



Strategies to increase access and linkage to care for Hepatitis C

HEAD-Start project (Hepatitis C Elimination through Access to Diagnostics)

Sonjelle Shilton, Deputy Head HCV Access
World Hepatitis Alliance webinar, February 2020





FIND is a global non-profit, driving diagnostic innovation to combat major diseases affecting the world's poorest populations

- WHO Collaborating Centre for Laboratory Strengthening & Diagnostic Technology Evaluation
- WHO SAGE-IVD member
- ISO-certified quality management system for IVD clinical trials

ANTIMICROBIAL
RESISTANCE

HEPATITIS
& HIV

MALARIA & FEVER

NEGLECTED
TROPICAL DISEASES

PANDEMIC
PREPAREDNESS

TUBERCULOSIS

We address market failure by partnering to develop and deliver diagnostic solutions to LMICs





Available information on strategies to increase access and linkage to care



Available information on strategies to increase access and linkage to care

- World Health Organization (WHO) Guidelines on Hepatitis B and C Testing
 - Chapter 17; Service delivery approached for viral hepatitis testing – examples from the field, can be found [here](#)
- Available published systematic reviews of HCV interventions include interventions from high income countries
 - Interventions to enhance testing, linkage to care and treatment uptake for hepatitis C virus infection among people who inject drugs: A systematic review, Bajis et al., *International Journal of Drug Policy Volume 47, September 2017*
 - A systematic review and meta-analysis of community and primary-care-based hepatitis C testing and treatment services that employ direct acting antiviral drug treatments, Radley et al., *BMC Health Services Research 28 October 2019* ([open access](#))
- Forthcoming systematic review ‘Service Delivery for Hepatitis C Care: A systematic review and Meta-analysis’ by Oru et al., Includes 85 studies, 19 from LMIC
 - Poster presented at the International Liver Conference 2019 can be found [here](#)





HEAD-Start Country studies and projects



Georgia:

Settings:

- Harm Reduction Sites
- National Reference Laboratory

Activities:

- Decentralization of testing
- Comparison study cAg as test of cure
- Simplification of testing algorithm
- Integration of HCV VL in existing decentralized testing platforms

India, Manipur:

Settings:

- NGOs that serve PWID

Activities:

- Decentralization of HCV care at community level

India, Punjab:

Settings:

- Secondary and primary facilities

Activities:

- Decentralization of HCV diagnosis at ART clinics

Myanmar:

Settings:

- Drug Treatment Center and community-based clinic
- National Reference Laboratories

Activities:

- Integration of testing (RDTs and POC) in decentralized settings
- Optimization of existing polyvalent central platforms

India, Delhi:

Settings:

- Primary facilities and district hospitals

Activities:

- Hub-spoke model with decentralized screening and centralized confirmation

Malaysia

Settings:

- Secondary and primary facilities to support DNDi phase 3 trial and MOH NHP
- National Reference Laboratory

Activities:

- Hub-spoke model with decentralized screening and centralized confirmation

Acronyms

cAg	Core Antigen
DNDi	Drugs for Neglected Diseases <i>initiative</i>
HCV	Hepatitis C virus
MOH	Ministry of Health
NGOs	Non-governmental organizations
POC(T)	Point of care (test)
PWID	People who inject drugs
RDT	Rapid diagnostic test
VL	Viral Load



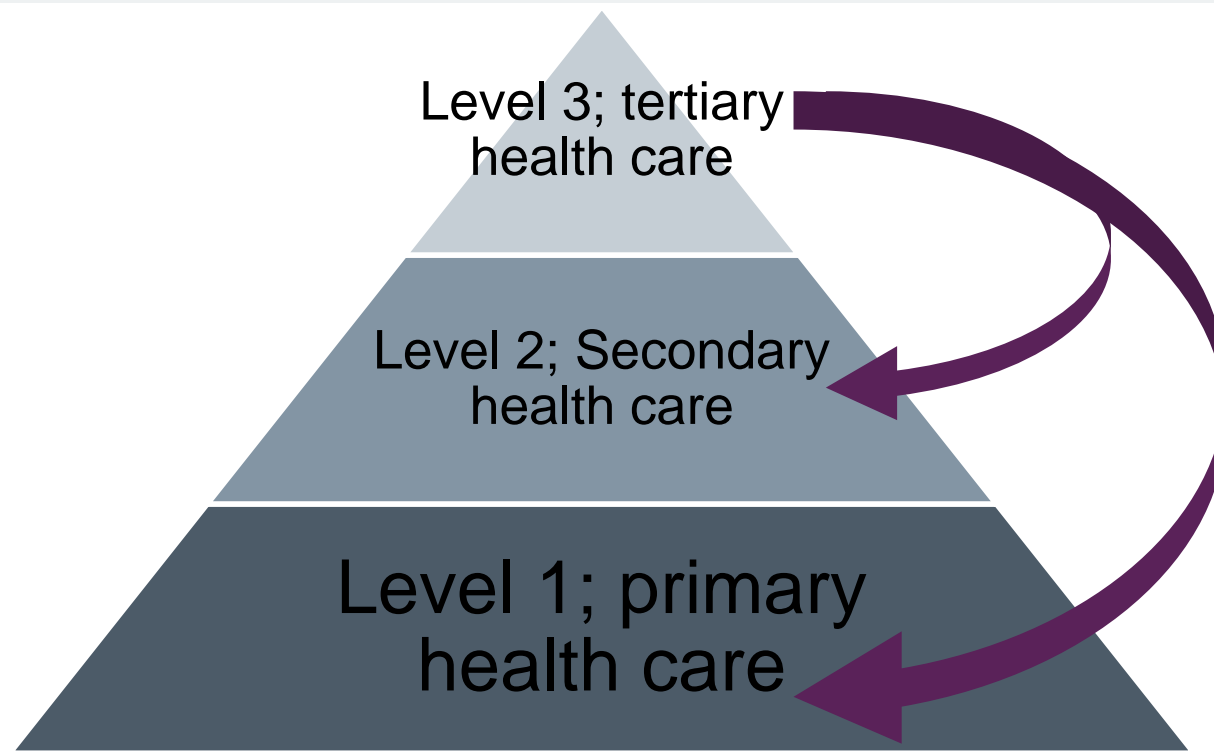
1. Decentralization

2. Simplification

3. Integration



1. Decentralization





- Increases availability of HCV testing
 - Malaysia: bringing screening from centralized to primary health care in public sector using risk-based screening
 - Georgia: bringing point of confirmation to Harm Reduction Sites from centralized level
- In both countries, catalytic effect of decentralizing diagnosis → decentralized treatment



