



BMJ Open Feasibility of decentralised, task-shifted hepatitis C testing and treatment services in urban Myanmar: implications for scale-up

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To cite: Draper BL, Yee WL, Shilton S, *et al*. Feasibility of decentralised, task-shifted hepatitis C testing and treatment services in urban Myanmar: implications for scale-up. *BMJ Open* 2022;**12**:e059639. doi:10.1136/bmjopen-2021-059639

► Prepublication history and additional supplemental material for this paper are available online. To view these files, please visit the journal online (<http://dx.doi.org/10.1136/bmjopen-2021-059639>).

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Received 01 December 2021
Accepted 04 April 2022



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ABSTRACT

Objectives To assess the feasibility considerations for a decentralised, one-stop-shop model of care implemented in Yangon, Myanmar.

Setting Two primary care level clinics in urban Yangon, Myanmar.

Design This is a feasibility study of a highly effective care model. Using Intervention Complexity Framework by Gericke *et al*, we collated and analysed programmatic data and evaluation data to outline key project implementation requirements and experiences.

Participants Programmatic data were collected from clinical records, GeneXpert device test and maintenance reports, national guidelines, product and device instructions and site monitoring visit reports. Healthcare providers involved in delivering care model contributed interview data.

Results The main feasibility considerations are appropriate storage for test kits and treatments (in response to temperature and humidity requirements), installation of a continuous stable electricity supply for the GeneXpert device, air-conditioning for the laboratory room hosting GeneXpert, access to a laboratory for pretreatment assessments and clear referral pathways for specialist consultation when required. Lessons from our project implementation experiences included the extensive time requirements for patient education, the importance of regular error monitoring and stock storage reviews and that flexible appointment scheduling and robust reminder system likely contributed to high retention in care.

Conclusions Detailed documentation and dissemination of feasibility requirements and implementation considerations is vital to assist others to successfully implement a similar model of care elsewhere. We provide 10 recommendations for successful implementation.

Trial registration number The trial was registered at ClinicalTrials.gov NCT03939013 on May 6, 2019. This manuscript presents post-results data on feasibility.

INTRODUCTION

An estimated 58 million people live with chronic hepatitis C virus (HCV) infection worldwide, 75% in low-income and

Strengths and limitations of this study

- ⇒ This feasibility study is one of the first studies from a low-income or middle-income country to document the operational considerations of implementing a decentralised testing and treatment care model for hepatitis C.
- ⇒ Key strength of this study is that while it was a research study, the model was partially embedded in the healthcare system allowing for identification of scalability challenges.
- ⇒ Another strength is the use of various data sources for the evaluation of the feasibility of this care model.
- ⇒ Key limitation of this study is that external funding covered modifications required to overcome key implementation challenges, namely laboratory set-up.
- ⇒ There is the risk of response bias in the healthcare staff interviews as interviews were conducted by study coordinator.

middle-income countries (LMICs).^{1 2} In 2016, the World Health Organization (WHO) targeted HCV elimination by 2030³; however, few countries are on track to achieve it,⁴ and 80% of people living with HCV lack access to treatment.² Highly efficacious pan-genotypic direct-acting antiviral (DAA) regimens (rendering genotyping unnecessary) and simple non-invasive liver fibrosis assessment using aspartate/platelet ratio index (APRI) simplify HCV clinical pathways and allow for adoption of a ‘treat all’ approach.^{5 6} The ‘treat all’ approach, now recommended by WHO, refers to offering DAA treatment to all persons diagnosed with HCV⁵; previously, only assessment for treatment was recommended given the complexities and lower efficacy of the previous interferon-based treatments.⁷ Coupled with diagnostic point-of-care (PoC) testing, these advances enable

decentralised care. Decentralisation of care from central tertiary hospitals into district-level hospitals, primary care clinics or harm reduction sites is important for increasing access to care, partly by increasing geographical coverage of care sites. The unaffordability of diagnostics and DAAs and insufficient financing of national HCV programmes continue to prevent elimination⁸ and necessitate finding more cost-effective ways to provide care in resource-constrained settings.

Further scale-up of HCV testing and treatment in LMICs is needed, in turn requiring affordable, simplified HCV clinical pathways. In 2018, WHO endorsed eight good practice principles for simplified HCV service delivery.⁵ Creating and evaluating such models of care is vital to achieve elimination.⁶ Evidence supporting the effectiveness of decentralised HCV care models and task-shifting is growing, although with gaps in data from LMICs.⁹ A systematic review of 142 studies showed that full decentralisation and integration of HCV testing and treatment into harm-reduction sites or primary care improved access to testing and treatment.⁹ Moreover, task-shifting of treatment to non-specialists produced cure rates similar to those from specialist care, across multiple populations and settings.⁹ Decentralised HIV models have already shown how community-based interventions improve retention in HIV care and clinical outcomes in LMICs.^{10–12} Now, we need operational research evidence to guide implementation of decentralised HCV models of care, simplified clinical pathways and task-shifting. Evidence of such programme implementation and effectiveness will inform the planned 2021 update of WHO's HCV guideline recommendations for simplified service delivery and use of PoC HCV viral load (VL) testing.

To assess feasibility and implementation considerations to inform future models and scale-up, we evaluated a simplified, 'one-stop-shop' HCV model of care in Yangon, Myanmar.^{13 14} Myanmar (population 53 million) is a South-East Asian LMIC¹⁵ with a mixed epidemic of HCV, with 2.7% anti-HCV positivity in the general population and 56% among people who inject drugs (PWIDs),¹⁶ and an estimated million people living with HCV. Access to HCV care is limited by the number of hepatologists (estimated at 25 nationwide) and unaffordability of diagnostics and DAAs. The national treatment programme has treated approximately 11 000 people living with HCV,¹⁷ but considerable scale-up and expansion is required to reach all affected.¹⁸ Fortunately, general practitioners (GPs) can prescribe DAAs and national guidelines also support simplified pretreatment assessments (no genotyping or FibroScan).¹⁹ Creating and evaluating a simplified clinical pathway and model of care for Myanmar is an important step towards expanding decentralised primary care-based HCV testing and treatment.

In this paper, we outline the implementation requirements of our simplified HCV model of care and our experiences in implementing it in Myanmar.

METHODS

Study design

We aimed to assess the implementation requirements and feasibility considerations for our model of care and potential scale-up. We assessed the feasibility of the HCV testing workflow (delivering PoC serological rapid diagnostic tests (RDTs) and onsite PoC HCV RNA GeneXpert tests for VL confirmatory diagnosis) and treatment workflow (GP-led prescription of DAAs).

