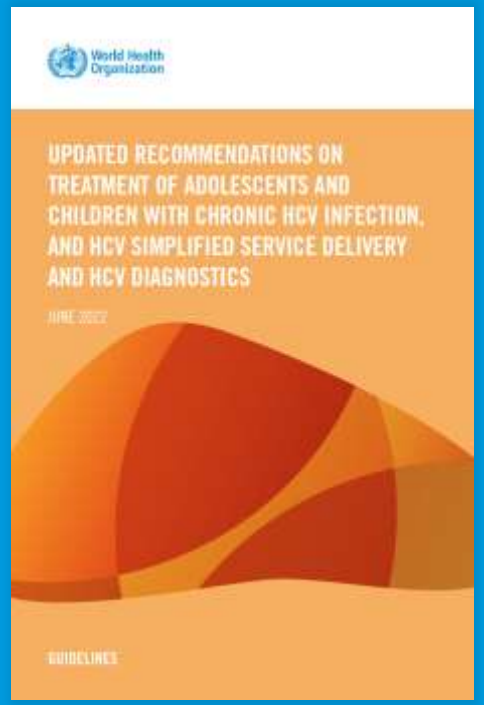
New WHO Guidance on HCV simplified service delivery, diagnostic innovations and treatment of adolescents and children

World Health Organization



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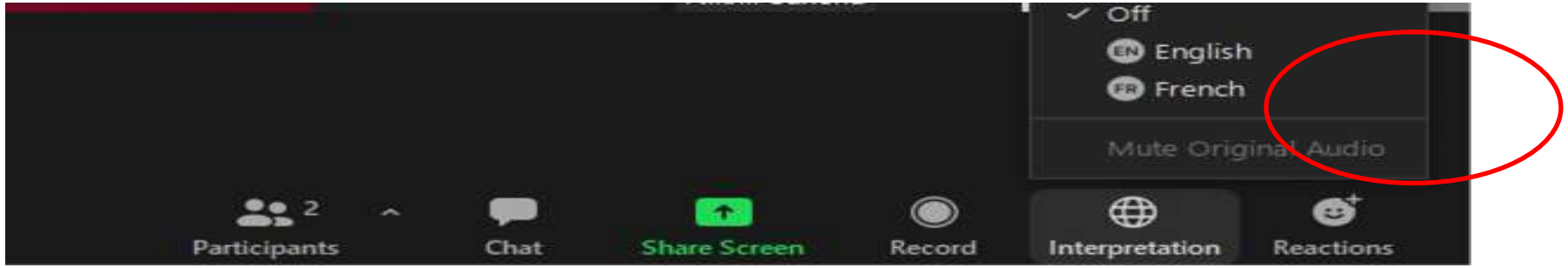
Click on “Interpretation” and choose the language that you would like to hear. To hear the interpreted language only, click “Mute Original Audio”



Questions and Chat

Use **Q&A** feature for questions regarding the topic and presentations

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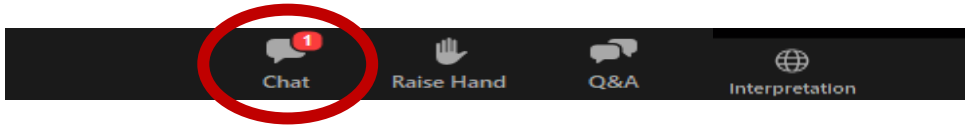


Recordings and Certificate

- **This session is being recorded** and your attendance is consent to be recorded. **Recordings will be shared after the session in English, French and Spanish.**

- **A Certificate of Attendance** will be available through the University of New Mexico via link in the Chat at the end of the session
- This session is organized in collaboration with Project ECHO

Agenda

World Health Organization

Time	Topic	Speaker
13.00-13.05	Welcome remarks	Meg Doherty (WHO HQ, Switzerland)
13.00-13.15	Overview of updated recommendations on HCV simplified service delivery and diagnostics and treatment of adolescents/children	Philippa Easterbrook (WHO HQ, Switzerland)
13.15-13.25	Community perspectives on simplified service delivery: Values and preferences survey	Cary James (World Hepatitis Alliance)
13.25-2.00 (5 min country spotlights)	Simplified service delivery in action - *Decentralisation* to primary care - *Integration* at harm reduction sites - *Task-shifting to nurses* - *Use of POC viral load* assays among PWID - *Case-finding strategies to reach adolescents and children*	Muhammad Radzi Abu Hassan (Malaysia) Eka Adamia (Georgia) Keo Samley (Cambodia) Bridget Draper (Myanmar/Australia) Manal El-Sayed (Egypt)
14.00-14.30	Q&A Updated recommendations in context – reflections from the panellists	Moderators: Professor Saeed Hamid, GDG Co-Chair (The Aga Khan University, Pakistan) and Oriel Fernandes (CHAI)

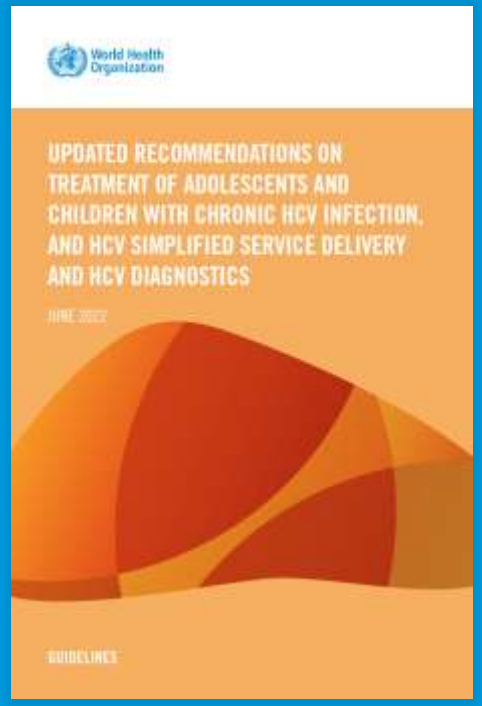
New WHO Guidance on HCV simplified service delivery, diagnostic innovations and treatment of adolescents and children

Welcome Remarks

New WHO Guidance on HCV simplified service delivery, diagnostic innovations and treatment of adolescents and children

World Health Organization

Dr Philippa Easterbrook
Global HIV, Hepatitis, STI Programmes
WHO HQ, Geneva



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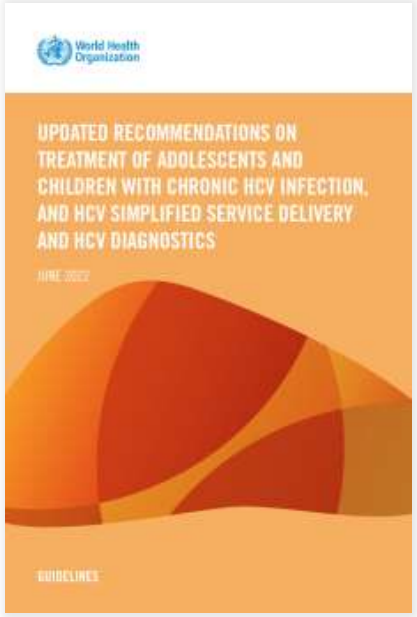
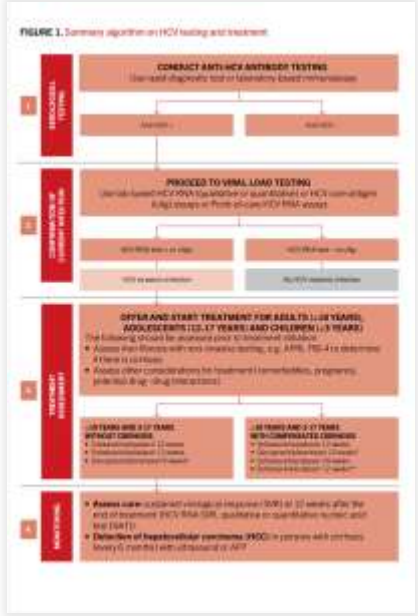
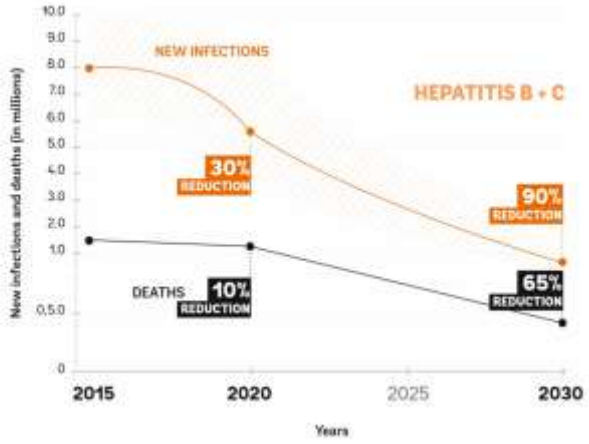
Outline

- **Global HCV Testing and treatment gap**
- **Evolution of WHO HCV guidelines**
- **2022 new HCV recommendations**
  - Simplified Service Delivery (Decentralization, integration and task-sharing)
  - HCV diagnostics (Point-of-care viral load, reflex viral load testing)
  - Treatment of adolescents and children
- **Recommendations**
- **Evidence summary and rationale**
- **Implementation considerations**



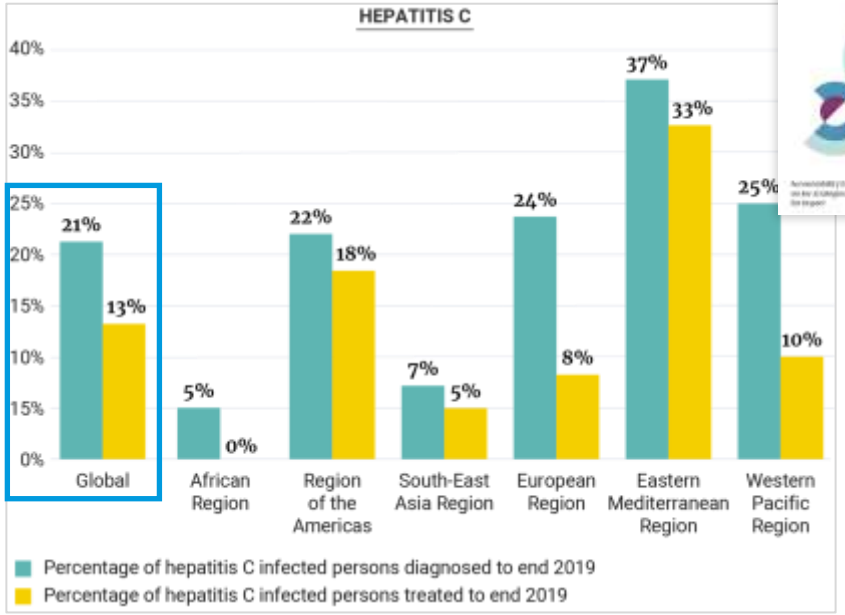


Rationale: Still Major gaps in HCV testing and treatment uptake on path to elimination



			Targets	
Interventions	**Indicator**	**2015 baseline**	**2020**	**2030**
1 Hepatitis B vaccination	HEPB3 coverage	84%	90%	90%
2 HBV PMTCT[a]	HEP vaccine birth dose coverage	39%	50%	90%
3 Blood safety	Donations screened with quality assurance	89%	95%	100%
Injection safety	Proportion of unsafe injections	5%	0%	0%
4 Harm reduction	Syringes & needles distributed/PWID/year	27	200	300
5 Testing services	% HBV-infected diagnosed	9%	30%	90%
	% HCV-infected diagnosed	20%	30%	90%
6 Treatment	% diagnosed with HBV on treatment	8%[b]	–[c]	80%[d]
	% diagnosed with HCV started on treatment	7%[b]	–[c]	80%[d]

- **90%** of those infected diagnosed (2030)
- **80%** of those diagnosed treated (2030)



- In 2019, 58 million with chronic HCV infection, 1.5 million new infections, 290,000 deaths
- **21% of 58 million diagnosed** and **13% treated** (9.4m treated 2015-2019)

Evolution of WHO HCV Guidelines Towards Simplified HCV Service Delivery

World Health Organization

Topic	2014	2016	2018	2022
Who to treat?			Treat All	Treat All
Genotyping	Yes	Yes	No	No
Regimens	PEG-IFN+RBV	DAAs preferred	Pan-genotypic DAAs	Pan-genotypic DAAs
	8 options - PEGIFN+RBV - SOF+RBV - SIMP or TELAP or BOCEP /PEGIFN+RBV	6 options DAAs preferred by GT or cirrhosis	3 options SOF/DAC SOF/VEL G/P PEGIFN phase out	3 options SOF/DAC SOF/VEL G/P
Age group	Adults ≥18yrs	Adults≥ 18yrs	Adults ≥18yrs and adolescents ≥12 yrs	Adults, adolescents and children≥3 yrs
Service Delivery			8 Good Practice Principles for Simplified Service	Decentralization Integration Task-shifting

SIMPLER TREATMENTS

TREATMENT OF CHILDREN AND ADOLESCENTS

SIMPLIFIED SERVICE DELIVERY

CHAPTER 6. SIMPLIFIED SERVICE DELIVERY FOR A PUBLIC HEALTH APPROACH TO TESTING, CARE AND TREATMENT FOR HCV INFECTION

Box 6.1. Good practice principles for health service delivery

1. **Comprehensive national planning for the elimination of HCV infection** based on local epidemiological context, existing health-care infrastructure, current coverage of testing, treatment and prevention, and available financial or human resources
2. **Simple and standardized algorithms** across the continuum of care from testing, linkage to care and treatment
3. **Strategies to strengthen linkage from testing to care,** treatment and prevention
4. **Integration of hepatitis testing, care and treatment with other services** (e.g. HIV services) to increase the efficiency and reach of hepatitis services
5. **Decentralized** testing and treatment services at primary health facilities or harm reduction sites to promote access to care. This is facilitated by two approaches:
   - 5a. **task-sharing,** supported by training and mentoring of health-care workers and peer workers;
   - 5b. a **differentiated care** strategy to assess level-of-care needs, with specialist referral as appropriate for those with complex problems.
6. **Community engagement and peer support** to promote access to services and linkage to the continuum of care, which includes addressing stigma and discrimination
7. **Strategies for more efficient procurement and supply management** of quality-assured, affordable medicines and diagnostics
8. **Data systems to monitor the quality of individual care and coverage** at key steps along the continuum or cascade of care at the population level.

Distinctive Features of WHO Guidelines

World Health Organization

Feature	WHO Guidelines	Other Guidelines
Settings	• Low- and middle-income countries • Generalised/concentrated epidemic settings	• High-income countries
Target audience	• National Program Managers	• Treating clinicians
Approach	• The "public health approach" • Simplified and standardized approaches • Preferred regimens	• Individualized treatment • Multiple treatment options
Formulating recommendations: Evidence-based approach	• GRADE - Feasibility, equity, end-user acceptability, resource use considered	• Variable use of evidence-based framework
Guidelines Committee representation	• 50% LMICs, programme managers, civil society	• Clinicians and researchers HICs

The WHO Guidelines process, GRADE and formulation of recommendations

PICO QUESTION

PICO 1

Can HCV care and treatment be delivered effectively and safely in lower level health facilities (decentralisation)?

POPULATION:	Adults and adolescents (PWID, prisoners, PLHIV, general population).
INTERVENTION:	HCV testing, care and treatment outside of hospital-based facilities (harm reduction sites, prisons, ART clinics, primary care). Full decentralisation (and integration) of testing and treatment at the same site. Partial decentralisation (and integration) of testing at decentralised site, and referral for treatment.
COMPARISON:	HCV testing, care and treatment in hospital-based facilities (i.e. no decentralisation or integration).
MAIN OUTCOMES:	Uptake of testing, viral load confirmation, linkage to care, treatment initiation, SVR12 cure assessment, SVR12. Patient satisfaction. Stratified according to population and setting.

Formulating Recommendations

GRADE-ing recommendations

- Strength of recommendation
  - Strong=do in most circumstances
  - Conditional=different choices may be appropriate under certain conditions
- Good practice statements: Can apply to recommendations that are "obvious" and for which certainty is high—even though this is difficult to prove directly

Strength of Recommendation	Quality of Evidence			
Strong	High	Moderate	Low	Very Low
Conditional	High	Moderate	Low	Very Low

RECOMMENDATIONS

Decentralization, Integration and Task-shifting

Moving treatment and care out of speciality clinics

Decentralization:
We recommend delivery of HCV **testing** and **treatment** at peripheral health or community-based facilities, and ideally at the same site, to increase access to diagnosis, care and treatment.
These **facilities** may include primary care, harm reduction sites, prisons and HIV/ART clinics as well as community-based organizations and outreach services.

Integration:
We recommend integration of HCV **testing** and **treatment** with existing care services at peripheral health facilities.
These **services** may include primary care, harm reduction (needle and syringe programme (NSP)/opioid agonist maintenance therapy (OAMT) sites), prison and HIV/ART services.

Strong recommendation/ moderate certainty of evidence (PWID/prisoner) low (general population, PLHIV)

Task-sharing: We recommend delivery of HCV **testing, care and treatment** by trained non-specialist doctors and nurses to expand access to diagnosis, care and treatment.

Strong recommendation/ moderate certainty of evidence

RATIONALE for Recommendations on Decentralization, Integration and Task-sharing

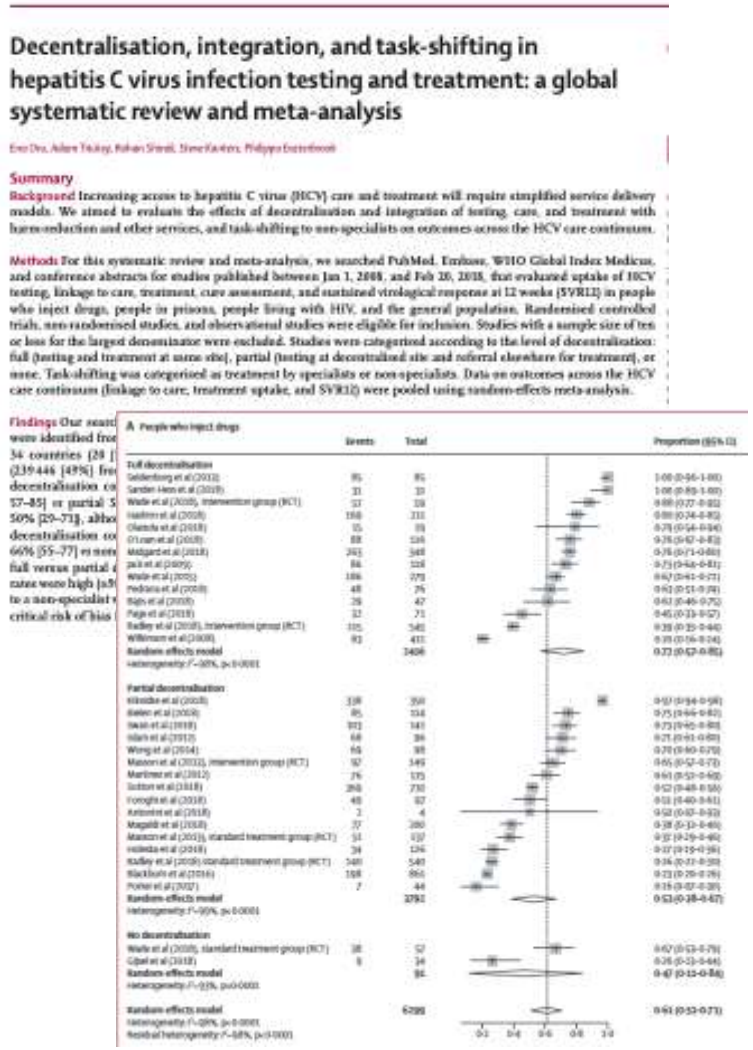
World Health Organization

Evidence review

- 142 studies from 33 countries (14%) LMICs) compared full decentralization/integration vs. partial decentralization or none, and task-sharing to non-specialists.
- Increased uptake of HCV viral load testing, linkage to care and treatment among people who inject drugs and prisoners for full decentralization/integration.
- Comparable SVR12 cure rates between specialists and non-specialists across all populations and in all settings

Acceptability by end-users

- Three related surveys and a series of in-depth interviews showed strong support for fully decentralized and integrated HCV services offering testing and treatment at same community site and near to people's homes rather than in hospitals.
- Importance of a non-judgmental/non-stigmatizing approach among health care providers highlighted, especially among PWID and PLHIV.



