



World Health
Organization

GUIDELINES



RECOMMENDATIONS AND GUIDANCE ON
**HEPATITIS C VIRUS
SELF-TESTING**

JULY 2021

HEPATITIS TESTING SERVICES

RECOMMENDATIONS AND GUIDANCE ON

HEPATITIS C VIRUS SELF-TESTING

JULY 2021

Recommendations and guidance on hepatitis C virus self-testing

ISBN 978-92-4-003112-8 (electronic version)

ISBN 978-92-4-003113-5 (print version)

© World Health Organization 2021

Some rights reserved. This work is available under the Creative Commons Attribution-NonCommercial-ShareAlike 3.0 IGO licence (CC BY-NC-SA 3.0 IGO; <https://creativecommons.org/licenses/by-nc-sa/3.0/igo>).

Under the terms of this licence, you may copy, redistribute and adapt the work for non-commercial purposes, provided the work is appropriately cited, as indicated below. In any use of this work, there should be no suggestion that WHO endorses any specific organization, products or services. The use of the WHO logo is not permitted. If you adapt the work, then you must license your work under the same or equivalent Creative Commons licence. If you create a translation of this work, you should add the following disclaimer along with the suggested citation: "This translation was not created by the World Health Organization (WHO). WHO is not responsible for the content or accuracy of this translation. The original English edition shall be the binding and authentic edition".

Any mediation relating to disputes arising under the licence shall be conducted in accordance with the mediation rules of the World Intellectual Property Organization.

Suggested citation. Recommendations and guidance on hepatitis C virus self-testing. Geneva: World Health Organization; 2021. Licence: CC BY-NC-SA 3.0 IGO.

Cataloguing-in-Publication (CIP) data. CIP data are available at <http://apps.who.int/iris>.

Sales, rights and licensing. To purchase WHO publications, see <http://apps.who.int/bookorders>. To submit requests for commercial use and queries on rights and licensing, see <http://www.who.int/about/licensing>.

Third-party materials. If you wish to reuse material from this work that is attributed to a third party, such as tables, figures or images, it is your responsibility to determine whether permission is needed for that reuse and to obtain permission from the copyright holder. The risk of claims resulting from infringement of any third-party-owned component in the work rests solely with the user.

General disclaimers. The designations employed and the presentation of the material in this publication do not imply the expression of any opinion whatsoever on the part of WHO concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted and dashed lines on maps represent approximate border lines for which there may not yet be full agreement.

The mention of specific companies or of certain manufacturers' products does not imply that they are endorsed or recommended by WHO in preference to others of a similar nature that are not mentioned. Errors and omissions excepted, the names of proprietary products are distinguished by initial capital letters.

All reasonable precautions have been taken by WHO to verify the information contained in this publication. However, the published material is being distributed without warranty of any kind, either expressed or implied. The responsibility for the interpretation and use of the material lies with the reader. In no event shall WHO be liable for damages arising from its use.

Design and layout: 400 Communications Ltd.

CONTENTS

Acknowledgements	iv
Abbreviations and acronyms	vii
Glossary	viii
Executive summary	ix
1. INTRODUCTION	1
1.1 Background and rationale	1
1.2 Objectives	2
1.3 Intended audience	2
1.4 Guiding principles	3
2. METHODS FOR GUIDELINES DEVELOPMENT	4
3. REVIEW OF THE EVIDENCE AND RECOMMENDATION	5
3.1 Systematic review of effectiveness: benefits and harms	5
3.2 Values and preferences	6
3.3 Feasibility	7
3.4 Cost and cost-effectiveness	8
3.5 Equity and human rights	8
3.6 Recommendation	9
4. IMPLEMENTATION CONSIDERATIONS	10
4.1 Considerations for successful implementation and strategic planning	10
4.2 Policy and regulatory frameworks	12
4.3 Service delivery approaches for HCVST	12
4.4 Support options for HCVST	14
4.5 Linkage to service following HCVST	14
4.6 Monitoring and reporting	15
5. PRIORITY RESEARCH GAPS	16
References	17
List of Web Annexes	20

ACKNOWLEDGEMENTS

The World Health Organization (WHO) gratefully acknowledges the contributions of many individuals and organizations to the development of these guidelines.