To guide the assessment, we adopted indicators (table 1A and B) from Intervention Complexity Framework (hereafter, Framework) by Gericke *et al*²⁰ and used mixed methods to collect data on study implementation and evaluation (including interviews with healthcare providers) and routine programme data. The Framework categorises health interventions by technical complexity (the quality and quantity of non-financial resources required to implement and sustain an intervention) to assist prioritising and scaling up interventions in resource-constrained settings.²⁰ We used the Framework to analyse the implementation requirements and feasibility considerations of the care model, using all data sources.

Description of clinical model of care

We trialled a decentralised 'one-stop-shop' model of care for HCV at two community clinics in Yangon between January 2019 and August 2020. Its defining features are a simplified clinical pathway (single rapid test for HCV antibodies, no HCV genotyping, use of blood-based biomarkers only for fibrosis assessment), community-based sites (no tertiary-level hospitals) and onsite phlebotomy and PoC testing for HCV diagnosis, minimising patient visits.

Clinical study procedures¹³ and outcomes are detailed elsewhere; for clarity, this study was a feasibility trial with no comparator arm.^{13 14} In brief, a laboratory technician took venous blood at patient enrolment; if rapid anti-HCV test (SD Bioline) was positive, reflex PoC HCV RNA testing (GeneXpert) was conducted on-site (no external laboratory confirmatory testing was performed for HCV diagnostic testing). After collecting baseline information and performing a physical examination and liver staging, the study GP initiated pan-genotypic DAA therapy (generic sofosbuvir, 400 mg; daclatasvir, 60 mg) according to national guidelines at the second visit for those with active HCV infection and eligible for treatment within the study. Treatment course length was determined using APRI score, as per national guidelines. Participants with physical signs of decompensation were referred to hepatologists, and those with significant comorbidities to other specialists, prior to DAA initiation. Drug dispensing and assessment of drug adherence and side effects occurred every 4 weeks. Figure 1 summarises the clinical steps and data collection relevant to this feasibility study.

Outcome results are published elsewhere.¹⁴ In brief, we found very high retention in care (100% (606/606) of antibody-positive patients underwent RNA testing) and uptake of treatment (99.8% (488/489) among

Table 1 (A) Evaluation of intervention complexity (HCV testing workflow); (B) evaluation of intervention complexity (HCV treatment workflow)

A	
Category: criteria	Point-of-care tests: HCV RDTs, GeneXpert
Intervention characteristics	
Basic product design: stability, standardisability, safety profile, ease of storage, ease of transport	HCV RDTs (SD Bioline) require storage at 1°C–30°C and are sensitive to humidity. For this study, RDTs were stored in refrigerators or in air-conditioned rooms. Xpert cartridges require storage at 2°C–28°C; Xpert device requires laboratory environment at 15°C–30°C, stable continuous electricity supply, no direct sunlight and an environment controlled to minimise dust and humidity. We stored Xpert cartridges upright in refrigerators. Xpert cartridges must be disposed of appropriately, ideally using high-temperature incinerators.
Supplies: need for regular supplies	RDTs have a shelf life of 24 months from manufacture. Xpert cartridges have a shelf life of 12 months from manufacture. For this project, this generally meant shelf life of 6–9 months after clearing customs. Demand monitoring is important to ensure regular supplies of diagnostics without wastage.
Equipment: high-technology equipment and infrastructure needed, several different types of equipment needed, maintenance needed	Basic set-up for Xpert assays requires centrifuge and Xpert device, plus computer, printer and barcode scanner (as per manufacturer's instructions). For this project, due to unstable and interrupted electricity, we required one online UPS and voltage stabiliser per Xpert device. The Xpert device requires annual calibration checks to maintain warranty, and ad hoc maintenance and module replacements to resolve recurrent errors; these require technical support personnel onsite. For this study, the two Xpert machines required six module replacements, one at the BI and five at the MLF site, during the 19-month period.
Intervention delivery characteristics	
Facilities: level of care, type of service, retail sector requirements	PoC testing occurred in two shopfront community-based clinics (equivalent to primary care facilities); rooms were renovated to provide laboratory services. Basic laboratory infrastructure required at primary healthcare clinics includes a sturdy table for centrifuge and Xpert device and laptop, air-conditioner for temperature control, room with a door to minimise dust, clinical waste disposal bins and access to sink with running water for basic laboratory cleaning and accident management. External laboratory testing facilities (tier 2 or above) were required for cirrhosis assessment, specifically to perform the AST and platelet tests to calculate the APRI score.
Human resources: skill level required for service provision and staff supervision, intensity of professional services	RDTs are simple to use, but some training is required for lateral flow assays and specific test kits. Laboratory experience or specific skill training is required for preparing plasma samples for GeneXpert centrifuging and pipetting exact sample amounts. The test device requires specific training, but laboratory experience is not necessary.
Communication and transport	Samples were transported from clinic to a private external laboratory daily and results sent via email, plus hard-copy result next day; this is standard process for private laboratories in Yangon.
Government capacity requirements	
Regulation/Legislation	Governments should regulate approved test devices through national testing guidelines or relevant treatment guidelines.
Management systems	Use of RDTs and Xpert cartridges should be monitored if procurement and implementation occur at national/regional level.
Collaborative action: need for intersectoral action within government, civil society/external agencies	Pooled procurement of RDTs and supplies could reduce costs and improve supply management. External support for sites to conduct internal quality control and participate in External Quality Assurance Scheme (EQAS) must be tailored to specific contexts and fit for purpose, considering feasibility, affordability and practicality for a government or private laboratory.
Usage characteristics	
Ease of usage: need for information and education of consumers/staff, need for supervision of consumers/staff	Staff reported that the RDTs are simple to use. GeneXpert requires minimal training and is designed for PoC use; training may be required for plasma sample preparation (fingerstick cartridges may be easier to use). In this project, there were low invalid and error rates (5% total, 3% BI site and 6% MLF site) indicated that GeneXpert was easy to use and produced consistently accurate results. Higher error at MLF site was partly attributed to high humidity and excessive dust in the laboratory room, and one module had a manufacturing fault. Overall, staff found performing phlebotomy onsite straightforward and generally acceptable to patients. However, BI staff described considerable difficulties taking venous blood samples from approximately 10 participants due to challenging venous access.
Pre-existing demand: need for promotion of intervention	HCV RNA testing in Myanmar is available through private and public laboratories at a cost unaffordable to most people living with HCV (approximately US\$40–70), other than through the national free-of-charge testing and treatment programme. Consequently, there is high pre-existing demand.
Black-market risk: need to prevent resale/counterfeiting	Risk of resale of test kits is low; RDTs are easily accessible and cheap, and Xpert cartridges are only useful with Xpert machines and trained operators.

