Protecting all against tetanus

Guide to sustaining maternal and neonatal tetanus elimination (MNTE) and broadening tetanus protection for all populations

World Health Organization

Protecting all against tetanus

Guide to sustaining maternal and neonatal tetanus elimination (MNTE) and broadening tetanus protection for all populations

World Health Organization

Protecting all against tetanus: guide to sustaining maternal and neonatal tetanus elimination (MNTE) and broadening tetanus protection for all populations

ISBN 978-92-4-151561-0

© World Health Organization 2019

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. Protecting all against tetanus: guide to sustaining maternal and neonatal tetanus elimination (MNTE) and broadening tetanus protection for all populations. Geneva: World Health Organization; 2019. 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.

Printed in Switzerland

Contents

Acknowledgments v

Abbreviations and acronyms vi

About this guide vii

Chapter 1:
Introduction 1

Why is there a global goal for maternal and neonatal tetanus elimination (MNTE)? 3

How can protection against tetanus and MNTE be sustained? 6

Chapter 2:
Building routine immunization for long-term protection against tetanus 9

What is the WHO recommended routine vaccination schedule for TTCV? 11

What TTCVs can be used for the childhood vaccination schedule? 12

Why use tetanus-diphtheria containing combination vaccines (DT/Td) rather than TT? 14

Are TTCVs safe? 15

What strategies can be used to achieve high coverage of the primary series of TTCV? 16

What strategies and opportunities can be used for TTCV booster doses? 19

Is it necessary to introduce all three TTCV booster doses into the immunization schedule together at the same time? 32

What is the catch-up schedule for children >1 year of age or adolescents who missed or did not complete the primary series of TTCV? 33

What activities need to be undertaken to ensure successful roll out of a routine childhood 6-dose TTCV schedule? 35

Chapter 3:
Antenatal care (ANC) contacts and tetanus vaccination status of pregnant women 39

What is the role of vaccinating pregnant women and how will this change as countries establish the 6-dose routine child/adolescent schedule? 41

What are current WHO recommendations for antenatal care (ANC) contacts? 42

How to screen and vaccinate pregnant women for protection against tetanus? 44

What records/cards do pregnant women need to keep? 47
What does "protection at birth" (PAB) mean and why is it important? 48
What is routine administrative TTCV2+ coverage monitoring? 51

Chapter 4:
Ensuring clean birth and umbilical cord care practices 53
Why are clean birth and umbilical cord care important for MNTE? 55
How can clean birth and clean cord care practices be achieved? 56
What practices ensure a clean birth and cord care? 58
What are clean birth kits (CBK) and childbirth checklists? 60

Chapter 5:
Tetanus surveillance 65
What is tetanus surveillance and why is it necessary? 67
What are the WHO recommended standards for tetanus surveillance? 69

Chapter 6:
Monitoring & Evaluation (M&E) 73
What monitoring and evaluation is required for tetanus vaccination? 75
Programmatic M&E: what monitoring tools need to be in place or revised? 75
How to periodically assess if MNTE status is sustained? 77

Annexes 87
Annex 1. What is tetanus? 88
Annex 2. Estimating target populations using UN Population Division estimates and projections 92
Annex 3. Determining the number of TTCV doses to be administered to a pregnant woman at ANC contact 94
Annex 4. How to implement the protection at birth (PAB) method in practice? 96
Annex 5. Example of national tally sheet for TTCV2+ (or Td2+) for pregnant women 100
Annex 6. Five moments for hand hygiene 101
Annex 7. WHO Recommended Surveillance Standards for Neonatal Tetanus (NT) 102
Annex 8. WHO Recommended Surveillance Standards for Non-NT 111
Annex 9. Illustrative example of job aid on screening for vaccine eligibility 120
Annex 10. Serosurveys 121
Annex 11. Methodology for a post-validation assessment of MNTE 132

Acknowledgments

This document was developed by the Expanded Programme on Immunization (EPI), Department of Immunization, Vaccines and Biologicals (IVB) of the World Health Organization (WHO) with extensive review and inputs from numerous colleagues in headquarters and regional offices, individuals and consultants, and partner organizations. Sincere thanks to all those who contributed their experience and knowledge.

This Guide's development and publication was possible thanks to support and contributions from various donors.

Abbreviations and acronyms

AEFI	Adverse event(s) following immunization
ANC	Antenatal care
CBK	Clean birth kit
CHD	Child Health Days
cMYP	Comprehensive multi-year plan
DHS	Demographic and Health Survey
HBR	Home-based records
HMIS	Health management information system
HPV	Human papillomavirus
ICC	Interagency Coordinating Committee
IEC	Information, Education and Communication
LQA-CS	Lot quality assurance – cluster sample
MCHD	Maternal and Child Health Days
M&E	Monitoring and evaluation
MICS	Multiple Indicator Cluster Survey
MNTE	Maternal and neonatal tetanus elimination
NITAG	National Immunization Technical Advisory Group
Non-NT	Non-neonatal tetanus
NT	Neonatal tetanus
PAB	Protection at birth
PCV	Pneumococcal conjugate vaccine
PIRI	Periodic intensification of routine immunization
RCA	Root cause analysis
RED/REC	Reaching Every District/Reach Every Child
SBA	Skilled birth attendant
SIA	Supplementary immunization activity
Td	Tetanus-diphtheria toxoid
Tdap	Tetanus-diphtheria-acellular pertussis
TIG	Tetanus immune globulin
TTCV	Tetanus toxoid-containing vaccine
TTCV2+	Two or more TTCV doses at the time of last pregnancy
WRA	Women of reproductive age
2YL	Second year of life

About this guide

For the first time, this document pulls together in one place all the latest information, recommendations, and strategies that are required to both sustain maternal and neonatal tetanus elimination (MNTE) and broaden protection against tetanus for **all** people. It is a technical resource that is relevant not only for countries that have already successfully achieved elimination status, but also for those still working towards MNTE.

This guide is intended for use by national immunization programme managers and staff, and immunization partners involved in providing implementation support to countries.

The specific objectives of this guide are:

- to describe the strategies and activities required to (i) sustain the elimination of maternal and neonatal tetanus, and (ii) ensure long-term protection against tetanus for all people;
- to inform the policy discussions and operational decisions related to tetanus vaccination and sustaining MNTE at the country level;
- to provide up-to-date references on global policy recommendations as well as technical and strategic issues.

This document provides guidance and options to assist countries to decide and plan the policy changes and activities that are needed to successfully sustain MNTE and ensure long-term protection against tetanus for all populations.

Chapter by chapter, this guide explains how the core programmatic components for preventing MNT [antenatal care (ANC) vaccination of pregnant women and clean births with skilled health personnel] are interconnected with the implementation of routine tetanus vaccination (for both sexes with booster doses across the life course) to ensure elimination is sustained and that all populations are protected.

CHAPTER 1

Introduction

In this introductory chapter you will learn:

- Why there is a global goal for MNTE;
- How protection against tetanus and MNTE can be sustained;
- What are the recommended strategies for achieving and sustaining MNTE.

You can use this information to:

- Improve/refresh your technical knowledge and understanding of MNTE;
- Prepare briefing notes for policy and decision makers (including NITAGs);
- Develop training curriculum for health workers.

Why is there a global goal for maternal and neonatal tetanus elimination (MNTE)?

Tetanus: quick facts

- The causative agent of tetanus is the bacterium ***Clostridium tetani***.
- Spores of ***C. tetani*** are found everywhere in the environment.
- Tetanus occurs when spores enter the human body through wounds and produce neurotoxin.
- Vaccination against tetanus is the main means of protection.

The burden of maternal and neonatal tetanus (MNT) is a health equity issue affecting those who are the most disadvantaged, poor, and without access to adequate health services. MNT has often been referred to as a "silent killer" since the victims often die without being officially recorded. A case of maternal and/or neonatal tetanus represents a triple failure of the public health system – failure of the routine immunization programme, failure of antenatal care, and failure of ensuring clean and safe birth practices.

Unlike polio and smallpox, tetanus cannot be eradicated as the spores are ubiquitous in the environment and there are animal reservoirs (tetanus spores in soil or fomites contaminated with animal and human faeces can contaminate wounds of all types). However, MNT can be eliminated through universal active immunization of children, mothers, and other women of reproductive age and improving maternity care with emphasis on hygienic birth and cord care practices, i.e. the number of cases can be reduced to an extent that it ceases to be a public health problem.

While considerable progress has been achieved, by end 2018, 14 countries in three regions[1] still have not reached MNTE status. **Figure 1** shows the dynamic of progress made by the countries since neonatal tetanus (NT) was first declared a target in 1989.

The elimination of neonatal tetanus as a public health problem is defined as having less than one NT case per 1 000 live births in every district or similar administrative unit in the country each year. Maternal tetanus is assumed to be eliminated once NT elimination has been achieved.[2]

As more and more countries are validated[3] as having achieved MNTE, attention and activities must shift towards ensuring that this accomplishment is sustained over the long term.

1 The priority countries where MNT is still a public health problem include: Afghanistan, Angola, Central African Republic, Chad, Congo DR, Guinea, Mali, Nigeria, Pakistan, Papua New Guinea, Somalia, Sudan, South Sudan and Yemen. Two countries have partially eliminated MNT: Pakistan (Punjab province) and Nigeria (south-east region).
2 The neonatal tetanus indicator acts as a proxy for maternal tetanus.
3 For overview of MNTE validation process see http://www.who.int/immunization/diseases/MNTE_initiative/en/index2.html.

Maternal and Neonatal Elimination (MNTE) Goal: key details

When in the late 1980s WHO estimated that annual global neonatal tetanus (NT) mortality rate was approximately 6.7 NT deaths per 1000 live births, the global health community committed itself to decrease incidence of NT cases.

— In 1989: the 42nd World Health Assembly called for the elimination of neonatal tetanus in 59 priority countries by 1995.
— In 1990: the World Summit for Children listed neonatal tetanus elimination as one of its goals.
— In 1991: the MNTE goal was endorsed by the 44th World Health Assembly, but due to slow implementation of the recommended strategies for NT elimination, the target date for the attainment of elimination by all countries was postponed to 2000.
— In 1999: progress towards the attainment of the global elimination goal was reviewed by UNICEF, WHO, and UNFPA, and the Initiative was re-constituted. Elimination of maternal tetanus was added to the goal with a 2005 target date, which was later shifted to 2015.
— By the end of 2015, there were still 21 countries that had not yet attained elimination.
— Progress continues: today only 14 countries remain to eliminate MNTE.

Global Vaccine Action Plan (GVAP) goal 2: Achieve MNTE by 2020

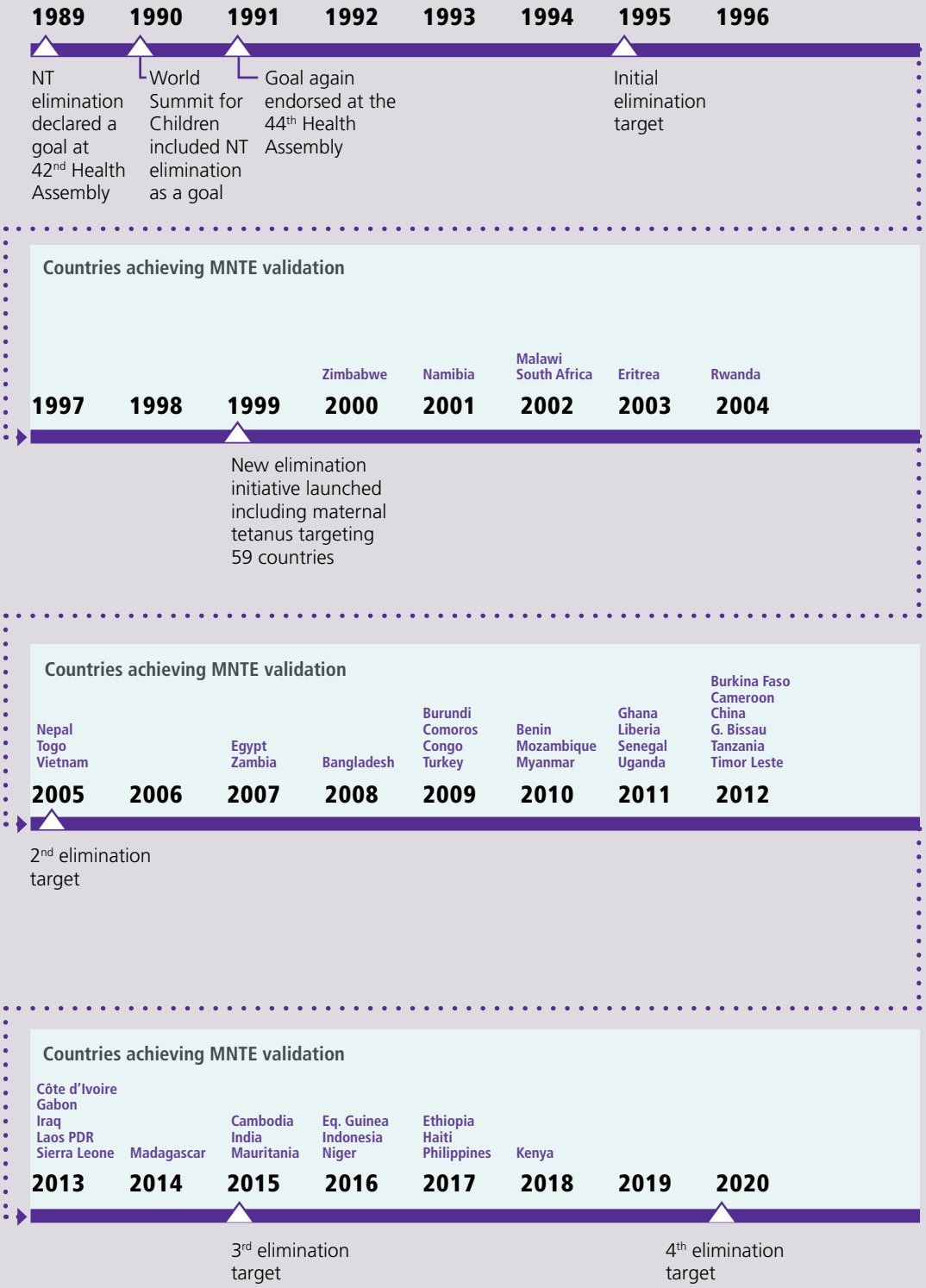
— As a result of implementing recommended strategies in the period 1988–2015, the global estimate of NT deaths declined by 96%.
— Almost all the remaining priority countries will achieve MNTE by the GVAP) target of 2020, **if** implementation challenges are addressed such as vaccinating high-risk populations due to geographical and/or security issues.
— Efforts must be made to ensure funding for activities and innovative approaches (e.g. TT Uniject) to reach vulnerable populations.