Decentralisation, integration, and task-shifting in hepatitis C virus infection testing and treatment: a global systematic review and meta-analysis

Summary

Background Increasing access to hepatitis C virus (HCV) care and treatment will require simplified service delivery models. We aimed to evaluate the effects of decentralisation and integration of testing, care, and treatment with harm-reduction and other services, and task-shifting to non-specialists on outcomes across the HCV care continuum.

Methods For this systematic review and meta-analysis, we searched PubMed, Embase, WHO Global Index Medicus, and conference abstracts for studies published between Jan 1, 2000, and Feb 20, 2018, that evaluated uptake of HCV testing, linkage to care, treatment, cure assessment, and sustained virological response at 12 weeks (SVR12) in people who inject drugs, people in prisons, people living with HIV, and the general population. Randomised controlled trials, non-randomised studies, and observational studies were eligible for inclusion. Studies with a sample size of ten or less for the largest denominator were excluded. Studies were categorised according to the level of decentralisation: full (testing and treatment at same site), partial (testing at decentralised site and referral elsewhere for treatment), or none. Task-shifting was categorised as treatment by specialists or non-specialists. Data on outcomes across the HCV care continuum (linkage to care, treatment uptake, and SVR12) were pooled using random-effects meta-analysis.

Findings Our search
were identified fro
34 countries (28
(239 446 [49%] fro
decentralisation co
57–85] or partial
50% [29–71], altho
decentralisation co
66% [55–77] vs non
full versus partial
rates were high (≥9
to a non-specialist
critical risk of bias

IMPLEMENTATION CONSIDERATIONS

World Health Organization

Decentralization and Integration

- **Adaptation of service delivery recommendations for different contexts and countries and for specific populations.**
- **Implementation alongside other existing good practice principles of simplified service delivery**:- standardized algorithms, differentiated care strategy, community engagement and peer support, more efficient procurement, supply management and data systems, strengthening linkage and referral systems.
- **Planning and coordination needed for effective delivery of integrated care** – establishing integrated data systems and cross-training of health care providers.
- **Decentralization of HCV testing and treatment services may not be appropriate for all settings or acceptable to all clients.** May be inefficient and costly in HICs with low burden of infection - a centralized service delivery model with community linkage may be more appropriate.

Task-sharing

- **Appropriate Training and ongoing mentorship** at decentralized site and access to additional support or referral to tertiary sites for more complex cases.
- **Defining roles, standards of care and clear lines of responsibility** for key staff.
- **An appropriate regulatory framework** to enable tasks to be performed by different cadres of health care workers.

Operational Characteristics and Curricular Features of Identified HBV and HCV Online Training Curricula for Healthcare Workers

Online Training	Website Address	Key Source Institution, Country	Number of Modules	Covers HBV, HCV or Both	Estimated Time to Complete	Free Continuing Education Credits (Y/N)	Updated in Last 2 years**	Information on Key Populations	Info on mgmt. of advanced liver disease	Info on when to refer to higher level of care	Curriculum covers continuum of care	Self-assessment	Use of clinical vignettes
Hepatitis C Online	https://www.hepatitisc.uw.edu/	University of Washington, USA	8	HCV	2-4hrs per module	Yes	√	√ (PWID, prisoners)	√	√	√	√	
Hepatitis B Online	https://hepatitisb.uw.edu/	University of Washington, USA	9	HBV	30mins – 2hr	Yes	√			√	√	√	
Liver Learning: Fundamentals of Liver Disease: • Hepatitis C 2.0 • Hepatitis B 2.0	https://liverlearning.aasld.org/	AASLD, USA	15	HBV, HCV	30-40mins each	Yes	√	√ (peds, separate webinar for treatment in PWID)	√*	√	√	√	
ASHM	hnc.ashm.org.au/	Australasian Society for HIV, Viral Hepatitis and Sexual Health Medicine, Australia	Variable depending on the training Max 8	HBV, HCV	Variable	Yes	√	√ (PWID)	√	√	√	√	√
HIV/HCV Co-infection: An AETC National Curriculum	aidsetc.org/hivhcv	AIDS Education and Training Center (AETC), USA	6	HCV, HCV/HIV	1-2hrs per module	Yes	√	√ (HIV+, racial minorities)		√	√	√*	
IAPAC • HBV Clinical Management • HCV Clinical Management	iapac.org/education/african-regional-capacity-building-hub/	International Association of Providers of AIDS Care (IAPAC), South Africa	11	HBV, HCV	1 day per module	No				√	√	√	√
CATIE • Hepatitis C Basics • Hepatitis C Treatment	https://www.catie.ca/education-publications-websites-education/self-directed-learning-0	Canadian AIDS Treatment Information Exchange, Canada	8	HCV	3hr per module	No		√ (PWID)		√*	√	√	√
Health E Knowledge	[illegible]	Addiction Technology Transfer Center Network, USA	4	HCV	90mins total	Yes				√		√	√
Know HBV and HCV	[illegible]	Stanford University, USA	5	HBV	8hrs	No	√					√	

Evolution in Hepatitis C testing and diagnostic recommendations

World Health Organization

Topic	Recommendation in 2017 testing recommendation
Who to test?	• **Focused testing** for most affected populations*, those with a clinical suspicion of chronic viral hepatitis, family members/children, and sexual partners (HBV), healthcare workers. • **General population testing:** In settings with ≥2% or ≥5% (intermediate/high) HBsAg or HCV Ab prevalence.
How to test?	• A **single** serological assay (**EIA or RDT**) that meets minimum performance standards with prompt NAT testing + linkage to care
Confirmation of HCV viraemia	• **Lab-based Nucleic acid testing (NAT) (quantitative or qualitative RNA)** or **core HCV antigen assay**, with comparable clinical sensitivity
Promoting uptake and linkage	• **Use of DBS specimens for virology ± serology** • **On-site or immediate RDT testing + same day results** • Trained peer and lay health workers • Clinician reminders to prompt provider initiated, facility-based testing • Testing as part of integrated services at a single facility



2021 and 2022 Updates

How to test - serologic
- 2021 HCV self-testing guideline

Use of POC HCV RNA NAT
- For detection of viraemia
- For test of cure

Linkage to care
- Dried blood spots (HCV serology and virology) manafacturers protocols
- Reflex viral load

RECOMMENDATIONS

2022 Recommendations on HCV diagnostics

World Health Organization

HCV point-of-care (POC) viral load RNA testing:

- Point-of-care (POC) HCV RNA viral load assay can be an alternative approach to laboratory-based HCV RNA NAT assays to **diagnose HCV viraemic infection**.

- Point-of-care (POC) HCV RNA assays with comparable limit of detection to laboratory-based assays can be used as an alternative approach as **test of cure**.

Conditional recommendation /moderate certainty of evidence

Reflex HCV viral load testing

We recommend reflex HCV RNA testing in those with a positive HCV antibody test result as an additional key strategy to promote linkage to care and treatment.

This can be achieved either **through laboratory-based reflex HCV RNA testing using a specimen already held in the laboratory** or **clinic-based reflex testing in a health facility through immediate specimen collection** following a positive HCV antibody RDT.

Conditional recommendation /low certainty of evidence

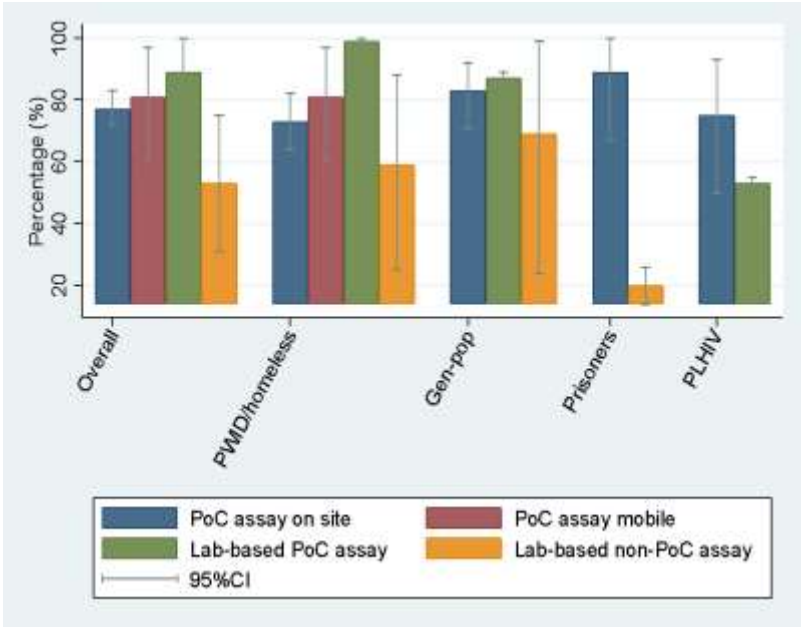
RATIONALE for *Conditional* Recommendation on use of HCV POC RNA assay

World Health Organization

Evidence review

- 45 studies comprising 27 364 persons (49%) LMICs) compared POC HCV RNA assays on site with Lab-based assays.
- **Better outcomes for POC assays:** Shorter turn-around time between HCV antibody test to treatment initiation (18.5 days [95% CI: 14–53]) vs (67 days [50–67])
- Increased RNA viral load uptake (RR 1.11 [0.89–1.38] and treatment uptake (RR 1.32 [1.06–1.64]
- High sensitivity and specificity of POC assays (99% [98–99%] and 99% [99–100%) across all settings, populations, assays and specimen types

- Multi-cohort analysis of 5973 cases of detectable viraemia at SVR12. 97% with detectable viraemia at SVR12 are above 1000 IU/mL (within LoD for PoC assays).



Other Benefits

- POC HCV RNA platforms can be used in lower levels of health facilities near where patient is receiving care.
- Opportunity for integration - POC molecular platforms are already in use for a number of other infectious diseases.

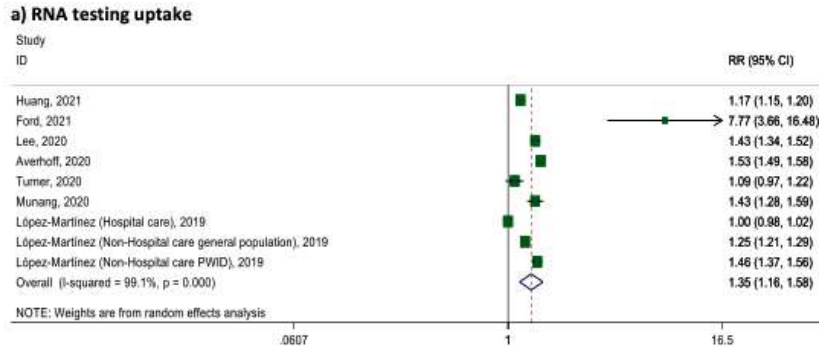
RATIONALE for Conditional Recommendations on use of Reflex viral load testing

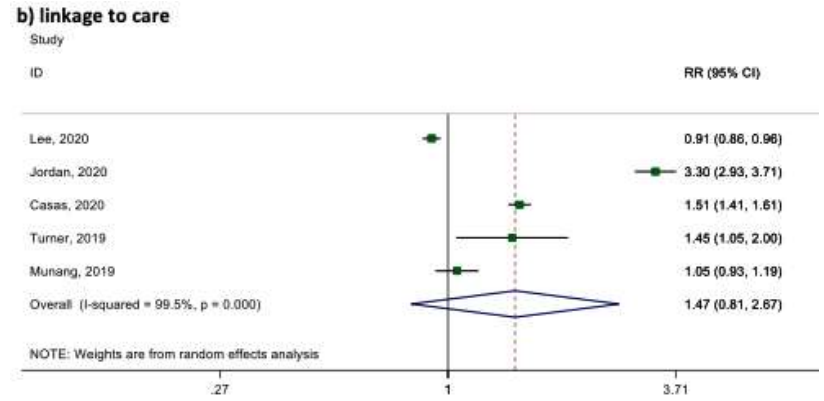
Evidence review

- 51 studies (32 used laboratory-based reflex testing, and 19 used clinic-based reflex sample collection)
- Increased uptake of HCV viral load testing (RR 1.35 (95%CI: 1.16–1.58) and improved linkage to care (RR of 1.47 (95% CI: 0.81–2.67).

Acceptability, cost and feasibility

- Simplifies care pathway and reduces need for additional clinic visits, and time to HCV RNA
- Avoids need for additional blood draws, preferable to PWID
- Cost-saving
- Feasible to implement and potential for wide adoption to promote HCV testing and treatment uptake.
  - Lab-based reflex HCV testing already performed routinely in HICs.
  - Clinic-based reflex testing following a positive HCV antibody RDT common practice in LMICs





RATIONALE Community Values and preferences for Service delivery and RNA testing and treatment

If it were possible to conduct the viral load test outside the hospital, respondents preferred:

- community-based organization (45%)
- primary care (GP) clinic (44%)

88% would like to conduct the initial and confirmatory tests on the **same day**

- possibility to be treated more quickly (76%)
- possiblity to confirm status more quickly (81%)

92% would like to conduct the initial and confirmatory tests at the **same place**

- community-friendly site (60%)
- convenience (70%)

85% would like to **start treatment on the same day if they had positive viral load**

- avoid exposing family and friends to hepatitis C (28%)
- continued follow-up from testing to treatment (27%)

92% would like to be tested and treated in the same place

- convenience (34%)
- continued follow-up from testing to treatment (32%)

I struggle to do doc appointments so the less places and times I have to go the better and more likely that I get them done

– Respondent X

Same site means clear continuity of care, avoiding having to repeat personal story / issues and build trust with new clinician or worker

– Respondent Y

IMPLEMENTATION CONSIDERATIONS

HCV POC HCV RNA assays

- **Strategic choice - use of lab-based vs POC NAT platforms:** will depend on characteristics of testing site. eg. (storage facilities, infrastructure, level of staff skills) and costs.
- **Priority settings for placement of HCV POC platforms** eg. PWID at harm reduction sites at high risk of loss to follow-up, where fast-tracking diagnosis can increase treatment uptake.
- **Optimal placement of a POC instrument is where testing and treatment are at the same site – a "one-stop shops"**
- **Opportunity for diagnostic integration across programmes** using **multi-disease testing platforms.** Countries with existing platforms for HIV viral load or TB testing, can consider collaboration and integration of HCV RNA testing.

HCV Reflex viral load testing

Choice of laboratory-based reflex testing or clinic-based reflex HCV RNA testing for different country contexts

- **Laboratory-based reflex testing approach** - settings with large testing volumes for HCV antibody supported by extensive sample transport networks.
- **Clinic-based reflex specimen collection approach** - settings where RDTs used and limited access to lab services, and for populations such as PWID.

RECOMMENDATIONS

2022 Treatment Recommendations in Adolescents and Children

World Health Organization

Treatment of HCV in adolescents (12—17 years), older children (6—11 years) and younger children (3—5 years)

Whom to treat? New recommendations for adolescents and children

We recommend the use of pangenotypic DAA regimens for all adults, adolescents and children ages 3 years and above with chronic hepatitis C infection, regardless of stage of disease:

Adolescents (12–17 years[1]): *strong recommendation; moderate/low certainty of evidence*
Older children (6–11 years): *strong recommendation; moderate/very low certainty of evidence*
Younger children (3–5 years): *conditional recommendation; very low certainty of evidence*

[1] For consistency, we use the same age groupings as those used in the trials for regulatory submissions.

What DAA regimens to use? New recommendations for adolescents and children

We recommend the use of the following pangenotypic DAA regimens in adults (18 years and above), adolescents (12–17 years), older children (6–11 years) (all strong recommendations) and younger children (3–5 years) (conditional recommendation):

- **SOF/DCV[1]** for 12 weeks[2]: *certainty of evidence: high (adults), high (adolescents and older children); very low (younger children)*
- **SOF/VEL** for 12 weeks: *certainty of evidence: high (adults), low (adolescents and older children); very low (younger children)*
- **G/P** for eight weeks: certainty of evidence: *high (adults), moderate (adolescents and older children); very low (young children).*

[1] Most widely use regimen in adults due to availability of quality-assured, low-cost generics
[2] In those without cirrhosis. Treatment for 24 weeks in those who are treatment-experienced or with compensated cirrhosis.

Reconciling DAA regimens across adults, adolescents and children

Age groups	Recommended pangenotypic DAA regimens			Non-pangenotypic DAA regimen (in settings with minimal GT3 infection)[2]
	SOF/DCV[1]	SOF/VEL[2]	G/P	SOF/LED
Adults (18 years and above)	12 weeks	12 weeks	8 weeks	12 weeks
Adolescents (12–17 years)	12 weeks	12 weeks	8 weeks	12 weeks
Older children (6–11 years)	12 weeks	12 weeks	8 weeks	12 weeks
Younger children (3–5 years)	12 weeks	12 weeks	8 weeks	12 weeks

RATIONALE for Treatment Recommendations in Adolescents and Children

World Health Organization

Treatment of HCV-infected adolescents and older children is highly effective and safe.

Systematic review of **49 studies** (1891 adolescents (35 studies); 472 older children (13 studies); and 167 younger children (7 studies).

- SVR12 rates ≥95% in all age groups for SOF/DCV, G/P and SOF/VEL.
- Serious adverse events and treatment discontinuations were uncommon.

Benefits of earlier treatment in childhood and adolescence include :-

- Achieving a cure before onset of disease progression will prevent HCV-associated liver damage and extrahepatic manifestations.
- Avoiding stigmatization of infected children and prevention of transmission to others

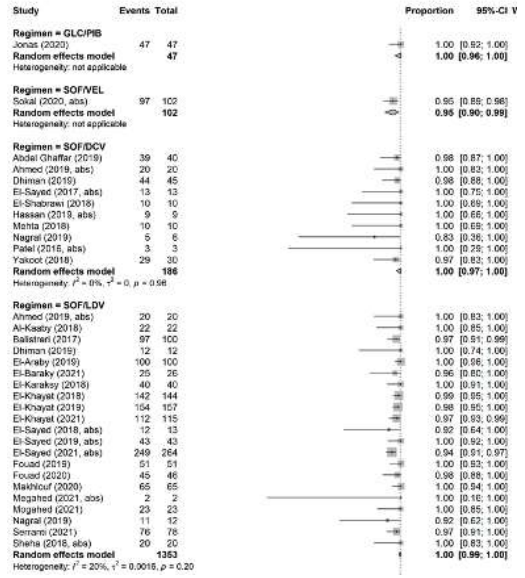
Approvals by key regulatory agencies

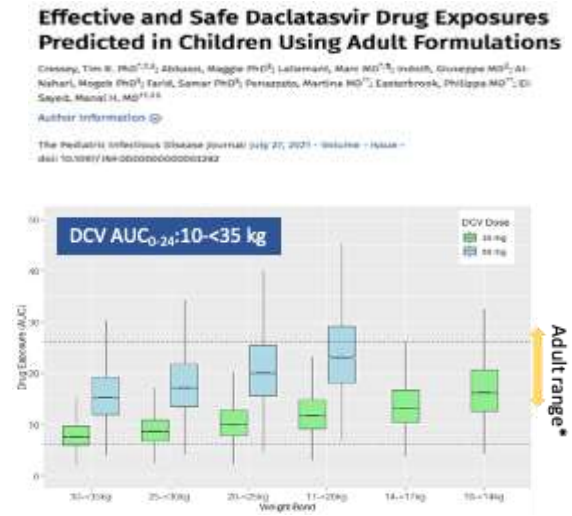
- DAA regimens (SOF/VEL, G/P) + SOF/LED have regulatory approval down to three years

Rationale for *conditional* recomm to treat younger children (3–5 years)

- Low frequency of HCV-related liver disease, lack of any direct studies on use of SOF/DCV, more treatment discontinuations. Very low certainty of evidence for all regimens in younger children.