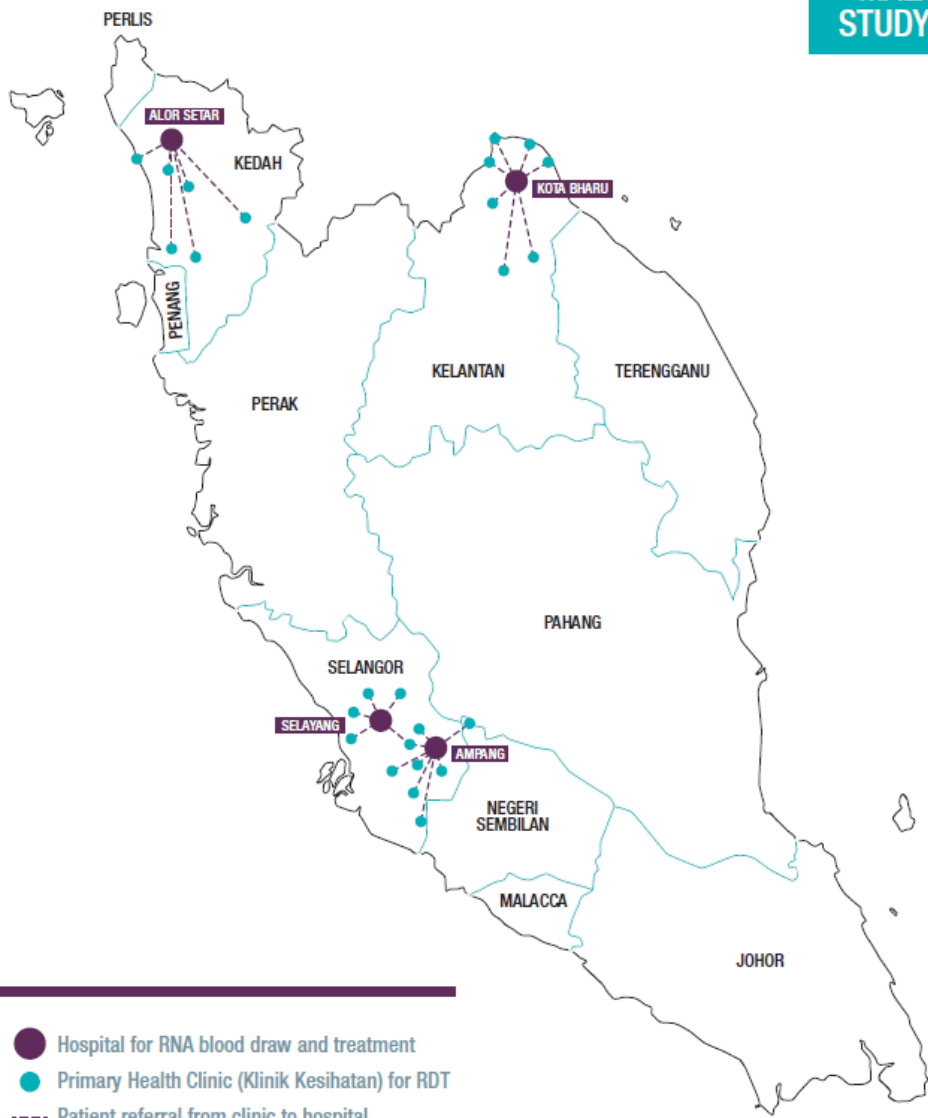
Malaysia; decentralization of the screening test



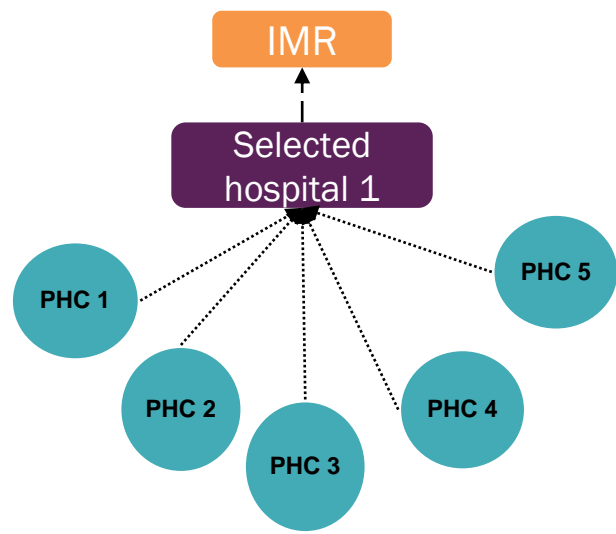
Malaysia study sites and design: Introducing HCV RDTs into the Malaysian public health system in a decentralized screening model

A project funded by

 Innovation in Global Health



MALAYSIA STUDY SITES



National epidemiology
 Population: 32 million
 HCV % Gen Pop: 0.3%–2.5%
 HCV % PWID: ~89.9%

Key	
.....	Patients referred to selected treatment site
-----	Samples referred to IMR for HCV RNA testing
●	Community-level screening site, using rapid diagnostic tests (RDTs)
■	HCV treatment site referring samples for RNA testing
■	Site with existing RNA capacity (National Reference Lab)