GRADE methodologist

Nandi Siegfried (independent clinical epidemiologist, South Africa).

Guideline Development Group

Co-chairs: **Karin Hatzold** (Population Services International, South Africa) and **Saeed Sadiq Hamid** (Aga Khan University, Pakistan)

Tanya Applegate (Kirby Institute, Australia), **Nadia Badran** (Soins Infirmiers et Développement Communautaire, Lebanon), **Ajeet Singh Bhadoria** (All India Institute of Medical Sciences, India), **Meghan DiCarlo** (FHI 360 EpiC, United States of America (USA)), **Mauro Guarinieri** (International Network of People Who Use Drugs (INPUD), Switzerland), **Irsan Hasan** (Ministry of Health, Indonesia), **Cary James** (World Hepatitis Alliance, United Kingdom of Great Britain and Northern Ireland (United Kingdom)), **Anushiya Karunanithy** (Malaysian AIDS Council, Malaysia), **Giten Khwairakpam** (TREAT Asia/amfAR, Thailand), **Karine Lacombe** (Sorbonne Université, St Antoine Hospital, France), **Segundo R Leon** (San Juan Bautista Private University of Peru, Peru), **José Boulosa Alonso Neto** (Ministry of Health, Brazil), **Midnight Poonkasetwattana** (Asia-Pacific Coalition on Male Sexual Health (APCOM), Thailand), **Christian Ramers** (Clinton Health Access Initiative (CHAI), USA), **Janvier Serumondo** (Rwanda Biomedical Centre, Rwanda) and **Ernst Wisse** (Médecins du Monde, France).

Observers

Lee Abdelfadil (Global Fund to Fight AIDS, Tuberculosis and Malaria, Switzerland), **Paige Armstrong** (United States Centers for Disease Control and Prevention (CDC), USA), **Nathan Furukawa** (CDC, USA), **Heather Ingold** (Unitaid, Switzerland), **Elena Ivanova Reipold** (Foundation for New Innovative Diagnostics (FIND), Switzerland), **Sonjelle Shilton** (FIND, Switzerland), **Indri Sukmaputri** (Ministry of Health, Indonesia), **Karin Timmermans** (Unitaid, Switzerland), **Josephine Walker** (University of Bristol, United Kingdom) and **Vincent Wong** (United States Agency for International Development (USAID), USA).

External Review Group

Paige Armstrong (CDC, USA), **Taryn Barker** (Children's Investment Fund Foundation, United Kingdom), **Elkin Bermudez** (independent consultant, Netherlands), **Yap Boum** (Epicentre, Cameroon), **Colleen Daniels** (Harm Reduction International, United Kingdom), **Maka Gogia** (Georgian Harm Reduction Network, Georgia), **Kimberly Green** (PATH, USA), **Radzi Hassan** (Ministry of Health, Malaysia), **Asha Hedge** (PATH, India), **Elena Ivanova Reipold** (FIND, Switzerland), **Moses Kumwenda** (London School of Hygiene and Tropical Medicine, United Kingdom), **Jeffery Lazarus** (Barcelona Institute for Global Health (ISGlobal), Spain), **Mohammed Majam** (Ezintsha, South Africa), **Guillermo Martínez Pérez** (University of Zaragoza, Spain), **Francesco Negro** (European Association for the Study of the Liver (EASL), Switzerland), **Danil Nikitin** (INPUD, Kyrgyzstan), **Jean Njab** (independent consultant, Nigeria), **Chase Perfect** (Coalition Plus, France), **Danvic Rosadiño** (Love Yourself, Philippines), **Sanjay Sarin** (FIND, India), **Sonjelle Shilton** (FIND, Switzerland), **Mark Sonderup** (University of Cape Town, South Africa), **Christian Stillson** (CHAI, Malawi), **Ketevan Stvilia** (National Center for Disease Control and Public Health, Georgia), **Geoffery Taasi** (Ministry of Health, Uganda), **Katayoun Tayeri** (Ministry of Health, Islamic Republic of Iran), **Thiago Torres** (Fiocruz, Brazil), **Joseph Tucker** (University of North Carolina at Chapel Hill, USA), **Peris Urasa** (Ministry of Health, United Republic of Tanzania), **John Ward** (Coalition for Global Hepatitis Elimination, USA), **Carolyn Wester** (CDC, USA), **Vincent Wong** (USAID, USA).