Continued

Table 1 Continued

B	
Category: criteria	GP-led care and prescription of DAAs
Intervention characteristics	
Basic product design: stability, standardisability, safety profile, ease of storage, ease of transport	DAAs generally require storage under 30°C. We stored DAAs in air-conditioned rooms. DAAs are generally safe and well tolerated. Prescribing clinicians must assess for hepatic decompensation, other significant comorbidities and serious drug-drug interactions before initiating DAAs.
Supplies: need for regular supplies	DAA shelf life is 24 months. For this project, supply was complicated by procurement and customs processes resulting in substantial delays. However, supply via local distributors is more straightforward.
Equipment: high-technology equipment and infrastructure needed, several different types of equipment needed, maintenance needed	We used OpenMRS for clinical data. This required a server (laptop or microserver), laptop, firewall, internet access, external hard drive for backups and a UPS or generator to ensure performance during longer power outages.
Intervention delivery characteristics	
Facilities: level of care, type of service, retail sector requirements	Treatment was prescribed and dispensed from two shopfront community-based clinics, equivalent to primary care facilities. Patients with physical signs of decompensation or criteria for hepatologist referral were referred to an outreach hepatologist attending MLF weekly, or to a public hospital liver unit. Patients with other complications requiring specialist review (eg, suspected tuberculosis) were referred to the nearby public hospital.
Human resources: skill level required for service provision and staff supervision, intensity of professional services	Trained GPs were required to prescribe DAAs, and given referral criteria and pathways aligned with Myanmar's National Guidelines. Hepatologists reviewed the first 10 patients enrolled and gave some ongoing mentoring/advice in relation to cirrhotic or complicated patients.
Communication and transport	Communication between service levels is required for timely referrals. GPs and specialists communicated using the patient booklet, a paper notebook in which patients note specific health problems and doctors record results, treatment plans and appointment dates.
Government capacity requirements	
Regulation/Legislation	Governments need to regulate licensing of DAAs, standardise procurement procedures, enforce regulations, set standards and monitor quality.
Management systems	DAA uptake should be monitored for supply management if procurement and implementation occur at national/regional level.
Collaborative action: need for intersectoral action within government, civil society/external agencies	DAA procurement could be improved through further use of pooled government-led mechanisms to reduce prices and create transparent price consistency for all populations.
Usage characteristics	
Ease of usage: need for information and education of consumers/staff, need for supervision of consumers/staff	GPs require some training on the HCV clinical pathway, as per national guidelines. Clinical pathway training included introduction to HCV, natural history of HCV, staging of liver disease, DAA overview, HCV case studies and the specific treatment pathway for this study. GPs and nurses provided pre-test and post-test HCV counselling and detailed treatment information to patients during consultations, including on the importance of adherence, potential side effects of DAAs and when to access healthcare if experiencing side effects.
Pre-existing demand: need for promotion of intervention	Access to DAA treatment is poor in Myanmar, particularly to free programmes. Most people cannot afford to pay for treatment.
Black-market risk: need to prevent resale/counterfeiting	Risk of DAA resale is dependent on the national supply chain and access to treatment. There is a risk of resale of DAAs due to scarcity in Myanmar; treatment numbers in the free national programme are capped, and private treatment is only available at high cost.
APRI, aspartate/platelet ratio index; AST, aspartate transaminase; BI, Burnet Institute; DAA, direct-acting antiviral; GP, general practitioner; HCV, hepatitis C virus; MLF, Myanmar Liver Foundation; PoC, point-of-care; RDT, rapid diagnostic test.	

those eligible), and high treatment completion rates (98%, 477/488). We also found high cure rates in the whole participant group (92%; 421/456), including among PWID site: 91% (146/161) and people with

compensated cirrhosis (83%, 19/23), all treated by trained GPs in the community. Median time from RNA testing to treatment initiation was 3 days (IQR 2–5).¹⁴

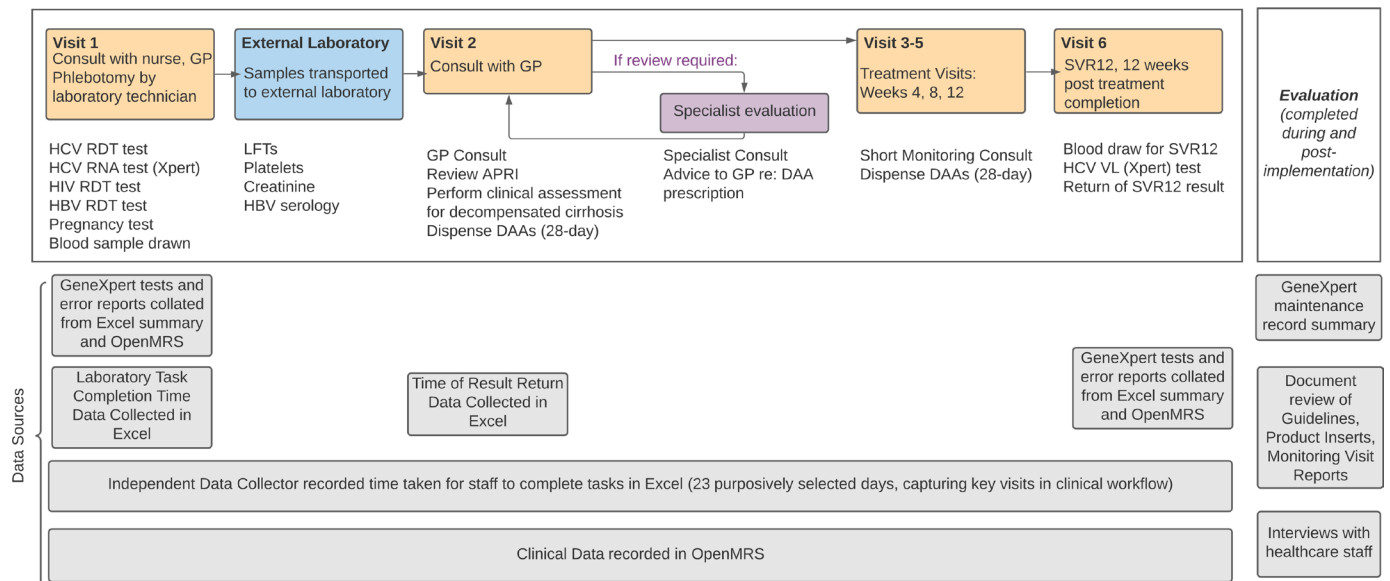


Figure 1 CT2 feasibility—workflow and data collection. APRI, aspartate/platelet ratio index; DAA, direct-acting antiviral; GP, general practitioner; HBV, hepatitis B virus; HCV, hepatitis C virus; LFT, liver function test; RDT, rapid diagnostic test; SVR, sustained virological response; VL, viral load.