● Hospital for RNA blood draw and treatment
 ● Primary Health Clinic (Klinik Kesihatan) for RDT
 ---- Patient referral from clinic to hospital

DNDi
 Drugs for Neglected Diseases *initiative*

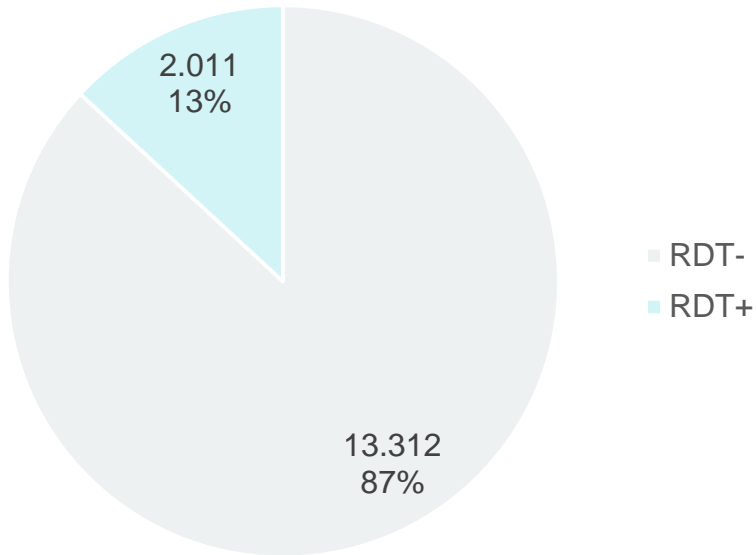
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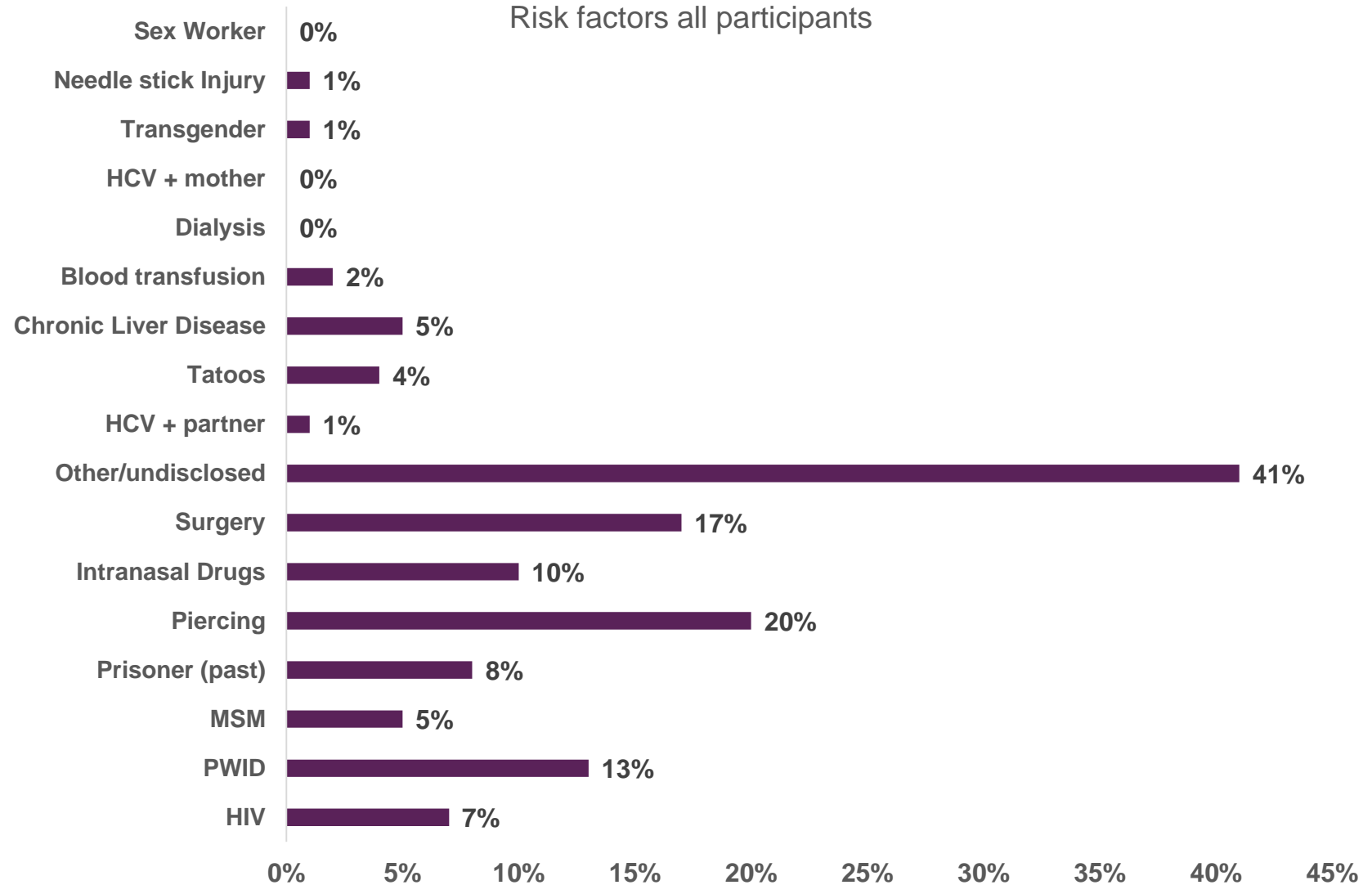
Malaysia, targeted screening results in high yields

27 December 2018 –31 December 2019 (preliminary data)

Total number screened; 15,323



Cost per patient identified \$6.23





Georgia; decentralization of the confirmatory test



HEAD-Start: Georgia study design

National epidemiology

Population: 3.7 million
HCV seroprevalence in Gen Pop: 7.7%
Est. number of PWID: 49,700 (2015)
HCV seroprevalence PWID: 50-91.9%