For latest update on the progress towards MNTE see GVAP Secretariat Report (2018) available online at: http://www.who.int/immunization/global_vaccine_action_plan/previous_secretariat_reports_immunization_scorecards/en/.

More information on MNTE initiative, strategies and validation of MNT elimination, and programmatic update is available at http://www.who.int/immunization/diseases/MNTE_initiative/en/. For more on tetanus disease see **Annex 1**.

Figure 1

Maternal and neonatal tetanus elimination progress since 1989: priority countries validated for elimination



How can protection against tetanus and MNTE be sustained?

The principal strategies for achieving MNTE focused on provision of tetanus toxoid (TT) immunization through routine and supplementary immunization activities (SIAs) to vaccinate women 15-49 years of age in areas with limited access to health services, strengthening of clean birth services, and effective surveillance to detect areas and populations at high risk for NT. Although these strategies have been very successful, once elimination status is achieved, the strategies used to reach it need to be adjusted to sustain elimination (see **Table 1**).

Table 1
Recommended strategies for achieving and sustaining MNTE

Achieving MNTE	Sustaining MNTE
Strengthen **antenatal care (ANC) immunization** of pregnant women with tetanus toxoid-containing vaccine (TTCV).	Strengthen **immunization of pregnant women** and **routine vaccination of all children/adolescents** (both sexes) to receive 3 primary infant doses and 3 booster doses of TTCV before adolescence.
TTCV Supplementary Immunization Activities **(SIAs)** in selected high risk areas, targeting women of reproductive age (15–49 years) with 3 properly-spaced doses of the vaccine.	**Antenatal screening** of pregnant women to verify tetanus vaccination status (to ensure tetanus protection at birth – PAB) and vaccinate if required.
Promotion of **clean birth and clean cord care** practices and health education.	Increased access to **skilled health personnel** at birth and clean birth/cord care practices.
Reliable **NT surveillance** including case investigation and response.	Strong **T/NT surveillance and regular review of data** to identify districts at risk of re-emergence of MNT and needing corrective action.

Sustaining MNTE requires a comprehensive multi-pronged approach. In the short to medium term, key activities will continue to focus on women but plans need to begin to shift towards adjusting the national immunization schedule to provide long-term protection against tetanus for all people. This means achieving high coverage for both sexes with 6 doses of tetanus toxoid-containing vaccine (TTCV[4]) – 3 primary infant doses and 3 booster doses through routine childhood and adolescent vaccination.[5] Once high homogeneous vaccination coverage (≥90%) with the 6-dose child/adolescent schedule has been realized, a large share of future cohorts of women of reproductive age (WRA) will be fully protected against tetanus throughout their

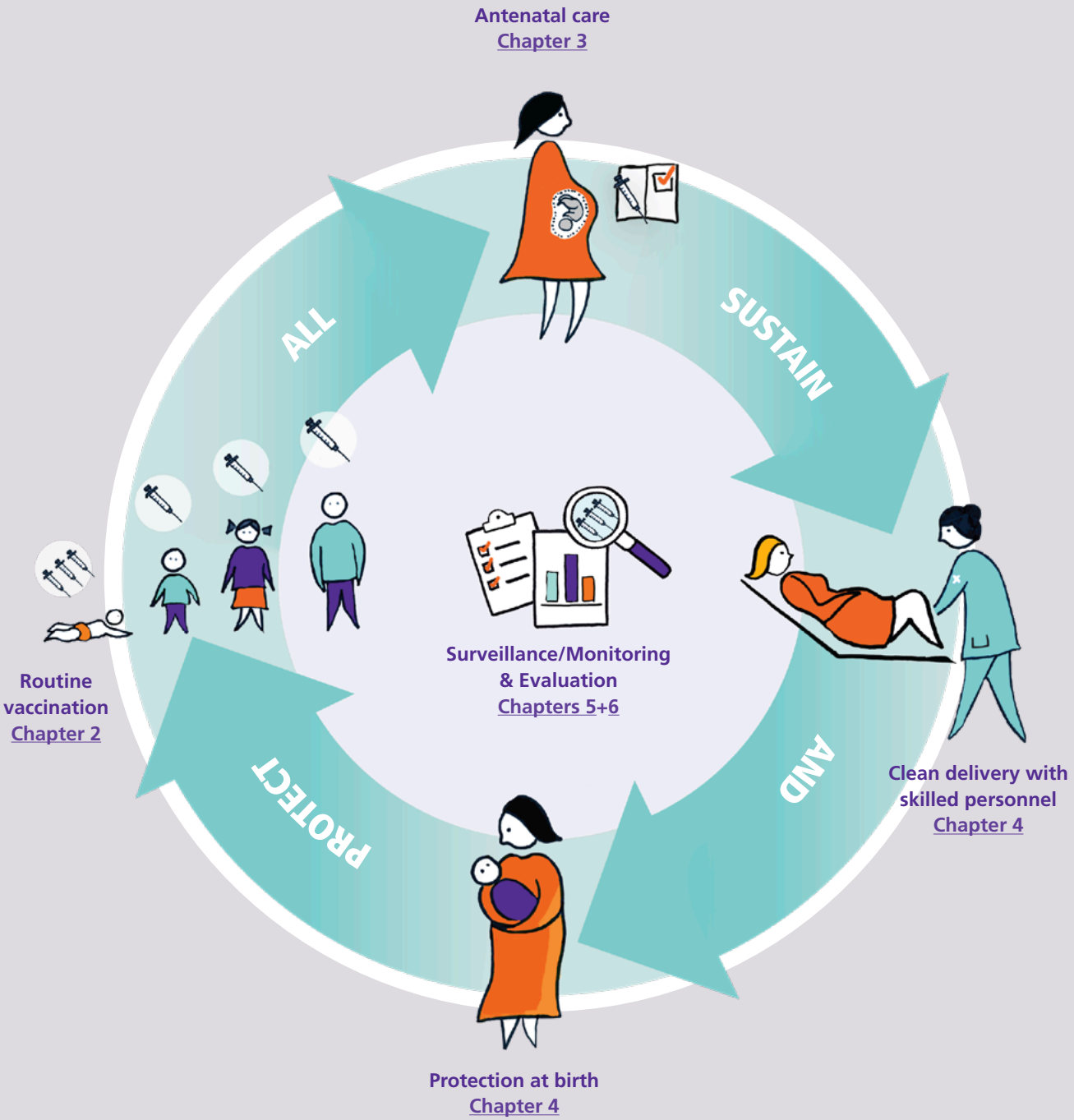
4 Since 1998 WHO has recommended that all countries replace tetanus toxoid (TT) with the combination tetanus-diphtheria (Td) vaccine, in order to sustain protection against diphtheria following waning immunity after the primary series.
5 WHO (2017). Tetanus vaccines. WHO Position Paper. Weekly Epidemiological Record. 92:53–76 (http://www.who.int/immunization/policy/position_papers/tetanus/en/, accessed 22 November 2018).

reproductive years and beyond. As a result, antenatal care (ANC) contacts will increasingly be used to screen and verify the vaccination status of pregnant women, and less as the primary means to vaccinate them with TTCV. This will also make SIAs targeting WRA unnecessary.

Plans for achieving/sustaining MNTE should be included in the country's comprehensive multiyear plan (cMYP) for immunization. The guidelines for developing/revising a cMYP are available online at: http://www.who.int/immunization/programmes_systems/financing/tools/cmyp/en/.

Figure 2 diagrammatically shows how this guide describes a comprehensive approach to sustaining MNTE and protecting all.

Figure 2
Overview of activities and strategies to sustain MNTE



CHAPTER 2

Building routine immunization for long-term protection against tetanus

(3 primary infant and 3 booster doses of TTCV)

In this chapter you will learn:

- The WHO recommended routine vaccination schedule for TTCV;
- What vaccines to use, and when and why to use DT/Td rather than TT;
- Strategies to achieve high coverage for the primary series of TTCV;
- Strategies and opportunities for TTCV booster doses;
- Interim strategy for TTCV booster dose introduction using multi-age cohort vaccination schedules;
- Catch-up schedule for children >1 year old or adolescents with incomplete or unknown TTCV primary series vaccination status;
- Activities to ensure successful roll-out of a routine childhood 6 dose TTCV schedule.

You can use this information to:

- Plan the introduction of TTCV booster doses to help achieve and/or sustain MNTE, and so that all persons are protected;
- Decide the best delivery strategies for 3 booster contacts in your country;
- Develop an introduction plan with necessary activities.

What is the WHO recommended routine vaccination schedule for TTCV?

In 2017 WHO issued updated policy recommendations for tetanus vaccination.[6] WHO recommends that all populations worldwide should be vaccinated against tetanus. In order to provide protection throughout adolescence and adulthood, national immunization programmes should provide a total of 6 doses consisting of 3 primary infant doses and 3 booster doses, preferably administered in childhood and completed by adolescence (**Box 1**).

Box 1

WHO recommendation: routine vaccination schedule for TTCV

Primary series: The primary infant series of 3 doses of TTCV is the foundation for building lifelong immunity, with the first dose administered from 6 weeks of age. Subsequent doses should be given with a minimum interval of 4 weeks between doses. If possible, the primary series should be completed by 6 months of age.

Booster doses: Three booster doses should be given at ages: 12–23 months, 4–7 years, and 9–15 years. Ideally, there should be at least 4 years between boosters.

Note: All HIV-infected children should be vaccinated against tetanus following the same schedule.

Data from serological studies suggest that a primary series of 3 TTCV doses in infancy plus a booster during the second year of life (12–23 months) will provide 3–5 years of protection. A further booster dose (e.g. in early childhood, or at school entry, 4–7 years) will provide protection into adolescence, and another booster during adolescence (9–15 years) will induce immunity that lasts through much of adulthood and which protects women through their childbearing years (**Figure 3**).

Within age limits specified above, countries can adjust or tailor their TTCV vaccination schedule based on local epidemiology, the objectives of the immunization programme, or any programmatic issues or opportunities (e.g. existing child health contacts), keeping in mind the optimal 4-year interval between boosters.

6 WHO (2017). Tetanus vaccines. WHO Position Paper. Weekly Epidemiological Record. 92:53–76 (http://www.who.int/immunization/policy/position_papers/tetanus/en/, accessed 22 November 2018). Other background documents can be found at: http://www.who.int/immunization/sage/meetings/2016/october/presentations_background_docs/en/ and http://www.who.int/immunization/policy/position_papers/tetanus/en/.

What TTCVs can be used for the childhood vaccination schedule?

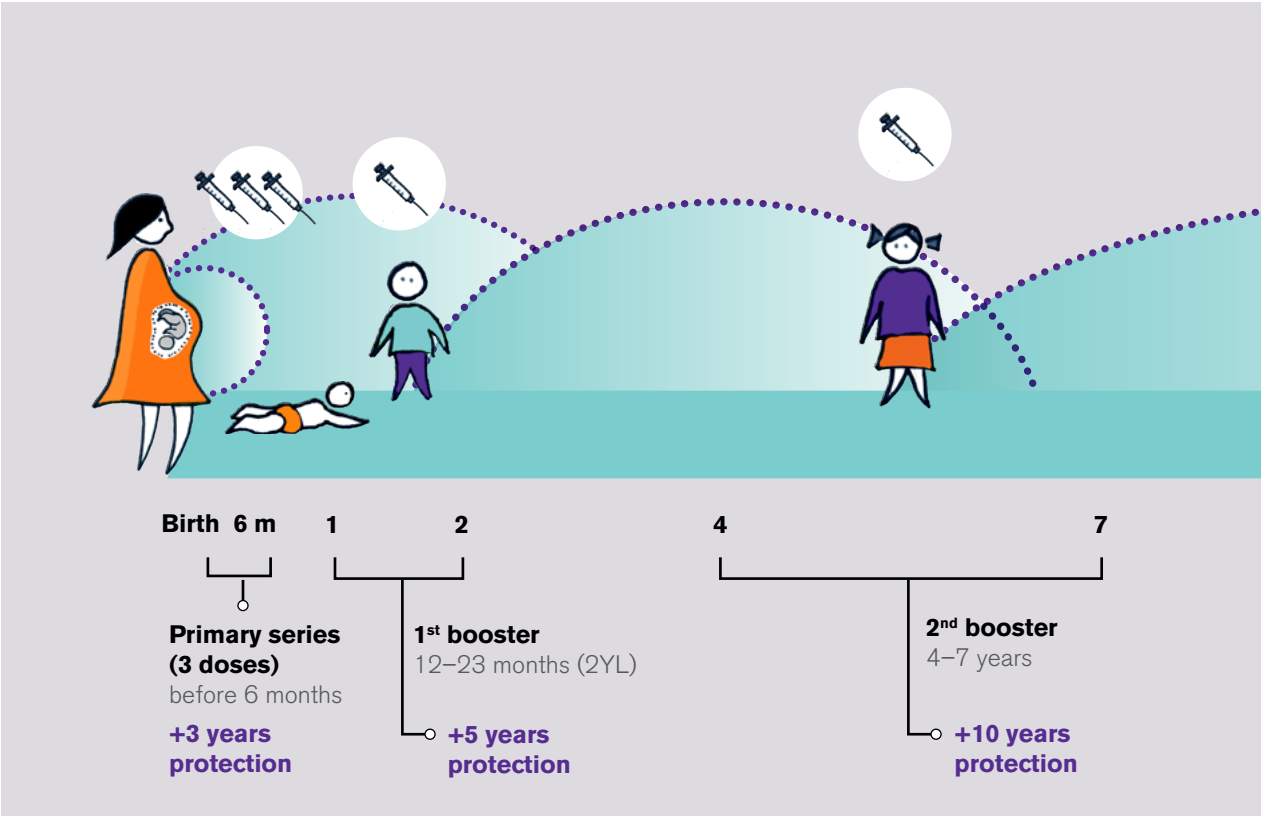
Tetanus toxoid is available in a single-antigen vaccine (TT) and in combination vaccines against other vaccine-preventable diseases such as diphtheria, pertussis, polio, hepatitis B, and *Haemophilus influenzae* type b.

Many different TTCVs are licensed worldwide. The choice of which TTCV to use and when depends on many factors such as price, supply availability, target age, programmatic simplicity, cold chain capacity, and other vaccines in the national immunization schedule.

