RAPID HEPATITIS C TREATMENT INITIATION AMONG PEOPLE WHO INJECT DRUGS IN ARMENIA, GEORGIA, AND TANZANIA: TRIAL PROTOCOL

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Background: Most people living with hepatitis C (HCV) are unaware of their status, hindering broad treatment uptake. The cost of HCV RNA testing to confirm current infection is a specific barrier to treatment provision in many low-and middle-income countries. Also, the two-step diagnosis pathway often results in attrition prior to treatment initiation.

Recent evidence suggests that shortened read-time of the OraQuick HCV-antibody (Ab) test may indicate current infection (rather than exposure only).

Methods: This study will be conducted at fixed and mobile harm reduction sites and opioid agonist therapy program sites in Georgia, Armenia, and Tanzania commencing in 2024.

A shortened read-time of the OraQuick HCV-Ab test – 5-minutes rather than 20-minutes – will be used to indicate if the participant has a high probability of current HCV infection, confirmed by RNA testing.

In the intervention Arm, if the HCV-Ab test is reactive at 5-minutes, participants will be offered same-day treatment initiation and provided with 28-days of SOF/VEL. Participants will be notified of RNA testing and liver function test results via a phone call, alongside advice to continue or halt treatment. The simplified care Arm (comparison) will only provide treatment following confirmatory RNA test.

Results: The accuracy of the shortened read-time of the HCV-Ab test will be determined. The proportion commencing treatment in the rapid treatment initiation Arm will be compared to the simplified care Arm. Also, the proportion starting treatment subsequently determined to be RNA negative will be measured. Mixed effects modelling will be used to compare outcomes, including treatment uptake, completion and SVR, between Arms. Cost and cost-effectiveness of the intervention will be calculated.

Conclusion: Exploring the feasibility, effectiveness and acceptability of simplified diagnostic algorithms and rapid treatment initiation pathways is critical for improving HCV diagnosis and treatment, reducing associated costs, and informing sustainable HCV programs in low-and middle-income countries.

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