- For SOF/DCV, based on extrapolation from PK modeling studies in adolescents – can use existing adult dose of SOF/DCV (400 mg/60 mg) in children >25 kg and half dose (200 mg/30 mg) for 14–25 kg.





RATIONALE Healthcare Worker Values and preferences for treatment in children

142 individuals from **37 countries** across all 6 WHO regions responded

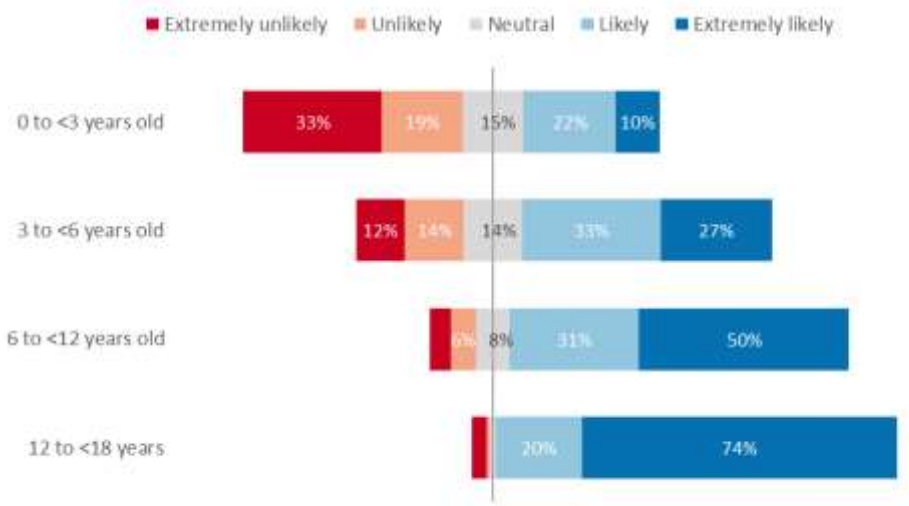
Who to treat?

- 60% of respondants indicated strong preference for treating all children ≥3 years old.
- Clear trend towards higher preference for treating older age groups (94% 12-17 yrs; 81% 6-12 yrs; 57% 3-6 yrs)

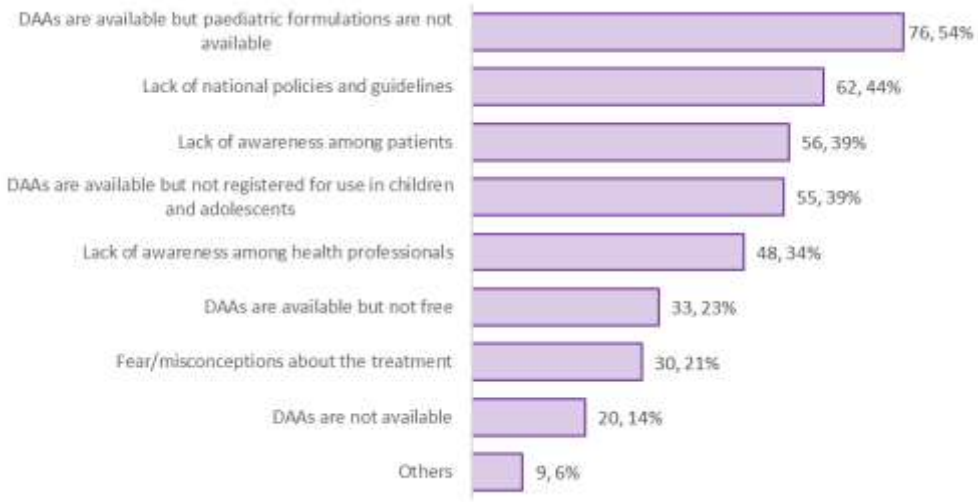
What to treat with?

Most commonly available and used DAA regimens across all age groups were: sofosbuvir/velpatasvir, sofosbuvir/ledipasvir, glecaprevir/pibrentasvir

Who to treat



Barriers faced



IMPLEMENTATION CONSIDERATIONS to promote treatment for HCV infected adolescents and children

World Health Organization

1. Inclusion of Case-finding, testing, care and treatment of children and adolescents in national plans and guidelines

BOX 1. Testing approaches to improve hepatitis case-finding among infants and children

- Prioritize testing children of all HCV-positive mothers (especially if the mother is HCV/HIV-coinfected) through home- or facility-based testing.
- Offer testing to all children and adolescents presenting with signs and symptoms that suggest acute viral hepatitis, including anorexia, nausea, jaundice, right upper quadrant discomfort and abnormal liver function tests.
- Focus HCV testing on children who have had medical interventions or received blood products in countries with a high prevalence of hepatitis C, or where screening of blood is not routine or medical equipment is inadequately sterilized.
- Offer viral hepatitis testing or retesting to mothers and infants in immunization clinics or under-5 clinics.
- Consider offering viral hepatitis testing to all children and adolescents attending HIV services, STI clinics and tuberculosis clinics or admitted to hospitals in high prevalence regions.

Low-cost available adult DCV formulations together with approved paediatric doses of SOF could expand global access to HCV treatment for children

2. Resource and Access co

- Availability of existing generic products
- Paediatric formulations for young children
- Cost and potential for further cost reductions

Direct acting antiviral	WHO pre-qualified suppliers
Sofosbuvir (400 mg)	Hetero, Mylan, Strides, European Egyptian Pharmaceutical Limited (Pharco)
Daclatasvir (30 mg and 60 mg)	Cipla, Hetero, Mylan, Laurus Labs
Sofosbuvir/daclatasvir FDC (400 mg/60 mg)	Cipla, Mylan
Sofosbuvir/ledipasvir FDC (400 mg/90 mg)	Mylan
Sofosbuvir/velpatasvir FDC (400 mg/100 mg)	Mylan
Sofosbuvir/velpatasvir/voxilaprevir FDC	None
Glecaprevir/pibrentasvir (300 mg/120 mg)	None

3. Service Delivery for Adolescents

- Delivery of adolescent-friendly services
- Vulnerable adolescents
- Age of consent for testing

Acknowledgements

Guidelines Development Group and WHO Steering Committee

Co-chairs: Anchalee Avihingsanon (HIV-NAT, Thai Red Cross AIDS Research Centre, Bangkok, Thailand) and Saeed Sadiq Hamid (The Aga Khan University, Pakistan). **GRADE methodologist:** Roger Chou (Oregon Health and Science University, Portland, USA).

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WHO Steering Committee

WHO headquarters staff: Philippa Easterbrook, Emmanuel Fajardo, Asma Hafiz, Olufunmilayo Lesi, Niklas Luhmann, Robert Luo, Martina Penazzato, Lara Vojnov, Anita Sands

WHO regional office staff: Po-Lin Chan (WPRO), Casimir Mingiedi Mazengo (AFRO), Bridget Mugisa (EMRO), Antons Mozalevskis (EURO), Bharat Bhushan Rewari (SEARO),

New WHO Guidance on HCV simplified service delivery, diagnostic innovations and treatment of adolescents and children

Community perspectives on simplified service delivery: Values and preferences survey

Community values and preferences for HCV testing and treatment

Cary James – World Hepatitis Alliance

World Hepatitis Day

World Hepatitis Alliance

PLUS

World Health Organization

Context and objectives

Despite major advances in the quality and affordability of treatment in recent years, the service pathway remains particularly cumbersome for many individuals with exposure to or living with HCV.

Moreover, HCV disproportionally impacts marginalized communities who may also face barriers related to stigma and discrimination.

It is therefore important to identify the values and preferences regarding service delivery amongst people living with hepatitis C and people likely to be exposed to hepatitis C to propose services that are adapted to their needs.

Objective:

To understand the values and preferences towards decentralization, task-shifting, and integration of HCV services among potential end users.

Methods

- An anonymous, self-administered online survey. English only.
- The survey was developed as a collaborative effort between the World Hepatitis Alliance, Coalition PLUS, and the World Health Organization.
- The survey consisted of a total of 42 multi-choice questions, option to provide additional information
- Participants were 18 years or older, were living with or affected by hepatitis C, and confirmed willingness to participate in this survey
- The survey was promoted by Coalition PLUS, the World Hepatitis Alliance, regional WHO offices, and the Treatment Action Group, through social media, mailing lists and direct contacts.
- Data collection: 8 – 22 September 2021

Results

In total **210 people from 49 countries** participated in the survey.

Median age was 42 years [IQR: 33-52]

A majority of participants were **male** (56%, n=113), 40% were female (n=81), 1% transgender (n=2), and 2% gender non-binary (n=4).

Participants more often reported living in an **urban/large city area** (69%, n=137) and reported completing **tertiary schooling** (88%, n=175).

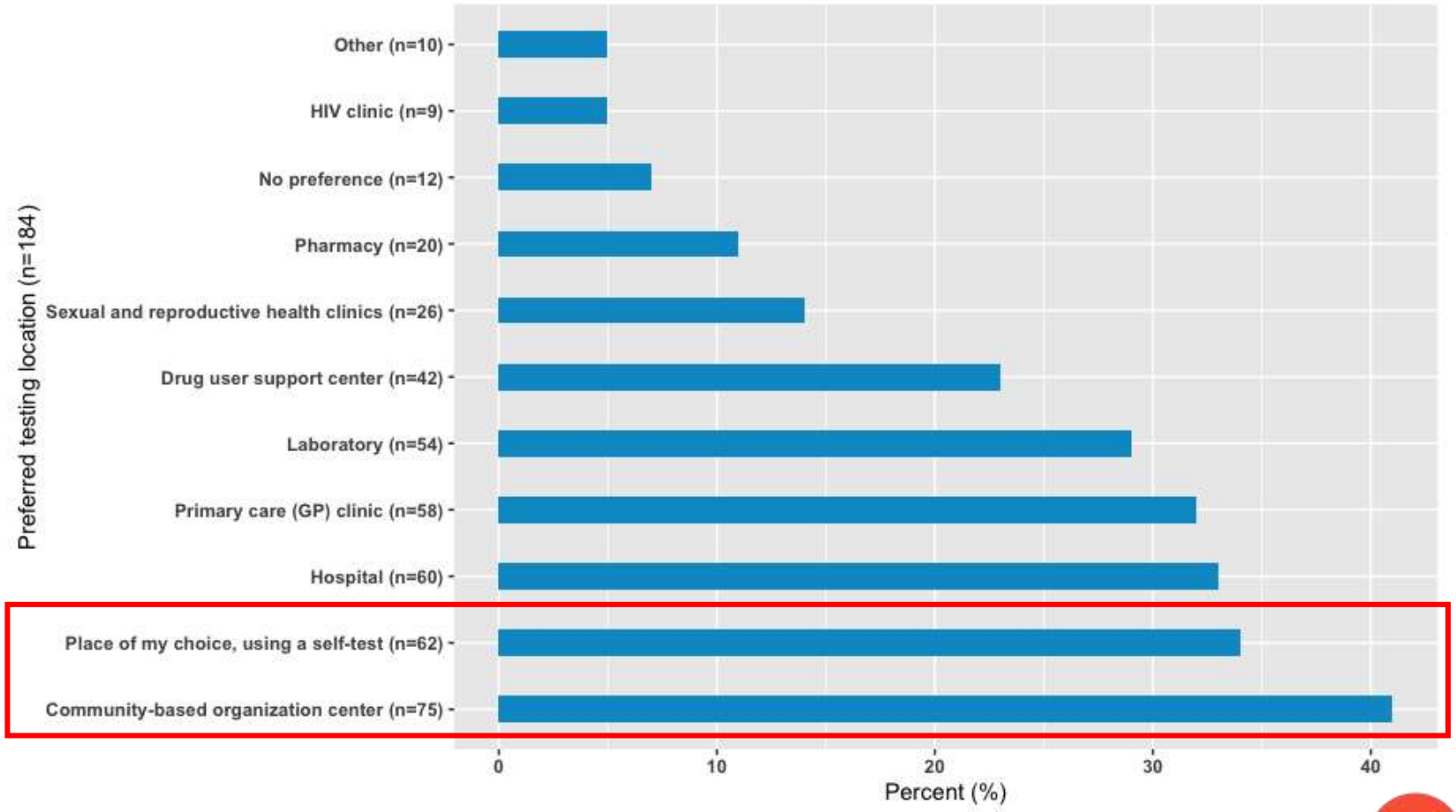
72% (n=150) of participants had previously been **tested for HCV** among whom 40% (n=60) had **tested positive**.

Among the 56 respondents who provided information regarding hepatitis C treatment, 91% (n=51) are **currently being treated or have been treated for hepatitis C**.

Participants identified with the following groups (not exclusive):

23% people living with HCV
18% people who inject drugs
21% people who formerly injected drugs
16% people living with HIV

Results – preferred testing location* (n=184)



"I would like to be tested by someone with living experience of drug use (not past experience) and lived experience of Hep C. A place where there is no discrimination. So no to hospital, laboratory, pharmacy…"

- participant from Australia who identified with people who inject drugs.

*a maximum of three choices was possible

Results – confirmatory test location preferences

If it were possible to conduct the viral load test outside the hospital, respondents most preferred :

- community-based organization (45%)
- primary care (GP) clinic (44%)

88% would like to conduct the initial and confirmatory tests on the **same day**

Main reasons for this preference were:

- possiblity to confirm status more quickly (81%)
- possibility to be treated more quickly (76%)

93% would like to conduct the initial and confirmatory tests at the **same place**

Main reasons for this preference were:

- convenience (70%)
- community-friendly site (60%)

I struggle to do doc appointments so the less places and times I have to go the better and more likely that I get them done

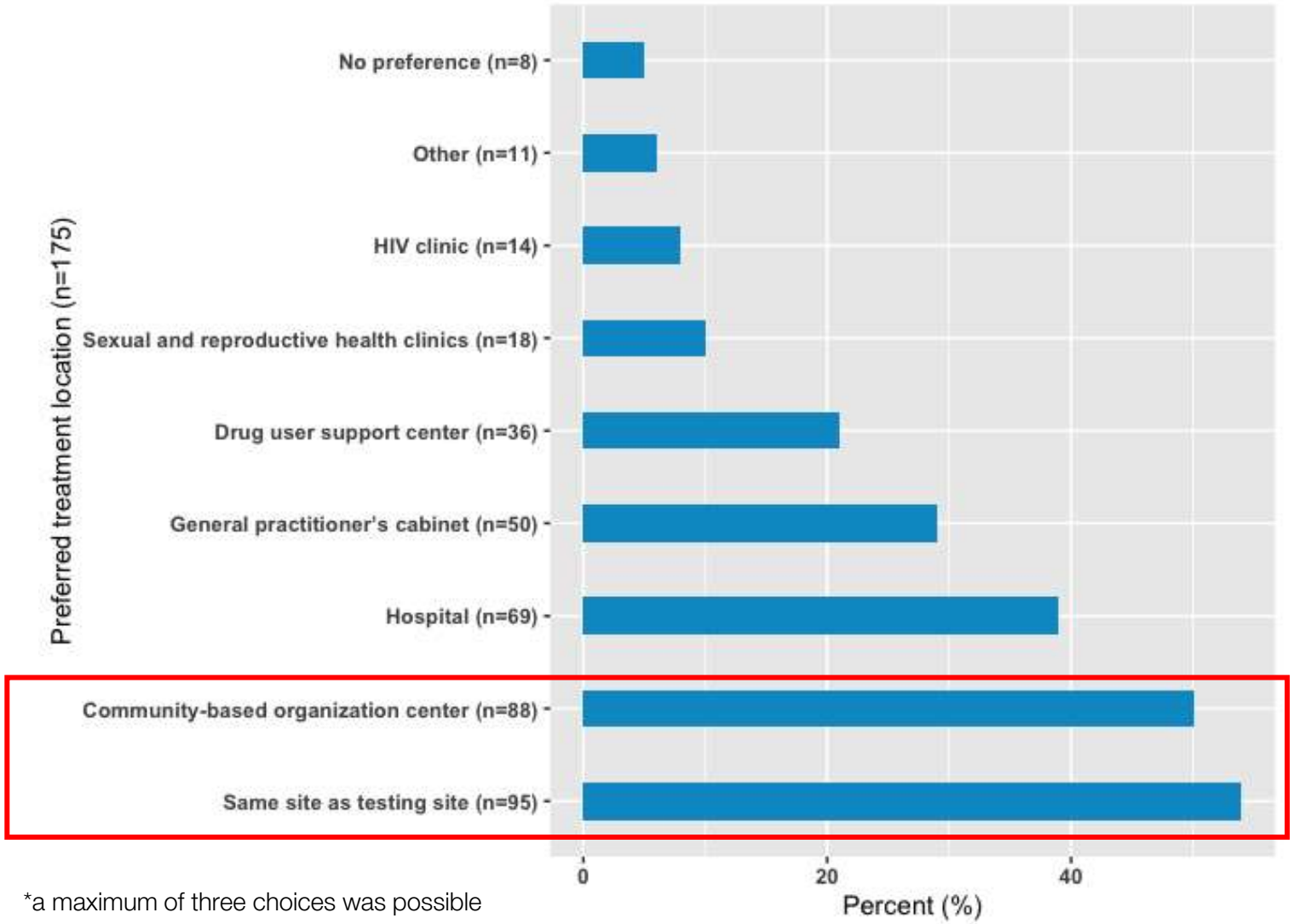
- Participant from the United States who identified with people who formerly injected drugs, sex workers and partners of someone who belongs to a key population

World Hepatitis Alliance

PLUS

World Health Organization

Results – preferred treatment location* (n=175)



*a maximum of three choices was possible

It needs to be somewhere that I feel comfortable and not face negative attitudes

- Participant from the UK who identified with people who inject drugs

Results – treatment location preferences

85% of participants indicated they would like to **start treatment on the same day if they had positive viral load**

Main reasons for this preference:
- avoid exposing family and friends to hepatitis C (28%)
- continued follow-up from testing to treatment (27%)

92% would like to be tested and treated in the same place
- convenience (34%)
- continued follow-up from testing to treatment (32%)

Same site means clear continuity of care, avoiding having to repeat personal story / issues and build trust with new clinician or worker

- Participant from Australia who identified with people who inject drugs

Conclusions

- **Decentralized services** seem to be particularly advantageous **for both testing and treatment.**
- Having a **culturally competent approach** is an important consideration regarding testing and treatment services.
- Strong preferences were observed for having **testing and receiving treatment on the same day and in the same place**, which could potentially increase linkage to care.

A range of HCV testing and treatment solutions/ options would be beneficial to respond to the different needs of different populations and situations.