National immunization programmes have considerable flexibility in the choice of TTCVs and given the above mentioned factors, it is expected that the same TTCV product may not be used for all six of the childhood doses. **Table 2** provides a summary of the TTCV product options that currently exist.

TTCVs can be co-administered with other childhood vaccines. All vaccines that are age-appropriate and consistent with the child's prior immunization history can be administered during the same visit. However, conjugate vaccines such as Hib (PRP–TT)

Figure 3
WHO recommended vaccination schedule and duration of protection



and MenA (PsA–TT), unless co-administered with TTCV (i.e. given at the same visit), should be administered at least one month before TTCV.

WHO recommendations for childhood vaccination for tetanus and diphtheria are the same.

It is important to note that WHO recommendation for diphtheria childhood vaccination follows the same schedule as tetanus (i.e. 3 primary infant doses of diphtheria toxoid-containing vaccine, plus 3 booster doses as 12–23 months, 4–7 years, and 9–15 years).

WHO recommendations for childhood vaccination for tetanus and pertussis are aligned.

After the primary infant series (3 doses), a booster dose of pertussis vaccine is recommended for children aged 1–6 years, preferably during the second year of life (≥ 6 months after last primary dose), unless otherwise indicated by local epidemiology. This schedule should provide protection for at least 6 years for countries using whole-cell pertussis vaccines (wP). For countries using acellular pertussis (aP) vaccine, protection may decline appreciably before 6 years of age.

See WHO vaccine position papers at http://www.who.int/immunization/documents/positionpapers/en/.

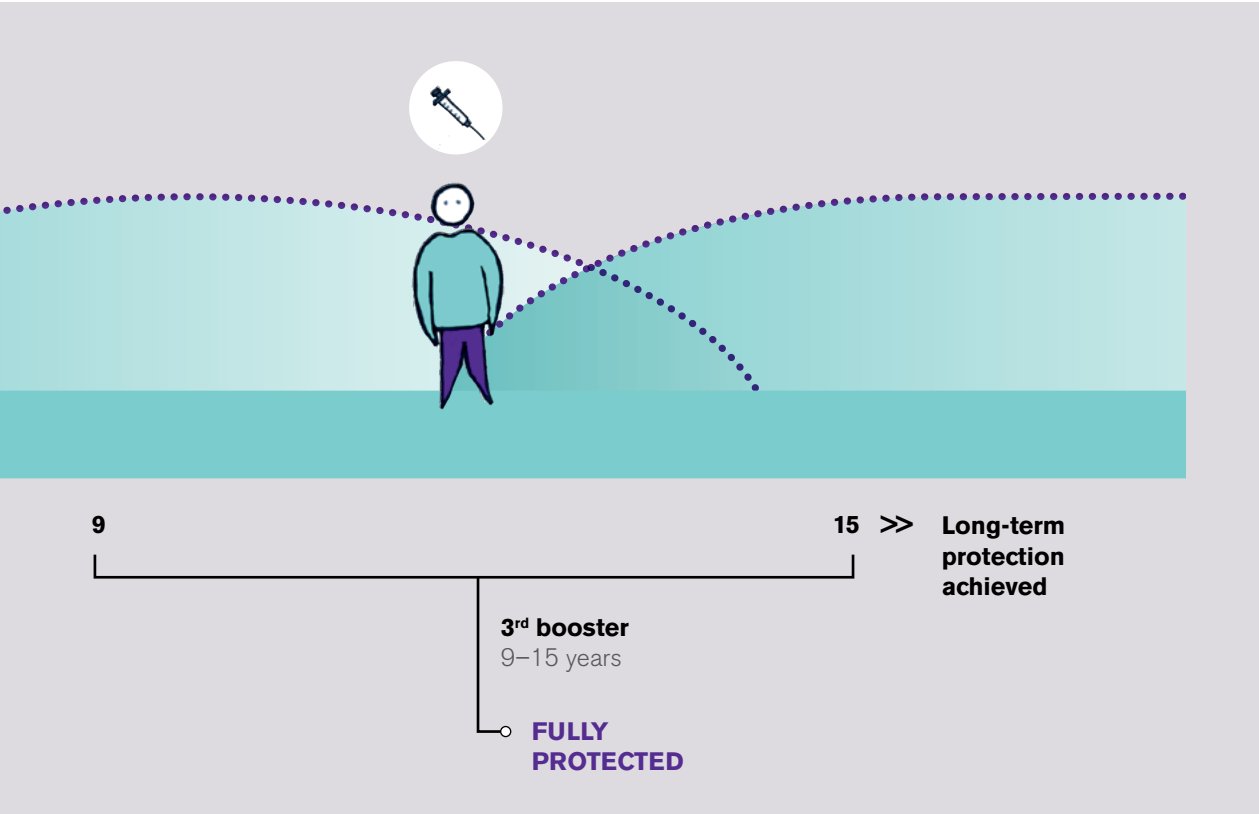


Table 2
Tetanus vaccination schedule and TTCV product options[1]

Primary series (3 doses)	2nd year of life (12–23 months) (1st booster)[2]	4–7 years (2nd booster)	9–15 years (3rd booster)
DTwP or DTaP[3] Quadrivalent (*DTwP-HepB; DTaP-HepB; DTaP-Hib*; DTwP-Hib) Pentavalent (DTwP-Hib-HepB; *DTaP-Hib-IPV; DTaP-HepB-IPV*) Hexavalent (DTaP-Hib-HepB-IPV)	DTwP or DTaP Quadrivalent (DTwP-HepB, DTwP-Hib; DTaP-HepB, DTaP-Hib) Pentavalent (DTwP-Hib-HepB; DTPaP-Hib-IPV; DTaP-HepB-IPV) Hexavalent (DTaP-Hib-HepB-IPV)	DTwP or DTaP DT or Td	Td TdaP[4]

1 WHO-prequalified vaccine options in regular font, non-prequalified vaccines in italics.
2 WHO recommends that a pertussis containing combination vaccine is preferred for the TTCV booster administered in the second year of life (2YL).
3 In most countries the use of DTP for the primary series has been replaced by quadrivalent or pentavalent vaccines.
4 Only acellular pertussis (aP) should be used for persons ≥7 years of age.

For up-to-date product information on the different TTCVs that are prequalified[7] by WHO check:
http://www.who.int/immunization_standards/vaccine_quality/PQ_vaccine_list_en/en/.

For up-to-date information on UNICEF Supply Division vaccine prices see:
https://www.unicef.org/supply/index_57476.html.

Why use tetanus-diphtheria containing combination vaccines (DT/Td) rather than TT?

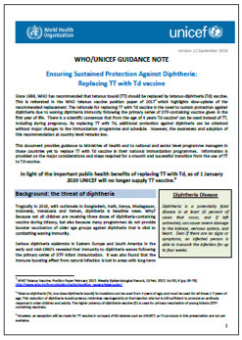
To avoid the threat of diphtheria outbreaks and to improve protection against diphtheria, since 1998 WHO has recommended that all countries replace TT with Td for vaccination of reproductive age/pregnant women, older children and

7 WHO provides a service to UNICEF and other UN agencies that purchase vaccines, to determine the acceptability, in principle, of vaccines from different sources for supply to these agencies. For an overview of the procedure see http://www.who.int/immunization_standards/vaccine_quality/pq_system/en/.

adolescents. The WHO position paper on diphtheria vaccine[8] provides the background for this recommendation.

Although simply replacing TT with Td vaccine provides dual protection with negligible programmatic shift and marginal increase in cost, globally, however, this replacement has been incomplete and somewhat slow. As of May 2018, 133 of 194 countries made the change from TT to Td, which has been proven to be safe and cost effective. Yet, there are still about 61 countries remaining to fully implement the recommendation in order to ensure longer lasting protection against diphtheria. In the light of the important public health benefits of replacing TT with Td, as of January 2020 UNICEF will no longer procure and/or supply TT vaccine.

Box 2
WHO/UNICEF Guidance on TT-Td replacement



WHO/UNICEF Guidance Note on replacing TT with Td vaccine (12 September 2018) – provides background, rationale and practical action steps to make change from TT to Td.

Available online at: http://origin.who.int/immunization/diseases/tetanus/Guide_to_TT_to_Td_Replacement_Final_12.09.2018.pdf.

Are TTCVs safe?

TTCVs have an excellent safety record. Mild local reactions (e.g. redness, swelling, pain) and systemic reactions (e.g. fever ≥38°C, irritability, malaise) are common after both primary and booster TTCV administration. In general, combination vaccines **do not** result in increased frequency and/or severity of adverse reactions compared to the individual vaccines given alone. Serious reactions, for example anaphylaxis or brachial plexus neuritis are very rare or extremely rare respectively.

For further information on TTCV vaccine safety refer to *WHO position paper on tetanus vaccine*[9] and a WHO information sheet *Observed rate of adverse reactions for diphtheria, pertussis, and tetanus vaccines* available online at: https://www.who.int/vaccine_safety/initiative/tools/DTP_vaccine_rates_information_sheet.pdf.

8 WHO (2017). Diphtheria vaccine. WHO Position Paper. Weekly Epidemiological Record. 92: 417–436 (https://apps.who.int/iris/bitstream/handle/10665/258681/WER9231.pdf, accessed 22 November 2018).
9 WHO (2017). Tetanus vaccines. WHO Position Paper. Weekly Epidemiological Record. 92:53–76 (http://www.who.int/immunization/policy/position_papers/tetanus/en/, accessed 22 November 2018).

2

What strategies can be used to achieve high coverage of the primary series of TTCV?

The first three primary doses of TTCV in the infant vaccination schedule are most commonly given at 6, 10 and 14 weeks, or 2, 3, 4 months, or 2, 4 and 6 months. These doses are the foundation for building long-term immunity to tetanus, and therefore it is essential that national immunization programmes strive to achieve the GVAP coverage goal of ≥90% (with at least 80% coverage in every administrative unit).

High vaccination coverage depends on well-functioning immunization programmes, strong health systems and acceptance/demand from the population. There exist many strategies and resources to assist countries to improve their infant vaccination coverage (see **Box 3**). Key among these is the Reaching Every District (RED) approach.

Reaching Every District (RED) approach*

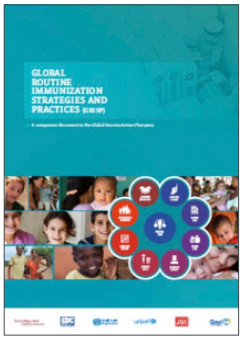
The RED approach highlights the following five operational components to increase vaccination coverage:

1. **Planning and management of resources** – for better managing of human, material and financial resources.
2. **Reaching all eligible populations** – for improving access and use of immunization and other health services by all children, adolescents and adults.
3. **Monitoring and using data for action** – for analyzing the data at all levels to direct the programme in measuring progress, identifying areas needing specific interventions and making practical revisions to plans.
4. **Supportive supervision** – for regular on-site capacity-building, feedback, and follow-up with health staff.
5. **Engaging with communities** – for partnering with communities to promote and deliver immunization services which best fit local needs.

*WHO Regional Office for Africa (2017). Reaching Every District (RED). Brazzaville: WHO Regional Office for Africa

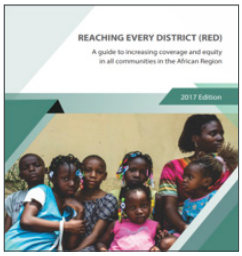
Box 3

WHO resources for increasing vaccination coverage



Global Routine Immunization Strategies and Practices (GRISP) – contains a comprehensive framework of strategies and practices for routine immunization, and nine transformative investments to achieve better immunization programme outcomes.

Available online at: https://apps.who.int/iris/bitstream/handle/10665/204500/9789241510103_eng.pdf.

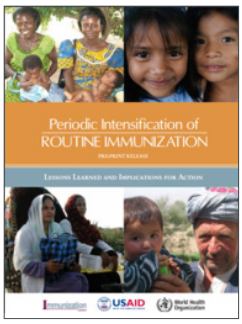


Reaching Every District (RED), 2017 Edition – a guide to increasing coverage and equity in all communities in the African Region. Its purpose is to support countries to plan and implement the five components of the RED approach.

Available online at: http://www.afro.who.int/sites/default/files/2018-02/Feb%202018_Reaching%20Every%20District%20%28RED%29%20English%20F%20web%20v3.pdf.

Reducing Missed Opportunities for Vaccination (MOV) – resource guides for reducing MOV by making better use of existing vaccination sites and existing health contacts.

Available online at: http://www.who.int/immunization/programmes_systems/policies_strategies/MOV/en/.

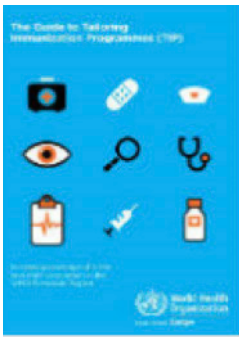


Periodic Intensification of Routine Immunization (PIRI) – a paper which summarizes a wide array of PIRI experiences, based on a desk review of available documents and grey literature.

Available online at: https://www.who.int/immunization/programmes_systems/policies_strategies/piri_020909.pdf.

Immunization in Practice (2015 revision) – a practical guide targeted at district and health facility staff, building upon the experiences of polio eradication.

Available online at:
https://apps.who.int/iris/bitstream/handle/10665/193412/9789241549097_eng.pdf.



Guide to Tailoring Immunization Programmes (2013) – provides tools to identify susceptible populations, determine barriers to vaccination and implement evidence-based interventions in order to assist national immunization programmes design targeted strategies that increase uptake of infant and childhood vaccinations.

Available online with other related publications at:
http://www.euro.who.int/en/health-topics/communicable-diseases/poliomyelitis/publications/2013/guide-to-tailoring-immunization-programmes.

Training for Mid-Level Managers (MLM) – 8 modules on the operational components of the routine immunization programme.

Available online at:
http://www.who.int/immunization/documents/mlm/en/.

What strategies and opportunities can be used for TTCV booster doses?

In addition to completing the primary series, WHO recommends that three booster doses of TTCV should be administered as follows:

(i) 1st booster: in the 2nd tear of life (12–23 months of age)
(ii) 2nd booster: between 4–7 years of age
(iii) 3rd booster: between 9–15 years of age.

In many low-income countries, national immunization programmes do not have any booster doses of vaccines in their current schedules. Therefore, experience providing vaccination to older target age groups may be limited. While there is increasing attention of the need to vaccinate throughout the life-course, extending vaccination beyond the first year of life can be a challenging step which takes special effort and planning to be successful.