Harm Reduction Sites
(8 HRS)

Nonrandomized assignment

Arm 1:
(on-site POC molecular)
4 HRS

- Blood draw at point-of-care service (HRS)
- HCV confirmatory testing
- HCV viremia results given at HRS on same day



1. Tbilisi New Vector
2. Zugdidi Xenon
3. Kutaisi New Way
4. Batumi Imedi

Arm 2:
(on-site blood draw for centralized cAg)
2 HRS

- Blood draw at point-of-care service
- Plasma shipped to central lab for HCV confirmatory testing



1. Tbilisi Akeso
2. Rustavi New Vector

Arm 3:
(patient who screens RDT+ referred to HCV treatment site SOC)
2 HRS

- Standard of care: patients referred to treatment center for blood draw and confirmatory testing

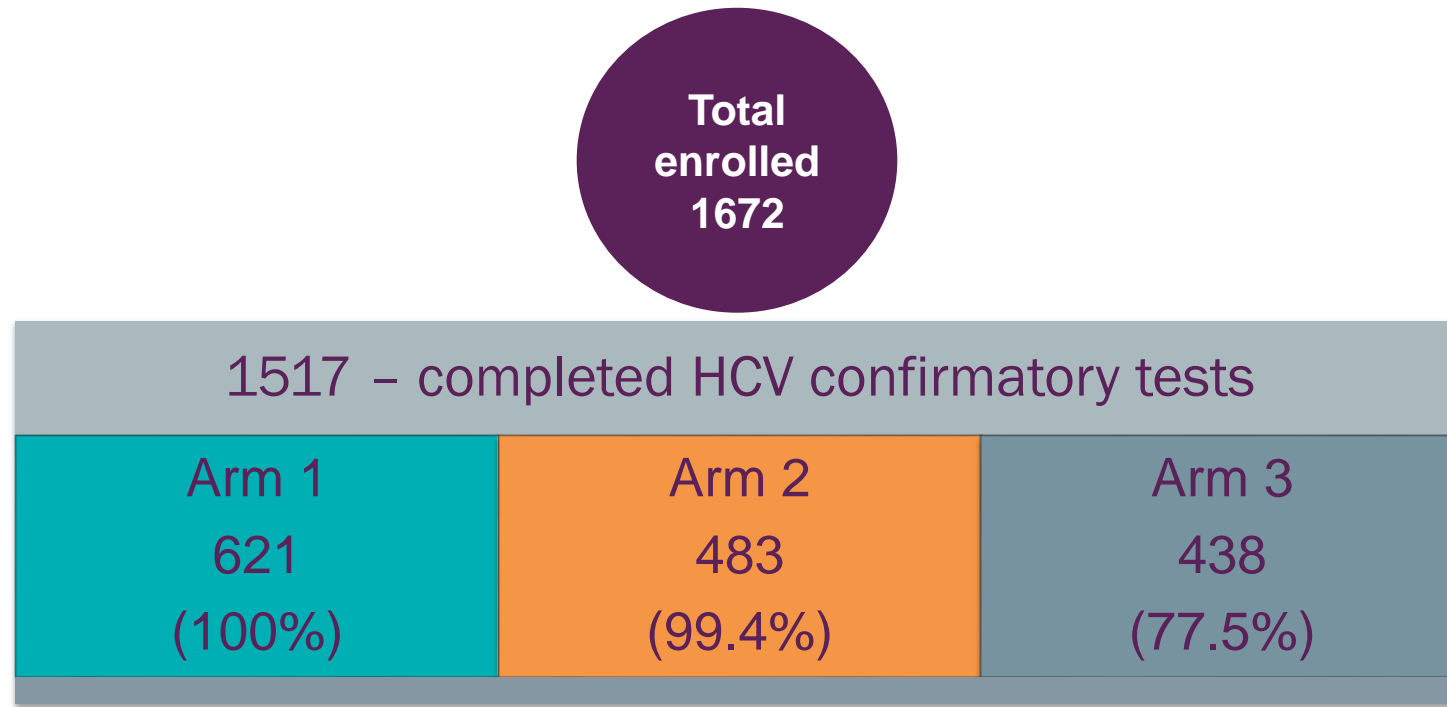


1. Gori Step to Future
2. Tbilisi New Way



Proportion of participants receiving HCV confirmatory test: preliminary data

The proportion of study participants who completed HCV viremia test, as of 1 Nov 2019, by arms



1255 (81.4%)	- Positive HCV Confirmatory results
262 (18.6%)	- Negative HCV Confirmatory results



Key considerations

Decentralizing screening and confirmatory services can increase access to testing

Screening approaches that are targeted cost less per patient identified than a 'screen all who attend for care' approach

On-site blood draw and on-site point of care testing for confirmatory tests results in very high completion of confirmatory testing



2. Simplification



Simplification: why it's better



Easier for patient: fewer visits, reducing number of tests

- 1 visit for both screening and blood draw (for confirmation and liver staging results) for high retention patients in the HCV care cascade, as seen in HEAD-Start Delhi

Easier for system: fewer tests = less monetary outlay from government budgets

- Reducing tests to bring algorithms in line with WHO recommendations
- Quickest treatment initiation is seen when genotyping and ultrasound (as standard for all patients) are removed



HEAD-Start Delhi study design



- Introducing HCV care into 5 district hospitals, and screening at 15 polyclinics and screening camps



Directorate of Health Services,
Dept. of Health & Family Welfare, Govt of NCT of Delhi

Delhi State epidemiology
Population: 18 million
HCV % (Gen Pop): estimated 1%



HEAD-Start # of patient visits (uncomplicated)

