



CONTROLLED TEMPERATURE CHAIN:
Strategic Roadmap for
Priority Vaccines
2017-2020

© World Health Organization 2017

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. Controlled Temperature Chain Working Group. Controlled temperature chain: strategic roadmap for priority vaccines 2017-2020. Geneva: World Health Organization; 2017(WHO/IVB/17.20). 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.

This publication contains the collective views of the Controlled Temperature Chain Working Group and does not necessarily represent the decisions or the policies of WHO.

Design and layout by Patrick McKern, PATH

Printed in Switzerland

CONTENTS

I. ACKNOWLEDGEMENTS	v
II. ACRONYMS.....	vi
III. INTRODUCTION.....	1
IV. BACKGROUND ON CTC: PROGRAMME RATIONALE AND PROGRESS TO DATE	2
A. The role of CTC in addressing immunization programme needs	3
B. Progress to date.....	4
1. Availability of CTC guidance for manufacturers.....	4
2. Availability of CTC-labelled vaccines.....	4
3. Recent CTC and out-of-the-cold-chain introductions and assessments.....	5
4. CTC guidance and tools for national immunization programmes	5
5. Current barriers and issues.....	5
6. Strategic prioritization by the CTC-WG.....	6
V. PRIORITY VACCINES FOR CTC.....	6
A. Human papillomavirus vaccine.....	7
1. Supply.....	7
2. Programmatic use	7
3. Planned achievements by 2020	8
4. Proposed activities: HPV vaccine	9
B. Oral cholera vaccine	12
1. Supply.....	12
2. Programmatic use	12
3. Planned achievements by 2020	12
4. Proposed activities: OCV	13
C. Tetanus toxoid containing vaccine	15
1. Supply.....	15
2. Programmatic use	15
3. Planned achievements by 2020	15
4. Proposed activities: TT	16
D. Hepatitis B vaccine birth dose	18
1. Supply.....	18
2. Programmatic use	18

3. Planned achievements by 2020	19
4. Proposed activities: HepB-BD	20
VI. OTHER PROPOSED ACTIVITIES	22
REFERENCES	23
ANNEX 1: Background information on initial priority vaccines for CTC licensure and use.....	26
ANNEX 2: Proposed roles and responsibilities of key CTC stakeholders	28

I. ACKNOWLEDGEMENTS

The roadmap was developed by the Controlled Temperature Chain Working Group (CTC-WG), which includes various experts in affiliation with their institutions, as well as independents experts: Craig Burgess (John Snow Inc., JSI), Jon Colton (Independent), Gisele Corrêa Miranda (Developing Countries Vaccine Manufacturers Network), Tanja Ducombe (Médecins Sans Frontières, MSF), Michael Free (Independent), Stephen Jarrett (Gracious Group), Drew Meek (WHO), Marion Menozzi-Arnaud (Gavi, the Vaccine Alliance), Julien Potet (MSF), Chris Morgan (Burnet Institute), Lyn Morgan (International Federation of Pharmaceutical Manufacturers and Associations), Ann Ottosen (United Nations Children's Fund, UNICEF) and Adelaide Shearley (JSI Country project).

The development of the CTC Strategic Roadmap was led by the CTC-WG Secretariat: Rachel Bauquerez (WHO), Anna-Lea Kahn (WHO), Dörte Petit (WHO) and Debra Kristensen (PATH). Overall guidance was provided by Nora Dellepiane, Chair of the Working Group.

The roadmap was reviewed and endorsed by the members of the Immunization Practices Advisory Committee.

The CTC Strategic Roadmap was edited by Joe Little and Debra Kristensen from PATH. The CTC-WG thanks them for their valuable contributions.

The development of the CTC Strategic Roadmap was made possible thanks to a financial contribution from the Bill & Melinda Gates Foundation. The views expressed herein are solely those of the authors and do not necessarily reflect the views of the Foundation. The CTC-WG acknowledges its support.

II. ACRONYMS

CDC	US Centers for Disease Control and Prevention
CPAD	compact prefilled autodisable device
CTC	Controlled Temperature Chain
CTC-WG	Controlled Temperature Chain Working Group
DT	diphtheria tetanus vaccine
ECTC	extended controlled temperature conditions
EPI	Expanded Programme on Immunization
GVAP	Global Vaccine Action Plan
HBsAG	hepatitis B surface antigen
Hep B	hepatitis B
HepB-BD	hepatitis B vaccine birth dose
HPV	human papillomavirus
IPAC	Immunization Practices Advisory Committee
JSI	John Snow Inc.
MNT	maternal neonatal tetanus
MSF	Médecins Sans Frontières
OCC	out of the cold chain
OCV	oral cholera vaccine
Q	Quarter
Td	tetanus diphtheria (low dose) vaccine
Tdap	tetanus–diphtheria–acellular pertussis
TSE	total system effectiveness
TT	tetanus toxoid
TT-CV	tetanus toxoid – containing vaccines
UNICEF	United Nations Children's Fund
WHO	World Health Organization

III. INTRODUCTION

The “Controlled Temperature Chain” (CTC) is an innovative approach to vaccine management that allows vaccines to be kept at temperatures outside of the traditional cold chain of +2°C to +8°C for a limited period of time under monitored and controlled conditions, as appropriate to the stability of the antigen. A CTC typically involves a single excursion of the vaccine into ambient temperatures not exceeding +40°C and for a duration of a specific number of days, just prior to administration.