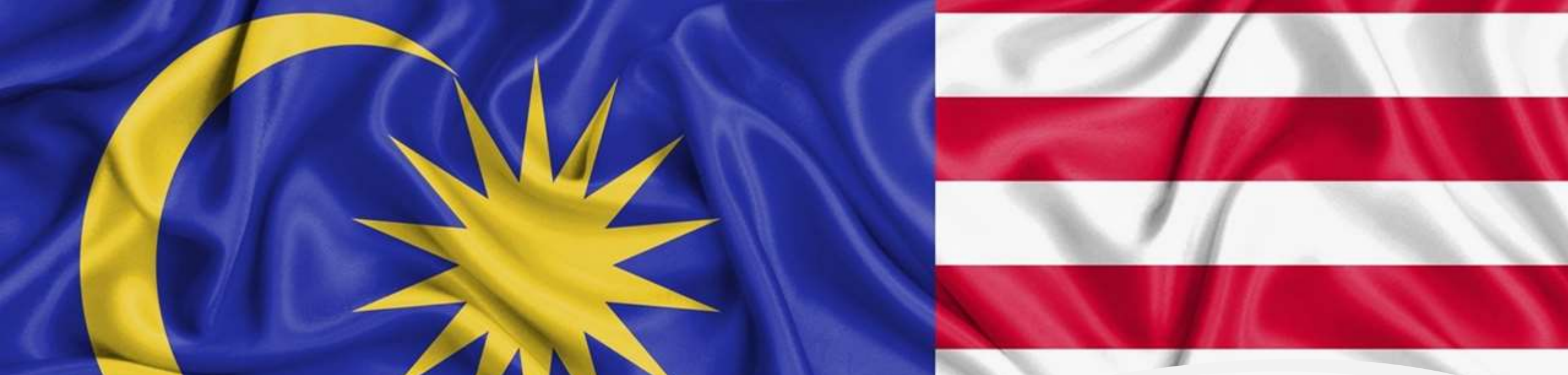
Thanks to the participants of the values and preferences survey and to you for your attention.

For more information:

Cary James, World Hepatitis Alliance cary.james@worldhepatitisalliance.org
Rosemary Delabre, Coalition PLUS rdelabre@coalitionplus.org

New WHO Guidance on HCV simplified service delivery, diagnostic innovations and treatment of adolescents and children

Simplified service delivery in action - country spotlights

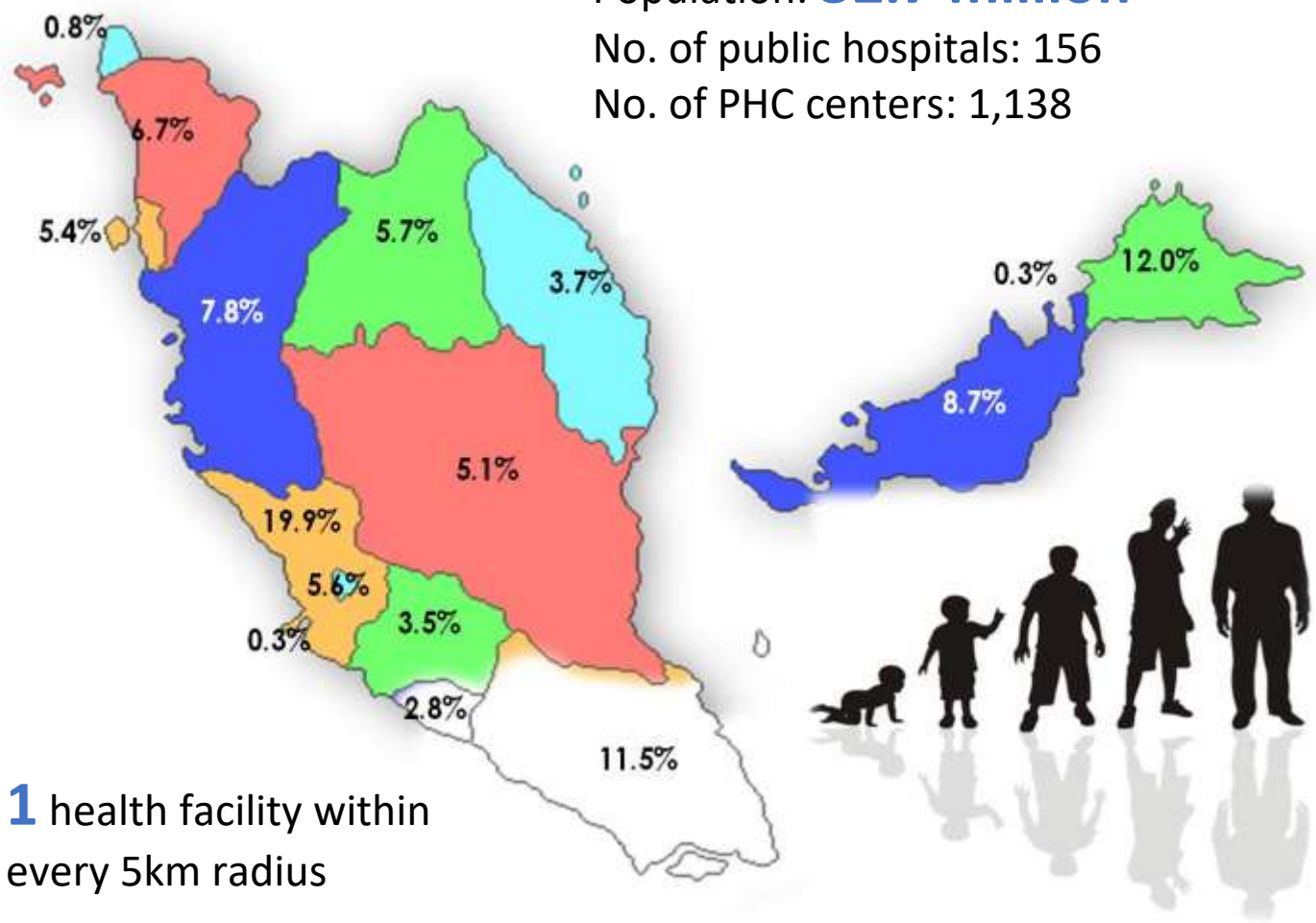


Malaysia's Journey
Implementation of Decentralized HCV Care Delivery

Datuk Dr Muhammad Radzi Abu Hassan
Deputy Director-General of Health (Research and Technical Support)
Ministry of Health Malaysia

HCV Burden in Malaysia

Population: **32.7 million**
No. of public hospitals: 156
No. of PHC centers: 1,138



1 health facility within every 5km radius

Viremic HCV prevalence	**0.2-0.3% (70,000)**
Unreached PWID	**30,000**
Estimated people living with HCV	**100,000**

Source: Muhammad NA et al. (2020). Seroprevalence of hepatitis B virus and hepatitis C virus infection among Malaysian population. Sci Rep, 2020 12 03;10(1):21009.

Key Milestones of HCV Agenda in Malaysia

2016

Breaking through the barrier

- ❑ Compulsory licensing on SOF

2019-2020

Setting a tone for treatment decentralization

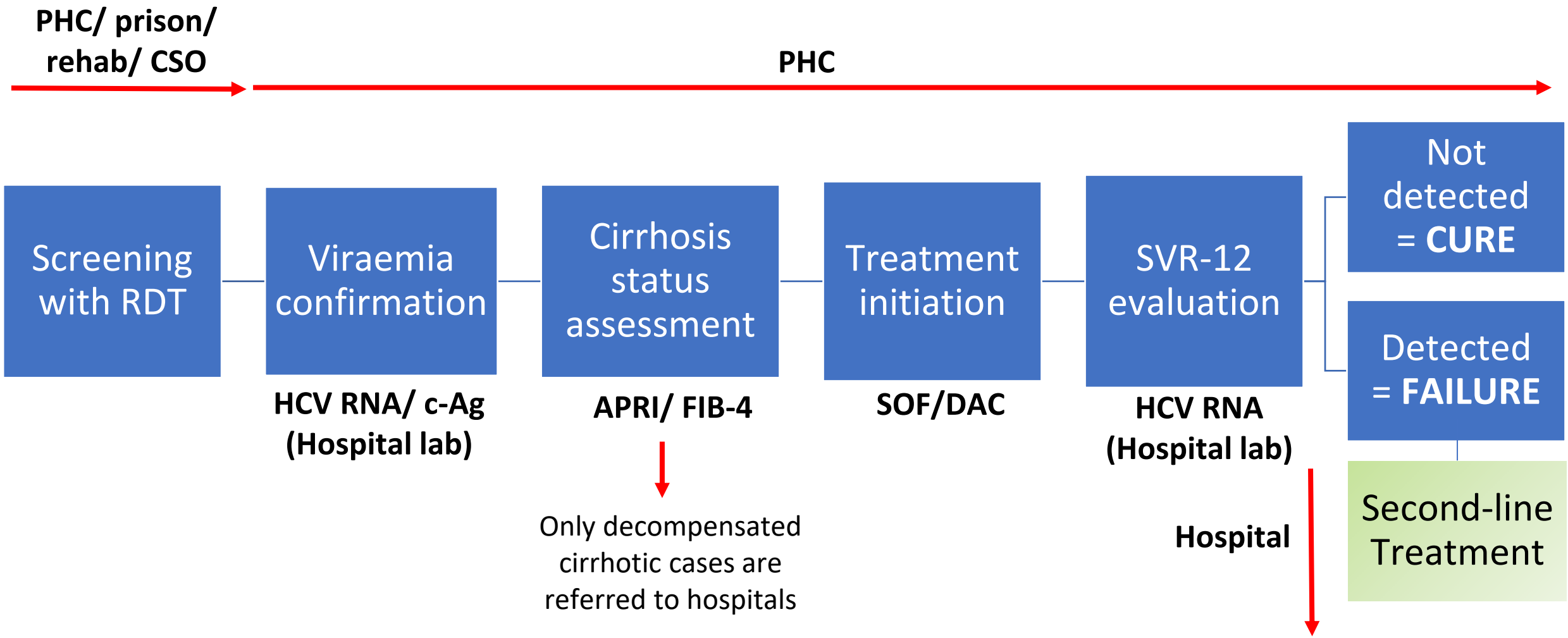
- ❑ National Strategic Planning (2019-2023)
- ❑ Making screening services & DAAs (SOF/DAC) available in primary healthcare centers

2022 onward

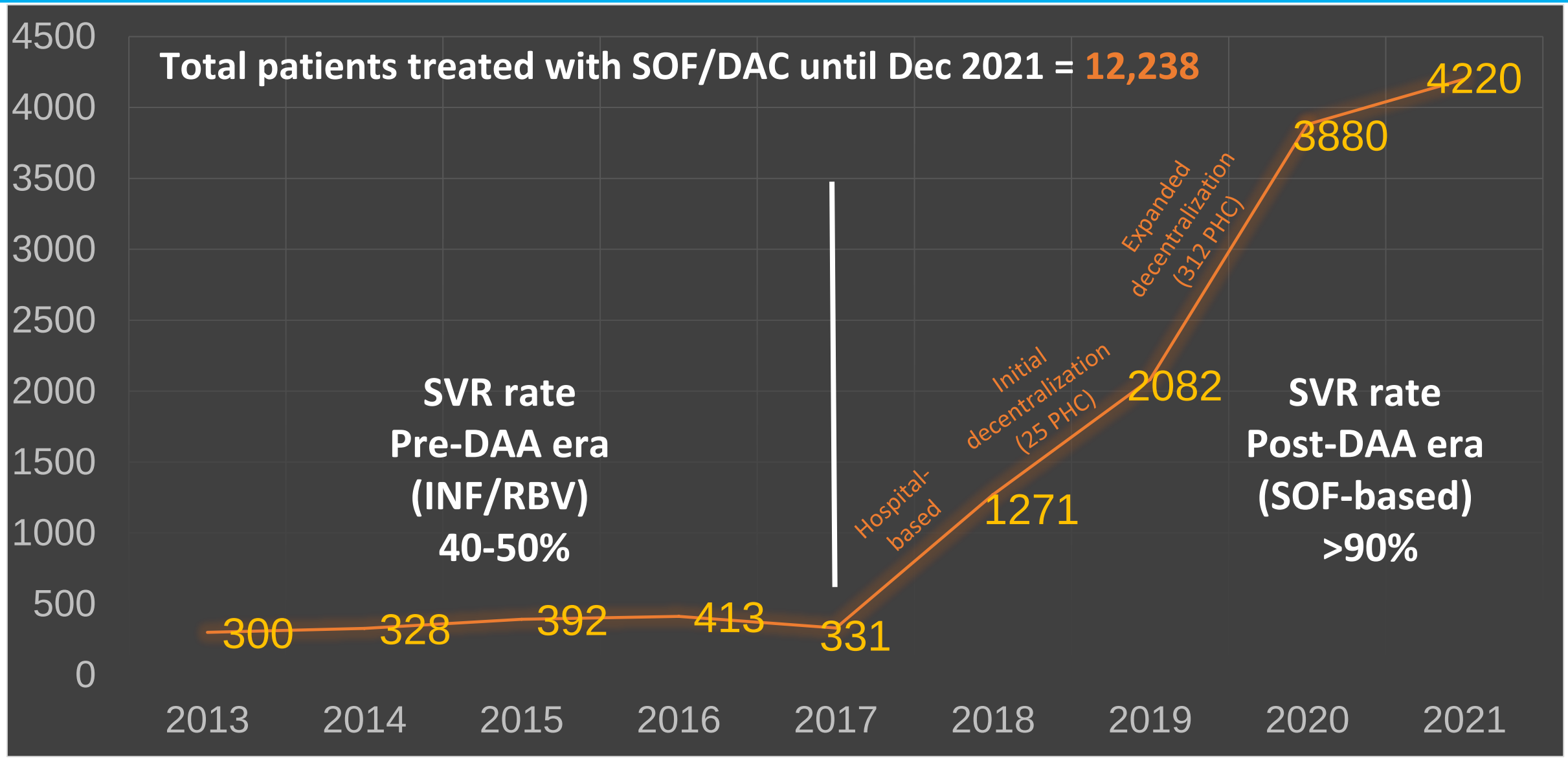
Going beyond low-hanging fruit

- ❑ Large-scale screening campaign to **find the missing million**

HCV Treatment Decentralization Model in Malaysia



Continuous Expansion of HCV Treatment Coverage



Two key challenges in Malaysia

How to break down silos and get all stakeholders on board?

VS

Where to find the missing millions?

Government-led partnerships

Ministry of Health

Inter-ministerial

- ✔ To offer HCV screening & treatment in correctional settings

International

- ✔ To enhance access to HCV screening and treatment by R&D

Local

- ✔ To link key populations to HCV care

Going Beyond Low-Hanging Fruit

PWID under opioid replacement therapy

~ to promote “one-stop-shop” model

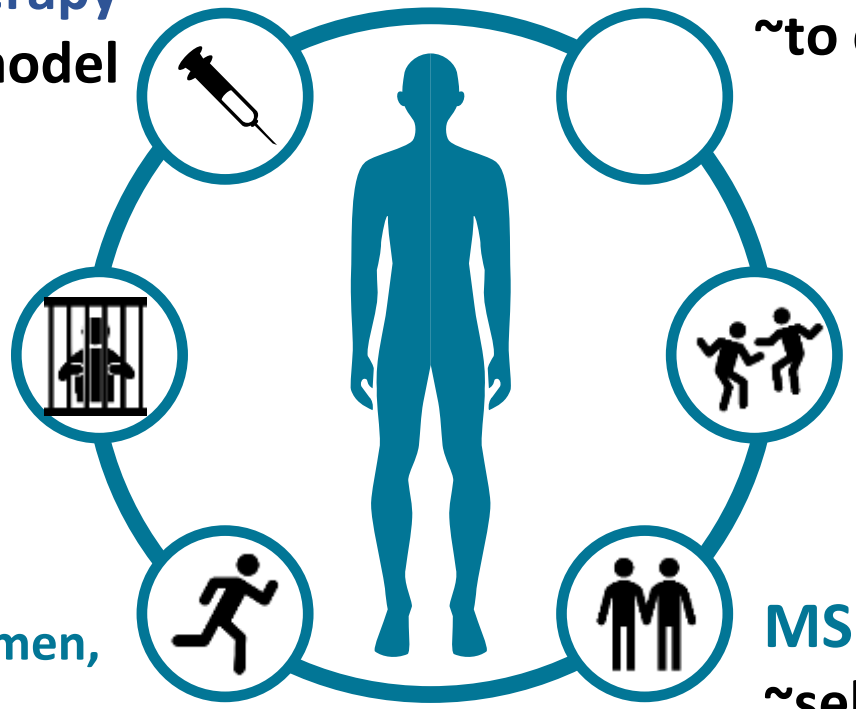
Correctional settings

~ to step up screening & treatment initiation

Unreached PWID

(alternative substance abusers, fishermen, estate workers & island residents)

~outreach programs



Refugees

~to collaborate with MSF

Sex workers

~outreach programs

MSM

~self-testing & social media


Thank you

COUNTRY EXAMPLE FOR INTEGRATING TESTING AND TREATMENT AT HARM REDUCTION SITES FOR PWID

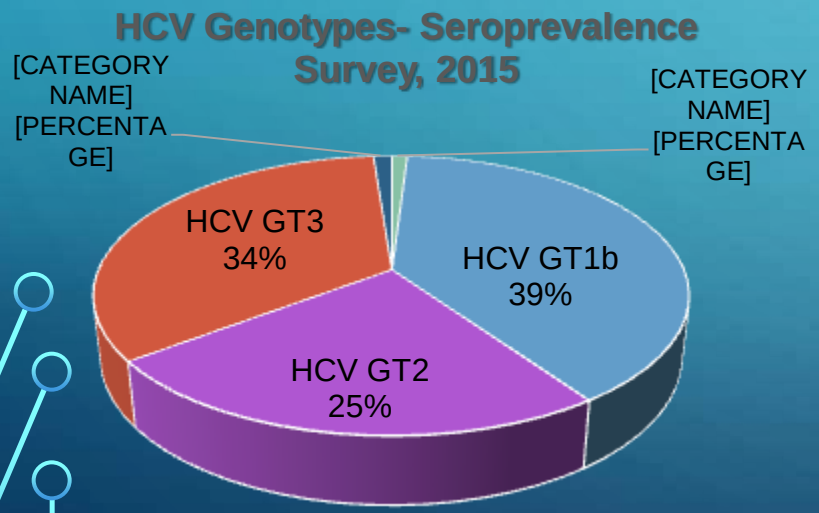
DR EKATERINE ADAMIA, MOH GEORGIA

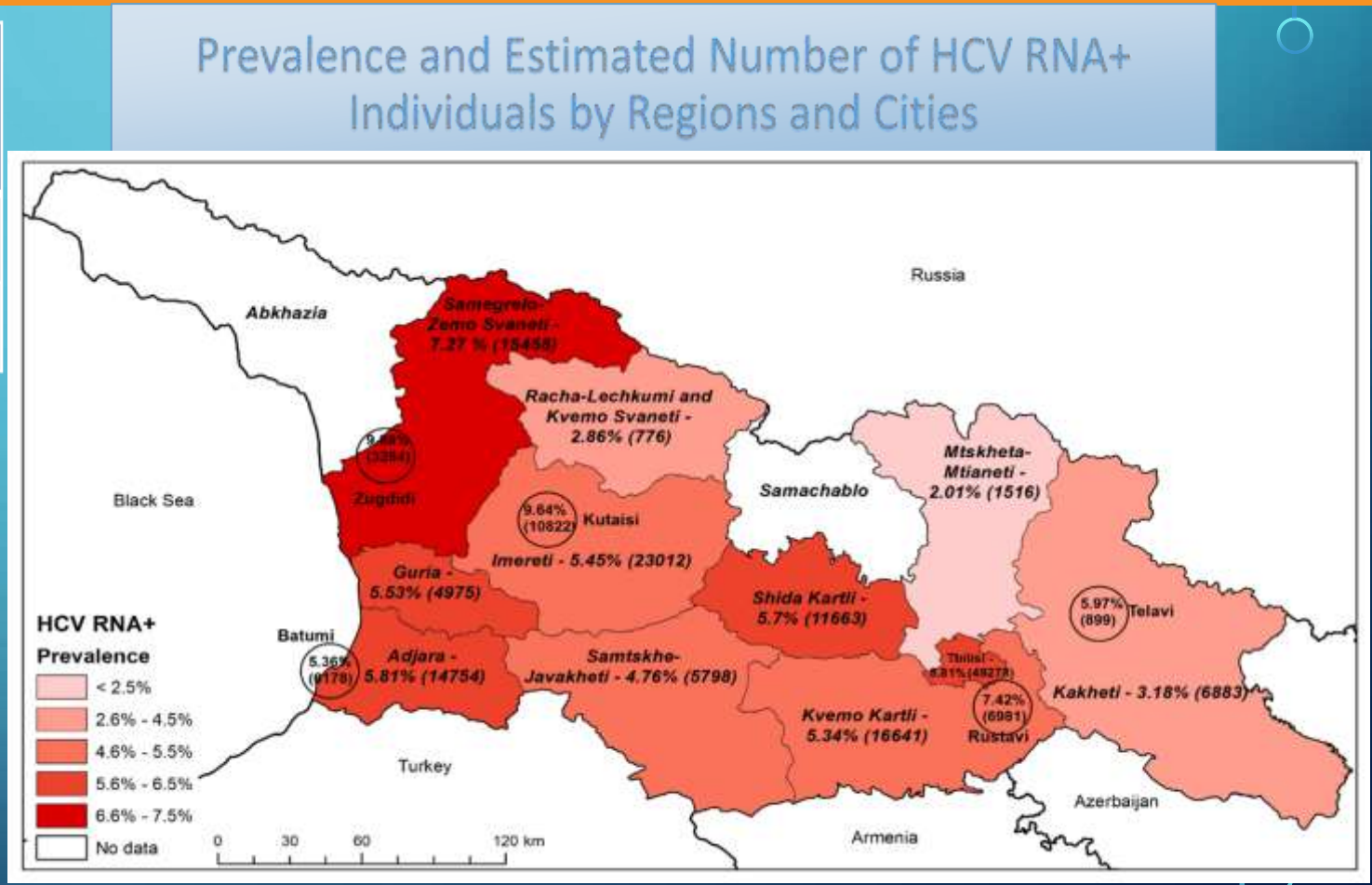
JULY, 2022

HCV BURDEN IN GEORGIA

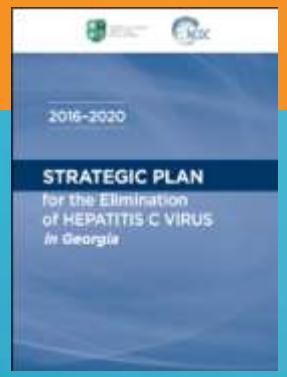
SEROPREVALENCE SURVEY, 2015

Characteristic	n	Weighted %	Estimated # nationwide ≥18 years
Anti-HCV+	425	7.7%	215,000
HCV RNA+	311	5.4%	150,000