In many ways, introducing a booster dose can be similar to the introduction of a new vaccine – it requires all of the same processes such as decision-making, policy revision, supply forecasting, cold chain capacity assessment, training of health staff, revision of home-based records (child vaccination cards), adaptation of recording and reporting forms/systems, advocacy, communication and social mobilization, strengthened supervision, etc. (see *What activities need to be undertaken to ensure successful roll out of a routine childhood 6-dose TTCV schedule?*, page 35).

Deciding on the best age and strategy to deliver a TTCV booster dose involves careful review of the opportunities and challenges. Each country will have its unique context and synergies with other programmes/interventions to consider. The possible platforms to build upon for each of the TTCV boosters are highlighted below.

(i) 1st TTCV booster in the second year of life (2YL platform)

Providing a TTCV booster between 12–23 months aligns with other WHO childhood vaccination recommendations such as the 2nd dose of measles-containing vaccine (MCV2), meningitis A, and alternative 2+1 schedules for PCV[10], as well as boosters of pertussis and diphtheria.[11] Additionally, countries may have a well-child visit, vitamin A supplementation, and/or deworming contacts scheduled within this age range.

Importantly, a 2YL vaccination contact also provides the opportunity to catch up children on doses of any vaccines they may have missed earlier. In this way, the coverage levels of fully immunized children by 2 years of age (FIC2) can be increased and the individual/public health benefit of greater population immunity realized.

Comprehensive guidance documents already exist for introducing a routine second dose of measles vaccine, and for 2YL vaccination (see **Box 4**). These materials contain

10 Alternative PCV 2+1 schedule: 2 doses of PCV before 6 months of age, plus booster dose at 9-15 months of age.
11 See WHO Recommendations for Routine Immunization: Summary Tables, available online at: http://www.who.int/immunization/policy/immunization_tables/en/.

detailed information which is relevant and helpful for planning and implementing a 1st TTCV booster in the 2YL.

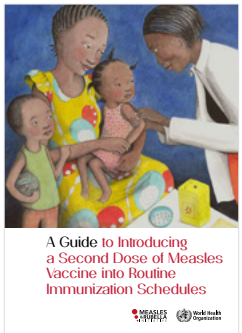
Regarding the options of the vaccine product that can be used for the 1st TTCV booster please refer to **Table 2**.

WHO recommends that both pertussis and diphtheria boosters should be given to children in the second year of life, so the use of TTCV combination vaccines that include these antigens is strongly encouraged.

For children who are 12–23 months of age, combined vaccines with diphtheria antigen should contain full strength paediatric formulation (i.e. capital "D", not small "d").

Box 4

WHO resources for planning the introduction of interventions in the routine immunization programme in the second year of life (2YL)

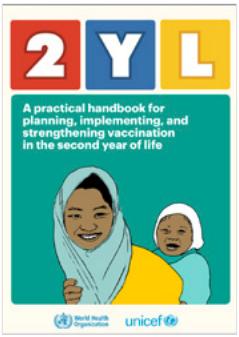


A Guide to Introducing a Second Dose of Measles into Routine Immunization Schedules (2013) – provides guidance to support policy discussions and operational aspects of the introduction of a second dose of measles vaccine into the routine immunization schedule.

Available online at: https://apps.who.int/iris/bitstream/handle/10665/85900/WHO_IVB_13.03_eng.pdf.

Establishing and strengthening immunization in the second year of life: Practices for immunization beyond infancy (2018) – provides practical guidance on how to improve vaccination coverage during a scheduled visit in the second year of life that may include other child health interventions.

Available online at: https://apps.who.int/iris/bitstream/handle/10665/260556/9789241513678-eng.pdf.



A handbook for planning, implementing, and strengthening vaccination into the second year of life (2019) – a companion resource to the WHO publication 'Establishing and strengthening immunization in the second year of life: Practices for vaccination beyond infancy'.

Available online at: https://apps.who.int/iris/bitstream/handle/10665/311642/9789241514194-eng.pdf.

(ii) 2nd TTCV Booster at 4–7 years

For many national immunization programmes, providing vaccination between 4–7 years of age can be an entirely new endeavour. The same introduction processes described above for the 1st TTCV booster dose will need to be considered.

Depending on a country's programme and capacity, reaching children 4–7 years of age may be challenging. If vaccination is to be delivered through fixed-site services (either clinic-based or outreach) then an investment in information, education, and communication (IEC) will be necessary to ensure mothers/caregivers understand the need to bring their older children back for vaccination. This IEC effort will need to be continued for many years in order to change behaviours and assure demand and ultimately high coverage.

A day-care/crèche- or school-based vaccination strategy is an option, as 4–7 years is the age when many children are in day-care or begin primary school. This may also be an opportunity to implement school entry vaccination screening at the time of enrolment, to determine if children of this age have been fully vaccinated. Children with incomplete vaccination must be referred to health services to determine eligibility and receive their missing vaccine doses. Such an approach will require strong collaboration with the Ministry of Education, policy directives, and possibly a legislative or legal framework to empower the implementation. Depending on the national context, issues of parental consent may also need to be addressed if vaccination is to take place in nurseries/day-care/crèches/primary school because children will be unaccompanied by their mothers/caregivers, unlike for infant vaccination. See **Box 6** for WHO document on consent to vaccination.

There are multiple factors to consider when deciding to implement vaccination in schools or nurseries/day-care/crèches. These are further discussed in the section on the 3rd TTCV booster dose below.

(iii) 3rd TTCV Booster at 9–15 years

Reaching children/adolescents in the 9–15 year old age group with a booster dose of TTCV is particularly important because it is this age group which is approaching their reproductive years. Girls especially need to have their tetanus immunity strengthened

by a 3rd booster dose to enable the transfer of antibodies to their newborn (protection at birth) during future pregnancies. For coverage equity, boys also need to be protected against tetanus to avoid any future risk of exposure through contamination of wounds from medical interventions, occupational risks or accidents.

Moreover, when both boys and girls are vaccinated, it can help avoid false rumours about female sterilization and contraception which have sometimes accompanied tetanus vaccination activities that targeted girls and women only.

For the 3rd TTCV booster between 9–15 years, there are two current platforms that can provide opportunities for integration. Within the immunization programme there is the provision of HPV vaccine (which targets roughly the same age group). More broadly, there is the global momentum for improving adolescent health (see **Box 5**).

WHO recommendations for HPV vaccination* and tetanus 3rd booster dose overlap

For girls 9–14 years, WHO recommends a 2-dose schedule of HPV vaccine with a 6-month interval between doses. An interval no greater than 12–15 months is suggested in order to complete the schedule promptly and before becoming sexually active. If the interval between doses is shorter than 5 months, a third dose should be given at least 6 months after the first dose.

A 3-dose schedule (0, 1–2, 6 months) should be used for all HPV vaccinations initiated ≥15 years of age. Three doses are also needed for those younger than 15 years who are known to be immunocompromised and/or HIV-infected.

Opportunities should be sought to link the introduction of HPV vaccination to other vaccinations carried out at the same age (e.g. diphtheria and tetanus vaccination) and programmes targeting young people (e.g. through school and adolescent health services).

* WHO (2017). Human papillomavirus vaccines. WHO Position Paper. Weekly Epidemiological Record. 92:241–268.

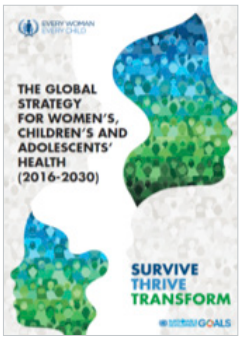
The vast experience from pilot and/or nationwide HPV vaccine introductions can help to inform the decision, design, and planning for an adolescent TTCV booster (see **Box 6**). Where HPV vaccination activities are already part of the national immunization programme, the 3rd dose of TTCV can be integrated and delivered together with HPV, although for TTCV it is necessary to vaccinate **both** boys and girls. As of October 2018, more than 85 countries have introduced HPV vaccine, and in some Td and other vaccines are co-administered during the same visit. But many countries that have introduced HPV vaccine have not yet taken advantage of the opportunity to link HPV and Td vaccination.

Box 5

Global commitment to adolescent health

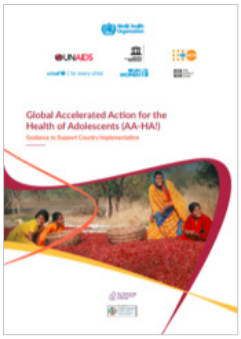
There are few interventions targeting young adolescents, and those that do exist are not adequately reaching them. This is because the number of contacts with adolescents in the health system is generally low.

For years, the unique health issues associated with adolescence have been little understood or in some cases, ignored. But this has now changed.



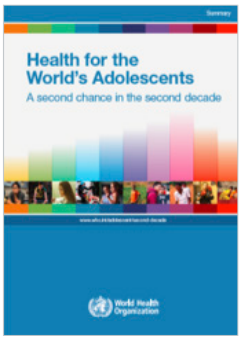
Adolescent health and development was made an integral part of the **Global Strategy for Women's, Children's and Adolescents' Health (2016-2030)** (The Global Strategy) in support of the Sustainable Development Goals (SDGs).

Available online at: http://www.who.int/life-course/partners/global-strategy/globalstrategyreport2016-2030-lowres.pdf.



The Global Accelerated Action for the Health of Adolescents (AA-HA!): Guidance to Support Country Implementation (2017) provides technical guidance to policy-makers and programme managers as they respond to the health needs of adolescents in their countries.

Available online at: https://apps.who.int/iris/bitstream/handle/10665/255415/9789241512343-eng.pdf.

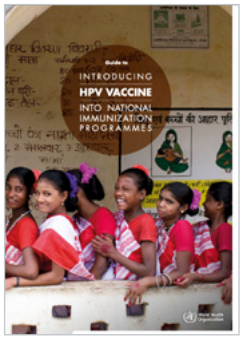


A multimedia interactive report, **Health for the World's Adolescents: A Second Chance in the Second Decade (2014)** provides global and regional overview of health–related behaviours and conditions among adolescents, pulls together WHO recommendations and guidance, and proposes key actions and approaches that would strengthen national responses to adolescent health issues.

This report is available online at: http://www.searo.who.int/indonesia/documents/health-for-world-adolescent-who-fwc-mca-14.05-eng.pdf.

Box 6

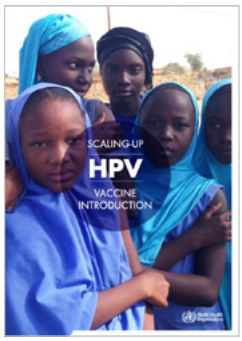
HPV vaccine introduction resources to inform planning and implementation of TTCV adolescent booster



A guide to introducing HPV vaccine into national immunization programmes (2016) – provides policy and operational aspects of HPV vaccine introduction and up-to-date references on global policy and technical and strategic issues.

Available online at: https://apps.who.int/iris/bitstream/handle/10665/253123/9789241549769-eng.pdf.

Resources on delivery strategies:

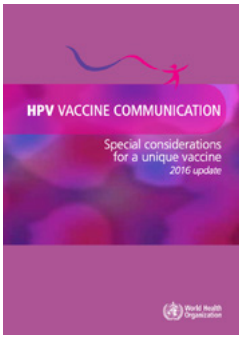


Scaling up HPV vaccine introduction (2016) – provides a summary of country-reported experiences introducing HPV vaccine in their national immunization programme.

Available online at: https://apps.who.int/iris/bitstream/handle/10665/251909/9789241511544-eng.pdf.

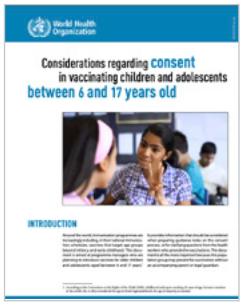
HPV Vaccine Lessons Learnt – comprehensive review of HPV vaccine delivery experiences across 46 low- and middle- income countries.

Available online at PATH Cervical Cancer Library: http://www.rho.org/HPVlessons/index.htm.



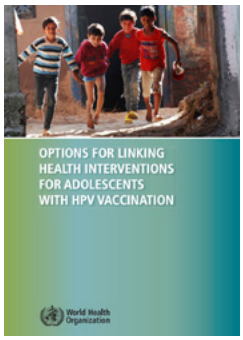
HPV Vaccine Communication: Special considerations for a unique vaccine (2016 update) – provides communication guidance for countries introducing HPV vaccine at the national or subnational levels.

Available online at: https://apps.who.int/iris/bitstream/handle/10665/250279/WHO-IVB-16.02-eng.pdf.



Considerations regarding consent in vaccinating children and adolescents between 6 and 17 years old (2014) – provides principles and practical approaches to obtaining consent for vaccinations among unaccompanied minors.

Available online at: https://apps.who.int/iris/bitstream/handle/10665/259418/WHO-IVB-14.04-eng.pdf.



Options for linking health interventions for adolescents with HPV vaccination (2014) – provides an evidence-based overview of opportunities for synergy and joint delivery of HPV vaccination with other interventions.

Available online at: http://www.who.int/immunization/diseases/hpv/AdoPlusHPV.pdf.

There are several commonly used strategies for HPV vaccination which would be adaptable for TTCV booster delivery:

- vaccine delivery at health-care facilities (may be in conjunction with schools)
- vaccine delivery through outreach (including school-based outreach)
- vaccine delivery through campaigns.

Vaccination at health facilities

Adolescent vaccination at health facilities has been shown to achieve more coverage if offered as "vaccination days" with minor incentives for those who attend (such as short waiting times, music, discussion groups, or videos in the waiting areas).

However, a fixed-site, health-care facility delivery strategy may not be effective if there are barriers for adolescents to access the health-care facility, for example, if opening hours are not convenient, or if the health facility is far away.

Schools can have an active role in a facility-based delivery strategy. For example, in some countries, schools are notified on a specific day to bring children/adolescents for vaccination to the health facility or nearest scheduled outreach session.

Vaccination through outreach

In the context of vaccine delivery, outreach refers to any strategy that requires health workers to leave their facility in order to transport and deliver vaccination services to a variety of permanent or temporary sites close to large numbers of the target population. Some examples of outreach venues are community centres, school buildings, markets or places of worship, if appropriate.

