

# UPDATED RECOMMENDATIONS ON SIMPLIFIED SERVICE DELIVERY AND DIAGNOSTICS FOR HEPATITIS C INFECTION

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**POLICY BRIEF** 

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Updated recommendations on simplified service delivery and disagnostics for hepititis C infection: policy brief

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## **ACRONYMS AND ABBREVIATIONS**

ART	antiretroviral treatment	LoD	limit of detection
DBS	dried blood spot	NAT	nucleic acid testing
EID	early infant diagnosis	NSP	needle and syringe programme
EQA	external quality assessment	OAMT	opioid agonist maintenance therapy
GDG	Guidelines Development Group	POC	point-of-care
GRADE	Grading of Recommendations	RCT	randomized controlled trial
	Assessment, Development	RDT	rapid diagnostic test
	and Evaluation	RNA	ribonucleic acid
GRC	Guidelines Review Committee	SVR	sustained virological response
HCV	hepatitis C virus	STI	sexually transmitted infection
HIV	human immunodeficiency virus	TAT	turn-around time
IQC	internal quality control	ТВ	tuberculosis
LMIC	low- and middle-income countries	WHO	World Health Organization

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### BACKGROUND

Hepatitis C virus (HCV) infection is a major public health problem and cause of chronic liver disease that leads to approximately 400 000 deaths annually. In 2019 WHO estimated that 58 million persons were chronically infected and living with hepatitis C, with a disproportionately high burden in low- and middle-income countries (LMICs). In 2016 WHO developed the Global Health Sector Strategy on viral hepatitis 2016–2021, with the ambitious goal to eliminate viral hepatitis as a public health threat by 2030. While good progress has been made in several champion countries, there remains a major testing and treatment gap. In 2019, still only 21% of the 58 million persons with chronic HCV infection had been diagnosed, and 13% treated (1). Achieving the 2030 90% testing and 80% treatment coverage targets for HCV elimination will require a radical simplification of care pathways to overcome barriers in access to HCV testing and treatment.

Reaching the 2030 90% testing and 80% treatment coverage targets for HCV elimination will require a substantial simplification of service delivery.

### **OVERVIEW OF UPDATED HCV GUIDELINES**

The WHO 2022 HCV guidelines, Updated recommendations on treatment of children and adolescents and children with chronic HCV infection, and HCV simplified service delivery and HCV diagnostics (1) provide updated, evidence-based recommendations on priority HCV-related topics where there is key new evidence and other supporting data. It builds upon the 2018 WHO Guidelines for the care and treatment of persons diagnosed with chronic hepatitis C virus infection (2) and the 2017 WHO Guidelines on hepatitis B and C testing (3).

The three main areas of new recommendations are:

 Simplified service delivery (decentralization, integration and task sharing): Expansion of HCV testing and treatment services, ideally at the same site, through decentralization of care to lower-level facilities; integration with existing services, such as in primary care, harm reduction programmes, prisons and HIV services; and promotion of task sharing through delivery of HCV testing, care and treatment by appropriately trained non-specialist doctors and nurses.

 HCV diagnostics – use of Point-of-care (POC) HCV RNA viral load and reflex HCV RNA viral load testing: The use of pointof-care (POC) HCV ribonucleic acid (RNA) assays is now recommended as an alternative approach to laboratory-based RNA assays to diagnose viraemic infection. This is especially applicable to marginalized populations, such as persons who inject drugs, and hard-to-reach communities with limited access to health care and high rates of loss to follow-up.

Reflex HCV RNA testing in those with a positive HCV antibody test is recommended as an additional strategy to promote linkage to care and treatment. This can be achieved either through laboratory-based reflex HCV RNA testing following a positive HCV antibody test, using a specimen already held in the laboratory, or clinic-based reflex testing in a health facility through immediate specimen collection for HCV RNA testing following a positive rapid HCV antibody test. Both these approaches avoid the need for an additional clinic visit.

 Use of direct-acting antiviral (DAA) treatment of adolescents and children ages ≥3 years<sup>1</sup>: New treatment recommendations extend the 2018 "treat all" recommendation for adults with chronic HCV infection to include adolescents and children down to 3 years. They also align existing recommended DAA regimens for adults (sofosbuvir/daclatasvir (SOF/DCV), sofosbuvir/ velpatasvir (SOF/VEL) and glecaprevir/ pibrentasvir (G/P)) to use in adolescents and children. This alignment is expected to simplify procurement, promote access to treatment among children in LMICs and contribute to global efforts to eliminate the disease<sup>1</sup>.

<sup>1</sup> WHO Updated recommendations on treatment of adolescents and children with chronic HCV infection. Policy Brief. Geneva: World Health Organization; 2022

These guidelines also include updates to existing chapters without new recommendations, such as inclusion of new manufacturers' protocols on use of dried blood sport (DBS) specimens for HCV serology and RNA viral load testing, and new data to inform limit of detection (LoD) for HCV RNA viral load assays as a test of cure.

This policy brief, one of two on the updated HCV guidelines, focuses on the new recommendations on simplified service delivery for a public health approach to HCV testing, care and treatment. These recommendations include decentralization, integration and task-sharing, in addition to the use of POC HCV viral load assays and reflex viral load testing. In 2023 all updated recommendations for hepatitis B and C will be collated along with existing recommendations into a single consolidated guidelines on prevention, testing, care and treatment of hepatitis B and C, containing all relevant guidance on viral hepatitis.

guidelines. These guidelines will also be useful for laboratory managers in reference and key hospital laboratories who are responsible for development of national testing algorithms, and procurement of assays, quality control (QC) and quality assurance (QA). Finally, the guidelines will serve as a reference for health care providers who offer and implement hepatitis testing, care and treatment for persons with hepatitis C virus infection, including those working in community-based programmes.

#### **Guidelines methodology**

In accordance with the procedures established by the WHO Guidelines Review Committee (GRC), a regionally representative and multidisciplinary Guidelines Development Group (GDG) met in October 2021 to formulate the recommendations using the GRADE (Grading of Recommendations Assessment, Development and Evaluation) approach (4). Evidence to inform the recommendations included four commissioned systematic reviews and

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