This strategic roadmap takes stock of progress to date and identifies the path forward (2017 to 2020) for the CTC. It reflects the consensus reached by the Controlled Temperature Chain Working Group (CTC-WG), which reports to the World Health Organization’s (WHO’s) Immunization Practices Advisory Committee (IPAC). The mission of the CTC-WG is to convene key stakeholders to (i) define a shared vision and strategy for CTC; and (ii) to advocate for this innovative vaccine delivery and supply chain strategy, where appropriate, with vaccine manufacturers as well as with potential implementing countries. The overall objective of the global CTC agenda remains the facilitation of vaccine delivery to achieve immunization coverage and equity targets for CTC-qualified vaccines, as per the Global Vaccine Action Plan (GVAP) for 2011 to 2020.^{1,i} The CTC approach, in its licensed standards,² is believed to be an effective means of improving access to vaccination, especially in middle- and low-income countries with limited resources and poor infrastructures, by rendering the delivery of vaccines more efficient and with broader reach.

This document defines the necessary activities required to meet the objectives for CTC over the next four years, which consist mainly of:

- Improving stakeholder involvement, advocacy and alignment on CTC work streams;
- Increasing the base of evidence in support of CTC and characterising the value proposition of CTC with respect to improving immunization coverage and equity;
- Developing operational guidance and communication tools in support of CTC practices; and
- Supporting efforts towards the licensure and prequalification of appropriate vaccines for CTC.

This roadmap focuses primarily on four vaccine types selected by the CTC-WG and endorsed by IPAC in February 2017: vaccines against human papillomavirus (HPV), oral cholera vaccine (OCV), tetanus toxoid vaccine (including TT [tetanus toxoid] vaccine, Td [tetanus diphtheria low dose] vaccine, or other TT-CVs [tetanus-toxoid-containing vaccines]) and hepatitis B vaccine birth dose (HepB-BD). These four vaccine types are the leading priorities of the CTC programme of work between 2017 and 2020.

This document provides background information about each of the priority vaccines and the current status of CTC efforts, along with the required steps over the next four years (2017 to 2020) to effectively advance the CTC agenda. The roadmap addresses supply and programmatic issues, aiming for priority vaccines to become licensed for CTC use and facilitating uptake of the CTC vaccine delivery approach. The four-year time frame purposefully aligns with the GVAP. The roadmap also includes efforts to identify

ⁱ The number of vaccines that have either been relicensed or licensed for use in a CTC is one of the indicators of Strategic Objective 6 of the Global Vaccine Action Plan: Strategic Objective 6: Country, regional and global research and development innovations maximize the benefits of immunization; Indicator SO6.4: Number of vaccines that have either been relicensed or licensed for use in a CTC at temperatures greater than the traditional +2°C to +8°C range.

future vaccine candidates for CTC use and encourages a proactive approach to CTC licensure during product development.

Note that execution of the proposed activities will be contingent on effectively securing the necessary funding support.

IV. BACKGROUND ON CTC: PROGRAMME RATIONALE AND PROGRESS TO DATE

CTC has been on the global immunization agenda for many years.¹ Since 2007, WHO and PATH, with support from the Bill & Melinda Gates Foundation, have explored the possibilities of storing and transporting certain heat-stable vaccines in a CTC. Upstream, supply-level investments and initiatives gained momentum with the licensure of the first CTC-compatible vaccine, MenAfriVac® (meningitis A vaccine), which was followed by intensive downstream, programme-level work with countries to ensure successful implementation of this new approach.

Experience so far shows that CTC use of vaccines relieves health workers of many of the burdens associated with ensuring an adequate cold chain to the point of vaccination, thereby freeing health personnel time and resources, improving efficiencies and potentially enabling increased immunization coverage and equity for CTC-labelled vaccines.³ Vaccinators in the field welcome this new option for vaccine management as it greatly facilitates their work by saving them from burdensome journeys to renew ice stocks and from carrying heavy vaccine carriers. Finally, staff time that would be required to condition ice packs during campaigns is saved and can be redirected back to maintaining routine immunization services, which often are compromised during campaigns. Today, regulatory and WHO prequalification pathways exist to label vaccines for CTC use.^{4,5} Two vaccines currently bear such labels; three additional vaccine products should have CTC labels soon; and work towards CTC criteria for six other vaccines is under way. As of May 2017, close to 4 million individuals worldwide have received MenAfriVac® delivered in a CTC in six countries. WHO produced guidance materials for the planning and implementation of CTC in these countries.

This is a pivotal time for advancing CTC use of vaccines. The CTC experience to date has demonstrated that the approach entails a complex agenda of activities at multiple levels; this agenda has progressed well so far but still requires an extensive amount of work and investment. Manufacturers have confirmed their interest and commitment to qualifying vaccines for CTC use. It remains key that this is matched by an equal level of engagement and action by WHO and partners. HPV vaccine was prequalified in mid-2016 and oral cholera vaccine (OCV) is currently under review for CTC prequalification. Some manufacturers of HenB-BD and TT vaccines are preparing to seek CTC licensure. This will require focused

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_25709