School-based (outreach) strategy

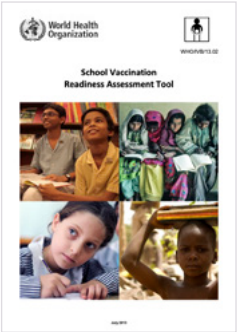
In most countries, >90% of both boys and girls attend primary school. In countries where school health programmes exist and a designated healthcare worker provides regular health services either at the school or at the health facility, the operational costs of adding TTCV vaccine delivery to an existing and already funded school health programme infrastructure may be minimal, assuming the costs for salary and transport are already provided in the health budget.

If, however, a school health programme with designated staff does not exist, a school-based delivery strategy may require the health facility staff to travel away from the health centre to reach all the schools in the catchment area. This is likely to require additional resources and can be disruptive to delivery of regular services. It may also be inefficient if school enrolment is low. In this case, special complementary efforts to reach and vaccinate out-of-school adolescents with TTCV would be needed.

The learning from measles, polio and HPV vaccination is that school-based programmes can be highly successful. If implemented in a campaign mode they may be costly, however, a school platform can deliver benefits across interventions and presents an opportunity to share costs. It should be noted that school children are exposed to a tetanus risk by participating in various school activities (e.g. sports, gardening). Therefore, TTCV should be offered to school children of both sexes. Before initiating a school-vaccination programme, countries need to be able to assess the capacity, strengths, and weaknesses of their school and health systems to support such programmes (see **Box 7**).

Box 7

WHO publication for readiness assessment of schools to support vaccination programmes



School Vaccination Readiness Assessment Tool – provides methodology specifically designed to assess country-wide readiness to implement school vaccination. It also provides information useful for assessing and subsequently improving broader school health services.

Available online at: http://www.who.int/immunization/hpv/plan/school_readiness_assessment_tool_who_2013.pdf.

Interim strategy: using schools to catch up and deliver three booster doses

A routine 6-dose TTCV childhood schedule is the preferred tetanus vaccination strategy because it offers continuous protection throughout childhood, elicits a stronger immune response, and results in early life-long protection for both boys and girls.

While countries work towards building a routine childhood 6-dose TTCV schedule, some interim strategies may be considered specifically targeting young children/ adolescents so that they are fully protected against tetanus prior to entering their reproductive years. If high coverage can be achieved, this approach can contribute significantly to sustaining MNTE, thus reducing thus the need for vaccination through ANC clinics and SIAs. As an alternative interim strategy, the complete TTCV 3-dose booster series with Td vaccine could be delivered in primary school using the multi-age cohort schedule proposed below. After 3 years of implementation, the older grades will have been caught up and boosters will need to be administered only to grades A, B and C.

School multi-age cohort Td vaccination strategy

Level of enrolment / Years since start	Year 1	Year 2	Year 3	Year 4 and beyond
Grade A	1st booster dose	1st booster dose	1st booster dose	1st booster dose
Grade B	1st booster dose	2nd booster dose	2nd booster dose	2nd booster dose
Grade C	1st booster dose	2nd booster dose	3rd booster dose	3rd booster dose
Grade D	1st booster dose	2nd booster dose	3rd booster dose	
Grade E		2nd booster dose	3rd booster dose	
Grade F			3rd booster dose	

High enrolment and attendance, plus good record keeping in order to track doses and children who change or drop-out of school are essential for success.

Vaccination through campaigns

In some instances there may be benefits or opportunities to deliver a TTCV booster through a campaign. It may be possible to include a TTCV booster as part of another planned campaign such as Child Health Days/Weeks, measles-rubella vaccination campaigns targeting up to 15 year olds, or even invite the adolescent boys to attend tetanus supplementary immunization campaign planned for reproductive age women (preferably using Td). Provided that resources are available, countries may wish to organize a catch-up campaign for the 3rd TTCV dose booster targeting all 9–15 year old children, before reverting to a routine health-facility based vaccination strategy to deliver the booster dose to all future cohorts of 9 year olds.

In countries with very small and/or hard-to-reach populations (for example, island states) the use of a campaign strategy for TTCV adolescent booster may be the most practical and cost-effective. This strategy could be repeated every 5–6 years to ensure complete coverage of the next cohort of adolescents 9–15 years.

In order to boost routine coverage in all children, WRA, and pregnant women, countries may opt for a "hybrid" approach, referred to as periodic intensification of routine immunization (PIRI). PIRI activities are time-limited, and depending on local planning and flexibility to arrange outreaches, may be organized once or twice a year. During PIRI, routine services are intensified and expanded to include not only fixed and outreach strategies but also many additional vaccination posts and possibly house-to-house services.

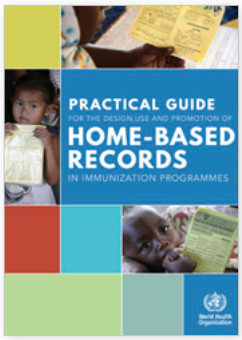
Table 3 provides a summary of considerations for different TTCV 3rd dose booster delivery strategies which are also applicable to the 2nd booster for 4–7 year olds. In practice, a balance of the pros and cons will need to be made. Countries may need to consider trade-offs between strategies that maximize coverage and those that are most feasible, affordable and sustainable. Ultimately, a combination of strategies may be required to achieve high coverage while optimizing resources.

Regardless of the strategy applied, doses should be correctly tallied and recorded in facility-based administrative records and recorded on the appropriate home-based child or adolescent record. Long term retention of records should be ensured so that the history of tetanus vaccination can be verified. WHO has produced a number of resources that provide practical experience and guidance on the design and use of home-based records (see **Box 8**).

NOTE: During the transition period, as countries move away from the high-risk SIA approach of vaccinating women of reproductive age (except in selected hard-to-reach areas with limited health services) and work towards providing 3 childhood booster doses of TTCV, it may be necessary to catch up young children/adolescents who were not able to benefit from the provision of the first two TTCV boosters (i.e. at 12–23 months and 4–7 years). This is discussed in section *Vaccination through outreach* (page 26).

Box 8

WHO resources on home-based records



Practical Guide for the Design, Use and Promotion of Home-Based Records in Immunization (2015) — In response to a recognized need for more guidance on the content and design of home-based records, WHO has developed a practical guide to provide direction to immunization programme managers and national health programmes on how to improve the use and design of home-based records, and serve as a reference with developing or revising home-based records.

Available online at: http://www.who.int/immunization/monitoring_surveillance/routine/homebasedrecords/en/.

The home-based vaccination record repository — An online repository for home-based vaccination records, including national immunization or child health cards, is maintained by UNICEF to support the free and open exchange of information related to home-based record content and design, with the aim of improving child health outcomes.

Available online at: https://www.technet-21.org/en/topics/home-base-records.

WHO recommendations on home-based records for maternal, newborn and child health (2018) — This report summarizes the final recommendation and the process for developing the guideline on home-based records for maternal, newborn and child health. The primary audience for the guideline is policy makers and health programme managers of MNCH and immunization programmes in ministries of health where decisions are made and policies created on the use and implementation of home-based records.

Available online at: www.who.int/maternal_child_adolescent/documents/home-based-records-guidelines/en/.

Table 3
Considerations for different adolescent (3rd booster dose) TTCV delivery strategies

Considerations	Delivery strategy			
	Health facility	Outreach		Campaign
		Community outreach	School-based outreach	
Access	Adolescents must come to health centre (may not be successful if the adolescents are shy; requires facilities to be "adolescent friendly") May need coordination with schools to encourage and release adolescents to go to facility Parents may be present at time of vaccination Does not require health workers to leave Working hours may need to be adapted to be made more convenient if the health facility is far away	A variety of locations is possible May need special communications effort to make sure adolescents attend (e.g. through social media) Requires health workers to leave health facility but can be part of regular health facility outreach	If enrolment is high, larger number of adolescents vaccinated at the same time Requires health workers to travel to school Parental consent process Teachers can assist with vaccination sessions	Large number of adolescents can be vaccinated at the same time Large number of vaccinators needed (may disrupt regular services) Can be used as initial "catch-up" of several age cohorts
Equity	Accommodates in- and out-of school adolescents	In- and out-of school adolescents	In-school adolescents only	In- and out-of school adolescents
Community mobilization	May need intensive mobilization for adolescents to attend, partnering with communities	Using same outreach locations as for infant vaccination may make mobilization easier	Schools can help facilitate sensitization and mobilization of parents/communities	Needs comprehensive strategy and intense community mobilization
Frequency of vaccination	Continuous, all year round	Only when outreach is planned/ occurs	Requires regular visits to all schools (frequency will depend on the number of school classes targeted for vaccination)	Annual or periodically, depending on the number of cohorts targeted
Vaccine supply	Requires continuous available supply with other routine vaccines (ensure planning and placement of orders)	Challenging to know exact number of adolescents who will attend outreach session	Enrolment lists can facilitate estimate of needed vaccine and related supplies	Large volume of vaccine needed over short duration Distribution challenges - must be able to redistribute/ resupply quickly during campaign

Considerations	Delivery strategy			
	Health facility	Outreach		Campaign
		Community outreach	School-based outreach	
Cold chain management	Cold chain available at health centre	Vaccine carriers must be prepared to maintain cold chain	Vaccine carriers must be prepared to maintain cold chain	Vaccine carriers must be prepared to maintain cold chain as the large volume of vaccine required at one time may be challenging to store in the existing cold chain.
Integration with other interventions	With HPV (and other vaccines); may help to strengthen Adolescent Friendly Health Services	With HPV; possible co-delivery with interventions of short duration	With HPV; possible co-delivery with short-duration interventions possible; synergistic opportunities Integration with school health platform may be possible	Integrate with other vaccination campaigns or age-appropriate interventions, e.g. deworming
Monitoring	Tally sheets and registers available, as well as home-based records (HBRs)	Tally sheets, registers and HBRs available and taken to the outreach Persons asked to bring their HBRs, as available	Tally sheets, registers and HBRs available and taken to the school Persons asked to bring their HBRs, as available School enrolment lists can facilitate identifying and recording vaccinated students.	Need to consider volume and how to best record doses given, in tally sheets as well as HBRs
Cost	Low, when supported by national health budget	Medium-High (depends on use of existing outreach sessions that are already planned and funded in health budget)	Medium-high (depends on school enrolment, and on use of existing outreach sessions that are already planned and funded or if additional resources are required for healthcare workers to travel to schools)	Generally high (but for small populations may be cost-effective), needs to include expenses for per-diems and transport.

Note: A combination of strategies may be needed to achieve high coverage while optimizing resources and to include out-of-school/hard-to-reach/vulnerable targeted adolescents. Strategies may also vary throughout a country, based on local/provincial/district characteristics or opportunities.

2

Is it necessary to introduce all three TTCV booster doses into the immunization schedule together at the same time?

For sustainability, and to develop early long-term protection, countries should strive towards a routine childhood vaccination schedule that provides 6-doses of TTCV by adolescence. This will provide protection throughout the reproductive years thereby sustaining MNTE, and beyond.

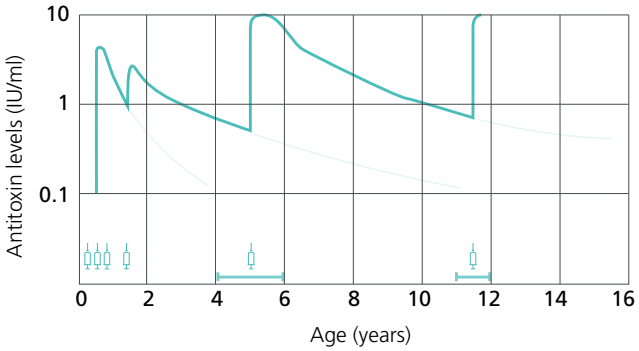
Benefit of vaccinating early

— Studies show that children develop higher antibody levels than adults.
— The immune response to TTCVs tends to decrease with age.

However, it is recognized that it may be difficult for many national immunization programmes in low-income countries to rapidly introduce all three of the TTCV booster doses at the same time, particularly if their programmes do not already have policies and activities in place to vaccinate school-age children. Countries may build their tetanus schedules incrementally, one booster at a time, also considering other new vaccine introductions (e.g. MCV2, HPV) as platforms for efficiently adding a TTCV booster.

Each and every additional booster dose of TTCV in childhood is of benefit. Although tetanus antibody levels are high after 3 primary TTCV doses in infancy, levels decline over time. A booster dose in the 2nd year of life rapidly increases antibody levels. Repeat boosting with two more doses by adolescence elicits a robust humoral immune response lasting decades (**Figure 4**).

Figure 4
Antibody response to TT and duration of immunity after 6 properly spaced doses[12]



12 Adapted from WHO (2018). The Immunological Basis for Immunization Module 3: Tetanus Update 2018. Geneva: World Health Organization. (https://apps.who.int/iris/bitstream/handle/10665/275340/9789241513616-eng.pdf, accessed 22 November 2018).

What is the catch-up schedule for children >1 year of age or adolescents who missed or did not complete the primary series of TTCV?

If tetanus vaccination is started ≥1 year of age (i.e. no primary series received) then only 5 appropriately spaced doses of TTCV are required to obtain long-term protection. The 5-dose "catch-up" schedule for children >1 year of age, adolescents and adults (including pregnant women) with no previous immunization against tetanus is the same for males and females and is as shown in **Table 4**.

Table 4

Catch-up vaccination schedule for previously unvaccinated and vaccine options according to age

Minimum interval from the most recent dose administered					
Vaccine (age-appropriate) / **No. of dose**	**1st dose**	**2nd dose**	**3rd dose**	**4th dose**	**5th dose**
1–4 years: DTwP, DTaP, or DT	As early as possible	At least 4 weeks after the 1st dose	At least 6 months after the 2nd dose	At least 1 year after the 3rd dose	At least 1 year after the 4th dose
4–7 years: DTwP, DTaP, Td, or DT					
>7 years: Td or TdaP					

The reason that older age groups need only 5 doses for catch up is because the third dose is given 6 months after the second dose, thereby eliciting a stronger antibody response. In infants (i.e. <1 year of age) the first three doses are given closer together (i.e. minimum interval of 4 weeks between doses), mainly to ensure immunity to pertussis and protect infants who are at risk for complications or death if they get pertussis at such a young age.

Generally, if the country is using a DTP-containing vaccine with a whole-cell pertussis (wP) component then children up to 7 years of age who are previously unvaccinated would benefit from receiving a catch-up vaccination with DTwP. Those who are 7 years or older can receive Td because vaccines containing wP component are not recommended for those ≥7 years.

For countries using aP combinations, these can be given to all age groups. Since the duration of protection of aP against pertussis is shorter than wP, more boosters of aP containing vaccines may be required.