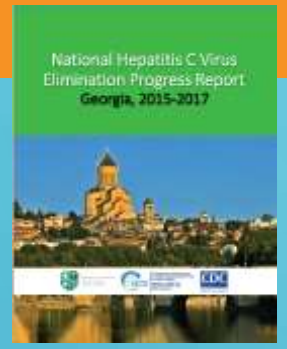
PROGRESS OF THE ELIMINATION PROGRAM



- Launch of the elimination Program
- Nationwide serosurvey: 5.4% adults with chronic HCV
- Beginning of National screening program
- Treatment available and free of charge
- The Technical Advisory Group (TAG) established

- First National Strategy 2016–2020 approved
- Clinical and Scientific Committees established
- Sofosbuvir/ Ledipasvir available
- A 10-year agreement between Gilead and the GOG signed

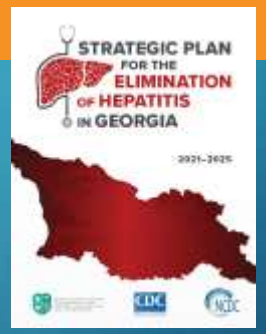
- A pilot project – Integration of HCV, TB, and HIV Detection at PHC level initiated
- National screening protocol approved and registry created
- Georgia awarded the title of NOhep Visionary for the European Region at the 2017 WHS
- Reflex CoreAg testing introduced



- Diagnostics available and free of charge
- Decentralization of HCV Diagnostic, Care, and Treatment Services to PHC and HR services
- Progress report published (2015–2017)

- Georgia named EILF Center of Excellence in Viral Hepatitis Elimination
- Progress report published (2017–June 2018)
- All diagnostics free of charge

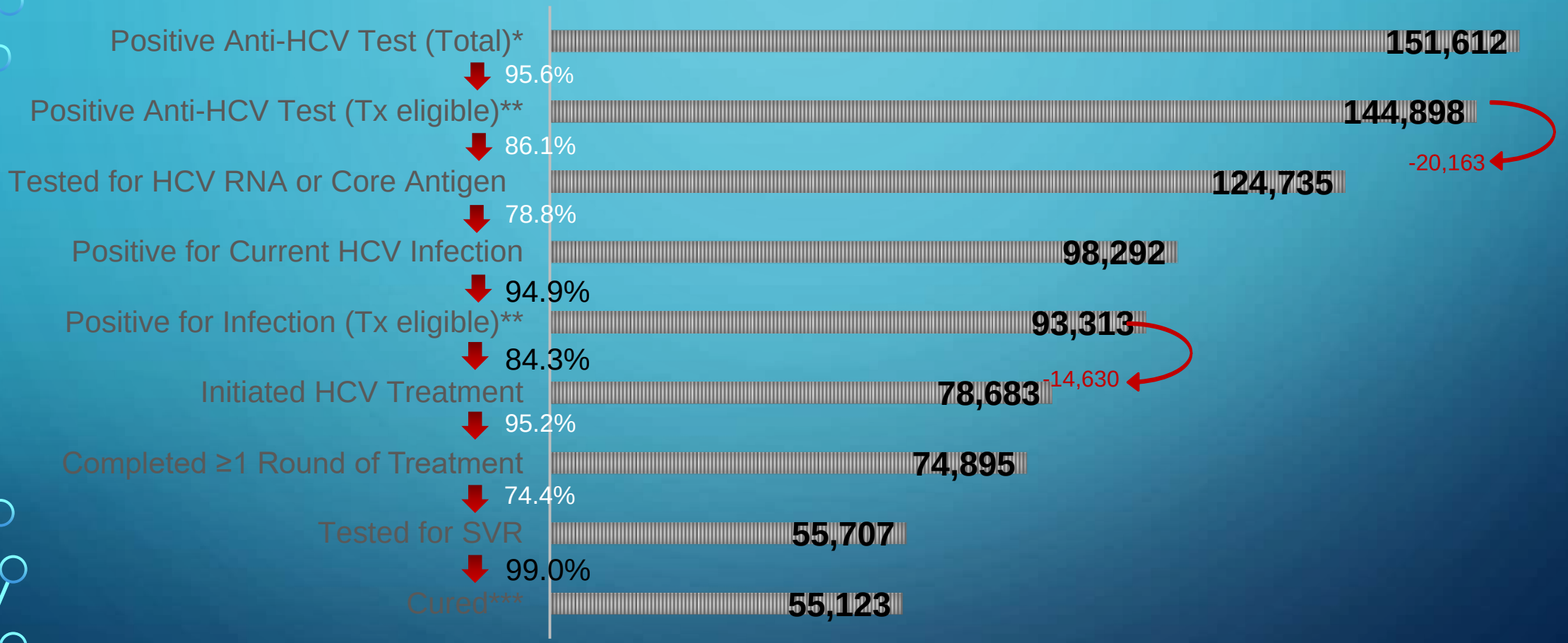
- The „linkage-to-care" program was initiated
- NAT testing implemented in Safe Blood Program



- National Strategy 2021–2025 Updated
- Population-based Serosurvey of Prevalence and Risk Factors for SARS-CoV-2, HCV, and HBV conducted
- Program received recognition by the CDC Director – Honor Award for Excellence in Partnering

2015 2016 2017 2018 2019 2020 2021

GEORGIA HEPATITIS C ELIMINATION PROGRAM CARE CASCADE, 28 APRIL 2015–30 JUNE 2022



* Among persons with national ID number. An additional 18,586 screened anti-HCV+ using an anonymized 15-digit code. Thus, their representation in the cascade cannot be confirmed; ** Age ≥12 years with no mortality data prior to progressing in cascade

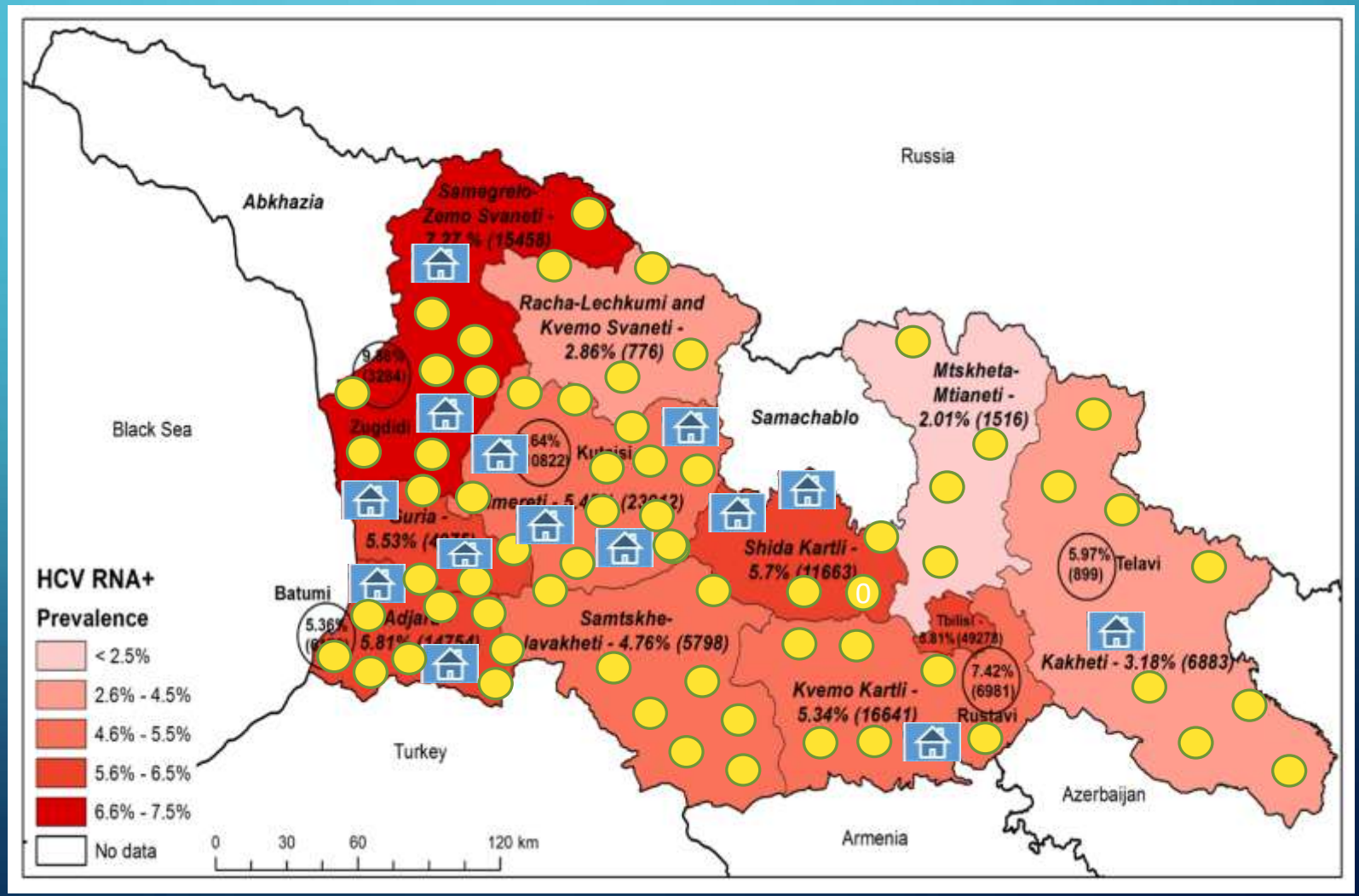
*** Per-protocol, includes retreatments. Among 56,014 persons tested after their **1st round of treatment**, 54,243 (96.8%) achieved SVR (Including 82.3% for **SOF-based regimens**, 98.2% for **SOF/LED regimens**, and 98.6% for **SOF/VEL regimens**). 2,028 persons were **retreated** with a 2nd round of treatment, with 94.5% (1,097/1,161) of those tested achieving SVR. Overall SVR by **Intention-to-Treat analysis:** 72.2%

DECENTRALIZATION CONCEPT

*(INCREASE **GEOGRAPHICAL ACCESSIBILITY** OF SCREENING, CARE AND TREATMENT SERVICES)*

After Decentralization in all regions and municipalities of Georgia at least one site

At present -**41 sites**
8 regions from 10 and **16 municipalities** from 69 are covered + 4 HR center (2 in Tbilisi, 1 Zugdidi, 1 Batumi)



OVERALL CONTEXT (PWID)

	All	Opioid Injectors
Estimated number of injectors in the country, (2016-2017)	52,500 (50,000 – 56,000)	31% (15,500 – 17,360)
National prevalence estimate for the injection drug use (for adults)	2.24% (2,13% - 2,39%)	
Main Drug Injected	Buprenorphine and Heroin, (including so called “sirets”), Ephedra	
Sharing of needles and syringes	9.6% (in some regions up to 24.4%)	
Prevalence of HCV and HBV ABs	HCV 63% (IBBSS) HBV 3.3%-4.8% (NSP Data)	

DECREASE HCV INCIDENCE AMONG PWID BY PROMOTING HARM REDUCTION

Services

Implemented by GHRN - Georgian Harm Reduction Network

Basic Services

- Needle and Syringe Program
- Condom distribution program
- Overdose Prevention – Distribution of naloxone
- HTC, Testing on Viral Hepatitis and STI
- Risk Reduction Counseling

Add on Services

- TB screening and Referral
- Medical and Legal Consultations
- Case Management Support – linkage to care
- Patient Schools and Peer meetings

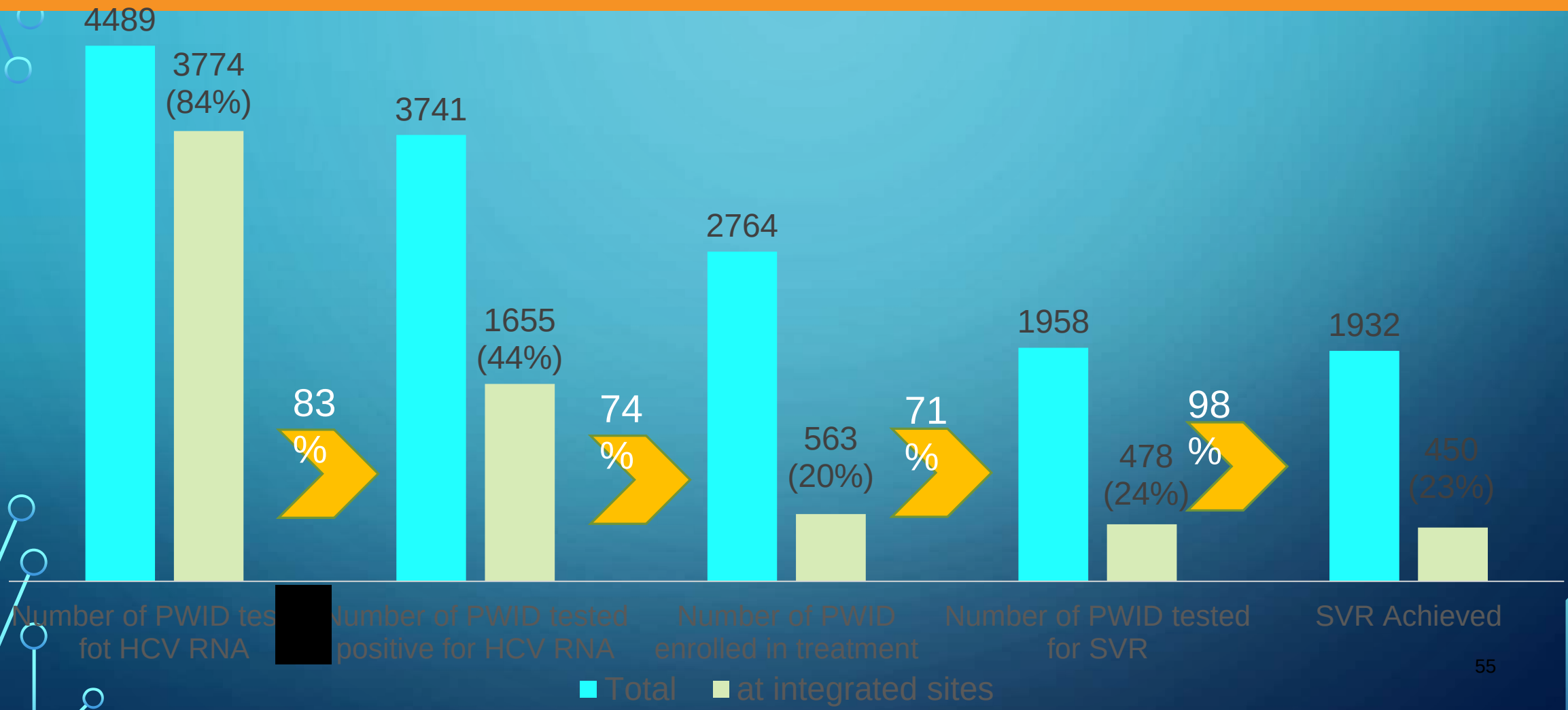
HCV and HBV AB Screening available at 16 NSP sites and through 9 mobile Ambulatories

HCV viremia (RNA) testing capacity is established at 5 NSP centers through a FIND HEAD-START project Decentralizing HCV Testing to Harm Reduction Sites

(From June 2018 through December 31st, 2021, 3,772 RNA tests have been completed at 5 NSP sites.. 1,361 tests were performed for re-infection with a positivity rate of 7.4%)

For other NSP sites linkage is established with reference labs and HCV treatment clinics

HCV TREATMENT CUMULATIVE CASCADE AMONG PWID



SUCCESSES

- Despite the Covid-19 pandemic, provision of NSP and OST services to PWID were fully sustained
- State Health Care funding for NSP and OST programs was secured and is reflected in the MTEF and the remaining funds will be covered by the Global Fund Program through 2025
- In 2021, the State provided GeneXpert Cartridges for HCV RNA testing (including testing for SVR and re-infection); the relevant budget is allocated in the 2022 State Program also
- Operations of the 4 NSP and OST integrated HCV treatment sites were sustained during COVID-19 epidemic
- 5-day take-home doses of methadone were provided to OST patients periodically based on the COVID-19 epidemiological situation and the public mobility restrictions

World Health Organization

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

EASL INTERNATIONAL LIVER FOUNDATION

L.I.F.E.R. LIVER INSTITUTE AND FOUNDATION FOR EDUCATION AND RESEARCH

NOhep

The Global Fund To Fight AIDS, Tuberculosis and Malaria

GILEAD

Thank you!