Description of implementation context

Setting

Yangon is Myanmar's largest city.²¹ Relevant to stock storage, minimum daily temperatures are 17°C–25°C and maximums 29°C–37°C.²² Humidity ranges from a dry season average of 62% to 86% in monsoon season.²² Frequent scheduled and unscheduled power outages affect health service delivery.²³

Sites and human resources

The two study sites were standalone clinics in residential streets. Each clinic had small onsite generators for power back-up. The Burnet Institute (BI) Thingangyun Key Population Service Centre served mainly PWIDs. It is a two-story apartment, equipped to meet clinic criteria, with a waiting area, consultation rooms, blood collection room and laboratory. The Myanmar Liver Foundation's (MLF) Than Sitt Charity Clinic is a well-established clinic serving patients with liver disease due to hepatitis B or C infection. The laboratory was renovated 11 months into the study to improve the set-up for the GeneXpert device; see online supplemental appendix 1 for photos (laboratory set-up and schematic flow).

Patients per month varied by site and recruitment phase—new participants and follow-ups, or follow-ups only. Median patients/month were 44 at BI clinic (IQR 3.5, 93.25, range: 0–209) and 75 at MLF clinic (IQR 14, 110.25, range: 1–429).

Each clinic was staffed by a GP, nurse, and laboratory technician. The BI site also had a peer worker for community outreach and sterile needle and syringe distribution.

Training was provided over 5 days to staff prior to project commencement, and then on-site training for the GeneXpert, quality assurance training and for the electronic medical records system—OpenMRS.

Further details on human resourcing and training are provided in online supplemental appendix 2.

Data collection

We used semi-structured interviews, GeneXpert test and maintenance report data, medical records and document reviews for this feasibility analysis, summarised in figure 1.

Healthcare provider interviews

At 14 months into study implementation, when most participants had completed treatment and were returning for sustained virological response (SVR) testing, we conducted semi-structured interviews with all six healthcare providers to understand their perceptions of the feasibility of community-based hepatitis C testing and treatment (figure 1, *evaluation stage*). The six healthcare staff—a GP, laboratory technician and nurse from each clinic—were invited to participate and assured of confidentiality, and gave written informed consent.

Our interviewer (WLY, who has qualitative research training and experience) asked about the healthcare providers' demographic characteristics, previous experience with laboratory procedures, GeneXpert testing and HCV treatment, advantages and disadvantages of community-based treatment versus hospital-based care and referral, logistics and storage procedures (the interview guide is shown in online supplemental appendix 3). Interviews were conducted face-to-face in Burmese in private at the clinics, audio-recorded and took about 1 hour. They were transcribed verbatim and translated into English by external consultants.

Operational data

To inform scale-up and task-shifting opportunities, we collated the following operational data: GeneXpert test

and maintenance reports, time for providers to complete tasks and review of relevant guidelines and product documentation.

We assessed GeneXpert device and operator performance using the following indicators: test outcomes (positive/negative, error, invalid), reason for error and maintenance schedule and outcomes (figure 1, visit 1, visit 6, evaluation stage). For a subset of participants, technicians collected timepoint data for laboratory procedures, including date and time of blood sample collection for HCV RDT and Xpert HCV VL testing, test start time, test read time and time to deliver test result; these were combined with treatment initiation date data to determine time to progress through the cascade. Time to complete specific clinical workflow tasks was recorded on 23 selected days (June 2019 to October 2019) across the study implementation period (to capture the recruitment, follow-up and SVR stages) as part of ingredients-based costing (figure 1), noting that no significant changes to clinical workflow occurred within the study period.

GeneXpert device requirements and instructions, DAA and RDT product inserts that provide information on its storage requirements, Myanmar national guidelines, and Foundation for Innovative New Diagnostics' site monitoring visit reports were reviewed and contributed to the Framework assessment.

Patient involvement

Patients were not involved in study design, implementation or dissemination; however, 29 patients were interviewed to assess the acceptability of the model (findings are reported elsewhere²⁴).

Data analysis

Quantitative data

GeneXpert HCV VL testing data (RNA testing for confirmation of viraemic infection for evaluation of treatment outcome and SVR 12±24 weeks post-treatment completion) from 30 January 2019 to 31 August 2020 were analysed for error frequency and error type by site. GeneXpert testing data were collated from OpenMRS and Xpert test log reports in Excel and imported into Stata V.15 (StataCorp) for cleaning and analysis. We calculated frequencies of tests and errors, error categories and codes and total testing days, by site.

GeneXpert maintenance reports were reviewed and key information summarised, including number of module replacements.

Qualitative data

Qualitative data, including interviews and documents, were managed and analysed using NVivo V.12 (QSR International, 2018). WLY and BLD independently conducted thematic analysis, using combined deductive coding based on the Framework and inductive coding for implementation considerations, matched to framework domains where applicable. WLY read and coded the healthcare provider interview transcripts in Burmese, and

BLD read and coded the translated transcripts (English) to identify patterns and meanings independently. WLY and BD reviewed the initial codes together, discussed minor discrepancies and reached consensus on an initial coding frame; no major interpretative differences were raised. Codes with similar meaning were grouped into subthemes within framework domains.²⁰

Data availability

No unpublished data available for sharing.

RESULTS

Evaluation of intervention complexity: requirements for implementation of the HCV care model

The requirements for implementing this decentralised one-stop-shop model of care for HCV are presented in table 1A and B. We assessed two specific model components: testing workflow (table 1A) and treatment workflow (table 1B). Detailed version of table 1 (including table 1A and B with further detailed information) is included as online supplemental appendix 4.

Project implementation experiences

Below we present experiences of project implementation, highlighting specific aspects that may be applicable when implementing similar models of care elsewhere. These data are mostly from provider interviews, and include data examining time to complete tasks and time to progress through care cascade.