HCV Diagnosis and Treatment Management

Visit No	Project Activities	Outcome
Visit 1	<p>HCV screening using RDTs and WBFPT & results shared within 20 mins.</p> <p>Blood collected from HCVab +ve patients for HCV RNA confirmatory test and baseline investigations</p>	<ul style="list-style-type: none"> • HCV screening result (Ab -ve or +ve) known to patient 20 minutes • Blood sample provided for confirmatory and baseline tests
Visit 2	<p>HCV RNA and baseline investigations reports shared with patient</p>	<ul style="list-style-type: none"> • HCV RNA: Detected / Not Detected; patient knows if they are viremic and thus needing treatment • Non-complicated cases initiated on HCV treatment
	<p>HCV treatment initiation for non-complicated cases</p>	<p>Complicated cases referred to ILBS for medical advice</p>
Visit 3	<p>Follow up visits of HCV Patients on Treatment</p>	<p>Patient management and HCV DAA refill</p>
	<p>HCV treatment initiation for complicated cases</p>	<p>Complicated cases initiated on HCV treatment</p>
Visit 4, 5	<p>Review on DAA treatment</p>	<p>HCV – DAA Refill</p>
Visit 6	<p>Test for sustained viral response (SVR)</p>	<p>Sample collection for SVR</p>
Visit 7	<p>SVR Report</p>	<p>SVR Test result collection</p>



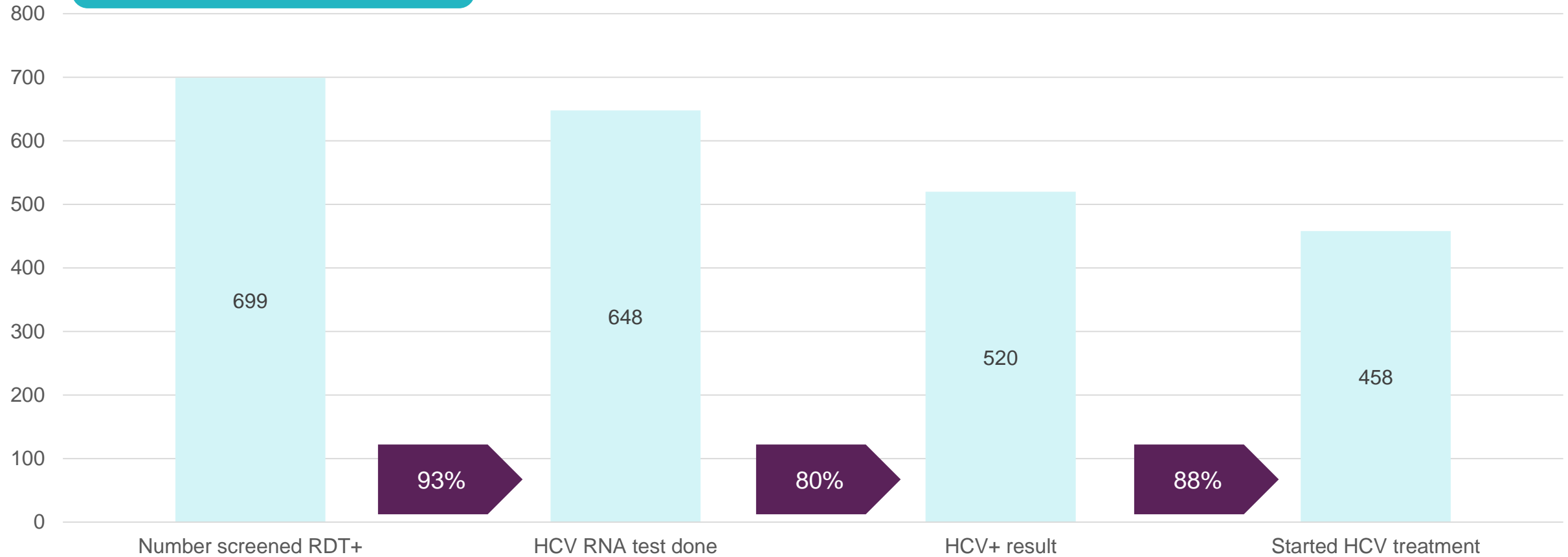
HEAD-Start Delhi: care cascade (28 Jan–30 Sept 2019)

preliminary data

Number screened: 22,756
3.1% RDT+

Cost per patient identified \$26.08

hospital care cascade





- Study conducted in partnership with Y.R.G. Care
- Demonstration study to provide model of care for PWID through offering decentralized HCV care
 - Simplified diagnostic algorithm which starts with HCV RDT screening in OST* centers
 - HCV point-of-care confirmation and treatment in primary health care centers