Project ECHO

NCDC

CDC Centers for Disease Control and Prevention

FIND Because diagnosis matters

Abbott

GHRN ზიანის შემცირების საქართველოს ქსელი GEORGIAN HARM REDUCTION NETWORK

World Hepatitis Alliance

Decentralization and Task sharing to nurses

25 July 2022

Dr. KEO Samley

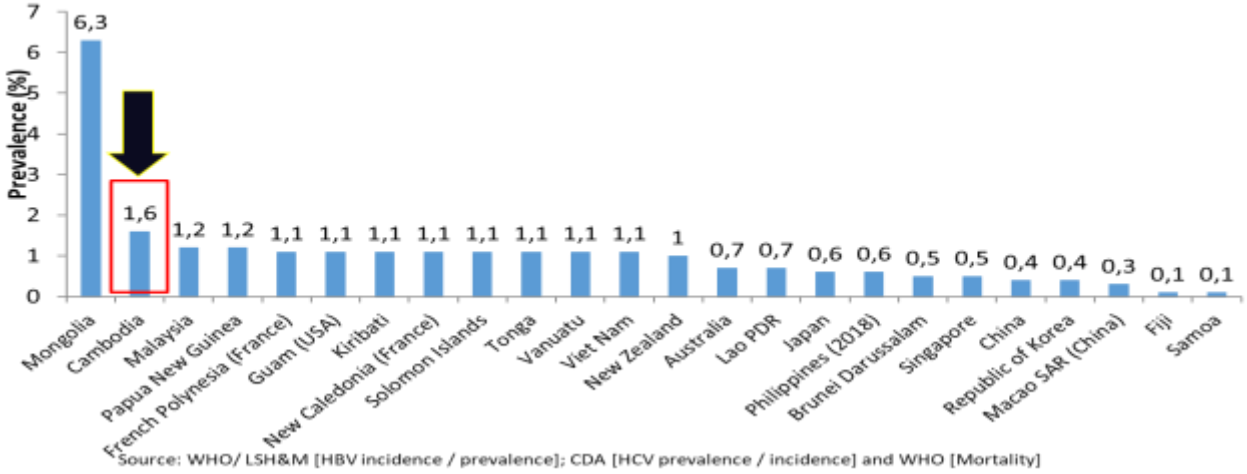
Vice chief of Bureau Prevention and Control/ Secretariat of Hepatitis,

CDC, Ministry of Health, **Cambodia**

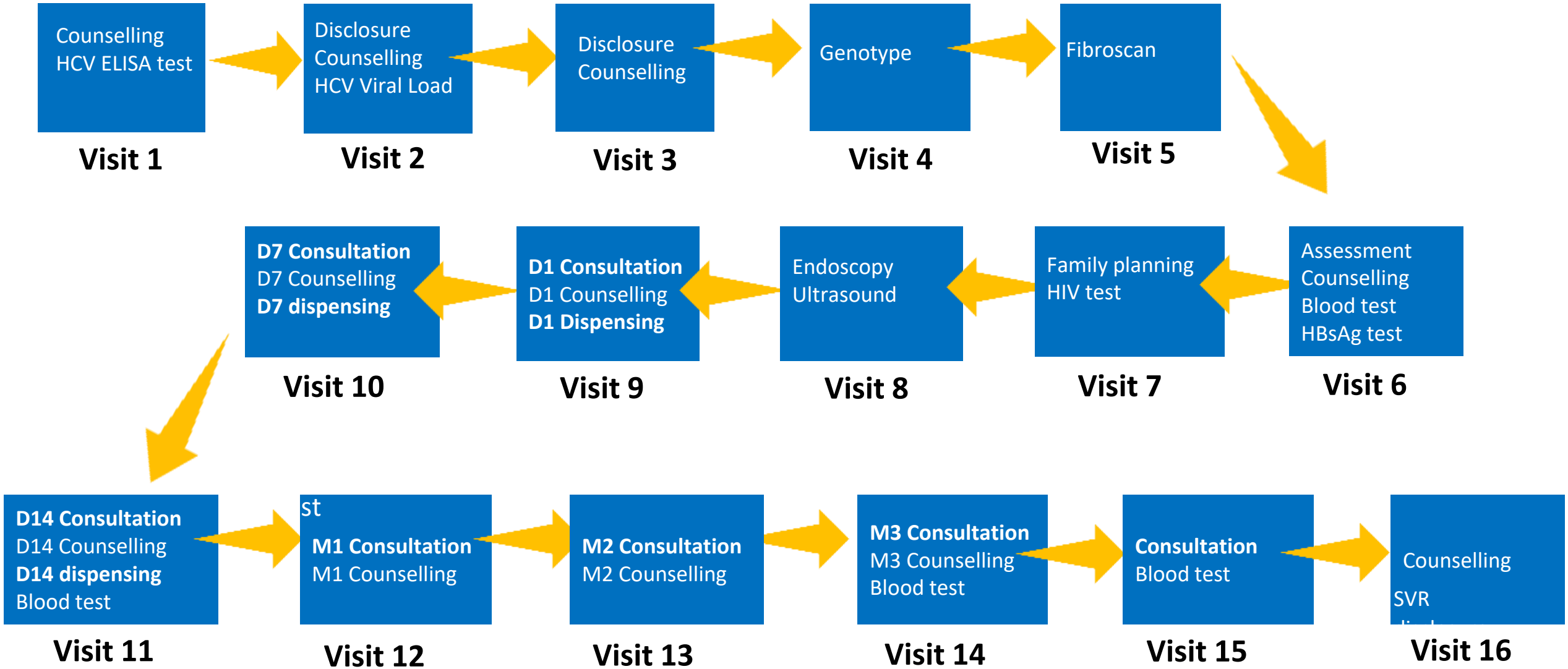
Viral Hepatitis C burden in Cambodia

HCV Indicators	
Viraemic prevalence (%)	1.6%
Estimated number of chronic HCV Infections	257,000
Estimated annual deaths Related to HCV	700
Incidence (annual)	3,800

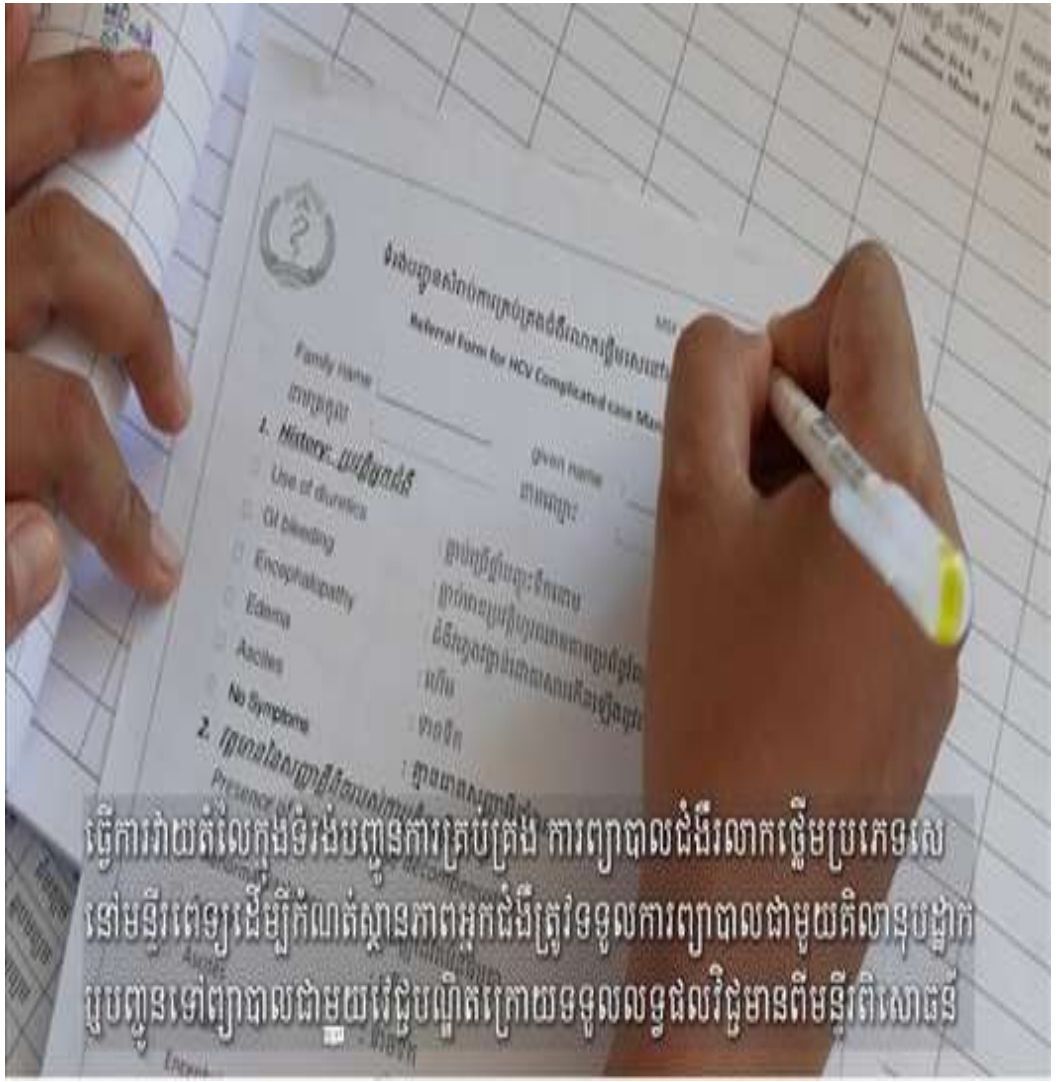
Second highest HCV prevalence in WPRO region



Initial care model (Sept. 2016)



Nurse-led DAAs initiation pilot (1st June 2020 - 30th September 2020)



Reasons for simplifications in HCV care pathway:

1- **Consistent patient outcomes above 97% cure** in multiple cohorts' HCV clinic Kossamak hospital.

2- **Very few Hepatologists** in Phnom Penh, none in other urban/rural areas.

3- **Limited access to fibroscan and additional diagnostic tests** either unaffordable or quality of tests varying (endoscopy, echography - US).

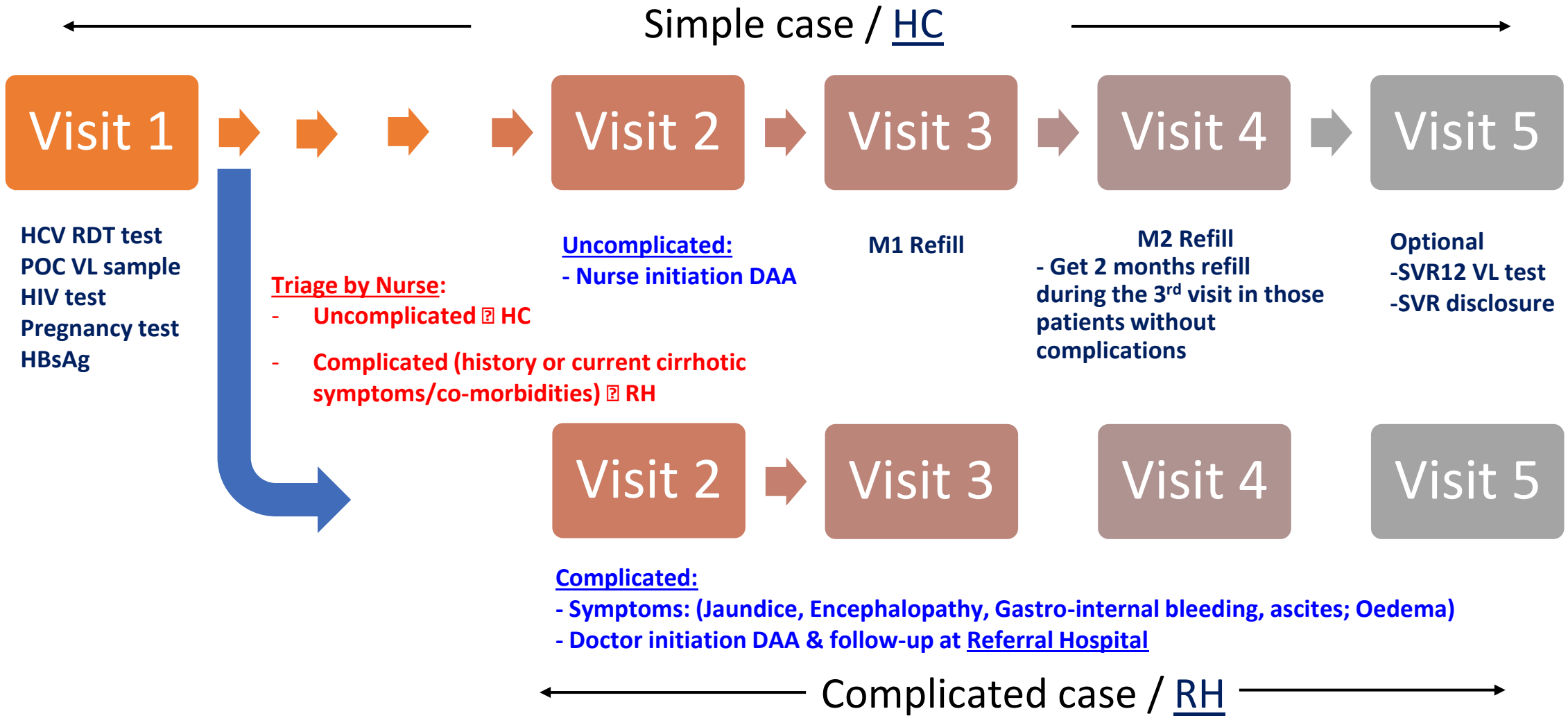
4- **Lack of laboratory standards** (IQC-EQA) , capacity – consistencies of results in rural areas (APRI).

- MoH-CDC / MSF implemented the **Nurse pilot project to evaluate pre-treatment assessment and DAA initiation/maintenance by nursing staff in two rural ODs** in Battambang (Sangke and Thmar Kaul), with 27 rural health centres
- The **pilot was implemented in HC without on-site doctors**, Fibroscan machines or full lab capacity
- **Patient screening** using RDT via **active case finding** in local villages and **passive case finding** in rural health centres
- **Prospective pre-treatment assessment** was performed at HCV-VL appointment.

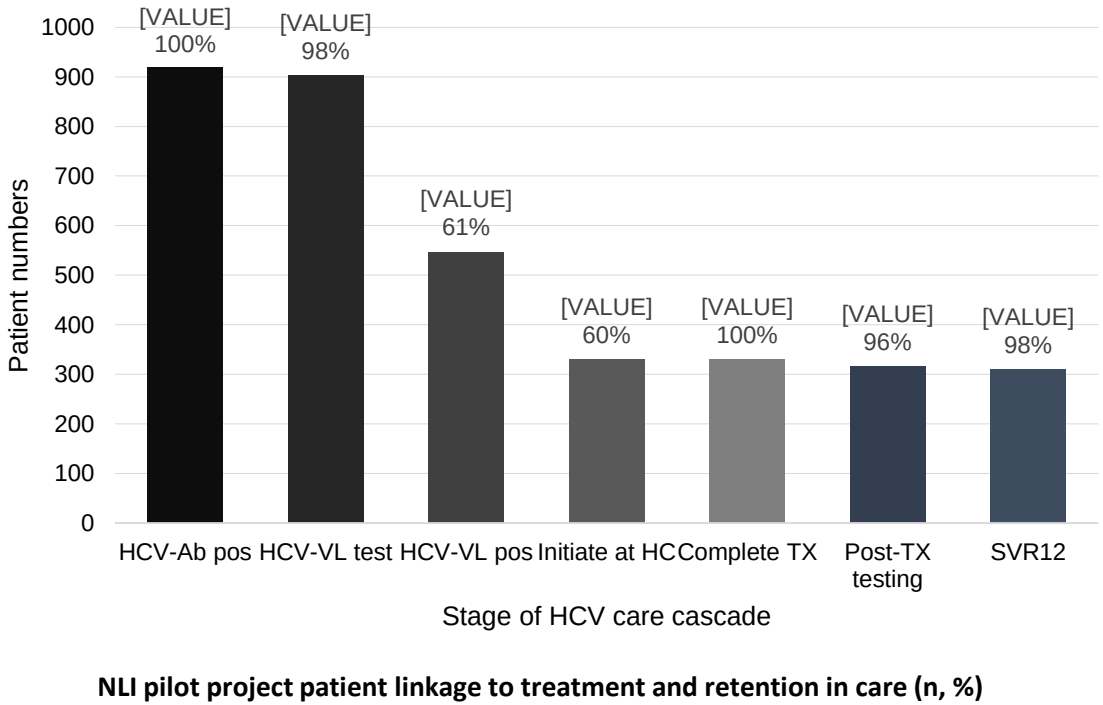
Hepatitis C simplified training for nurses, GP, laboratory technicians.

- **Training curriculum tailored 2 days session for GP, Nurses only 1 day for Lab tech** (already using Xpert for TB program).
- **Nurses were trained on how to screen**, **identify signs of decompensated liver cirrhosis** and refer them, provide information about **treatment adherence** and **potential side effects of DAA** during the treatment (i.e. fatigue, pain or allergy, etc.).
- All simple cases received in HC the Sofosbuvir (SOF)/Daclatasvir (DCV) 400/60mg orally daily for 12 weeks, provided in one-month prescriptions.
- All **complicated cases referred to secondary level referral hospital** to see the GP for further assessment.
- At treatment months one and two, patients Nurses checked for adherence to treatment
- **Regular supervision** for one month for each HC Nurse / quarterly later on.

MSF demonstration piloting of Decentralized and Simplify Hepatitis Service at Primary health care



Patients outcomes with Nurses led pilot



NLI pilot project patient linkage to treatment and retention in care (n, %)

- Of 547 patients, 204 patients were referred to the GP at referral hospital.
- All 329 simple cases patients initiated by Nurse completed the treatment.
- 14 patients did not return for post-treatment testing (2 due to death unrelated to HCV treatment and 12 LTFU).
- 310 patients (98%) achieved SVR12 and five (2%) experienced treatment failure.