Appointment scheduling and patient follow-up procedures

The healthcare providers described adapting appointment scheduling to the needs and convenience of patients (eg, allowing daily methadone dosing before appointments), and developed a reminder call system for upcoming appointments. Patients were generally asked to attend twice for dispensing after initial prescription (weeks 4 and 8). Staff mentioned that some patients would prefer to attend the clinic for DAA dispensing less often; future programmes could consider removing weeks 4 and 8 dispensing and provide a full course of DAAs at visit 2 to reduce follow-up appointments, in line with national guidelines.

Staff reminded all patients of appointments, and spent considerable time following up non-attenders. They reported some difficulties in reaching patients by phone, even when calling secondary contacts. If after multiple attempts the patient could not be reached, then the staff stopped calling but allowed them to continue with study appointments if they presented for care.

Recruitment targets for clinical workflow and workload

The number of new patients recruited daily was the key driver of healthcare provider workload. Staff set daily targets, adjusted weekly to reflect progress towards the overall target and the number of follow-up patients scheduled.

Staff described pressure to meet recruitment targets within the project's timeline. Recruitment was paused in April until mid-June due to delayed DAA treatment procurement. When recruitment resumed, it was accelerated to reach the original target; this increased the staff's workload and stress. Moreover, the four-module GeneXpert device meant that only eight samples could be run per day (the clinics operated 09:00–17:00 hours or 08:30–16:00 hours, unlike external laboratories, which have extended hours).

If we want to enrol more patients, like twelve to sixteen patients per day, we have to think about whether it is possible to do that here or collaborate with an external laboratory or run two GeneXpert machines simultaneously. (HCW05)

Recruitment capacity was reduced further when the modules required maintenance or replacement. Typically, five to eight new patients were recruited per day. Staff preferred steady enrolment. Generally, staff found the work manageable unless extra administrative and logistical tasks arose.

Managing workflow

The GP, nurse and laboratory technician combined to manage patient flow, with multiple patients seen at once at different stages of the workflow. Each healthcare provider had assigned tasks, but assisted each other as required, in particular with patient education and phlebotomy. Specific tasks were completed within each appointment, with some flexibility in order and timing to fit patient needs and clinic capacity.

HCV testing workflow performance

The median time from anti-HCV RDT to VL result delivery to participant was 159 min (IQR 140–430; n=154). Median GP time required was 10 min (IQR 8–12), nurse 30 min (IQR 16–37) and laboratory technician for initial study appointment, covering screening and diagnostic testing, 8 min (IQR 6–12). The nurse generally conducted pre-test counselling, and the GP conducted post-test counselling and medical history taking to prepare for treatment initiation.

HCV treatment workflow performance

For the second study appointment, when treatment was prescribed, median GP time was 12 min (IQR 8–16) and 4 min (IQR 1–15) for the nurse, covering review of pretreatment assessments, treatment prescription and dispensing and DAA education. Time with the nurse varied by site, dependent on workflow: at the BI site, median nurse time was 18 min (IQR 14–20) and at MLF site, 1 min (IQR 1–3).

The median time from RDT to DAA initiation was 3 days (IQR 2–5). There was a statistically significant difference between median time for the 95% of participants who did not require specialist review (3 days, IQR 2–5) and the 5% who did (20 days, IQR 15–36, p<0.001).

The most time-consuming aspect of consultations with healthcare staff was the patient education session. An education session was conducted after patients consented to participate. Consent and patient education procedures took up to 45 min. For patients with time constraints or concentration difficulties, staff covered the main points to save time. Staff refrained from disciplining patients because they focused on providing acceptable and accessible care to key population groups, as this example shows:

They keep talking on the phone and receiving calls during counselling. So, I had to let them talk because I cannot stop them ... it was a bit difficult, but not that difficult. (HCW01)

In addition, if many patients were waiting, counselling sessions were sometimes shortened to allow subsequent clinical procedures to be undertaken and to ensure pretreatment blood testing was completed within the 1 day. A healthcare provider from MLF clinic suggested a private room, enabling one-on-one education without other staff or patients present would be beneficial.

Patient education

Healthcare providers reported that, despite repeated education and information provision, some patients misunderstood the modes of HCV transmission and the difference between HCV antibody tests and HCV RNA tests. Staff reflected that patients' level of knowledge was related to their education, their interest in HCV and the general population's poor access to mainstream health information. Staff suggested displaying printed resources at the clinic, using visual aids such as colourful flip-charts with pictures, and distributing brochures with key messages to facilitate health education.

Online supplemental appendix 5, table 2 details the number and types of errors experienced during the study implementation period. The BI site experienced an error rate of 3% and the MLF site 6%. The most common error at the BI site was 'user/procedural' (6/13, 46%), and at the MLF site, 'other errors' (17/42, 41%), followed by user/procedural (11/42, 26%) and cartridge errors (8/42, 19%). User/procedural errors generally stem from incorrect sample preparation.

Stock storage

MLF staff struggled to keep the test kits and drugs below <30°C, especially when power outages occurred when the clinic was closed.

I have to push the staff a bit. For example, if the items and medicines are stored upstairs, I need to remind the staff to turn on the air-con. They are a bit forgetful like this. If I don't push them, they will forget to do it. I always remind them. (HCW05)

Delivering GP-led care and referral pathways

Most patients who required hepatologist review were referred to MLF with few difficulties, but referral to specialists at public

hospitals for comorbidities was challenging. Staff said patients often complained about long wait times at public hospitals. In addition, patients from the BI site told staff that early appointments meant they missed their morning methadone dose. The GP at one site described trying to avoid referring patients due to such difficulties. GPs suggested referrals to private clinics instead, but costs would be significantly higher than at public hospitals.

Referrals of hepatic complications are all right. It is a bit difficult to send [patients] to other specialists. The hard part is the queue time at the hospital ... They cannot wait for that long... (HCW05)

Implementing an electronic medical records system

Patients' clinical information was collected using OpenMRS. GPs preferred the electronic system (OpenMRS) over a paper-based system because as the electronic records were easily backed up and accessible. Staff reported that initial training on OpenMRS should include hands-on practice. Database field errors were common initially, but most were resolved quickly. Staff reported difficulty in resolving connectivity issues and errors without IT or technician support.

DISCUSSION

This feasibility study showed a simplified HCV clinical pathway can be implemented in primary care facilities in Myanmar. Previous literature supports the safety and effectiveness of decentralised and task-shifting models of care, but few address operational considerations relevant to implementation and scale-up.⁹ Here, we provide new evidence about implementation and scale-up considerations for simplified, decentralised HCV models of care in LMICs.