Epidemiology

Population: 2.7 million

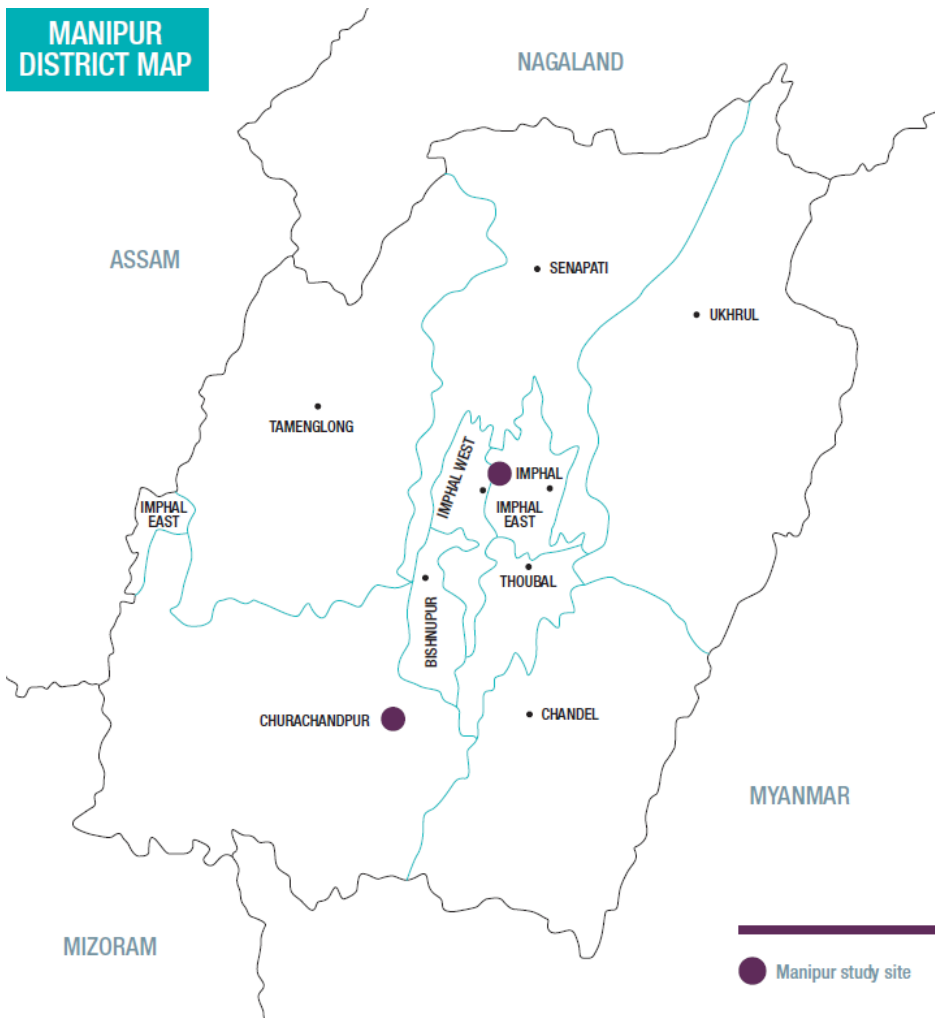
HCV PWID: 64.9%

*Opioid substitution therapy





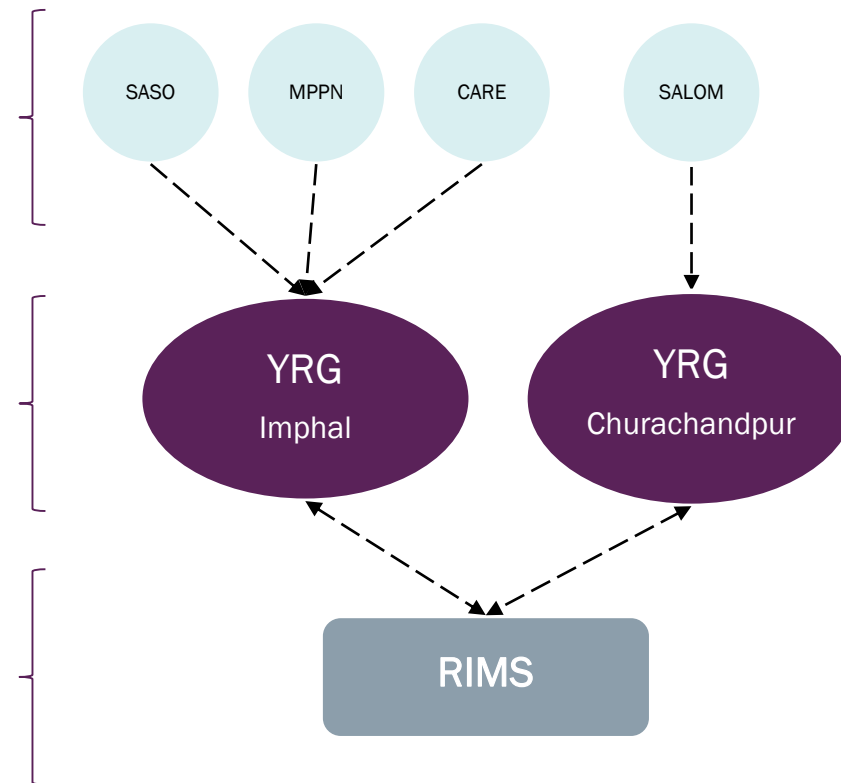
Manipur study sites



Screening at NGOs.
 Those screen positive referred to YRG sites

Confirmatory testing,
 treatment and SVR 12 at
 same site for non-
 complicated cases.

Confirmatory testing and SVR 12
 at YRG clinics with linkage to
 RIMS for treatment for
 complicated cases.



Key	
---	Represents care pathway which beneficiary will be assisted by 'navigator' to minimize LTFU
● (light blue)	NGO operated multi service center for PWIDs which includes OST, ART, and needle exchange
● (purple)	HCV RNA testing and treatment site
■ (grey)	Tertiary hospital with Hepatologist