In some countries of Eastern and Southern Africa, several cases of tetanus following male circumcision for the prevention of HIV infection have highlighted the tetanus immunity gap in adolescent and adult males.[13] See **Box 9** for vaccination opportunities and guidance specific for these situations.

Box 9

Voluntary male circumcision (VMMC) for HIV prevention and tetanus vaccination for adolescent boys and adult males[14]

WHO/UNAIDS recommends male circumcision as an intervention for HIV prevention in countries and regions with heterosexual epidemics, where there is high HIV burden and low male circumcision prevalence, and where there is limited contact with the health services. VMMC service delivery provides an opportunity to reach adolescent boys and adult men with relevant services, including vaccination with TTCV.

Methods for male circumcision have different risks for tetanus which should be mitigated. Several surgical methods are available including conventional and device-based circumcision.

For **conventional surgical** male circumcision, depending on the country context and the individual's vaccination record, a dose of TTCV may be added at the time of or prior to surgery. Another dose, with an interval of at least 4 weeks, could be given at the follow-up visit. The client should be referred to a health facility to receive a third dose 6 months later.

Circumcision using the **elastic collar compression (Day7) method** has the greater risk of tetanus compared to conventional surgery and should be undertaken only if the client has been adequately protected against tetanus prior to device placement.

— For those not previously vaccinated, 2 doses of TTCV should be administered at least 4 weeks apart, with the second dose at least 2 weeks before placement of the device.

— If an individual has documented evidence of 3 doses received in infancy, and 1 dose during adolescence or adulthood, a booster dose of TTCV should be given at least 2 weeks before the device placement.

Individuals should be provided with and educated to keep their vaccination record/card.

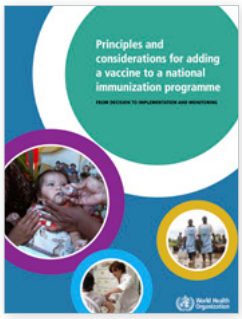
13 Dalal S, et al. (2016). Tetanus disease and deaths in men reveal need for vaccination. Bulletin of World Health Organization. 94: 613–621 (www.who.int/bulletin/volumes/94/8/15-166777.pdf, accessed 22 November 2018).

14 WHO (2018). Manual for male circumcision under local anaesthesia and HIV prevention services for adolescent boys and men. Geneva: World Health Organization (http://apps.who.int/iris/bitstream/handle/10665/272387/9789241513593-eng.pdf, accessed 22 November 2018).

What activities need to be undertaken to ensure successful roll out of a routine childhood 6-dose TTCV schedule?

Expanding the TTCV schedule to include three booster doses requires comprehensive planning. In many ways, this effort will follow the processes and activities that countries use for introducing a new vaccine (see **Box 10**).

Box 10
WHO guidance on new vaccine introduction



Principles and considerations for adding a vaccine to a national immunization programme: From decision to implementation and monitoring (2014) – resource document for countries that explains the principles, issues and processes to be considered when introducing a new vaccine into a national immunization programme.

Available online at: www.who.int/immunization/programmes_systems/policies_strategies/vaccine_intro_resources/nvi_guidelines/en/.

Rather than repeating in detail, some of the key activities and reference to additional resource materials is summarized below.

Decision-making and policies:

- Involve the National Immunization Technical Advisory Group (NITAG) or its equivalent.
- Review policies and legislation concerning vaccination of school children.
- Consider consent processes.
- Involve other ministries (e.g. education, finance, etc.).
- Obtain endorsement from inter-agency coordinating committee (ICC) where available, and engage key stakeholders, such as paediatricians', midwives' and nurses' associations.
- Estimate costs, prepare detailed introduction plan, update cMYP, and secure financial resources (submit applications to donors for funding, if applicable).

Forecasting and procuring supply:

- Estimate target populations using population data from various sources [UN Population Division (see **Annex 2**) school enrolment, census, other programmes, etc.].
- Estimate number of doses and injection equipment needed.

— Verify cold chain capacity and distribution schedule.
— Procure vaccine and injection equipment (using UNICEF Supply Division Procurement Services if needed).
— Procure tally sheets, registers and home-based records as needed.

Microplanning:
— Complete district level microplanning.
— Prepare and compile budgets.
— Develop a plan for using the TTCV booster contacts to provide catch up of previously missed doses of other childhood vaccines and estimate the supply needs of these other vaccines.

Recording and reporting:
— Adapt/revise home-based records/immunization cards, recording forms and systems.

Training and supportive supervision:
— Develop training materials and job aids.
— Undertake training of health workers.
— Distribute/communicate any revised policy directives.
— Revise supervision checklist and strengthen supportive supervision.
— Incorporate revised TTCV schedule into training curriculum of academic programmes for doctors, nurses and other healthcare professionals.

Communications/hesitancy:
— Develop a communication plan[15] including a crisis management plan[16], following Knowledge, Attitude and Practice (KAP) studies where appropriate (see **Box 11**).
— Identify target audiences (including media, parents, school teachers, etc.).
— Develop and test key messages (see **Box 12**).
— Anticipate rumours and proactively address vaccine hesitancy and possible anxiety-related reactions (see **Box 13**).

Monitoring and evaluation:
— Adapt immunization coverage wall monitoring charts, and monthly coverage reporting processes to include booster doses of TTCV (see **Chapter 5** for more information).
— Review monthly reporting of doses administered and coverage to assess performance and need for corrective action.

15 WHO Regional Office for Europe (2017). New vaccine introduction. Checklist for planning communication and advocacy. Copenhagen: World Health Organization Regional Office for Europe. (http://www.euro.who.int/__data/assets/pdf_file/0008/337490/02_WHO_VaccineSafety_SupportDoc_NewVaccIntro_Proof8.pdf, accessed 22 November 2018).
16 WHO Regional Office for Europe (2017). Crisis communications plan template. Copenhagen: World Health Organization Regional Office for Europe. (http://www.euro.who.int/__data/assets/pdf_file/0014/333140/VSS-crisis-comms-plan.pdf, accessed 22 November 2018).

— Consider doing a special post-introduction evaluation (PIE)[17], 6-months after implementation, or include in the next Immunization Programme Review.

Box 11

Crisis communications plan and vaccine safety

Countries should prepare crisis communication plans that allow for a rapid and effective response to adverse events following immunization (AEFI), anti-vaccine movements, and any allegation that can have a negative effect on public acceptance of TTCVs and trust in the immunization programme.

Countries should have in place the basic elements of a crisis plan, which may include:

— an AEFI committee at different levels which can meet immediately to discuss and plan action;
— clear channels of communication with various media;
— engaging with credible opinion and traditional leaders to address misconceptions and rumours;
— training of health workers on inter-personal communication and on how to communicate with the public about AEFI and safety concerns;
— an AEFI action plan with specific roles for immunization programme partners.

Box 12

Examples of key communication messages on TTCV boosters

— The organism that causes tetanus is present everywhere in the environment.
— Tetanus is deadly at any age and vaccination is the key method for protection.
— TTCV boosters for young children and adolescents are needed to give long-term protection to girls and boys against tetanus.
— Each additional booster vaccination against tetanus extends protection lasting for many more years.
— Everyone needs to be protected, but tetanus vaccination is especially important to prevent newborns and mothers getting tetanus during delivery (use local names for MNT).
— TTCV is safe and has been used around the world for many decades.
— TTCV boosters are available free of charge at (location) (date, time).
— Three boosters are needed for long-term protection at ages 12–23 months, 4–7 years and at 9–15 years.
— The government supports TTCV booster vaccination and has added it to the national immunization schedule.

17 Given the burden of multiple assessment and review exercises, WHO no longer recommends that a PIE should be conducted after every new vaccine introduction (unless the vaccine product or strategy is drastically different from current practice). All programmatic assessments should ideally be combined into one comprehensive EPI Programme Review and performed only every 3–5 years.

Box 13

WHO resources on vaccine safety and AEFI communication

WHO e-Learning Course in Vaccine Safety (2013) – remote training package developed as a course on Vaccine Safety Basics to help health workers understand the origin and nature of adverse events, the importance of pharmacovigilance, and risk and crisis communication.

Available as CD-ROM, downloadable PDF, and e-learning on: http://www.who.int/vaccine_safety/initiative/tech_support/ebasic/en/.

Vaccine Safety Events: Managing the Communications Response (2013) – provides practical, informative strategies and tools to help plan and manage a communications response following a vaccine-related event in a local community, at the national level, or beyond.

Available online at: http://www.euro.who.int/__data/assets/pdf_file/0007/187171/Vaccine-Safety-Events-managing-the-communications-response.pdf.

How to respond to vaccine deniers in public (2016) – based on psychological research on persuasion, on research in public health, communication studies and on WHO risk communication guidelines, this document provides basic broad principles for a spokesperson of any health authority on how to respond to vocal vaccine deniers.

Available online at: http://www.euro.who.int/__data/assets/pdf_file/0005/315761/Vocal-vaccine-deniers-guidance-document.pdf and http://www.euro.who.int/en/health-topics/disease-prevention/vaccines-and-immunization/activities/communication-and-advocacyfacing-vocal-vaccine-deniers-in-public-debate.

For more resources on building and restoring confidence in vaccines and vaccination in routine work and in crisis, see Vaccine safety communication library available online at: http://www.euro.who.int/en/health-topics/disease-prevention/vaccines-and-immunization/publications/vaccine-safety-communication-library.

CHAPTER 3

Antenatal care (ANC) contacts and tetanus vaccination status of pregnant women

In this chapter you will learn:

- The role of vaccinating pregnant women and how this will change as countries establish the 6-dose routine child/adolescent schedule;
- The current WHO recommendations for antenatal care (ANC) contacts;
- How to screen and verify the tetanus vaccination status of pregnant women;
- What records/cards pregnant women need to keep;
- What "Protection at Birth" (PAB) means and why it is important;
- Routine administrative TTCV2+ coverage monitoring.

You can use this information to:

- Plan how the ANC and EPI programmes can work together to protect against tetanus;
- Train health workers to screen correctly to determine what dose(s), if any, a pregnant women needs;
- Improve the use and retention of home-based records/cards;
- Ensure PAB and TTCV2+ coverage monitoring is implemented and calculated correctly.

What is the role of vaccinating pregnant women and how will this change as countries establish the 6-dose routine child/adolescent schedule?

In order to achieve and sustain MNTE, countries must ensure that **at least 80% of pregnant women** in every district are fully vaccinated against tetanus. Pregnant women can contract tetanus during unclean miscarriage, abortion, and childbirth.

Maternal tetanus: Tetanus occurring during pregnancy or within six weeks after any type of pregnancy termination (birth, miscarriage, abortion).

Increasingly, as countries implement the routine 6-dose child/adolescent tetanus schedule, fewer and fewer pregnant women will require tetanus vaccination during their pregnancy because they will have already been fully protected as children/adolescents.

However, achieving at least 80% coverage of 6 TTCV doses by adolescence in every district will take time. Because it is essential that every mother and newborn is protected against tetanus, it will **always** be necessary for ANC programmes to screen pregnant women to check that they are fully protected against tetanus, and administer any TTCV doses needed for long-term protection. It is important that received doses are accurately recorded on the appropriate home-based card and that their long-term retention is ensured so that the history of tetanus vaccination can be verified and unnecessary vaccinations avoided.

TTCVs are safe for pregnant women. There is no evidence of adverse pregnancy outcomes or risk to the foetus from TTCV vaccination during pregnancy.[18] TTCVs are also safe to use in HIV-infected and immunocompromised persons.

Anyone who receives 6 doses of TTCV starting with the primary series in infancy (or 5 doses if first vaccinated after infancy) achieves long-term protection and is protected against tetanus throughout their adulthood and beyond.

18 WHO (2014). Safety of Immunization during Pregnancy. Geneva: World Health Organization (http://www.who.int/vaccine_safety/publications/safety_pregnancy_nov2014.pdf, accessed 22 November 2018).

What are current WHO recommendations for antenatal care (ANC) contacts?

Following a comprehensive review of evidence in 2016, WHO issued new recommendations on ANC.[19]

WHO now recommends a **minimum of eight ANC contacts**, scheduled to take place as follows:

- the 1st contact in the first trimester (up to 12 weeks of gestation);
- two contacts scheduled in the second trimester (at 20 and 26 weeks of gestation); and
- five contacts scheduled in the third trimester (at 30, 34, 36, 38, and 40 weeks).

2016 WHO ANC Schedule	
First Trimester	
Contact 1:	up to 12 weeks
Second Trimester	
Contact 2:	20 weeks
Contact 3:	26 weeks
Third Trimester	
Contact 4:	30 weeks
Contact 5:	34 weeks
Contact 6:	36 weeks
Contact 7:	38 weeks
Contact 8:	40 weeks
Return for delivery at 41 weeks if not given birth.	

It is important that all pregnant women attend an antenatal clinic or can be reached by health staff in the community. Starting from the first ANC contact, WHO recommends verifying the TTCV status of pregnant women and administering TTCV if needed.[20] See *How to screen and vaccinate pregnant women for protection against tetanus?* (page 44) for vaccination schedule for TTCV unvaccinated and partially vaccinated pregnant women.

For effective implementation, ANC health-care providers need to be trained to screen the vaccination status of pregnant women and if needed, either refer for appropriate vaccination, or administer the TTCV themselves. The vaccine, equipment and supplies (refrigerator, needles and syringes, safety boxes) need to be readily available for provision of ANC vaccination in the facilities and/or during community outreach.

19 WHO (2016). WHO recommendations on antenatal care for a positive pregnancy experience. Geneva: World health Organization (https://apps.who.int/iris/bitstream/handle/10665/250796/9789241549912-eng.pdf, accessed 22 November 2018).

20 Policy-makers in low prevalence/high-income settings may choose not to include tetanus vaccination among ANC interventions if effective tetanus immunization programmes and good post-exposure prophylaxis exist outside of pregnancy.

When a pregnant woman attends an ANC visit, the health worker has an opportunity to:

— explain the advantages and encourage delivery at a health facility;
— reinforce the importance of delivery with skilled health personnel (competent maternal and newborn health professional) if the childbirth will happen outside of health facility and provide information on how to access such services;
— explain the principles of clean cord care practices, especially if unsafe practices are likely;
— emphasize the importance of timely infant vaccination and communicate the infant/child vaccination schedule to pregnant women.