We identified specific infrastructure requirements for successful HCV care, including continuous, stable electricity supply; adequate supply and stock management of Xpert cartridges; ongoing maintenance of the Xpert device; access to a laboratory for pretreatment assessment serology and established specimen referral logistics. The model was delivered by a trained GP; a laboratory technician or health worker trained in RDTs, phlebotomy and GeneXpert; access to a hepatologist for advice on suspected decompensated cirrhosis or complex cases and access to other specialists for comorbidities assessment. These were deemed the minimal requirements to deliver the HCV care model with fidelity.

We identified key operational challenges relating to laboratory set-up and procedures and successful completion of referral pathways, and propose solutions in the recommendations as mentioned in figures 2 and 3.

HCV testing workflow

Phlebotomy

Standard phlebotomy was required for all patients for HCV PoC testing, liver function tests, full blood examination, renal function and cirrhosis assessment via APRI.

Recommendation 1: Upskill laboratory technicians or other clinical staff conducting PoC testing and specimen collection to become specialised phlebotomists. This may include developing a difficult venous access protocol with the option of using specialised technology (eg, vein finder) if available, and; using fingerstick cartridges for populations with difficult venous access to aid diagnosis of active HCV infection prior to collecting a venous blood sample.

Recommendation 2: Implement continuous monitoring of errors, staff skill refreshers, and laboratory set-up reviews to reduce GeneXpert error rates.

Recommendation 3a: Purchase extended warranties on GeneXpert devices in LMICs or laboratories subject to factors such as high temperatures and humidity, excessive dust, and unstable electricity supplies, and/or with laboratory staff lacking GeneXpert experience or expertise.

Recommendation 3b: Enrol in an EQAS program for HCV VL tests to ensure high-quality care. Ideally, national laboratories will provide funds and training to build capacity to run local EQAS programs for decentralised sites. The cost of enrolment should be considered when funding decentralised programs.

Recommendation 4: Enable and monitor appropriate stock storage (e.g., refrigerators or air-conditioned rooms), train staff on its importance, and implement a daily task checklist. Ensure appropriate conditions (eg, air-conditioned rooms, continuous and stable electricity and/or UPS) for GeneXpert installation.

Recommendation 5: Remind patients of appointments and enable flexible scheduling to achieve high retention in care. Task-shifting and automation could reduce workload for clinical staff and reduce loss to follow-up.

Recommendation 6: Managing workflow and workload should involve setting realistic recruitment targets to manage patient workflow. For one GP provider and four-module GeneXpert, recruitment of eight patients/day is feasible. Eliminating on-treatment monitoring and monthly dispensing visits would also reduce overall workload. If introducing new electronic data systems, extra time should be allocated to upskilling and their use.

Figure 2 Key recommendations (recommendations 1–6). GP, general practitioner; HCV, hepatitis C virus; LMICs, low-income and middle-income countries; PoC, point-of-care; VL, viral load.

GeneXpert fingerstick assays for HCV diagnosis are simple, portable and require little equipment, increasing access and reducing test turnaround times. However, ensuring staff are well trained to collect blood from patients with difficult venous access remains important

Recommendation 7a: Task-shifting pre-test and post-test counselling and DAA education from GPs to other health workers, such as nurses, would reduce the costs of the model. Written resources and educational videos displayed in clinic waiting rooms could improve retention of pertinent information.

Recommendation 7b: Implement broader public education campaigns on HCV and DAA availability in conjunction with program scale-up to maximise reach and throughput of the model.

Recommendation 8: Ensure access to a nearby laboratory with appropriate qualifications and services, plus timely (sub-24-hour) processing, preferably with a sample collection service and results delivery via email or next-day hard copy.

Recommendation 9: Develop effective, convenient, and efficient referral pathways for GPs, patients, and specialists. They should be setting-dependent, but could be achieved through referral to private clinics to reduce wait time, or remote patient evaluation through case discussions between GPs and specialists or through remote consultation forms.

Figure 3 Key recommendations (recommendations 7–10). DAA, direct-acting antiviral; GP, general practitioner; HCV, hepatitis C virus.

when engaging PWIDs as phlebotomy for assessments prior to DAA therapy is still required.

2. Laboratory set-up and GeneXpert errors

Appropriate laboratory set-up was important for Xpert HCV VL testing. The total error rate, 5%, was slightly higher than the 1%²⁵ and 2%²⁶ reported in other studies in community settings. However, a field validation study in Tanzania²⁷ reported an error rate of 20% for HCV VL assays (plasma samples), possibly due to samples' exposure to high temperatures, humidity and movement for 10 min during transport to the onsite laboratory.²⁷ It is unclear exactly why our error rate was higher than other studies which report this, but it is likely due to a combination of factors including: the conditions of the room (ie, humidity, frequent power outages), faulty module and relative inexperience preparing samples.

External monitoring of error logs was useful for identifying common errors and methods to reduce error risk, and developed laboratory technicians' skills. Fingerstick cartridges may reduce errors associated with correct sample preparation by removing the need for centrifuging and pipetting an exact amount of plasma.

GeneXpert maintenance and quality assurance

Use of GeneXpert for POC HCV VL testing required regular device maintenance and quality control measures for assays. The local distributor provided maintenance, replacing six Xpert modules and installing extra equipment twice; hence, our extended warranty was highly cost-effective. Tuberculosis testing studies using GeneXpert in many LMICs have reported Xpert module replacement rates of 32% within 11 months²⁸ and 42% in 19 months.²⁹ Our study replaced more modules than those cited above (to date, no HCV studies have reported this outcome); most were replaced at the MLF site, which suffered excessive dust and moisture.

Programme implementation studies of Xpert for tuberculosis on *Mycobacterium tuberculosis* complex (MTB) and resistance to rifampin (RIF) have highlighted that while ambient temperatures in rooms where Xpert is installed are important, many temperature-related errors are associated with inadequate exhaust of warm air from devices, either due to fan filters clogging with dust or inadequate air flow.^{28 29} Timely module replacement ensured rapid return to full capacity.³⁰

The EQAS programme was difficult to establish because project staff were required to liaise with the study sponsor and Australia's National Reference Laboratory (NRL) regarding enrolment processes, acquiring test samples and organising appropriate training, which was time-consuming. However once implemented, the programme ran smoothly. The cost of EQAS may be prohibitive for small programmes, unless integrated through national health laboratories in Myanmar. To date, no HCV implementation studies in LMICs report enrolment in EQAS programmes for community-based sites; it is unclear if this is due to non-reporting of operational components

or non-implementation. Many implementation studies conducted globally are supported by Australia's NRL, but are often short term and do not describe this aspect of implementation.