External contributors to the development of the guidelines

Margaret Crampton (Frank H. Netter MD School of Medicine at Quinnipiac University, USA), **Ingrid Eshun-Wilson** (Washington University, St. Louis, USA), **Virginia Fonner** (Medical University of South Carolina, USA), **Ashley Germann** (Johns Hopkins University, USA), **Hunied Kautsar** (Johns Hopkins Bloomberg School of Public Health, USA), **Kathleen McGee** (London School of Hygiene and Tropical Medicine, United Kingdom), **Elena Ivanova Reipold** (FIND, Switzerland), **Sonjelle Shilton** (FIND, Switzerland), **Josephine Walker** and **Peter Vickerman** (University of Bristol, United Kingdom).

WHO staff and consultants

Overall coordination

Muhammad Shahid Jamil, **Niklas Luhmann**, **Cheryl Johnson**, **Philippa Easterbrook**, **Olufunmilayo Lesi** and **Rachel Baggaley** (Department of Global HIV, Hepatitis and Sexually Transmitted Infection Programmes) coordinated the overall development process under the leadership of **Meg Doherty** (Director, Department of Global HIV, Hepatitis and Sexually Transmitted Infection Programmes).

WHO Steering Committee

Department of Global HIV, Hepatitis and Sexually Transmitted Infection Programmes: **Rachel Baggaley, Magdalena Barr-DiChiara, Philippa Easterbrook, Emmanuel Fajardo, Muhammad Shahid Jamil, Cheryl Johnson, Olufunmilayo Lesi, Niklas Luhmann, Virginia Macdonald and Lara Vojnov.**

Other WHO headquarters staff: **Deirde Healy, Anita Sands and Ute Ströher** (WHO Department of Regulation and Prequalification).

WHO regional and country offices: **Po-lin Chan** (WHO Regional Office for the Western Pacific), **Zhongdan Chen** (WHO China), **Alaa Hashish** (WHO Egypt), **Nino Mamulashvili** (WHO Georgia), **Casimir Manzengo Mingiedi** (WHO Regional Office for Africa), **Antons Mozalevskis** (WHO Regional Office for Europe), **Van Thi Thuy Nguyen** (WHO Viet Nam), **Muhammad Safdar Pasha** (WHO Pakistan), **Bharat Rewari** (WHO Regional Office for South-East Asia), **Ahmed Sabry** (WHO Regional Office for the Eastern Mediterranean), **Jules Mugabo Semahore** (WHO Rwanda) and **Leandro Sereno** (WHO Brazil).

Belen Dinku and **Laurent Poulain** provided administrative support. **Yann Siegenthaler** provided communication support.

Mary Henderson and **Jura Editorial Services** edited the publication.

Funding

Unitaid provided funding to support this work, including the systematic reviews of evidence and evidence compilation and the development, editing and both print and electronic publication of these guidelines.



ABBREVIATIONS AND ACRONYMS

CDC	United States Centers for Disease Control and Prevention
FIND	Foundation for New Innovative Diagnostics
GDG	Guideline Development Group
HCV	hepatitis C virus
HCV cAG	HCV core antigen
HCVST	hepatitis C virus self-testing
HIV	human immunodeficiency virus
HIVST	HIV self-testing
IVD	in-vitro diagnostic
PICO	population, intervention, comparison, outcome
RCT	randomized controlled trial
RDT	rapid diagnostic test
RNA	ribonucleic acid
STI	sexually transmitted infection
UHC	universal health coverage
USAID	United States Agency for International Development
WHO	World Health Organization

预览已结束，完整报告链接和二维码如下：

https://www.yunbaogao.cn/report/index/report?reportId=5_23713