If these services are not available or affordable, or if women prefer to deliver at home (non-facility delivery) without skilled health personnel, health workers should make additional effort to instruct pregnant women and their family on:

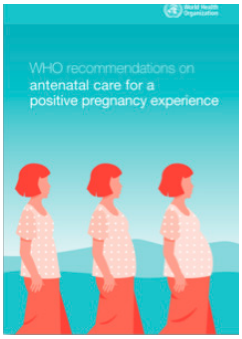
— how to ensure clean and safe childbirth at home
— how to ensure clean and appropriate cord care
— how to avoid harmful cord care practices
— how to recognize complications, especially early signs of tetanus
— when and where to seek care in case of complications.

Additionally, if appropriate and available, provide these women with a clean birth kit (CBK) and instruct them on how to use it (see *What are clean birth kits and childbirth checklists?*, page 60).

Home-based records for pregnant women and their unborn child may be distributed during ANC contacts and the importance of their retention well explained.

Box 14

WHO resources focusing on a positive pregnancy experience through improved quality of antenatal care



WHO recommendations on antenatal care for a positive pregnancy experience (2016) – comprehensive guideline intended to reflect and respond to the complex nature of the issues surrounding the practice and delivery of ANC, in accordance with a human rights-based approach.

Available online at: https://apps.who.int/iris/bitstream/handle/10665/250796/9789241549912-eng.pdf.

Antenatal care infographics – part of innovative, evidence-based approaches to antenatal care, focusing on contacts as an active connection between a pregnant woman and a health care provider, to ensure an effective transition of a positive pregnancy experience to positive labour, childbirth and motherhood experience.

Available online at: http://www.who.int/reproductivehealth/publications/maternal_perinatal_health/ANC_infographics/en/.

How to screen and vaccinate pregnant women for protection against tetanus?

At the first ANC contact the tetanus vaccination status of pregnant women should be verified by card or history.

If card and/or history confirm that the pregnant woman is fully protected against tetanus (i.e. has received 6 TTCV doses in childhood/adolescence, or 5 doses if first vaccinated after 1 year of age/during adolescence/adulthood, including during previous pregnancies), then no further vaccination is needed. Vaccination of a "fully protected" pregnant woman (or any individual) should be avoided in order to prevent the risk of increased local reactions caused by pre-existing high levels of tetanus antibodies. **However, it is still very important to record this pregnant woman as "fully vaccinated with TTCV" on her home-based record or ANC card and in the immunization register, even though she did not receive any TTCV doses in the current pregnancy.**

If the pregnant woman does not have a card and the history seems unreliable, her vaccination status is considered unknown. Pregnant women with unknown vaccination status and those who have not been previously vaccinated should receive at least 2 TTCV doses as early as possible, with an interval of 4 weeks between the doses. Administer the 2nd dose at least 2 weeks before birth to allow for adequate immune response. Further doses of TTCV should be administered as shown in **Table 5**.

If the pregnant woman has received 1–4 doses of TTCV in the past, administer one dose of TTCV before delivery (see **Table 5**). For various training scenarios see **Annex 3**.

If the pregnant woman can confirm by card that she has received some but not all the needed doses of TTCV, provide vaccination following the schedule for partially vaccinated women shown in **Table 6.** The last dose of TTCV must be administered at least two weeks before delivery.

If the woman underwent miscarriage or unsafe abortion, and if she is considered unprotected against tetanus, vaccinate her immediately as shown in **Table 5**, to protect her against future tetanus risks.[21]

3

Table 5

TTCV vaccination schedule for WRA and pregnant women with unknown vaccination status or without previous exposure to TTCV[22]

Dose of TTCV	When to give	Expected duration of protection
TTCV 1	At first contact or as early in pregnancy as possible	None
TTCV 2	At least 4 weeks after TTCV1 (at the latest 2 weeks prior to birth)	1-3 years
TTCV 3	At least 6 months after TTCV2, or during subsequent pregnancy	At least 5 years
TTCV 4	At least 1 year after TTCV3, or during subsequent pregnancy	At least 10 years
TTCV 5	At least 1 year after TTCV4, or during subsequent pregnancy	For all childbearing age and much of adulthood

21 In addition, offer prophylaxis with human tetanus immune globulins (TIG) if the wound is large and possibly infected with soil or unclean instruments. A single intramuscular dose is recommended as soon as possible. TIG should be readily available in all countries.

22 WHO (2006). Standards for maternal and neonatal care. Maternal immunization against tetanus. Geneva: World Health Organization (http://www.who.int/reproductivehealth/publications/maternal_perinatal_health/immunization_tetanus.pdf, accessed 22 November 2018).

Table 6
TTCV vaccination schedule for partially vaccinated pregnant women[23]

Age of last vaccination	Previous vaccinations (from vaccination record)	Recommended TTCV doses	
		At present ANC contact/pregnancy	Later (with interval of at least one year)
Infancy	3 TTCV primary doses	2 doses of TTCV (minimum 4 week interval between doses)	1 dose of TTCV
Early childhood/ school age	3 TTCV primary doses + 1 booster (total of 4 TTCV doses)	1 dose of TTCV	1 dose of TTCV
School age	3 TTCV primary doses + 2 boosters (total of 5 TTCV doses)	1 dose of TTCV	None (fully protected)
Adoles-cence	3 TTCV primary doses + 3 boosters (total of 6 TTCV doses)	None (fully protected)	None (fully protected)

All doses given should be properly recorded in the home-based record or ANC/maternal health card and in the standard facility register and tally sheet. Accurate recording by dose number (i.e. TTCV2, TTCV3, etc.) is important so that repeated unnecessary vaccinations can be avoided.

If a case of NT is identified, the mother should receive one dose of TTCV as soon as possible, and the infant should be treated according to national guidelines (see **Annex 1** for more information). A second dose of TTCV should be given to the mother at least 4 weeks after the first, and the third dose at least 6 months after the second. Other un- or under- vaccinated women living in the same area should be identified and vaccinated as appropriate (see **Table 5**). All cases of NT should be recorded and reported to the district authority, and all NT cases from low-risk areas should be investigated.[24]

23 WHO (2017). Tetanus vaccines. WHO Position Paper. Weekly Epidemiological Record. 92:53–76 (http://www.who.int/immunization/policy/position_papers/tetanus/en/, accessed 22 November 2018).
24 WHO (2006). Standards for maternal and neonatal care. Maternal immunization against tetanus. Geneva: World Health Organization (http://www.who.int/reproductivehealth/publications/maternal_perinatal_health/immunization_tetanus.pdf, accessed 22 November 2018).

Maternal and neonatal tetanus can be prevented if:

1. women of reproductive age are fully vaccinated against tetanus before they become pregnant;
2. pregnant women are screened for protection against tetanus and vaccinated with TTCV as appropriate;
3. clean practices are used during birth and in the care of infant's umbilical cord.

In countries which have not achieved MNTE status, the "high-risk" approach should be part of the elimination strategy. This entails coordinating three rounds of vaccination campaigns[25] and targeting all WRA in high-risk districts to provide 3 doses of TTCV, irrespective of previous vaccination status. The interval between rounds 1 and 2 (i.e. TTCV doses 1 and 2) should be at least 4 weeks, and between rounds 2 and 3 (i.e. TTCV doses 2 and 3) at least 6 months. Ensuring clean birth and cord care practices are essential complementary activities.[26]

What records/cards do pregnant women need to keep?

In many countries, women are given their own home-based record (HBR) or case notes to carry during pregnancy. These may be paper (e.g. card, journal, handbook) or in electronic format (e.g. memory stick), and women are expected to safeguard and bring them to all health visits.

In maternal and child health, the HBR can take various forms such as antenatal care records, vaccination cards, child health booklets, and antenatal and child health books. HBR or case notes contain patient data which facilitates access to women's medical records when needed (e.g. if women change health-care provider, in case of emergency, etc) and may serve as important data collection and surveillance tools. Depending on the design and content, they can also be an effective tool to improve health awareness and client– health care provider communication (e.g. reminders about next appointments). In some countries, TTCV vaccination of pregnant women is recorded in the same booklet/record used for the child's vaccination. In these instances, the mother/child vaccination record is given to the mother at the first ANC contact and she is instructed to keep and use it for her newborn child's vaccination history.

25 For more on campaigns see Field Guide: WHO (2016). Planning and Implementing High-Quality Supplementary Immunization Activities for Injectable Vaccines. Geneva: World Health Organization (https://www.who.int/immunization/diseases/measles/SIA-Field-Guide.pdf, accessed 23 January 2019).

26 WHO (2017). Tetanus vaccines. WHO Position Paper. Weekly Epidemiological Record. 92:53–76 (http://www.who.int/immunization/policy/position_papers/tetanus/en/, accessed 22 November 2018).

Promote lifetime vaccination records

Permanent, lifetime vaccination cards should be given to every woman who receives TTCV vaccination. The lifetime cards help health workers schedule vaccination appointments correctly and avoid giving women too many (or too few) vaccines. It is important that women understand that the record is valuable and should be kept safely. For example, make sure health workers ask women for their vaccination cards or home-based record every time they come for a health service as a means of reinforcing their importance.

For more information on HBR for maternal, newborn and child health and implementation recommendations see **Box 8** and http://www.who.int/maternal_child_adolescent/documents/home-based-records-guidelines/en/.

What does "protection at birth" (PAB) mean and why is it important?

Maternal tetanus immunization leads to the production of antibodies and trans-placental transfer of these to the developing foetus. Because this process of passively acquiring maternal antibodies is highly efficient, the infant usually has a serum tetanus antibody concentration at birth greater than, or equal, to that of the mother.[27] In this way, through maternal vaccination, both mother and infant are protected from tetanus occurring during the first few months after birth.

Protection at birth (PAB) against tetanus: A birth is considered protected against tetanus when occurring during the period of protection conferred by the maternal immunization status.

Protection at birth (PAB) is a monitoring method to determine whether a birth was protected against tetanus, based on written maternal records and/or questioning the mother (mother's recall) about the number and timing of TTCV doses she had previously received.

Only valid doses (at least two), or those given with the minimum required time intervals between doses, are to be counted. A birth is considered protected if it occurred within the duration of protection offered by the last valid dose (see **Table 7**). TTCV doses received by mothers during childhood are included only if documented in paper or electronic records (e.g. infant or school vaccination records).

27 Wilcox CR, et al. (2017). Factors affecting FcRn-mediated transplacental transfer of antibodies and implications for vaccination in pregnancy. Frontiers in Immunology. 8:1294 (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5671757/, accessed 22 November 2018).

Table 7

Protection at birth based on maternal vaccination history (birth is PAB or considered protected if it occurred within the duration of protection offered by the last tetanus vaccine dose)

Cumulative number of TTCV doses administered to mother	Minimal interval between doses to be considered valid	Duration of protection from receipt of last dose (PAB status)
TTCV2	4 weeks	3 years (PAB if birth within 3 years)
TTCV3	6 months	5 years (PAB if birth within 5 years)
TTCV4	1 year	10 years (PAB if birth within 10 years)
TTCV5	1 year	Much of adulthood (PAB for all subsequent births)

If a birth was assessed as unprotected, the mother should receive a dose of TTCV during that visit and should be followed up with a subsequent TTCV dose(s) if needed, thereby protecting future pregnancies. The same applies for mothers whose children were protected at birth but who remain eligible for additional TTCV doses in order to be fully vaccinated and protected.

How is protection at birth (PAB) implemented, recorded, and coverage calculated?

WHO recommends that PAB status is assessed and recorded to estimate protection against tetanus in pregnant women. Together with records on facility-based deliveries (if available), PAB coverage can be used as a proxy marker to assess the district level risk of MNT.

Traditionally, PAB has been assessed and recorded at the first vaccination contact for the new-born baby/infant, usually at the Penta1/DPT1 visit. However, all post-natal care visits (currently recommended at 24 hours, day 3, and between 7–14 days and 6 weeks after delivery) present an opportunity to check PAB. With the increased integration of maternal, post-natal and vaccination services there are other contact opportunities where PAB status could be assessed and recorded (see **Table 8**). PAB status can be recorded in the home-based record, ANC card, child's vaccination card, and tally sheets.

Table 8
Opportunities to implement assessment and recording of PAB status

Contact to assess/record PAB	Considerations
At birth	Best for countries with high proportion (%) of facility-based deliveries.
	Requires collaboration between maternal and immunization services.
	PAB could be recorded in mother's ANC card, or integrated maternal and child card, or child immunization card, and recorded on facility registers/tally sheets.
	Especially appropriate if Hep B and BCG are given at time of birth (along with vaccination card).
1st postnatal contact – ideally 24 hours after birth[28] (e.g. HepB birth dose)	Would capture all infants born (non-facility and facility) as mother is required to come to the health facility after birth, but requires strong postnatal programme implementation and access to services to achieve high coverage.
	Requires collaboration between maternal and immunization services.
	PAB could be recorded in mothers ANC card, or integrated maternal and child card, or child immunization card if it has been given, and recorded on facility registers/tally sheets.
First vaccination contact of the infant (Penta1/DTP1)	Vaccination services usually have high attendance (high Penta 1 coverage).
	Easy to do and record (cards and registers and tally sheets available) both for facility-based and outreach vaccination sessions.
	Does not require collaboration with other programmes.

PAB coverage is the proportion of births in a given year that can be considered as having been protected against tetanus as a result of maternal immunization. PAB coverage is calculated as follows:

$$\%PAB = \frac{\text{Total number of infants who were protected against neonatal tetanus by their mother's TTCV status}}{\text{Total number of live births}} \times 100$$

Annex 4 provides an overview of how to implement the PAB method in practice and examples of tools (i.e. reporting form, NT protection calculator, etc.).

28 WHO (2013). WHO recommendations on postnatal care of mother and newborn. Geneva: World Health Organization (https://apps.who.int/iris/bitstream/handle/10665/97603/9789241506649_eng.pdf, accessed 22 November 2018).

What is routine administrative TTCV2+ coverage monitoring?

Experience has shown that aggregated administrative monitoring of the second or subsequent dose of TTCV (TTCV2+) coverage of pregnant women is difficult to do accurately, particularly at the national level, unless countries have electronic registers.

Emphasis should be on making sure that doses of TTCV are recorded on home-based records for maternal, newborn and child health, and that these records/cards are retained over the long term or at least through reproductive age for women.[29]

Good recording of maternal and infant TTCV doses will enable PAB to be accurately monitored (see *What does "protection at birth" mean and why is it important?*, page 48).

Immunization coverage surveys (e.g. DHS, MICS) can be used to periodically assess TTCV2+ coverage in mothers who had a pregnancy in the past 12 months, and can also be used to validate PAB coverage.