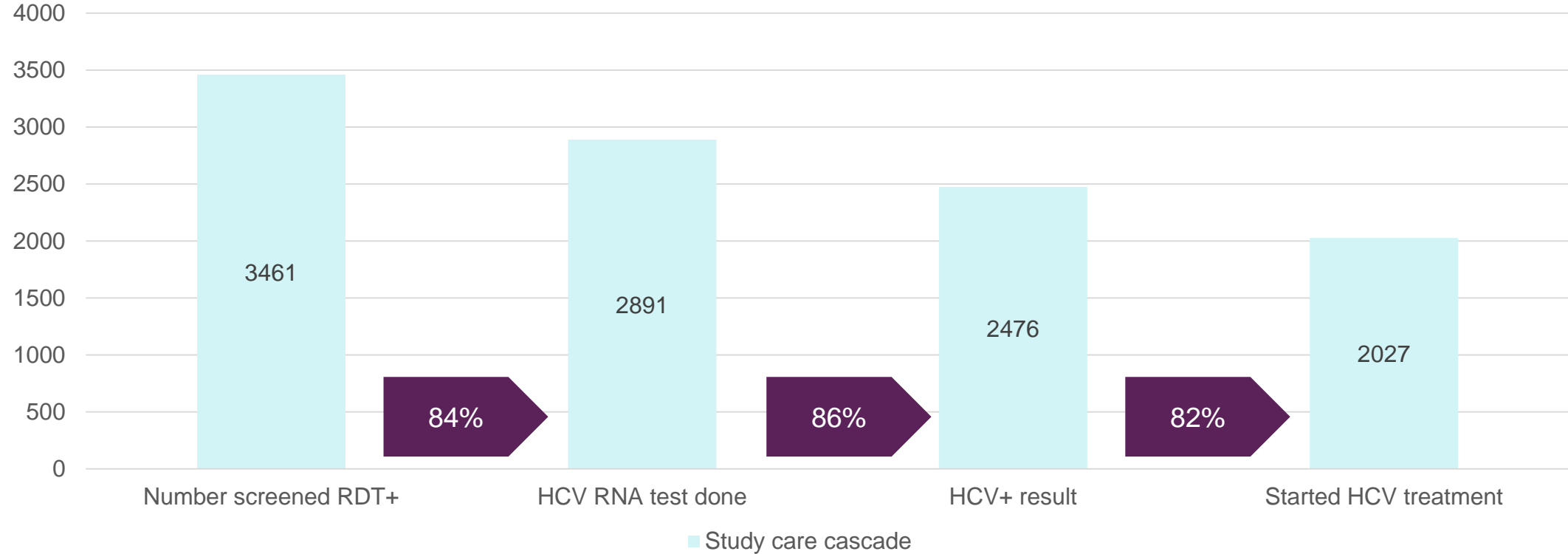
HEAD-Start Manipur: care cascade

preliminary data

Number screened: 6958
49.7% RDT+

Cost per patient identified \$1.72

Care cascade





Key considerations

Bringing HCV testing algorithms in line with WHO recommendations is a good place to start simplification

Reducing the number of visits a patient has to make to start treatment can decrease loss to follow up

Need to find balance between simplifying as much as prudent while still maintaining high quality care



3. Integration



Integration of HCV services and diagnostic testing

Integration of services: must be tailored to patient population, infrastructure

- Diagnostic algorithm adjusted to serve patients who are likely to return for other services
- Malaysia and Delhi integrating services in primary health care clinics; adjust diagnostic algorithm to reduce LTFU

Integration of diagnostic testing

- Many testing machines can perform tests for many different diseases depending on the assays and set up of the machine
- Integration of diagnostic testing looks at what happens when you introduce HCV testing onto a machine that is being used already for a different disease, such as TB or HIV



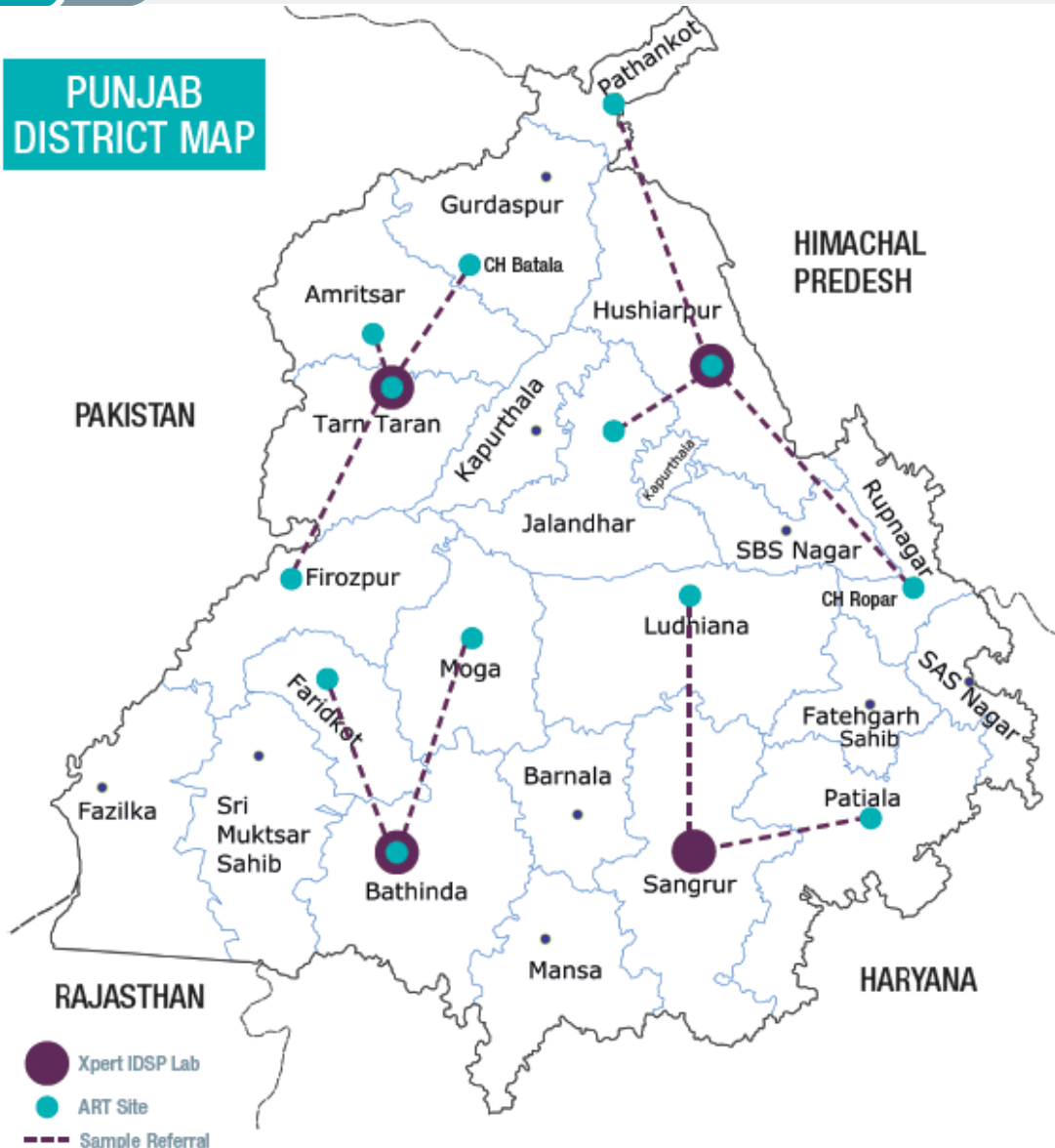


Integration of services



HEAD-Start Punjab project sites

PUNJAB DISTRICT MAP



■ Introducing HCV care into 13 existing ART centres / Hub and spoke model

- Simplifying the HCV algorithm by introducing RDTs
- Reflex RNA testing of those who screen HCV positive by sample referral from ART centers to 4 Xpert testing hubs