Stock storage

Storing stock at temperatures consistently under 30°C was difficult, partly due to high temperatures in Myanmar necessitating refrigerators and/or air-conditioned rooms. Overall, stock was managed adequately in this study, close to real-world implementation. Many staff at one site did not prioritise stringent stock storage. Sometimes project staff moved stock and troubleshooted barriers to correct storage with staff during site monitoring visits. Storing stock correctly is problematic in many community-based settings, especially those with high average temperatures and unstable electricity supply, as outlined in the Xpert MTB/RIF tuberculosis testing manual.³¹ To date, few studies of HCV VL implementation have addressed these operational challenges, which are critical for decentralised laboratories when implementing similar models of care.

HCV treatment workflow

Appointment scheduling and patient follow-up

Flexibility in appointment scheduling improved the model's convenience for many patients living outside of Yangon and/or who needed methadone dosing every morning. A structured patient reminder and follow-up process aided high retention in care, but added to GPs' and nurses' workloads. Task-shifting from nurse/GP to reception or peer worker staff might reduce key clinical staff workloads, and automated SMS reminders could reduce time spent calling patients. There is strong evidence that reminders increase appointment attendance,³² but the most effective mode of delivery (eg, SMS, telephone call, letter) may depend on the patient group and healthcare service.³³ Highly motivated, altruistic, well-educated and generous staff facilitated the care model and enabled intensive follow-up procedures.

Managing workflow and workload

Recruitment targets reflecting realistic patient flow were useful to manage clinical staff workload. For one GP provider, with nurse and laboratory technician assisting, a recruitment rate of eight patients per day (in addition to follow-up appointments) was achievable. In other settings, campaign-style recruitment can process substantially more participants. For example, in Egypt, 3 physicians, 7 nurses and 4 laboratory specialists screened 3663 people for hepatitis C and hepatitis B over 4 days.³⁴

Note that staff at both sites were almost exclusively focused on providing HCV care to patients, whereas many GPs must balance various patient needs. GPs involved in delivering care in this study had treated HCV with DAAs in other research and philanthropic work. All clinical staff were committed to offering their patients a cure and to the study's success, and had access to a broader

implementation team to support model implementation and troubleshoot problems.

Workload could be reduced by eliminating monthly DAA dispensing and monitoring visits (ie, weeks 4, 8 and 12). This would also reduce patients' transport costs and time off work, improving the model's affordability and cost-effectiveness. Evidence suggests a minimal monitoring approach is safe, efficient and effective. The recent minimal monitoring (MINMON) approach trial tested having the entire 12-week course dispensed at the treatment initiation visit, no scheduled visits or laboratory monitoring, and only two points of remote contact scheduled to check adherence at week 4 and then to schedule SVR12 assessment appointment.³⁵ Throughout, patients were able to attend for unplanned visits whenever they required assistance. The SVR rates were excellent, at 95% (379/399) for all those initiated treatment. No serious adverse events related to treatment were reported.³⁵ Further work assessing the safety and effectiveness of this model for diverse patient groups may be required, for example, only 14% of the patient group reported current substance use; however, these results suggest no issues with cure rates using this minimal monitoring method.³⁵

Patient education

General patient education covering pre-test and post-test counselling and DAA education was time-consuming, and providers felt that many patients did not absorb key information. Task-shifting to nurses or trained community health workers is common for patient education in HIV and maternal and child health programmes globally, including in LMICs,^{36–38} and could be explored for HCV.

Misconceptions about HCV transmission—including that HCV is transmitted through saliva or acquired through eating certain foods—appear to be common in Myanmar and hamper efforts to educate patients on avoiding reinfection. This is not confined to Myanmar; in China, mosquitoes and sharing food or utensils are commonly believed to transmit HCV.³⁹

Sample transportation and results communication

While this model used rapid PoC testing for HCV diagnosis, timely blood sample transportation for positive patients from the decentralised clinic site to an external laboratory for processing was essential, facilitating timely treatment initiation and minimising loss to follow-up.

Referral pathway

The main operational challenges for GP-delivered care were developing clear referral criteria, an accessible referral pathway and GP-specialist communication. These challenges are not unique to this feasibility study; difficulties in deciding when to refer, navigating referral processes and achieving effective GP-specialist communication are common in many speciality areas.⁴⁰ Our criteria for hepatologist review were stricter than the national guidelines require. They were intended to provide guidance and reassurance to treating GPs regarding

hepatic decompensation assessment, and reduce the risk of patients being treated with DAAs instead of being evaluated by specialists as per the national guidelines. Understanding when and how to involve specialists in GP-delivered care is critical to safe and effective delivery of HCV care in the community.

Myanmar's healthcare system restricts development of accessible referral pathways for specialist care. Public hospital outpatient departments do not offer scheduled appointments, but require patients to register and wait until called. Other options include referral to a rotating specialist at a non-governmental organisation (NGO) clinic, as in our study, or referral to private specialist clinics, which we did not promote due to them being prohibitively expensive for most patients. In addition, remote consultations could occur using video conferencing technologies or secure, group instant messaging services to review patients' specific treatment plan remotely or to review as case presentations on a regular basis for ongoing education. Uptake of remote consultations has been spurred by the COVID-19 pandemic necessitating fewer face-to-face consultations.

Efficient referral and review processes are common challenges in healthcare, with various interventions trialled and evaluated.⁴¹ Our hub-and-spoke referral system was feasible, but could be improved via more options for referral to private clinics and financial support for this to facilitate timely review, and more direct GP-specialist communication to discuss cases such as through remote consultations.

Use of an electronic medical records system

Standalone training for use of OpenMRS for data collection was needed. Training was necessary to upskill staff to capture study data in this system, because many staff had never used electronic data capture tools and had minimal computer literacy.

Using OpenMRS improved data quality and was a good introduction to electronic data capture. It was not used for referral or sharing patient information with specialists, or for external laboratories to enter test results, or for real-time reporting to government or other bodies. However, these are technically feasible and logical applications.

Identifying capacity gaps and reducing identified constraints to scaling up

Assessing intervention scalability and preparing intervention scale-up plans requires considerable engagement with key stakeholders and resources. Generally, this involves structured thinking and decision-making guided by decision tools or frameworks.^{42 43} An intervention scalability assessment and a scale-up plan was outside the scope of this work; however, we provide some observations for those interested in replicating this model of care.

