Global collaboration in local viral hepatitis elimination efforts

Community Panel Discussion *Course Correction: Mapping a Path Towards Achieving Urban HCV Elimination*

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Outline

- Background
- New Global strategy (GHSS 2022-2030)
- Global collaboration for viral hepatitis elimination
- New recommendations for diagnosis and service delivery
- Next steps



Global burden of Hepatitis C Virus

Some of the fast tract cities in the different WHO regions have the highest burden of Hepatitis C







Global agenda: Elimination of viral hepatitis as a public health threat by 2030 –





Hep B & C- 6-10 m infections (in 2015) to 900,000 infections (by 2030). Specifically, 95% decline in HBV and 80% decline in HCV. All deaths : 1.4 m (in 2015) to 500,000 deaths (by 2030)

Changes in impact 2020-2030 HCV incidence (all)

- new HCV cases from 1.5 million to 170K
 HCV incidence (PWID)
- 8/100 to 2/100
 HCV deaths
- 290K deaths to 140k

Global Collaboration for viral hepatitis elimination

an important role in every strategic direction of GHSS 2020-2030



programmes/strategies

- Engage communities and civil society, including key and affected populations, and
- support their self-empowerment and pivotal role in advocacy, service delivery and policymaking,
- including to ensure that HCV services are culturally appropriate and responsive to community needs,
- and to address stigma and discrimination
- and tackle social and structural barriers.

Actions from the WHO GHSS 2022-2030

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



- 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)

Key enablers

- 1. Availability of simplified norms and standards
- 2. Quality-assured product options
- 3. Affordability in different country contexts
- 4. Equity in access for all populations in need
- 5. Efficiency in delivery

Political commitment is central to providing the enabling environment and unlocking domestic and international financing



New WHO strategy and guidelines 2021 and 2022 provide key shifts and radical simplification of the care pathway to support these enablers and overcome barriers

WHO guidelines Evolution in Hepatitis C testing and diagnostic recommendations

Торіс	Recommendation in 2017 testing recommendation	GUIDELINES On Hepatitis B and C te: Hornay 2007
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. 	2021 How
How to test?	 A single serological assay (EIA or RDT) that meets minimum performance standards with prompt NAT testing + linkage to care 	• 20 gu
Confirmation of HCV viraemia	 Lab-based Nucleic acid testing (NAT) (quantitative or qualitative RNA) or core HCV antigen assay, with comparable clinical sensitivity 	Use (→ • Fc • Fc
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 	Linka ● Dr se ma ● Re



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



WHO recommendation on HCV self-testing (2021) Hepatitis C virus (HCV) self-testing should be offered

as an additional approach to HCV testing services

(strong recommendation, moderate-certainty evidence)

Remarks

- Communities, including networks of key and vulnerable populations and peer-led organizations, need to be meaningfully and effectively engaged in developing, adapting, implementing and monitoring HCV self-testing programmes
- HCV self-testing needs to be followed by linkage to appropriate posttest services, including confirmation of viraemic infection, treatment, care and referral services, according to national standards.
- It is desirable to adapt HCV self-testing service delivery and support options to the national and local context, which includes community preferences.



Product pipeline

- No SRA approved product yet
- Promising prototypes for oral and blood based HCVST
- □ TSS published in Q1 2021
- Assessment phase of Global Fund ERPD Round 18 underway outcome Oct/Nov
- No PQ submission yet
- Pilot projects
- Georgia, Pakistan and Malaysia –
 FIND piloting distribution models

Recommendations and guidance on hepatitis C virus self-testing [Internet]. Geneva: World Health Organization; 2021 Jul. Web Annex D, Values and preferences on hepatitis C virus self-testing. Available from: https://www.ncbi.nlm.nih.gov/books/NBK572741/



New WHO recommendations on HCV diagnostics and service delivery (2022)

- Provide radical simplification of the care pathway for HCV to overcome barriers to uptake
- Based on scientific evidence from multiple studies and systematic reviews, global and community collaboration for evidence generation, implementation studies, lessons learned from successful pilots and scale-up
- Can be implemented at primary care, harm reduction sites, prisons and HIV/ART clinics as well as community-based organizations and outreach services.

