PORTFOLIO OF FIRST-EVER RANDOMIZED CONTROL TRIALS TO MEASURE IMPACT OF HEPATITIS C SELF-TESTING IN GEORGIA, MALAYSIA, AND PAKISTAN

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Introduction

Globally, only 21% of the estimated 58 million people living with hepatitis C virus (HCV) know their status. As a result, there is a significant need to scale up HCV testing if the WHO 2030 hepatitis elimination goals are to be achieved. HCV self-testing (HCVST), which was recently recommend by WHO as an additional approach to HCV testing, may help close this gap but there are currently no data on the real-world impact of HCVST. In these three studies, we aim to evaluate the acceptability and impact of 3 different HCVST models in Georgia, Malaysia, and Pakistan.

Methods

Georgia is a 5-arm project design, with intervention and control arms for 1,250 participants made up of people who inject drugs (PWIDs) and men who have sex with men (MSM), in Batumi and Tbilisi (Figure 1). Malaysia is a 2-arm project design for a total of 750 participants made up of anyone residing in the country who identifies as a key population. In both studies, participants will be randomized for an intervention group receiving HCVST (either oral-fluid or blood-based) or receiving information on the nearest facility-based HCV testing service (Figure 2). In Georgia, participants are randomized to courier delivery of HCVST, peer-delivery of HCVST, or control, while in Malaysia, participants are randomized either for courier delivery of HCVST or control. Participants will enter their test results into an online platform and will complete knowledge attitude and practices (KAP) surveys and follow-up surveys in 1-4 weeks and 6-8 weeks post enrollment to collect information on risk behaviors. Pakistan is a cluster, randomized trial comparing secondary distribution of HCVST with secondary distribution of information pamphlets encouraging visits to a testing facility for HCV screening. The clusters, consisting of neighborhoods in 2 union councils in Karachi, Pakistan, are randomized either for home distribution of HCVST via study staff or for control clusters where information on HCV and a request to attend the local hospital for HCV screening (Figure 3) are handed out.















Expected results

For Georgia and Malaysia, completed study participant surveys will be collected through the online platform selftest.ge and jom-test.com. In Georgia, linkage data will be retrieved from the national hepatitis C database. In Malaysia, peer navigators will verify participant selfreported linkage data. In Pakistan, data will be collected by the study staff and entered in the OpenClinica data capture platform. Descriptive and bivariate analyses will be conducted to evaluate the impact of HCVST. In each country, a community stakeholder group will be convened to monitor for any potential social harms arising from HCVST and test results. The group will include members from the study population (MSM and PWIDs [Georgia and Malaysia], and the general population [Pakistan]). Each study is powered to detect at least a 20% between-group difference in HCV antibody testing based on 80% statistical power and an alpha level of 0.05. Ethical approval has been received by each relevant country body. Enrolment started on 7 September 2021 in Malaysia and in November in Pakistan and December in Georgia. Preliminary data sharing is expected in January 2022.

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