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Research paper

Estimating the cascade of hepatitis C testing, care and treatment among people who inject drugs in Australia

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ABSTRACT

Background: Hepatitis C virus (HCV) infection is endemic among people who inject drugs (PWID) globally. Despite high prevalence, treatment uptake is low, with cumulative uptake <10% in most settings. This study aimed to populate the cascade of HCV testing, care and treatment among PWID using data collected in Australia prior to the introduction of broadly accessible interferon-free direct-acting antiviral (DAA) therapies in March 2016.

Methods: The Australian Needle and Syringe Program Survey is a cross-sectional surveillance system that recruits ~2300 PWID annually and collects behavioural data and dried blood samples (DBS). HCV antibody and ribonucleic acid (RNA) test results from DBS collected in 2015 were combined with data on HCV diagnostic testing, care and treatment to populate the HCV cascade among Australian PWID.

Results: Among an estimated 93,000 PWID in Australia in 2015, the majority (89%) had a lifetime history of HCV antibody testing. More than half (57%) of PWID tested HCV antibody positive and of these, 79% had detectable HCV RNA consistent with active infection. Less than half (46%) of HCV antibody positive PWID had received confirmatory HCV RNA testing. Among the estimated 43,201 PWID with active infection or chronic infection that had been successfully treated, 31% had received specialist HCV assessment, 8% had received antiviral treatment and 3% were cured.

Conclusion: This study provides baseline estimates of the cascade of HCV testing, care and treatment among PWID through enhancement of a well-established surveillance mechanism. Characterisation of the HCV cascade among PWID will be crucial to evaluating and monitoring the roll out of direct-acting antiviral therapies in Australia, including assessing potential HCV treatment as prevention benefits.

Introduction

People who inject drugs (PWID) are at high risk of hepatitis C virus (HCV) infection, with one in every two PWID globally estimated to be living with active infection (Nelson et al., 2011). Despite high prevalence, HCV treatment uptake has been low historically, with cumulative treatment uptake among PWID <10% in most settings (Alavi et al., 2014; Iversen et al., 2014; Wiessing et al., 2014). Low treatment uptake among PWID has been attributed to a combination of barriers at the provider, system and patient level, including treatment complexity, the side effects of lengthy interferon-based treatment, stigma, discrimination and limited treatment capacity (Grebely et al., 2008; Grebely, Oser, Taylor, & Dore, 2013; McGowan & Fried, 2012; Volk, 2010). The HCV treatment landscape has improved dramatically in recent years, with a number of well-tolerated and highly efficacious interferon-free direct acting antiviral (DAA) therapies now available (Dore, 2012). While some of the historic barriers to treatment uptake among PWID may diminish with the advent of interferon-free therapy, other barriers to treatment uptake among PWID, for example stigma and discrimination, will likely remain (McGowan & Fried 2012; Walsh & Maher, 2012).

Australia is an ideal setting to monitor the potential for increased uptake of HCV treatment among PWID given subsidised DAA therapies became available for all adults with chronic HCV infection irrespective of disease stage or drug use in March 2016. In the interferon-based HCV treatment era, 1–2% of Australian PWID received treatment annually (Iversen et al., 2014). A modelling study estimated that 8% annual DAA treatment uptake among PWID in Melbourne, Australia, would achieve near elimination within 10 years (Martin et al., 2013). With increasing discussion

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regarding the feasibility of HCV treatment as prevention (Barreiro, Fernandez-Montero, de Mendoza, Labarga, & Soriano, 2014; Grebely, Matthews, Lloyd, & Dore, 2013; Hagan, Wolpe, & Schinazi, 2013; Hajarizadeh, Grebely, Martinello et al., 2016; Martin, Vickerman, Dore, & Hickman, 2015; Vos, Prins, & Kretzschmar, 2015), it is important to monitor treatment uptake among PWID and to evaluate both the individual and population-level impacts of DAA therapy.

The 'cascade of care' emerged as a framework to monitor system wide performance across key stages of the continuum of care among people with HIV (Gardner, McLees, Steiner, del Rio, & Burman, 2011). The cascade of care has been widely used to document uptake of care among people living with HIV and includes measurable indicators from HIV detection and diagnosis, through to linkage and engagement in care and treatment. While measurement varies, this framework can be applied widely or to key populations to inform HIV responses and document health disparities as it identifies losses at each stage along the continuum. Application of the cascade of care framework is increasingly being applied to other diseases, including HCV (Hajarizadeh, Grebely, McManus et al., 2016; Linas et al., 2014; Yehia, Schranz, Umscheid, & Re, 2014). However, as occurs with the HIV continuum of care, there is no established framework or agreed definitions for stages along the continuum of HCV care. Further, cascade of care data on key populations are limited (Risher, Mayer, & Beyrer, 2015) and to our knowledge, none have previously examined the HCV cascade of care among PWID.