Summary of progress

- Decentralized, simplified and integration of HCV care pathways in primary care services is feasible, reduces cost and the task shifting in uncomplicated cases does not compromise treatment safety and efficacy.
- Simplified and decentralized of HCV service is crucial in scaling up the hepatitis C care and treatment, regardless of the country's income classification.
- The model has been adopted in the VH NSP 2020-2024 and treatment guidelines 2019 and endorsed by MoH
- Maintaining and scaling implementation based on resources available

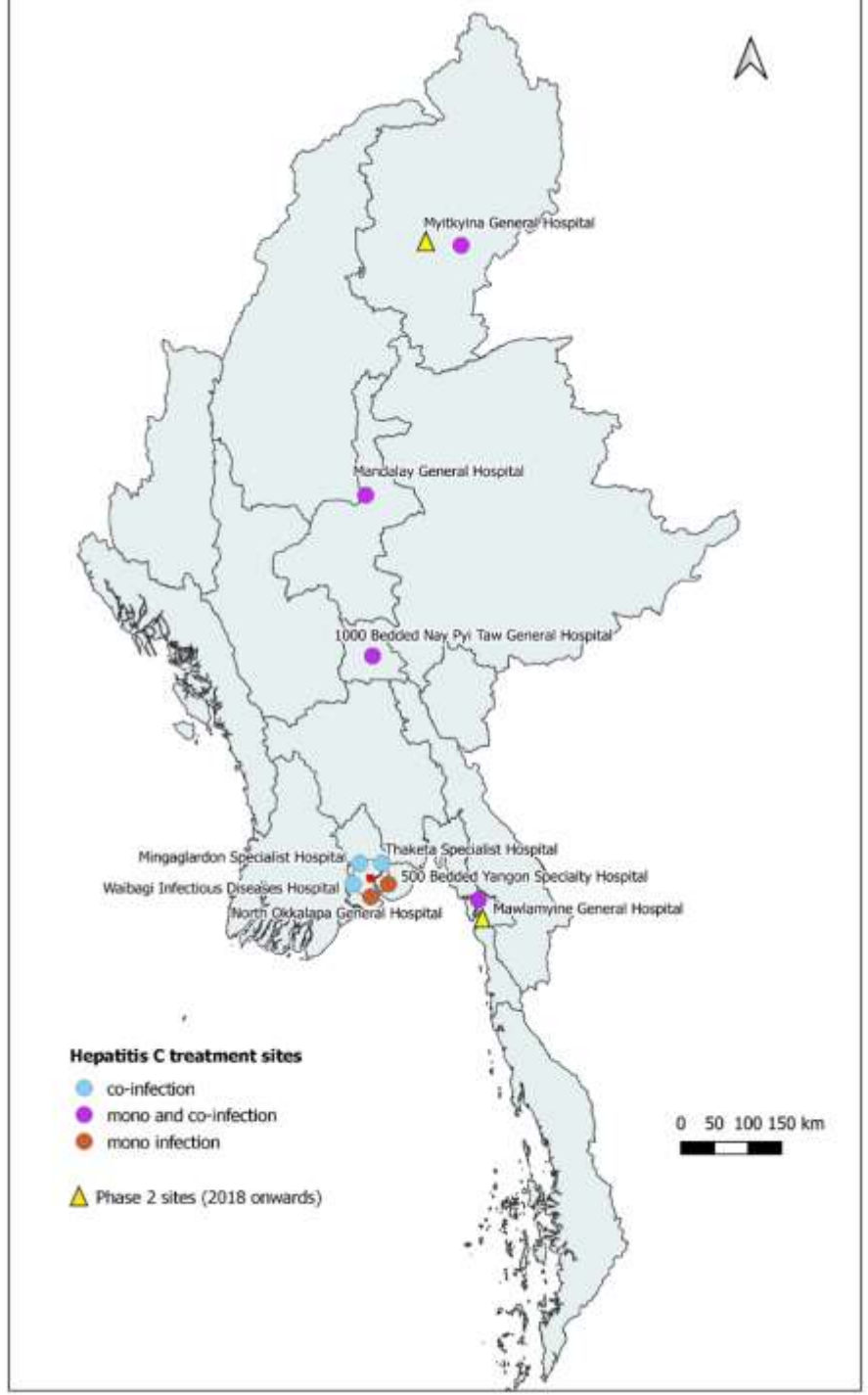
Burnet Institute
Medical Research. Practical Action.

Use of Point-of-Care HCV viral load testing: CT2 Study Myanmar

Bridget Draper
Research Officer, Burnet Institute

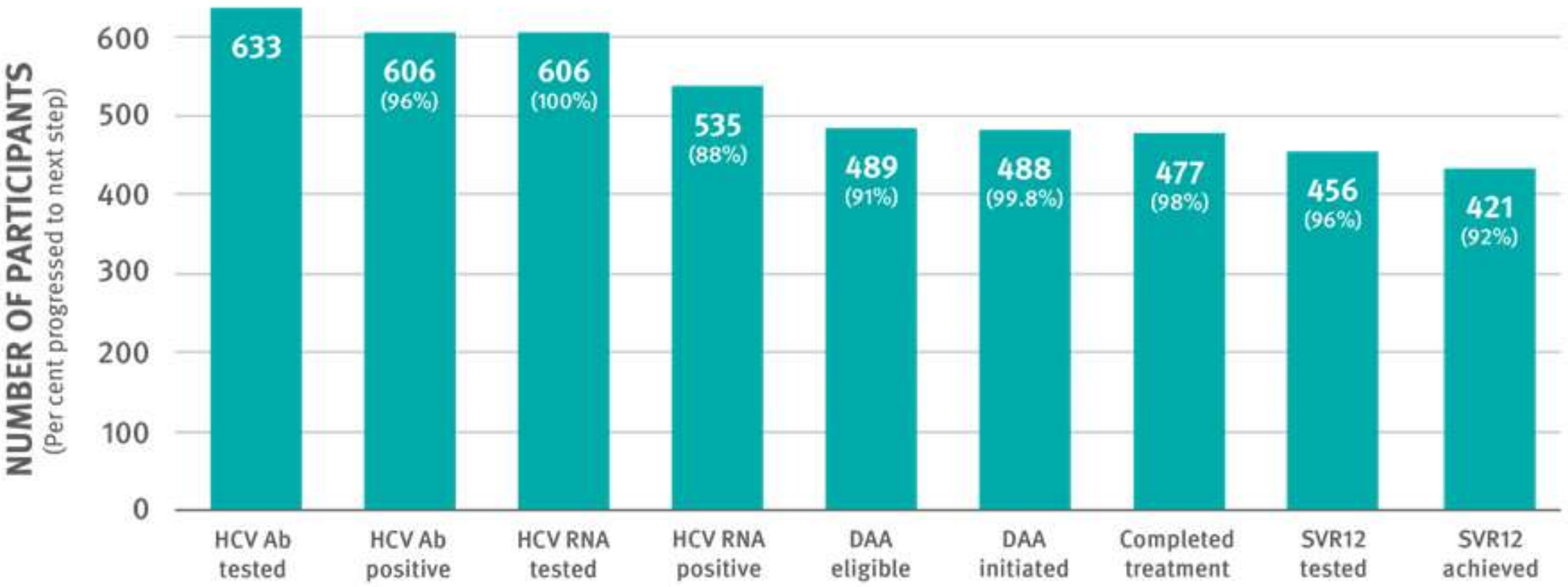
Hepatitis C in Myanmar

- 2.7% hepatitis C antibody positive
- Over 1 million people living with hepatitis C
- Transmission through formal/informal healthcare settings & injecting drug use
- 56% hepatitis C antibody positive among people who inject drugs
- National Hepatitis Control Program provides services in 13 hospital sites



CT2 Simplified Clinical Pathway

CT2 Cascade of Care



Draper BL, Htay H, Pedrana A, *et al*. Outcomes of the CT2 study: A 'one-stop-shop' for community-based hepatitis C testing and treatment in Yangon, Myanmar. *Liver Int*. 2021; 41: 2578– 2589

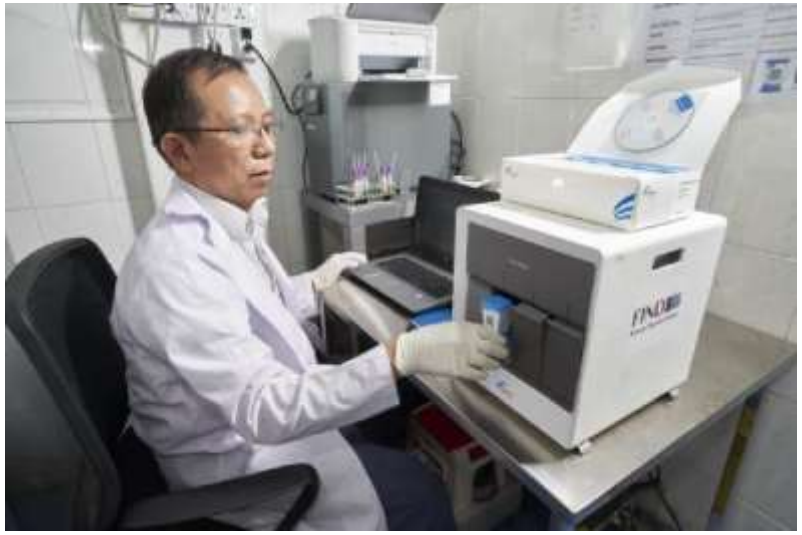
Operational Considerations for use and maintenance of GeneXpert POC HCV VL test

1. Infrastructure requirements
2. Storage, transport and disposal
3. Staff training
4. Module replacements, quality control and warranty

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.

Infrastructure requirements & Storage, transport, disposal

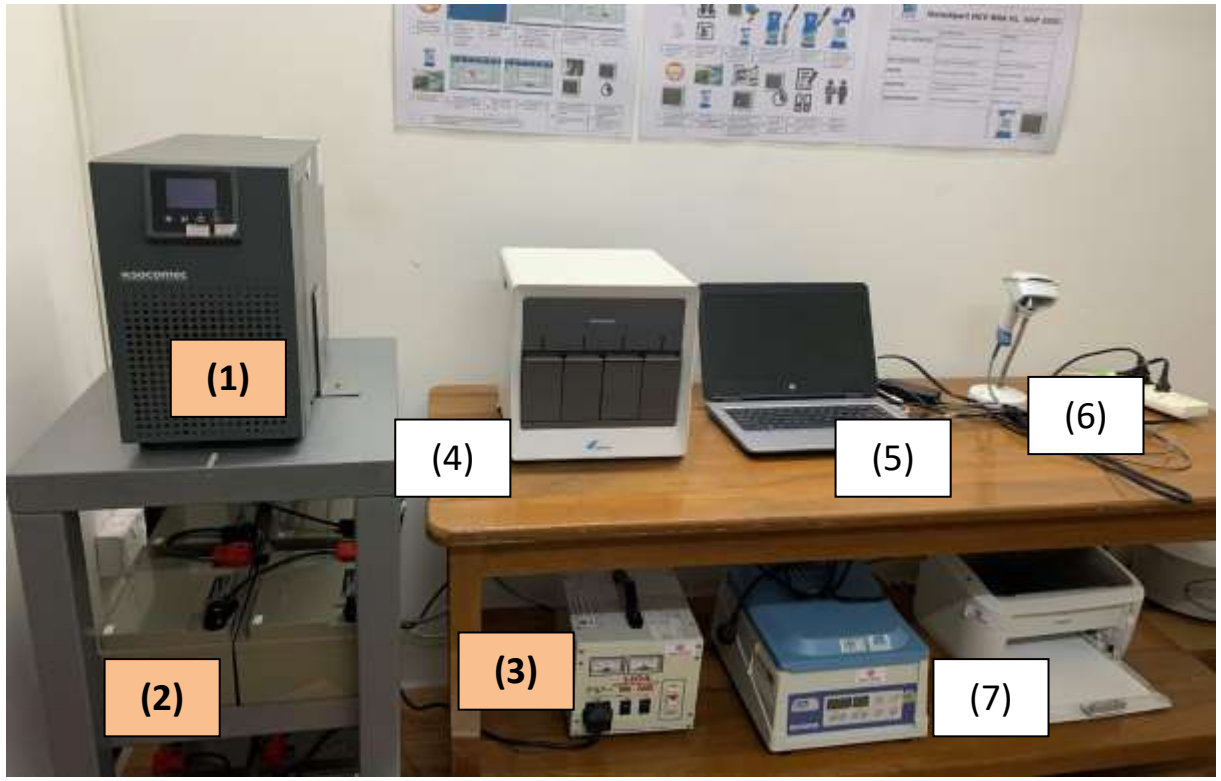
- GeneXpert device requires:
  - an environment controlled at 15–30°C
  - no direct sunlight, minimal dust and humidity
  - stable, continuous electricity supply



- Xpert cartridges require:
  - storage at 2-28°C, upright
  - transport at 2-28°C, upright
  - disposal at high temperatures / incinerator

Lessons learnt

- To achieve these conditions:
  - air-conditioning
  - adapt workflow and renovate room
  - install online uninterrupted power supply
- Our implementation experiences:
  - sometimes difficult for clinics to follow storage protocol
  - during site visits, we checked storage and helped trouble-shoot



Staff training and ease of use

- Training and skill requirements
  - undertake 1-2 day training program on device (no prior experience required)
  - require either experience or specific skill training for preparing plasma sample for GeneXpert
- Ease of use
  - staff reported no specific problems using Xpert, except for how to respond to errors or malfunctioning device
  - ease of use supported by low error rate (5%)

Lessons learnt:

- Allow for ~10 Xpert test runs
- Provide more information on how to respond to errors

Module replacements, quality control and warranty

- Module replacements
  - higher module replacement than other published data from Xpert device
  - module replacement -> downtime, but only for module not whole device
- Quality control
  - IQC - performed using cross-clinic samples weekly
  - EQAS – enrolled through NRL Australia, cost was expensive
- Warranty
  - annual maintenance required for Xpert device, useful to have technical support personnel located in same city

Lessons learnt:

- Monitor errors and module replacements and check conditions regularly
- EQAS is expensive if not available in-country
- Warranty on Xpert is worthwhile, covers module replacement

Summary of key operational considerations for POC HCV VL testing

- Requires basic infrastructure, with focus on electricity supply, conditions of room (dust, heat), and stock storage
- Requires access to and training in quality control / assurance options
- Requires training of staff, if not familiar with device or sample preparation
- Requires access to Xpert technicians for maintenance / replacements
- Extended warranty was useful, especially with high number of module replacements

Egypt-Case Finding Strategies to Reach Children and Adolescents

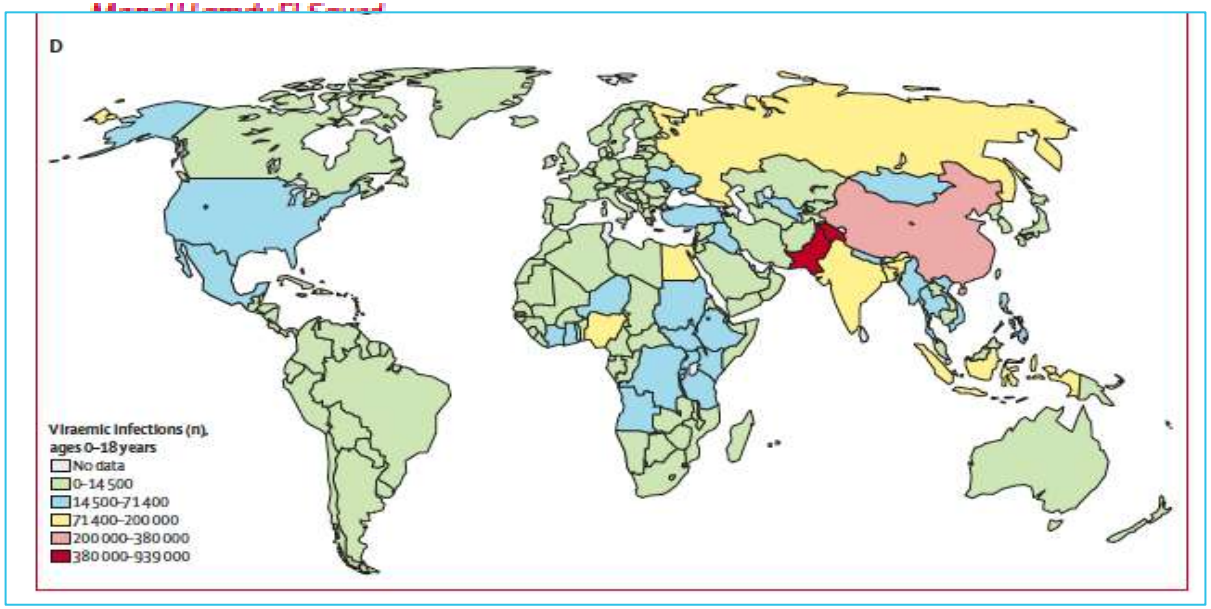
Professor Manal H El-Sayed
Chair of Pediatric Department
Director of the Clinical Research Center
Faculty of Medicine
Ain Shams University, Cairo, Egypt

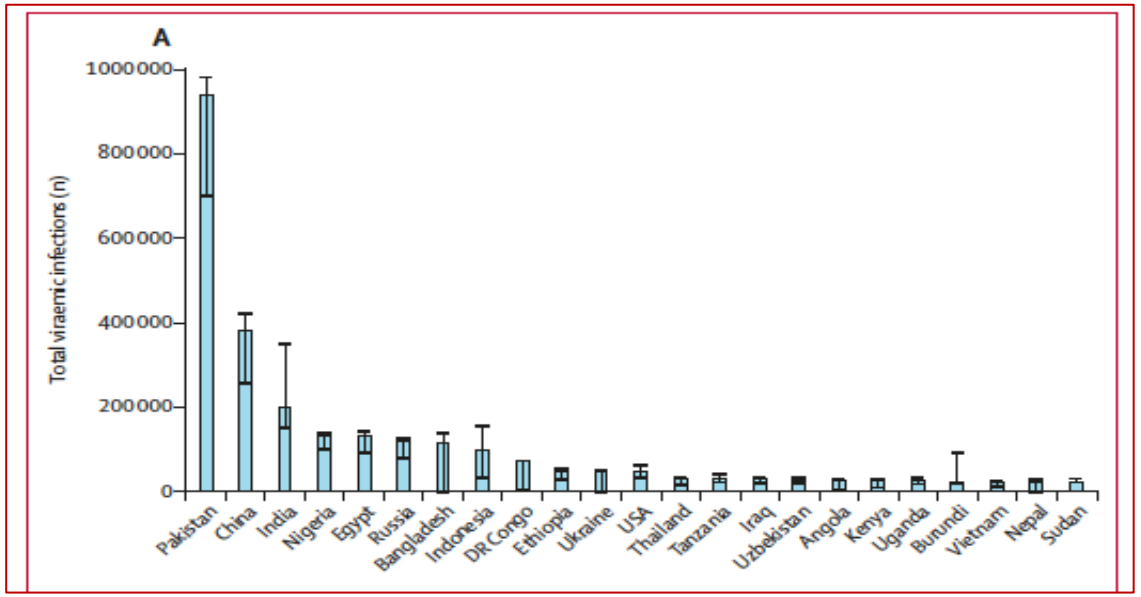
Global prevalence of hepatitis C virus in children in 2018: a modelling study

Jonathan Schmelzer, Ellen Dugan, Sarah Blach, Samantha Coleman, Zongzhen Cai, Mindi DePaola, Chris Estes, Ivane Gamkrelidze, Kathryn Jerabek, Siyi Ma, Shauna Montoya, Devin Razavi-Shearer, Kathryn Razavi-Shearer, Sarah Robbins-Scott, Homie Razavi,

Lancet Gastroenterol Hepatol 2020

Published Online January 16, 2020 https://doi.org/10.1016/S2468-1253(19)30385-1





The global estimate for *viremic prevalence in the pediatric population aged 0–18* years was **0.13%**

This corresponds to **3.26 million** (2.07–3.90) children with HCV in 2018

Global prevalence of hepatitis C virus in women of childbearing age in 2019: a modelling study

Ellen Dugan, Sarah Blach, Mia Biondi, Zongzhen Cai, Mindi DePaola, Chris Estes, Jordan Feld, Ivane Gamkrelidze, Shyamasundaran Kottilil, Siya Ma, Poonam Mathur, Shauna Montoya, Devin Razavi-Shearer, Kathryn Razavi-Shearer, Sarah Robbins-Scott, Jonathan Schmelzer, Homie Razavi

An estimated ***14 860000*** (95% uncertainty interval [UI] 9 667 000–18282000) women aged 15–49 years had HCV infection worldwide in 2019, corresponding to a viraemic prevalence of ***0·78%*** (95% UI 0·62–0·86

~ 2.3 billion children below 18 yrs today make up 24 % of the world's population in 2019