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







https://apps.who.int/iris/rest/bitstreams/1437827/

WHO recommendation on HCV Service delivery (2022)-summary

Laboratory diagnostics

HCV point-of-care (POC) viral load RNA testing: *Conditional/moderate*

Reflex HCV viral load testing

an alternative approach to laboratory-based HCV RNA NAT assays to diagnose HCV viraemic infection.

assays with comparable limit of detection to laboratory-based assays can be used as an alternative approach as test of cure.

as an additional key strategy to promote linkage to care and treatment.

Additional benefits & consideration

- lower levels of health facilities near where patient is receiving care,
- Strategic choice, enhances opportunity for integration
- Placement at harm reduction sites to facilitate "one-stop-shops", reduces needs for multiple clinic visits
- Suited to urban responses and shown to be acceptable and feasible

https://apps.who.int/iris/rest/bitstreams/1437827/

WHO recommendation on HCV diagnostics(2022)-summary

Service Delivery	HCV testing and treatment		
Decentralization*	at peripheral health or community-based facilities, and ideally at the same site, to increase access to diagnosis, care and treatment.		
Integration	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		
Task-sharing	delivery by trained non-specialist doctors and nurses to expand access to diagnosis, care and treatment Requires training and ongoing mentorship, well defined roles & responsibilities, referral to tertiary sites for more complex cases and an appropriate regulatory framework		



Additional benefits & considerations:

Service adaptation for different countries and context and suited to urban responses.

Suitable for standardized algorithms, differentiated care strategy, community engagement and peer support, efficient procurement, supply management and data systems, strengthening linkage and referral systems.

Evidence review & rationale for recommendations

Use of HCV POC RNA assay

- 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.

Use of Reflex viral load testing

- 51 studies (32 used laboratorybased 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).



Decentralization, Integration & task shifting

- 142 studies from 33 countries (14%) LMICs) compared full decentralization/integration vs. partial decentralization or none, and task-sharing to nonspecialists.
- 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 nonspecialists across all populations and in all settings

https://apps.who.int/iris/rest/bitstreams/1437827/

Community values and preferences for HCV testing and treatment

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.

World Hepatitis Alliance, 2021/2022

World **Hepatitis** Alliance *a maximum of three choices was possible



Community values and preferences for HCV testing and treatment



Results – preferred treatment location* (n=175)



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 XXXX

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

- Respondent XXXX





Service delivery: Research/Evidence Generation with Partners



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New WHO Evidence:

- Full decentralization of testing and treatment increased uptake of testing, linkage and treatment, and achieved comparable SVR12
- Task-shifting of treatment to trained non-specialists achieves similar SVR12 compared to specialist care.

TAT	HCV screening and sample collection VL	VL Sample collection and completion of testing	Total Time RNA Sample to Return to patient
Arm 1	Same day	1 hr 52 min	2 hr 17 min
Arm 2	1.4 days	5.5 days	21.5 days
Arm 3	3.7 days	6.4 days	18.6 days

Next steps

- Operationalize Global strategy (linked GHSS 2022-2030) and optimize strategic shifts towards elimination
- Country adoption and implementation of simplified HCV guidelines to accelerate progress
- Technical assistance & operational support for country implementation
- Collaboration with funders, MOH, civil societies and other stakeholders to strengthen advocacy, policy programme implementation and validation of elimination



Take home points

- 1. High global HCV burden with significant regional variation
- 2. Adoption of a public health approach and proposed new strategic shifts can transform the global response to viral hepatitis elimination
- 3. New recommendations for HCV diagnosis and treatment promote radical simplification and person-centered care
- 4. Important role of collaboration- with countries, communities, civil society and other stakeholder







SEVILLA FAST-TRACK CITIES 2022



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