New Infections among PWID Metric

Objective

The objective of the hepatitis C virus (HCV) new Infections among PWID metric is to measure the number of new infections of HCV from 2020-2030. Because new HCV infections primarily occur among persons who inject drugs (PWID), this metric will focus on measuring the rate of and total new HCV infections among PWID per year [1]. These will be estimated from an annual cross-sectional biobehavioral sero-study conducted at 10 syringe exchange programs (SEPs) throughout New York State (NYS), using an HCV recency assay conducted on dry blood spots (DBS). Baseline incidence will be determined in the first year of the study, with subsequent years used for analyses of trends in incidence rates.

Background

Monitoring HCV prevalence and incidence among PWID involves multiple challenges, including obtaining a representative sample of the population and enrolling and collecting data in a confidential way that assures accuracy while minimizing burden to the client. Surveillance studies in Australia, Canada, and Scotland provide helpful models for this endeavor, wherein PWID enrolled in syringe exchange and other programs throughout the jurisdictions of interest are tested for HCV annually and have been used to demonstrate changes in HCV incidence associated with scale-up of direct acting antivirals (DAA) and other programs [2-4]. In the Australian and Canadian programs, the study is conducted annually during a brief sampling period and the prevalence rate is estimated. The subset of participants captured in ≥2 waves are examined for HCV antibody (Ab) seroconversion to ascertain the incidence rate of primary infection. In the Scottish program, a newly developed HCV recency assay is now being applied to DBS obtained from persons testing HCV Ab and RNA positive, allowing for incidence rate estimation (again only primary infection)[5-7].

Methodology

This metric will utilize an annual study similar to those described above, which will be the first such HCV incidence program in the United States (US), conducted in NYS Department of Health (DOH)-approved SEPs throughout the state, building on experience with previous bio-behavioral studies, and enhanced with two features that address limitations of these international program models. The first is the inclusion of respondent-driven sampling (RDS) and other forms of community sampling to increase the diversity of participants beyond existing SEP clients who are already taking some harm reduction measures. This approach is similar to the National HIV Behavioral Surveillance Survey and the recent UPSIDE study in 3 upstate NY communities [8]. The UPSIDE study, conducted by NYSDOH AIDS Institute and UAlbany School of Public Health, was a SEP-based cross-sectional study of persons who inject drugs, recruited as SEP clients or persons referred from their networks, with the objectives of estimating HCV prevalence and extent of care, and associated factors. Participants were asked to take a survey and be tested for HCV and HIV. The second is the use of a laboratory-based assay for ascertaining recent infections to estimate the incidence rate. This method has superior statistical efficiency and validity properties relative to analyses of repeat HCV testers and of persons in the RNA+/Ab- window period [6]. This general approach was until recently used by CDC to monitor HIV incidence in the US, with all HIV recency testing being conducted at the NYS DOH Wadsworth Center. These assays have recently been developed for HCV infection and adapted for DBS [5].

The proposed project will involve an annual survey at SEP sites that represent diverse locations around NYS, recruiting 450 in NYC and 550 outside of NYC. Participants will be approached, consented, and will complete HCV/HIV rapid antibody testing and DBS confirmatory (HCV RNA) testing. A brief electronic survey (≤15 minutes) completed by participants will provide ancillary data on trends in risk behaviors, care receipt, and social determinants. A robust referral and community recruitment program will help to achieve a diverse sample of PWID.

DBS will first be tested for HCV RNA and samples from consented participants that confirm as RNA positive will be eligible for recency testing. During seroconversion, antibodies to HCV antigens develop. Early in infection, the antibody-antigen bond is weak, but over time, the antibodies mature, and the bond strengthens. The strength of an antibody-antigen bond, known as avidity, can be measured, and used to estimate recency of infection. The laboratory will use a published method in which a commercially available HCV antibody test is performed under modified conditions designed to assess the avidity of HCV antibodies in DBS samples [5]. Following this protocol, an avidity index is calculated, and samples with an avidity index below the established cutoff are classified as recent infections [5,6]. The DBS Avidity assay will be validated by the Wadsworth Center using well-characterized samples and DBS from known recent sero-converters, and then used to test all eligible HCV-positive DBS samples.

Metric estimation: From this annual incidence survey, a statewide HCV incidence rate will be calculated using the proportion of infections that are recent with Kasanjee et al.'s estimator, with possible poststratification weighting by state region using the distribution of new diagnoses [7]. NYC and rest-of-state estimates will be estimated annually, and biennially for more stability. In order to estimate the *total* number of new infections among PWID, these statewide rates will be multiplied by the current estimate of the number of PWID in NYS.

References:

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