Implementation context is critical to intervention feasibility and success. Note that the staff involved here were invested in providing an accessible service to their patients

and in the study's success. The staff's dedication to the service likely contributed to their acceptance of these challenges when providing a clinical service and their ability to adapt the service to overcome these challenges; the willingness of teams in other settings to overcome these challenges and adapt service delivery is unknown and should be considered when implementing in new contexts. Moreover, note that we covered the costs of all diagnostic tests, pretreatment assessments and treatment for patients (ie, patients paid nothing), which is unlikely to occur in a national government-funded primary care-based HCV programme. Paying for tests and treatment may reduce uptake of care drastically, and is important to evaluate to inform scale-up.

Briefly, scale-up of this model of care in Myanmar would require:

- ▶ identification of appropriate decentralised sites, including harm reduction sites (such as needle/syringe distribution programmes, opioid substitution therapy dispensing sites), primary care clinics and HIV treatment sites;
- ▶ an appropriately trained workforce, funding for human resourcing and development of referral pathways, given the very small hepatologist workforce in Myanmar;
- ▶ a robust supply chain for DAAs and Xpert cartridges (noting that COVID-19 and political instability can disrupt previously well-established mechanisms); this could be managed centrally by the National Hepatitis Control Programme;
- ▶ funding for diagnostics and DAAs, in a setting where even minimal out-of-pocket costs are unaffordable to most people;
- ▶ promotion of the benefits and availability of HCV treatment to ensure take-up beyond the 'willing and waiting'.

Scale-up of similar models of care within the primary healthcare system in Myanmar must be driven and supported by the Ministry of Health and Sports, in particular the National Hepatitis Control Programme.

Strengths and limitations of this study

The model being partially embedded in the healthcare system was a strength, in that patients were referred to public hospitals if required, the service settings were similar to those of other primary healthcare clinics and it allowed identification of specific scalability challenges. Another strength was the use of various data sources for evaluation, and high-quality clinical and operational data supported the feasibility evaluation and recommendations. While we had good quality data, we were unable to definitively determine the root cause of the higher GeneXpert error rate; detailed reporting of GeneXpert error rates and module replacement rates should be prioritised from other community-based HCV programmes in LMICs.

This model of care study's external funding covered key implementation challenges, including refining laboratory

set-up; lack of such support will threaten success in other settings. In addition, we evaluated the clinical model of care within a research setting, limiting its real-world applicability. Also, it should be noted that the staff at our clinics provided HCV testing and treatment as their primary work, as opposed to providing a broad suite of primary care services with HCV as one component. Also, for the purpose of this study, the clinics only treated those with HCV mono-infection; further modifications may be required to provide care to those with HIV or hepatitis B co-infection. The staff involved in providing clinical care were aware they were participating in a trial. This probably meant they invested more personal time and adjusted their standard of care to meet patients' needs (within the protocol's constraints); for example, being extra flexible with appointment times, calling patients to remind them of appointments, and occasional fundraising to cover the accommodation costs of patients from outside Yangon.

Finally, the study coordinator conducted provider interviews and, with the study manager, wrote the evaluation, feasibility assessment and scalability recommendations. Their investment in the trial's success potentially biased the questions asked when interviewing and the responses of staff regarding challenges in study implementation, as well as the interpretation of data.

CONCLUSION

Implementing a decentralised HCV care model in urban Myanmar is feasible, and was very successful in retaining people in care through to cure, with high cure rates over 90% achieved across both sites. However, implementation in these challenging circumstances required service adaptations and ongoing dedication of our resilient staff to provide a successful care model. Staff were well supported by a broader study team, and GPs had access to ongoing specialist mentoring and support. Our evaluation of the feasibility of the intervention, and experiences implementing the project lead us to 10 key recommendations, including importance for continuous error monitoring, extended warranties, infrastructure improvements to enable appropriate stock storage and laboratory conditions and options for further task-shifting. Requirements for implementation and feasibility considerations identified herein will assist in adapting this model to other settings, including general primary care facilities, decentralised national HIV programme sites and other NGO-led sites, in Myanmar and globally. Growing evidence for the effectiveness of decentralised, non-specialist-led HCV care supports expansion of this type of care model. Continued research is needed to generate more evidence on how to implement and adapt to context to improve HCV models of care.

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Acknowledgements Our study was implemented from January 2019 to August 2020; with all work completed prior to 1 February 2021. The authors acknowledge the collaboration and contributions of the National Hepatitis Control Programme of the Myanmar Ministry of Health and Sports, the Myanmar Liver Foundation, the study participants and the study team.

Contributors BLD and WLY led the preparation of the original draft, and subsequent editing, and had access to all the data. SS, JM, NN, HH, BLD and WLY led project administration of this work and contributed to the investigation processes. MH was responsible for funding acquisition. BLD, WLY, AB and AEP led data analysis and interpretation. PE, KPK, WN, KSA and TMW were involved in reviewing and editing the manuscript. MH, AEP and JH assisted with conceptualisation of the study, provided supervision, methodology support and reviewing and editing. BLD, WLY and MH accept full responsibility for the work and conduct of the study, and decision to publish. BLD and WLY are responsible for the overall content of the study and act as guarantors.

Funding The main study was supported by Unitaid, through the FIND-led HEAD-Start. Ancillary qualitative work was supported by Gilead, through Dr Win Lei Yee's Public Health Award Fellowship (#05378). The Australian National Health and Medical Research Council (NHMRC) provided funding to AB through an Early Career Fellowship, to BLD through an NHMRC postgraduate scholarship, and to MH through an investigator fellowship. The authors also wish to acknowledge operational support through the Victorian Operational Infrastructure Support Program received by the Burnet Institute.

Disclaimer Funding bodies had no influence on interpretation of the findings, writing the manuscript or the decision to publish.

Competing interests MH has received investigator-initiated grant funding from Gilead Sciences and AbbVie for unrelated work. AP has received investigator-initiated grant funding from Gilead Sciences, MSD and AbbVie and speaker fees from Gilead Sciences for unrelated work. JH has received investigator-initiated grant funding and speaker fees from Gilead Sciences for unrelated work. WLY has received Gilead Sciences Fellowship for related work. KPK has received non-financial support from Mylan, Hetero and Royal Ruby. WN has received non-financial support from Mylan and Cipla. All others declare no potential competing interests.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

Patient consent for publication Not applicable.

Ethics approval This study was approved by The Myanmar Department of Medical Research Ethics Review Committee (#2019-144) and The Alfred Hospital Human Research Ethics Committee (#244/17). Participants gave informed consent to participate in the study before taking part.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement No data are available. No unpublished data available for sharing.

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