Evaluating distribution of rapid HCV-antibody self-testing kits via needle/syringe vending machines: A protocol paper for the VEND-C pilot study

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Introduction

- Hepatitis C virus (HCV) affects approximately 58 million people globally, but only ~20% of those living with HCV are aware of their status (1,2)
- In 2021, the World Health Organization released recommendations for HCV self-testing, stating that it "should be offered as an additional approach to HCV testing services" (1)
- In most international regions, people who inject drugs remain the group most at-risk of HCV infection.
- Syringe dispensing machines (SDM) may reach sub-populations who do not prefer fixed-site needle and syringe programs. SDMs may therefore be an effective method of expanding HCV testing to unreached individuals
- The VEND-C study will evaluate an innovative model of delivering rapid HCV-antibody self-test kits via SDMs among people who inject drugs in community-based settings

Methodology

- VEND-C is a partnership project between the Burnet Institute and Monash Community Needle and Syringe Program (MCNSP)
- MCNSP operates four SDMs in various locations throughout the public health catchment of Monash in Melbourne's south-eastern suburbs
- VEND-C will distribute a limited number (n=210) of Orasure oral swab HCV-antibody testing assays via selected SDMs for a two month period (Aug-Sep 2022)
- The rapid HCV-antibody testing assays were included within a specially designed kit, which included information about where to access additional standard of care confirmatory HCV testing and treatment, if needed
- VEND-C will be evaluated using multiple data sources:

Automatically captured SDM data

- The SDMs use innovative data capture technology to record time/date and product type (e.g. the rapid test) ordered through the SDMs. Additionally, the SDMs require clients to input basic demographic information (gender, categorised age (e.g. 21-25 years) and residential postcode) prior to making an SDM order using an 0-9 numeric keypad

Quantitative questionnaire data

- On the front of the self-test kit, a sticker is placed with a link (QR code and URL) to a web-based quantitative questionnaire that participants can self-select to access. Following study information, the questionnaire asks about demographics, recent drug use, harm reduction access, HCV testing/treatment history, and use of the HCV-antibody rapid test. Participants can opt-in to complete additional questionnaires at three and six months post baseline questionnaire

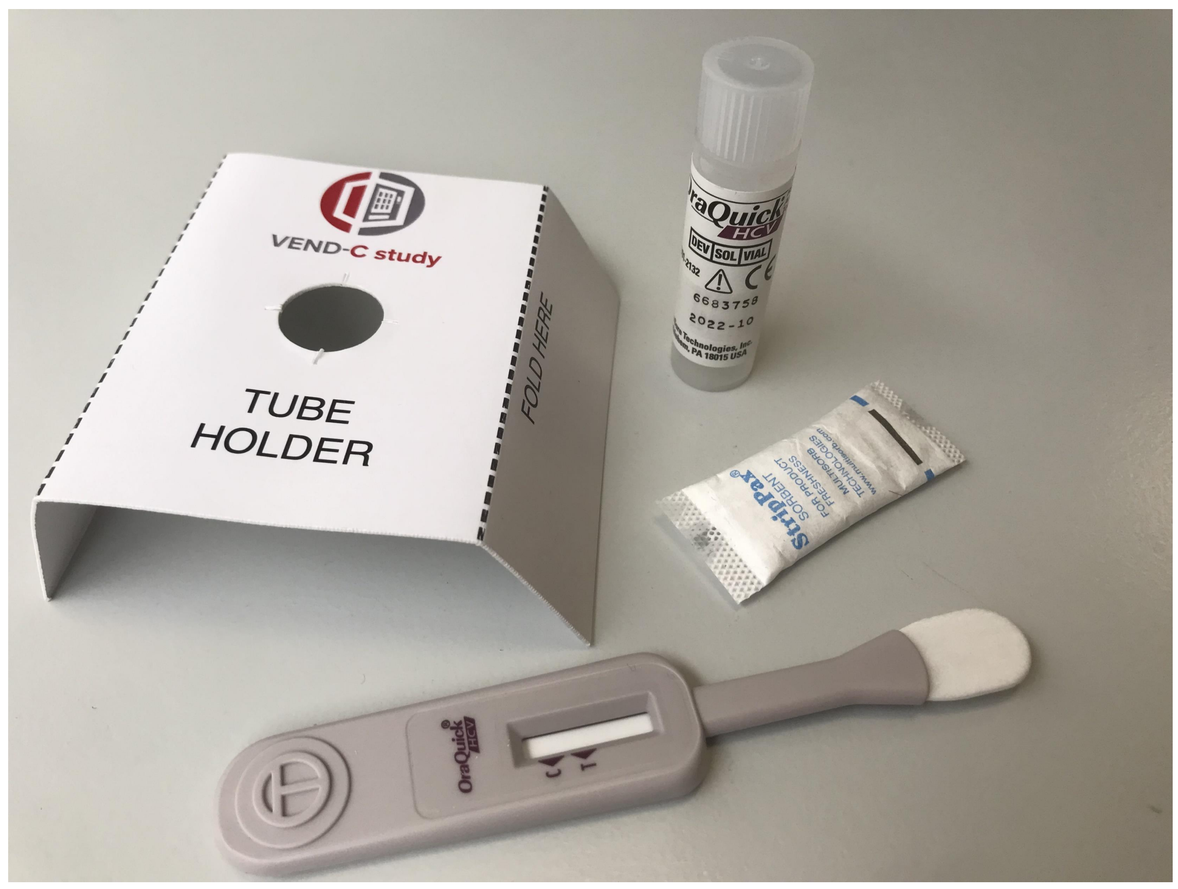
Qualitative interview data

- Qualitative interviews will be completed with a sub-set of participants previously completing the quantitative questionnaire to explore the experience and acceptability of accessing rapid HCV-antibody self-tests via the SDMs

Table 1. Dates of study milestones

Date	Study milestone
July 2022	All study approvals and agreements finalised
Aug 2022	Initial trial implementation initiated (n=20 tests)
Aug 2022	First study amendment approved; full implementation
Sept 2022	Second study amendment approved; second SDM utilised
Sept 2022	Distribution of self-test kits ends

VEND-C study



- The distributed rapid HCV-antibody self-test kits include: an oral swab and reagent tube for self-testing; a specially designed foldable card to create a stable holder for the reagent tube; detailed instructions for self-test performance; information about the VEND-C study, including a link to the quantitative questionnaire

Discussion

- The VEND-C study represents an innovative and world-first pilot study, exploring methods of distributing HCV-antibody self-test kits via SDMs to people who inject drugs in community settings
- At completion, VEND-C will provide crucial guidance for the replication of similar work internationally
- VEND-C responds to the World Health Organization's call to expand methods of HCV self-testing (1)
- VEND-C will provide data to support ongoing international HCV elimination efforts

1. World Health Organization, *Recommendations and guidance on hepatitis C virus self-testing*. 2021, World Health Organization: Geneva, Switzerland.
2. Stasi, C., et al., *Update on Hepatitis C epidemiology: Unaware and untreated infected population could be the key to elimination.* 2020, SN Compr Clin Med, 2(12)

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