	0–2 years		3–6 years		7–11 years		12–18 years		Total	
	HCV prevalence	Cases	HCV prevalence	Cases	HCV prevalence	Cases	HCV prevalence	Cases	HCV prevalence	Cases
(Continued from previous page)										
WHO region										
African	0·05% (0·03–0·07)	52 600 (31 700–67 700)	0·07% (0·04–0·08)	84 200 (50 400–107 000)	0·10% (0·06–0·13)	142 000 (85 600–180 000)	0·20% (0·12–0·26)	341 000 (207 000–436 000)	0·12% (0·07–0·15)	620 000 (374 000–791 000)
Eastern Mediterranean	0·17% (0·13–0·19)	90 000 (66 300–96 100)	0·26% (0·19–0·28)	174 000 (129 000–186 000)	0·42% (0·31–0·45)	313 000 (230 000–333 000)	0·67% (0·49–0·72)	625 000 (459 000–669 000)	0·42% (0·31–0·45)	1 202 000 (884 000–1 284 000)
European	0·07% (0·04–0·08)	23 000 (14 200–26 300)	0·08% (0·05–0·09)	37 000 (21 400–43 100)	0·10% (0·05–0·12)	59 000 (30 800–69 900)	0·28% (0·15–0·32)	203 000 (111 000–235 000)	0·15% (0·08–0·18)	322 000 (178 000–374 000)
The Americas	0·02% (0·01–0·02)	7700 (5000–9000)	0·03% (0·02–0·03)	15 200 (10 200–18 100)	0·04% (0·03–0·05)	29 800 (20 100–35 700)	0·06% (0·04–0·08)	69 600 (47 200–84 500)	0·04% (0·03–0·05)	122 000 (82 400–147 000)
South-East Asia	0·03% (0·01–0·04)	26 700 (10 800–38 800)	0·04% (0·02–0·06)	60 700 (25 900–88 800)	0·07% (0·03–0·10)	127 000 (57 400–188 000)	0·11% (0·05–0·17)	288 000 (134 000–428 000)	0·07% (0·03–0·11)	502 000 (228 000–743 000)
Western Pacific	0·03% (0·02–0·04)	24 100 (16 000–28 000)	0·05% (0·04–0·06)	52 600 (35 000–60 400)	0·09% (0·06–0·11)	111 000 (74 200–127 000)	0·18% (0·12–0·21)	300 000 (200 000–347 000)	0·11% (0·07–0·12)	488 000 (325 000–562 000)
World Bank income classification										
High-income	0·02% (0·01–0·02)	6100 (4000–8500)	0·02% (0·02–0·03)	13 400 (8800–18 800)	0·04% (0·03–0·05)	27 700 (18 300–38 900)	0·08% (0·05–0·11)	76 700 (50 600–109 000)	0·05% (0·03–0·07)	124 000 (81 600–175 000)
Upper-middle income	0·04% (0·02–0·04)	41 900 (27 400–46 800)	0·06% (0·04–0·06)	81 300 (53 100–91 100)	0·09% (0·06–0·10)	155 000 (101 000–174 000)	0·19% (0·12–0·21)	452 000 (298 000–502 000)	0·11% (0·07–0·12)	730 000 (479 000–814 000)
Lower-middle income	0·08% (0·05–0·09)	140 000 (92 000–162 000)	0·11% (0·07–0·13)	271 000 (176 000–316 000)	0·17% (0·11–0·20)	498 000 (321 000–588 000)	0·26% (0·17–0·32)	1 061 000 (674 000–1 272 000)	0·17% (0·11–0·21)	1 970 000 (1 263 000–2 338 000)
Low-income	0·05% (0·03–0·07)	36 100 (20 700–48 200)	0·07% (0·04–0·09)	58 700 (33 300–77 600)	0·10% (0·06–0·13)	101 000 (57 500–132 000)	0·20% (0·12–0·27)	238 000 (136 000–315 000)	0·12% (0·07–0·15)	433 000 (248 000–573 000)

Data are prevalence (95% UI) or n (95% UI). GBD=Global Burden of Disease. UI=uncertainty interval.

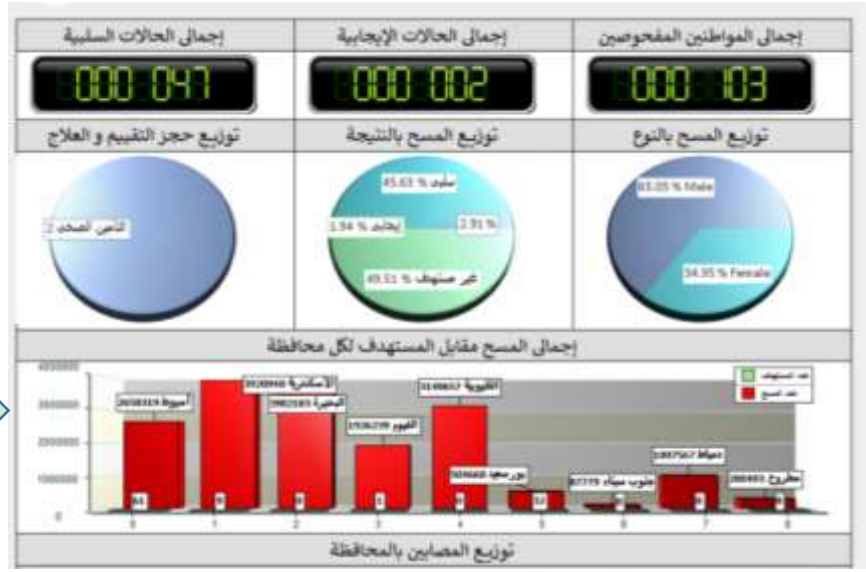
An average ~ **250,000** more are estimated in other North African countries: *Egypt, Libya Algeria, Tunisia and Morocco*. In addition to *Sudan, Somalia and Djibouti* considered as part of the WHO EMRO region

Schmelzer J et al; *Lancet Gastro Hepatol* 2020. S2468-1253(19)30385-1.

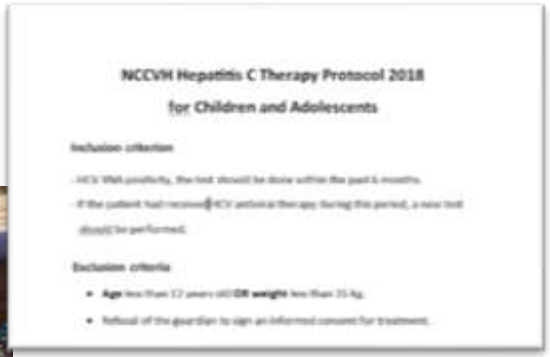
100 Million Healthy Lives Initiative

- *Each phase included: Urban, Rural, Frontier, Delta and Upper Egypt Governorates*
- Phase 1: 2 months, 9 Governorates
- Phase 2: 3 months, 11 Governorates
- Phase 3: 2 months, 7 Governorates

Website Operational
School Program
1st December 2018



- Targeted high school students: ~10 million (achieved until 2021)
- Teams: 380 (team of physician, nurse and data entry clerk- 1140 trained)
- Physicians trained on treatment protocol: 50



NCCVH Hepatitis C Therapy Protocol 2018

for Children and Adolescents

Ethical Considerations and Key Success Factors

- Voluntary participation
- Privacy
- Confidentiality (to avoid stigma)
- Parental Consent
- Campaign plan and consent were approved by the National Council for Childhood and Motherhood (NCCM)

Nationwide hepatitis C virus screening and treatment of adolescents in Egyptian schools

Ehab Kamal, Noha Asem, Mohamed Hassany, Galal Elshishiney, Wael Abdel-Razek, Heba Said, Sohair Abdel Hamid, Tamer Essam, Ahmed Rehan, Aysam Salah, Tarek Saad, Nasr Shawky, Abdalla Mostafa, Yasser Omar, Islam Ammar, Ramy Saeed, Mohamed AbdAllah, Jean Jabbour, Alaa Hashish, Samah Bastawy, Noha El Qareh, Nahla Gamaleldin, Khaled Kabil, Wahid Doss, Manal H El-Sayed, Hala Zaid

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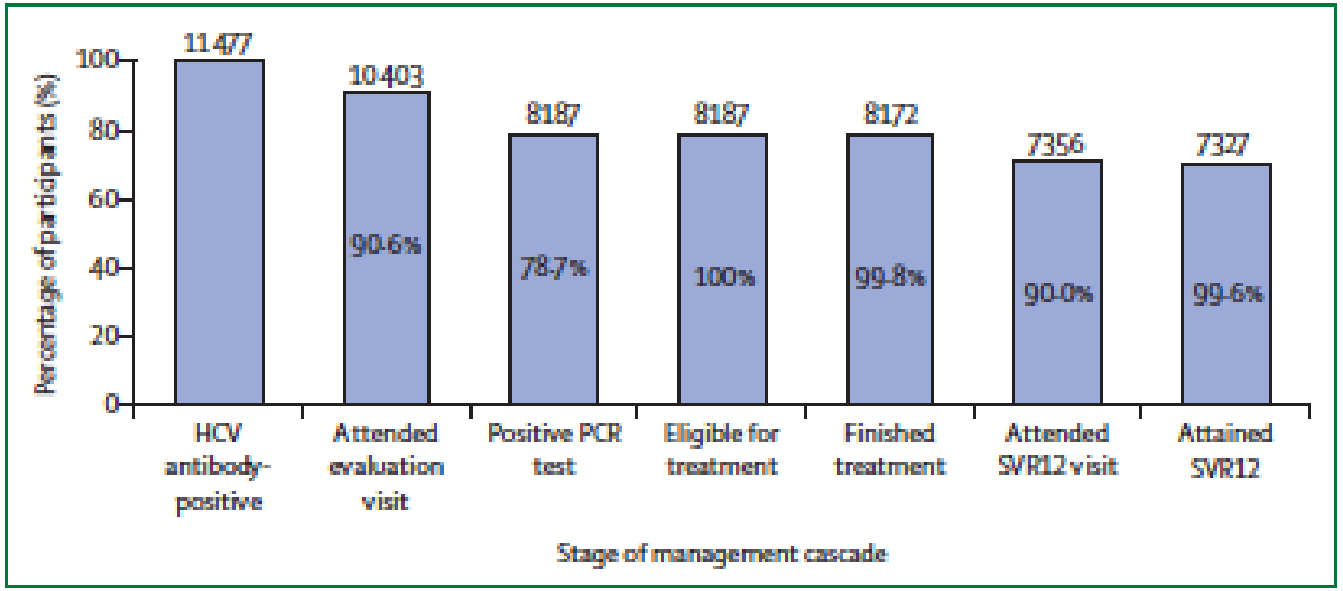


Figure: Management cascade of discovered HCV antibody-positive individuals
Numbers above the bars are the numbers of individuals. HCV=hepatitis C virus. SVR12=sustained virological response 12 weeks after completion of treatment.

	HCV seropositive rate in boys (%)	HCV seropositive rate in girls (%)	Overall HCV seropositive rate (%)	Odds ratio (for boys)*
Minia	1·03% (0·96–1·10)	0·88% (0·82–0·94)	0·95% (0·90–0·99)	1·17 (1·08–1·27)
Faiyum	0·87% (0·79–0·96)	0·57% (0·51–0·64)	0·72% (0·67–0·77)	1·53 (1·39–1·68)
Beni Suef	0·74% (0·66–0·83)	0·70% (0·63–0·78)	0·72% (0·67–0·78)	1·06 (0·90–1·21)
Sohag	0·64% (0·58–0·70)	0·42% (0·38–0·46)	0·52% (0·48–0·56)	1·52 (1·37–1·66)
Menofia	0·53% (0·47–0·59)	0·50% (0·45–0·55)	0·52% (0·48–0·55)	1·06 (0·91–1·20)
Sharkia	0·48% (0·44–0·52)	0·47% (0·43–0·50)	0·47% (0·45–0·50)	1·02 (0·91–1·13)
Assiut	0·49% (0·44–0·54)	0·39% (0·34–0·44)	0·44% (0·40–0·47)	1·25 (1·09–1·41)
Qalyubia	0·42% (0·38–0·46)	0·29% (0·26–0·33)	0·35% (0·33–0·38)	1·43 (1·28–1·58)
Gharbia	0·37% (0·33–0·41)	0·28% (0·24–0·31)	0·32% (0·29–0·35)	1·35 (1·18–1·51)
Dakahlia	0·36% (0·32–0·39)	0·26% (0·23–0·29)	0·30% (0·28–0·33)	1·37 (1·22–1·52)
Kafr El Sheikh	0·30% (0·25–0·35)	0·30% (0·26–0·34)	0·30% (0·27–0·33)	1·00 (0·79–1·22)
Alexandria	0·32% (0·28–0·36)	0·23% (0·19–0·26)	0·27% (0·25–0·30)	1·43 (1·23–1·62)
Beheira	0·34% (0·29–0·38)	0·21% (0·18–0·24)	0·27% (0·24–0·29)	1·58 (1·39–1·77)
Matrouh	0·21% (0·12–0·31)	0·27% (0·12–0·43)	0·23% (0·15–0·32)	0·79 (0·07–1·51)
Luxor	0·31% (0·24–0·39)	0·15% (0·10–0·20)	0·23% (0·18–0·27)	2·11 (1·68–2·53)
Damietta	0·26% (0·20–0·32)	0·18% (0·13–0·22)	0·21% (0·18–0·25)	1·49 (1·14–1·85)
Qena	0·24% (0·19–0·28)	0·18% (0·14–0·22)	0·21% (0·18–0·24)	1·30 (1·02–1·58)
Ismailia	0·25% (0·18–0·31)	0·16% (0·11–0·21)	0·20% (0·16–0·24)	1·51 (1·11–1·90)
Suez	0·21% (0·13–0·29)	0·15% (0·09–0·22)	0·18% (0·13–0·23)	1·39 (0·83–1·95)
South Sinai	0·28% (0·06–0·50)	0·05% (0·00–0·10)	0·17% (0·05–0·30)	5·24 (3·12–7·36)
Giza	0·21% (0·18–0·23)	0·14% (0·12–0·16)	0·17% (0·15–0·19)	1·45 (1·24–1·65)
Aswan	0·16% (0·11–0·21)	0·17% (0·13–0·22)	0·17% (0·13–0·20)	0·92 (0·50–1·34)
Cairo	0·17% (0·15–0·19)	0·11% (0·09–0·12)	0·14% (0·12–0·15)	1·58 (1·38–1·78)
New Valley	0·19% (0·08–0·30)	0·08% (0·01–0·16)	0·14% (0·07–0·20)	2·26 (1·20–3·32)
Port Said	0·16% (0·08–0·24)	0·10% (0·04–0·15)	0·13% (0·08–0·17)	1·64 (0·90–2·38)
Red Sea	0·11% (0·03–0·19)	0·11% (0·03–0·18)	0·11% (0·06–0·16)	1·03 (0·05–2·01)
North Sinai	0·10% (0·03–0·17)	0·07% (0·01–0·12)	0·08% (0·04–0·13)	1·49 (0·37–2·61)
Total	0·42% (0·41–0·43)	0·33% (0·32–0·34)	0·38% (0·36–0·38)	1·27 (1·24–1·31)

Numbers in parentheses are 95% CIs. HCV=hepatitis C virus. *Odds ratios are calculated for boys compared with girls. Odds ratios are adjusted by multivariate logistic regression analysis considering the age and gender distribution within each governorate.

Table 3: Seroprevalence of HCV antibody among students in all governorates disaggregated by gender

Nationwide hepatitis C virus screening and treatment of adolescents in Egyptian schools

Ehab Kamal, Noha Asem, Mohamed Hassany, Galal Elshishiney, Wael Abdel-Razek, Heba Said, Sohair Abdel Hamid, Tamer Essam, Ahmed Rehan, Aysam Salah, Tarek Saad, Nasr Shawky, Abdalla Mostafa, Yasser Omar, Islam Ammar, Ramy Saeed, Mohamed AbdAllah, Jean Jabbour, Alaa Hashish, Samah Bastawy, Noha El Qareh, Nahla Gamaleldin, Khaled Kabil, Wahid Doss, Manal H El-Sayed, Hala Zaid

Lancet Gastroenterol Hepatol 2022

Published Online April 27, 2022 https://doi.org/10.1016/S2468-1253(21)00464-7

WHO representative auditing the school screening program

Panel: Screening, evaluation, and treatment costs

Screening

- Rapid diagnostic tests: $1 723 865
- Consumables (gloves, printing materials, infection prevention and control measures, etc): $752 979
- Staff* : $627 442
- IT (hardware, servers hosting, internet connectivity, maintenance): $269 401
- Total cost of screening: $3 373 687
- Number of HCV-positive cases: 11 477
- Cost of identifying a positive case: $293·95

Evaluation

- HCV PCR: $72 821
- Evaluation (laboratory assessment, imaging, staff): $146 292
- Total cost of evaluation: $219 113
- Number of viraemic cases: 8187
- Cost of HCV RNA testing and evaluation per viraemic case: $26·76
- Cost of identifying a viraemic case: $438·84

Treatment

- Cost of treatment: $907 082
- Staff cost: $42 500
- Total cost of treatment: $949 582
- Cost of treatment per case: $115·98

Total costs

- Total cost of screening, evaluation, and treatment: $4 542 382
- Cure rate: 99·6%
- Cost of identifying and curing a case: $557·05

All costs are in US dollars. HCV=hepatitis C virus. *Three people in each team, 1049 teams in total.

Lessons Learned

- How to overcome *service delivery issues* in adolescents including consents, confidentiality and access to diagnosis and treatment
- *Schools* (both public and private) could be a platform for children and adolescents offering awareness and HCV testing in populations with high prevalence rates
- *Providers critical role:*

-Advocacy

-Awareness

-Removal of stigma and discriminations

-Access to diagnostics and medicine

- Testing and treating children and adolescents should be part of national programs offering access to diagnosis and care to adult populations to achieve *HCV elimination*

Acknowledgement

THANK YOU

School screening team

Manal H El-Sayed (Director)
Ehab Kamal
Ahlam Abdel-Mohsen
Khaled Kabil
Noha Asem
Mohamed Hassani

National Committee for Control of Viral Hepatitis

Wahid Doss (Chair)
Manal Hamdy El-Sayed
Gamal Esmat
Moustafa Kamal (late)
Magdy El-Serafy
Imam Waked
Yehyia El-Shazly
Maha Rabbat
Maha Gaafary
HIO Chair
Therapeutic Sector Chair
WHO representative

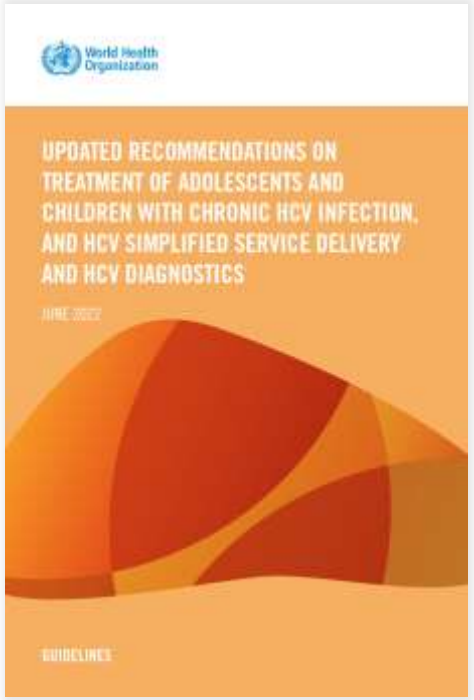
CHILDREN AND YOUTH CAN'T WAIT

Mohamed Hassani (*Executive Director*)
Khaled Kabil (*Assistant Chair*)

Eng Aysam (*IT Expert*)
Wafaa El-Akel (*Data Manager*)
Eng Tarek Saad (*Database*)

Heba Saeed (*HIO team leader*)

HEP CAN'T WAIT!


World Health Organization
UPDATED RECOMMENDATIONS ON TREATMENT OF ADOLESCENTS AND CHILDREN WITH CHRONIC HCV INFECTION, AND HCV SIMPLIFIED SERVICE DELIVERY AND HCV DIAGNOSTICS
GUIDELINES


World Health Organization
UPDATED RECOMMENDATIONS ON
TREATMENT OF ADOLESCENTS AND CHILDREN WITH CHRONIC HCV INFECTION
POLICY BRIEF
JUNE 2022


World Health Organization
UPDATED RECOMMENDATIONS ON
SIMPLIFIED SERVICE DELIVERY AND DIAGNOSTICS FOR HEPATITIS C INFECTION
POLICY BRIEF
JUNE 2022

Q&A