Although there is no established framework, key stages of the continuum of HCV testing, care and treatment among PWID involve screening for exposure to HCV, confirmatory testing among those exposed to distinguish between those with active and spontaneously cleared infection, engagement in care among those with active infection, followed by commencement of treatment and finally, sustained virologic response (defined as undetectable viral load 24 weeks after completion of treatment). This study utilises serological and self-reported data from a large national sample of Australian PWID to establish baseline estimates of key stages of the HCV cascade of testing, care and treatment among PWID prior to the introduction of broadly accessible interferon-free DAA therapy. A secondary aim was to identify sub-populations that may warrant targeted interventions to improve engagement and retention in care and treatment components of the cascade. Given confirmatory testing for active infection is a prerequisite for engagement in HCV care and treatment, we investigated factors associated with a self-reported history of confirmatory HCV ribonucleic acid (RNA) and/or genotype testing among PWID for whom treatment is indicated (those with serologically confirmed active HCV infection or treatment induced clearance).

Methods

Study population

The Australian NSP Survey (ANSPS) is an annually repeated cross-sectional bio-behavioural surveillance system that consists of a brief self-reported questionnaire and provision of a capillary dried blood spot (DBS). In 2015, the ANSPS was conducted at 47 Needle and Syringe Programs (NSPs) nationally. Respondents provided verbal consent for voluntary, anonymous, non-reimbursed participation and were eligible to participate in the study only once during the survey period. ANSPS methodology has been described in detail elsewhere (Iversen, Wand, Topp, Kaldor, & Maher, 2013; MacDonald et al., 1997) and previous research indicates that ANSPS samples are representative of the broader population of Australian NSP attendees (Topp et al., 2008). Ethical approval was obtained from the UNSW Australia Human Research Ethics Committee (HREC) and relevant jurisdictional and site-specific HRECs.

Measures

Respondents self-completed a brief questionnaire and provide information on their demographic characteristics and injection behaviour. In 2015, respondents were asked to self-report their current HCV status and provide information on their lifetime and recent (last 12 months) history of HCV diagnostic testing (including HCV RNA and HCV genotype testing), specialist HCV care (including assessment using FibroScan®) and history of HCV antiviral treatment (including type of treatment).

This study identified the following measures for inclusion in the HCV cascade of testing, care and treatment. Firstly, screening for exposure to HCV ('screened for HCV antibody'), applicable to all PWID. Secondly, 'confirmatory HCV RNA or genotype testing', applicable to the group exposed to HCV to distinguish between those with active or spontaneously cleared infection. Care and treatment-related measures are only applicable to the group with current or past active infection. Care and treatment measures were defined as 'HCV specialist assessment' (with or without FibroScan®), commencement of HCV antiviral treatment ('treated') and sustained virologic response defined as undetectable viral load 24 weeks after completion of treatment ('cured').

Serological testing

Capillary DBS were collected on 903 Whatman cotton-fibre protein saver cards (GE Healthcare, Chicago, United States) using a single use lancet. A modified third generation enzyme immunoassay (Monolisa anti-HCV Plus Version 2 EIA, Bio-Rad, France) was used to detect HCV antibodies. A modified cut-off value for optical density was calculated to capture greater than 95% of the seronegative population. Specimens were considered positive for HCV antibodies if the optical density to modified cut-off ratio was $\geq$1 on initial and subsequent testing.

HCV RNA was detected and quantified using a modified Abbott RealTimeTM (Illinois, United States) HCV RNA assay. The Abbot RealTime HCV RNA assay involves specimen extraction automation using the Abbott M2000SP coupled with the M2000RT Realtime PCR instrument. A bias (+1.91 Log10) applied post run gave a quantifiable DBS HCV viral load (VL) result with a lower limit of detection of 977 IU/mL (plasma equivalency). A qualitative result of $<$12 IU/mL detected (trace/equivocal) was applied to samples $<$977 IU/mL (plasma equivalency).

Analysis

Serological and behavioural data from the 2015 ANSPS were used to calculate mid-point and 95% confidence intervals for each stage in the HCV cascade of care. These data were subsequently applied to the estimated population of Australian PWID (Larney, 2016). Respondents who did not provide sufficient capillary DBS for HCV antibody serological testing were excluded from analysis. Respondents with and without sufficient remaining DBS to conduct HCV RNA testing were compared to assess any differences between these groups.

Self-reported data estimated the proportion of PWID who had received HCV diagnostic screening. DBS-based serology determined the proportion of PWID who were HCV antibody positive. Among the HCV antibody positive group, DBS HCV RNA testing and self-reported treatment data were used to identify four distinct groups: (1) those with current active infection (detectable HCV RNA) and no self-reported treatment (treatment naïve); (2) thosewith current active infection (detectable HCV RNA) and