in 97% of the treated prisoners.⁷⁷

Pharmacies. Available evidence supports including pharmacies as essential service venues in MoCs for treating HCV in PWID.⁷⁸ Some pharmacies dispense OST and thus have daily contact with people on OST, and some also offer needle and syringe services. One study demonstrated the feasibility of implementing DAAs through a community pharmacy for PWID receiving OST.⁷⁹

In addition, both rapid testing using dried blood spots⁸⁰ and syringe distribution⁸¹ have been proven effective in community pharmacies. These findings suggest that any further development of MoC designs and policies to incorporate HCV services for PWID at pharmacies should be based on the use of standard community pharmacies rather than hospital or specialist pharmacies, which can pose barriers to PWID access.

Sexual health clinics. Sexual health clinics provide a good platform for linkage to the HCV cascade. Australian and United Kingdom studies have demonstrated that interferon-based treatment in sexual health clinics, including follow-up and regular assessments, resulted in SVRs comparable to treatment at specialist clinics.⁸²⁻⁸⁴ However, we were unable to identify any studies assessing rapid point-of-care testing followed by DAA therapy in this setting. Other studies from Australia and the United Kingdom linking confirmed HCV infections in sexual health clinics to injecting drug use have shown that HCV and HIV screening is feasible there but probably insufficient.^{85 86} It has not yet been determined whether HCV screening in this setting should be clinician-led, as with these studies (which showed an HCV incidence of around 3%), or whether universal routine testing should be implemented there instead. In either case, the strategy is likely to achieve elimination in high-risk populations such as men who have sex with men (MSM).^{87 88}



What services to provide?

It is well worth consulting the latest HCV guidelines from WHO,^{89 90} the European Association for the Study of the Liver (EASL)⁹¹ and the American Association for the Study of Liver Diseases (AASLD).^{92 93} These guidelines all include concrete recommendations for providing HCV services to PWID, and the WHO guidelines specifically address the needs of low- and middle-income countries.

Simplicity, scalability and patient convenience should be the bywords in developing an MoC. They call for a test-and-treat model wherever possible, to eliminate the gaps between testing and treatment.⁹⁴⁻¹⁰⁰ Strong referral links in all directions between testing, treatment, harm reduction and social services are of paramount importance. In countries with high diagnosis rates, attention should be paid to reengaging PWID who have been diagnosed in the past and getting them into care. For a high-prevalence population like PWID, rapid antigen or RNA testing is appropriate, the latter providing results within an hour¹⁰¹⁻¹⁰³, and it may be sensible to omit genotyping if there is no major price differential between pangenotypic DAAs and genotype-specific ones. If transient elastography is not readily available, it may make sense to skip or postpone it too.

Particularly for a vulnerable, hard-to-reach population like PWID, DAA therapy is the treatment of choice and everything should be done to ensure its availability.^{104 105} Access to harm reduction and social services are critical, as discussed above. Finally, good patient follow-up and contact are essential to help ensure adherence and maximise cure rates.

Who to provide the services?

Throughout the HCV cascade of care, multidisciplinary teams of health care and social professionals can help ensure the best possible outcomes for infected PWID, which in turn improves public health. That is why the International Network for Hepatitis in Substance Users (INHSU) recommends treating HCV in a multidisciplinary team setting.¹⁰⁶ Multidisciplinary approaches encompassing biomedical, psychoeducational and social interventions have been shown to improve engagement in care,¹⁰⁷ treatment uptake,^{108 109} patient adherence and retention,¹¹⁰⁻¹¹⁵ management of HCV/HIV coinfection¹¹⁶ and of HCV in psychiatric patients,¹¹⁷ stigma reduction and patient well-being,^{118 119} and reduction in mortality.¹²⁰

As mentioned above, in moving from MoCs designed around interferon-based treatment to MoCs designed around DAAs, HCV services should be provided in a variety of settings to facilitate scale-up. With DAA therapy, HCV assessment and treatment no longer require specialist training, so it makes sense to expand who may assess HCV infection and prescribe treatment beyond specialists in tertiary care centres. With proper training, anyone can undertake assessment and prescribe DAAs competently, either as a delegated prescriber or a nonmedical prescriber – which again facilitates the scale-up of treatment. Evidence has shown good results from DAAs being prescribed by primary care providers, drug and alcohol service providers, nurse-practitioners, nurses and pharmacists.¹²¹⁻¹²⁴ The option of delegable prescribing may be a good option where prescribing is limited by statute.

Particularly when using non-specialist service providers, it is essential to invest in human resources, hiring the best people for the job and providing them with thorough and regular training. One model that has proven useful in helping such providers serve vulnerable and dispersed populations is the model promoted by Project ECHO (Extension for Community Healthcare Outcomes).¹²⁵ By engaging these frontline service providers with a continuous learning system and specialist mentors, it can dramatically increase the access of PWID to HCV care and treatment.^{126 127}



How to integrate the services?

In the DAA era, the ideal form for a successful MoC for PWID with HCV is either a one-stop-shop approach, in which all relevant services are integrated in locations where people are already accessing other services, or a flexible approach, in which various sites and services are well coordinated and strongly linked. The challenge in implementing the one-stop approach is to evolve towards comprehensive yet decentralised points of care¹²⁸, for instance through single-visit diagnoses.¹²⁹

Multidisciplinary and integration go hand in hand, yet it is important to emphasise two necessary features of the integration process in developing a robust MoC for PWID. First, integration should take place within systems where PWID already access services, particularly OST and NSPs.¹³⁰ The aim should be to bring services closer to the client, rather than expecting PWID will seek them out. And second, it requires training that is multidisciplinary and integrated, so that fewer kinds of professionals are providing more services in the same settings, thereby necessitating fewer visits to access them.

In their seminal review on MoCs for HCV, Bruggman and Litwin contrast various integrated MOCs with conventional secondary and tertiary care models.¹³¹ We advocate integration wherever feasible: delivering integrated care in nonspecialist settings that are better suited to PWID care. In Scotland, where managed care networks exemplify integrated multiagency MoCs, they have been shown to improve not only HCV outcomes, but also outcomes related to drug use.¹³²⁻¹³⁴

Conclusions

Models of care for HCV in PWID need to be redesigned to reflect the recent availability of DAAs if countries are to meet their commitments to eliminating HCV as a public health threat by 2030. In some countries, that will require major changes to established care pathways and systems. While further research on the feasibility of different MoCs in specific settings is needed, much can be learned from examining innovative MoCs from around the world, which suggest that an effective MoC for HCV infection in PWID should be simple, targeted, multidisciplinary, integrated and affordable.

Characteristics of an effective model of care

Simple

The less complex an MoC, the easier it is to implement, communicate and scale up.

Targeted

Needs to be adapted to the needs and characteristics of the target population.

Multidisciplinary

The coordinated efforts of professional service providers who have a variety of expertise can respond to a condition comprehensively.

Integrated

Concentrating services and professional skills in one facility or services obviates the need for unnecessary referrals.

Affordable

Negotiation with manufacturers is necessary to obtain the best possible price for diagnostic equipment and DAAs and facilitate scale-up.



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