Cost per patient identified \$4.29

Punjab State epidemiology

Population: 29.9 million

HCV % Gen Pop: 3.29%

HCV % PLWHIV: 20% (from HEAD-Start study)



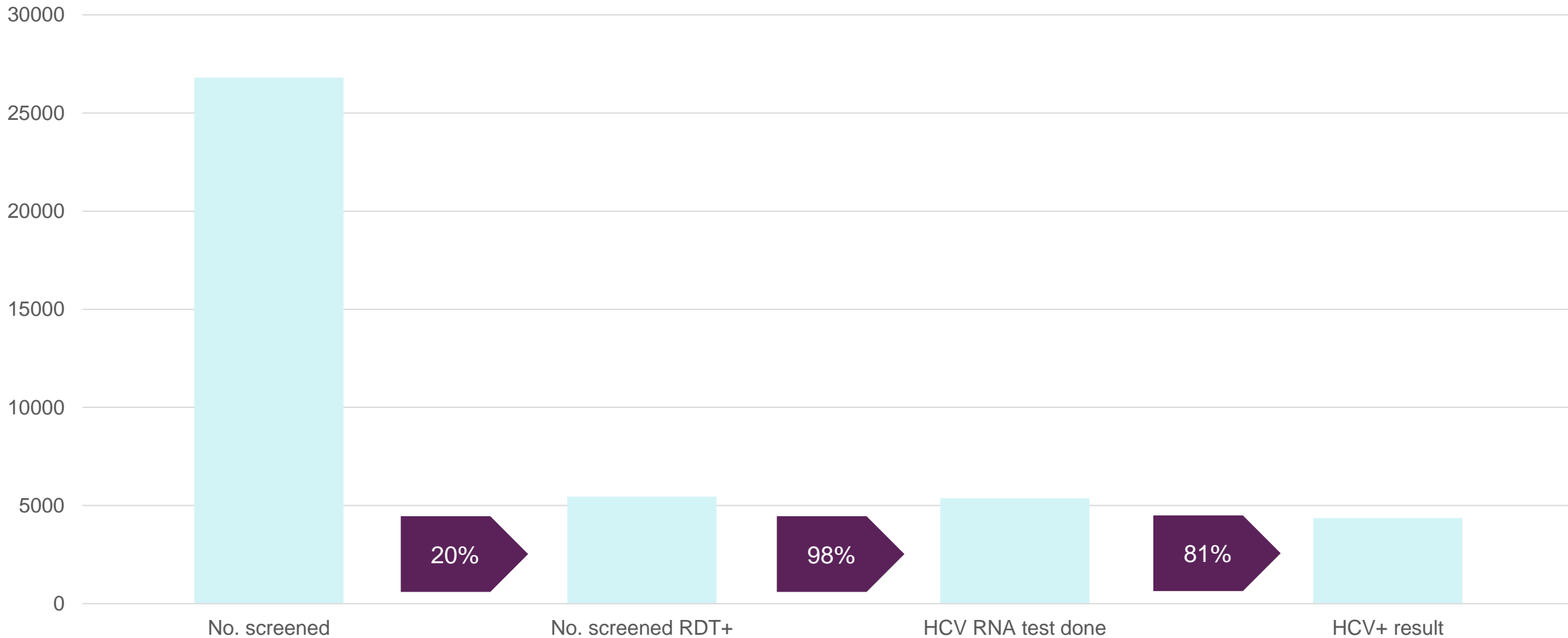
Figure 1. HEAD-Start sites in Punjab: HCV testing, hub-and-spoke model



HEAD-Start Punjab: care cascade; ART

(22 Oct 2018 to 30 Sept 2019) *preliminary data*

Care cascade





Key considerations

HEAD-Start Punjab project resulted in the screening of over 80% of all patients attending ART care who were eligible for HCV screening (32,000+ ART patients)

Cooperation between various departments and clear agreement on responsibilities is key for ensuring linkage of HCV positive PLHIV to care

Considerations of additional workload important with integrating a new service into an existing one; more work for same pay?



Key takeaways



■ The easier it is for the patient, the stronger (more effective and cost-efficient) the care cascade will be!

1. **Decentralization** of diagnostics to primary healthcare level can be done through RDTs, POC, or onsite blood draw with sample sent away for confirmation
2. **Simplification** is key to keeping patients engaged in the care pathway. It is possible to complete all needed blood draws on first visit after RDT+ result
3. **Integration** of HCV diagnostics into existing services results in high case finding, can be cost effective, and requires continuous coordination between departments and branches of the health system



Thank you!

Our HEAD-Start partners and collaborators



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GEORGIAN NATIONAL CENTER FOR DISEASE CONTROL AND PUBLIC HEALTH



MINISTRY OF INTERNALLY DISPLACED PERSONS FROM THE OCCUPIED TERRITORIES, LABOUR, HEALTH AND SOCIAL AFFAIRS OF GEORGIA



ზიანის შემცირების სპეციალური ქსელი
GEORGIAN HARM REDUCTION NETWORK

Technical collaborators and guidance



Directorate of Health Services,
Dept. of Health & Family Welfare, Govt of NCT of Delhi



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