In countries that continue with routine administrative monitoring of TTCV2+ coverage, as a refinement WHO recommends that the numerator includes those pregnant women who are already fully protected through previous TTCV vaccination to avoid underestimation.

TTCV2+ coverage for pregnant women is the proportion of pregnant women in a given year who are fully vaccinated for **this pregnancy** (who received TT2, TT3, TT4, or TT5 dose), **including** those pregnant women already fully protected/vaccinated against tetanus **prior to the pregnancy**.

%TTCV2+ coverage of pregnant women =

$$\frac{\text{Total no.of women vaccinated with 2 or more doses of TTCV during pregnancy + pregnant women already fully protected, in a year}}{\text{Estimated number of pregnant women during the year}^{30}}$$

ANC cards, immunization registers and tally sheets should be adapted to include a column for "Fully Immunized Prior to the Pregnancy". For an example of a tally sheet see **Annex 5**.

29 WHO (2018). WHO recommendations on home-based records for maternal, newborn and child health. Geneva: World Health Organization (http://www.who.int/maternal_child_adolescent/documents/home-based-records-guidelines/en/, accessed 22 November 2018).

30 For information on how to obtain estimates of national numbers of births see WHO Working Draft (2015) of Assessing and improving the accuracy of target population estimates for immunization coverage. Geneva: World Health Organization (https://www.who.int/immunization/monitoring_surveillance/data/Denominator_guide.pdf, accessed 22 November 2018).

CHAPTER 4

Ensuring clean birth and umbilical cord care practices

In this chapter you will learn:

- Why clean birth and umbilical cord care are important for MNTE;
- How can clean birth and clean cord care practices be achieved;
- What practices ensure a clean birth and cord care;
- What are clean birth kits (CBK) and childbirth checklists.

You can use this information to:

- Plan and improve birth practices so that there is no risk of tetanus and other causes of perinatal mortality;
- Train health workers;
- Develop information, education and communication (IEC) materials for women and communities.

Why are clean birth and umbilical cord care important for MNTE?

A clean birth, along with appropriate hygienic practices post-childbirth, can effectively reduce risks of tetanus, even if maternal TTCV coverage is suboptimal in a country. Clean birth can also reduce other causes of perinatal mortality such as infections other than tetanus that could result in neonatal sepsis.

A newly cut umbilical cord can be a pathway for local and invasive infections. Localized infection of the umbilical stump (omphalitis) may progress beyond the subcutaneous tissues, involve abdominal wall muscles, the umbilical and portal veins, and lead to systemic sepsis which, if untreated, has a high case-fatality rate.

In many cultures around the world there is a desire to actively care for the umbilical cord of the newborn, irrespective of whether they are born at home or in health-care facilities. These traditional practices vary by country or cultural groups within a country, and include application of a wide range of substances[31] such as:

- Oils, herbs/spices/plants;
- Minerals and powders;
- Animal dung;
- Water;
- Bodily fluids;
- Food;
- Heat (e.g. hot knife, steam, burning);
- Personal care or medical substances (e.g. creams, ointments, toothpaste, alcohol, iodine, herbal medicines, etc.);
- Other substances (e.g. burnt cotton, shells, tar, fish bones, crushed wasp nests, etc.).

Application of substances to the stump is not indicated because it delays the physiological drying of the umbilical cord stump and can be harmful. In settings with poor hygiene, adequate cord care practices for the newborn, especially if provided by skilled health personnel, has the potential to avoid preventable neonatal deaths. Evidence suggests that clean birth practices can reduce the incidence of NT by 55–99%.[32] See WHO recommendation for cord care in section *What practices ensure a clean birth and cord care?*, page 58.

31 Coffey PS, Brown SC (2017). Umbilical cord-care practices in low- and middle-income countries: a systematic review. BMC Pregnancy and Childbirth 17:68 (https://bmcpregnancychildbirth.biomedcentral.com/track/pdf/10.1186/s12884-017-1250-7, accessed 11 January 2019).

32 WHO (2016). Report of the SAGE working group on maternal and neonatal tetanus elimination and broader tetanus prevention, September 2016. Geneva: World Health Organization (http://www.who.int/immunization/sage/meetings/2016/october/1_Report_of_the_SAGE_Working_Group_on_Maternal_and_Neonatal_Tetanus_27Sep2016.pdf, accessed 11 January 2019).

How can clean birth and clean cord care practices be achieved?

Having skilled health personnel is key to ensuring clean birth and cord care (see **Box 15** for definition of skilled health personnel).

Increasing the number of deliveries with a competent maternal and newborn health professional in order to reduce maternal and neonatal deaths is a global goal of the Every Newborn Action Plan (ENAP)[33], the Global Strategy for Women's, Children's and Adolescent Health[34], the Sustainable Development Goals (SDGs)[35], and Ending Preventable Maternal Mortality (EPMM) Initiative[36].

At the community level, skilled health personnel will often be the only qualified and accredited health care workers with exclusive responsibility for the care of women during pregnancy, childbirth, and the immediate postnatal period. Others, ranging from traditional birth attendants (TBAs), nurses to specialist physicians, will certainly contribute to the care of women and newborns, but none of these will have either the wide-ranging competence or the mandate for all the tasks the skilled health personnel is required to perform.

Globally the proportion of women giving birth with a competent MNH professional has increased in the last two decades. However, there are great disparities in coverage and quality of care between and within countries. Countries are encouraged to ensure, without delay, that skilled health personnel providing care during childbirth are available to all pregnant women and newborn.

33 WHO (2014). Every newborn, an action plan to end preventable deaths. Geneva: World Health Organization (http://apps.who.int/iris/bitstream/10665/127938/1/9789241507448_eng.pdf, accessed 22 November 2018).
34 Promoting health through the life-course: Commitments to Every Woman Every Child's Global Strategy for Women's, Children's, and Adolescents' Health (2016-2030) [website]. Geneva: World Health Organization (http://www.who.int/life-course/partners/global-strategy/en/, accessed 15 January 2019).
35 Sustainable Development Goals [website]. United Nations (http://www.un.org/sustainabledevelopment/sustainable-development-goals/, accessed 15 January 2019).
36 WHO (2015). Sexual and reproductive health: Strategies toward ending preventable maternal mortality (EPMM). Geneva: World Health Organization (http://www.who.int/reproductivehealth/topics/maternal_perinatal/epmm/en/, accessed 15 January 2019).

Box 15

Sustainable Development Goals and definition of by skilled health personnel

A critical progress indicator adopted by the Sustainable Development Goals (SDG) and the Global Strategy for Women's, Children's and Adolescents' Health, 2016-2030 agenda is the "percentage of births delivered by skilled attendant at birth" (SBA).

WHO, UNFPA, UNICEF, ICM, ICN, FIGO and IPA proposed a revised definition of skilled health personnel providing care during childbirth (previously referred to as "skilled birth attendants" or SBAs) in order to standardize and improve the accuracy of measurement.[37]

Skilled health personnel are competent maternal and newborn health (MNH) professionals educated, trained and regulated to national and international standards. They are competent to:

i. provide and promote evidence-based, human-rights based, quality, socio-culturally sensitive and dignified care to women and their newborns;
ii. facilitate physiological processes during labour and delivery to ensure a clean and positive childbirth experience; and
iii. identify and manage or refer women and/or newborns with complications.

In addition, as a part of an integrated team of MNH professionals (including midwives, nurses, doctors, obstetricians, neonatologists, paediatricians and anaesthesiologists), they perform all signal functions of emergency maternal and newborn care to optimize the health and well-being of mothers and newborns within an enabling and supporting environment.

Box 16
WHO publication on skilled health personnel

Definition of skilled health personnel providing care during childbirth (2018) — This 2018 joint statement by the World Health Organization (WHO), the United Nations Population Fund (UNFPA), the United Nations Children's Fund (UNICEF), the International Confederation of Midwives (ICM), the International Council of Nurses (ICN), the International Federation of Gynecology and Obstetrics (FIGO) and the International Pediatric Association (IPA) presents the 2018 definition of skilled health personnel providing care during childbirth, which is revised and refined definition of the widely used term "skilled birth attendant" (SBA).

Available online at: http://www.who.int/reproductivehealth/publications/statement-competent-mnh-professionals/en/.

37 WHO (2018). Definition of skilled health personnel proiding care during childbirth. Geneva: World Health Organization (https://apps.who.int/iris/bitstream/handle/10665/272818/WHO-RHR-18.14-eng.pdf, accessed 22 November 2018).

What practices ensure a clean birth and cord care?

A clean birth is a delivery using hygienic practices and attended by competent maternal and newborn health personnel in a health care facility or at home.

Knowledge about the importance of clean birthing practice has been available for a long time. In various regions/countries practices may be summarized differently (e.g. 'three cleans'[38], 'five cleans'[39], 'six cleans'[40]) but they all emphasize ensuring clean hands, clean birth surface and clean cord care (cut, tie and stump).

Clean birth practices should include:

— **Clean hands of birth attendant:** wash hands with clean water and soap, once before the delivery and once before cord cutting (see **Annex 6**).

— **Clean delivery surface:** use a clean plastic sheet for mothers to lie on during delivery to maintain clean birth canal and perineum, and to protect the newborn from potential sources of infection.

— **Clean cord cut:** use a new razor blade or other new sharp instrument from its original packing to prevent the transmission of tetanus-causing spores and other pathogenic organisms via the umbilicus to the infant.

— **Clean cord ties:** use clean or sterile thread or narrow tape to tie the umbilicus tightly and keep the stump healthy.

— **Clean cord stump care:** in high neonatal mortality settings and where locally recommended for newborns born outside of health facilities, apply chlorhexidine to the cord stump (see below). For those born in health facilities, dry cord care is recommended as per national protocol.

Standard precautions and cleanliness as principles of good care should be observed at all times. These principles are:

1. Wash hands with soap and water
2. Wear gloves (sterile when attending to woman in labour, delivery and immediate postpartum care; clean when dealing with handling and cleaning instruments, handling contaminated waste, blood and body fluid spills).
3. Protect yourself from blood and other bodily fluids (wear gloves, long apron, protect your eyes and mouth).
4. Practice safe sharps disposal.

38 WHO Regional Office for the Americas (2005). Neonatal Tetanus Elimination Field Guide. Washington: WHO Regional Office for the Americas (http://www1.paho.org/hq/dmdocuments/2011/FieldGuide_NeonatalTetanus_2ndEd_e.pdf, accessed 22 November 2018).

39 WHO Collaborating Centre for Training and Research in Newborn Care (2005). Teaching aids on newborn care. New Delhi (http://www.newbornwhocc.org/teaching.html, accessed 22 November 2018).

40 The Partnership for Maternal Health (2006). Opportunities for Africa's Newborns. Geneva: WHO on behalf of The Partnership for Maternal Health (http://www.who.int/pmnch/media/publications/oanfullreport.pdf, accessed 22 November 2018).

5. Practice safe waste disposal.
6. Deal with contaminated laundry (do not touch directly clothing or sheets stained with blood or body fluids).
7. Sterilize and clean contaminated equipment.
8. Clean and disinfect gloves.*
9. Sterilize gloves.*

* Reusing gloves is not recommended. If it is necessary because of limited supply, gloves can be disinfected by soaking overnight in bleach solution or sterilized by autoclaving.

For updated recommendations relevant to maternal and perinatal health refer to *Pregnancy, Childbirth, Postpartum and Newborn Care: a guide for essential practice* (see **Box 17**).

WHO recommendations on cord clamping[41]

— **Late cord clamping** (performed after one to three minutes after birth) is recommended for all births while initiating simultaneous essential newborn care.

— **Early cord clamping** (<1 minute after birth) is not recommended unless the neonate is asphyxiated and needs to be moved immediately for resuscitation.

WHO recommendations on cord care[42]

— Daily chlorhexidine (7.1% chlorhexidine digluconate aqueous solution or gel, delivering 4% chlorhexidine) application to the umbilical cord stump during the first week of life is recommended for newborns who are born at home in settings with high neonatal mortality (30 or more neonatal deaths per 1000 live births).

— Clean, dry cord care is recommended for newborns delivered in health facilities and at home in low neonatal mortality settings. Use of chlorhexidine in these situations may be considered only to replace application of a harmful traditional substance, such as cow dung, to the cord stump.

41 WHO (2018). Intrapartum care for a positive childbirth experience. Geneva: World Health Organization (https://apps.who.int/iris/bitstream/handle/10665/260178/9789241550215-eng.pdf, accessed 22 November 2018).
42 WHO (2013). Postnatal care of the mother and newborn. Geneva: World Health Organization (https://apps.who.int/iris/bitstream/handle/10665/97603/9789241506649_eng.pdf, accessed 22 November 2018).

What are clean birth kits (CBK) and childbirth checklists?

Along with training of health workers, media and public health messaging, and community-based behaviour change and training, one of the approaches to increase uptake of clean childbirth practices includes the distribution of clean birth kits (CBK).

WHO established the contents of clean birth kits (CBK) and their correct use in the 1990s. They differ from country to country depending on local guidelines and regulations, and the contents will also vary depending on where it is intended to be used (i.e. home delivery without skilled health personnel, home delivery by skilled health personnel, essential newborn kits for health facilities, essential newborn kits for hospitals, see **Table 9**).

Mother-held CBKs are highly cost-effective and considered appropriate in conflicts or complex humanitarian emergencies, or in settings where there is low coverage of facility births, as long as they are not a disincentive for facility birth.

United Nations Population Fund (UNFPA), WHO and UNICEF have developed essential reproductive health kits for emergency situations[43] designed to respond to three month's need for various population sizes and intended for the use of:

- community: kits packaged for individual distribution to pregnant women and kits with equipment and supplies for skilled health personnel;
- primary health care level: kits with equipment and supplies for essential newborn care for uncomplicated births, newborn resuscitation, stabilizing newborns with serious infection prior to referral, and caring for preterm babies; and
- referral hospital level: kits with equipment and supplies to provide comprehensive emergency obstetric and newborn care at the hospital (e.g. complicated births, newborn infections, newborn resuscitation, care for preterm babies with complications.

For detailed information on the contents of the kits, guidance for their use and orders please see https://www.unfpa.org/resources/humanitarian-emergencies-procurement.

43 UNFPA. Reproductive health kits management guidelines for field offices. United Nations Population Fund (https://www.unfpa.org/resources/reproductive-health-kits-management-guidelines-field-offices, accessed 15 January 2019).

Table 9

Example of essential supplies for clean birth and newborn care[44,45]

Where?	What is needed?	Who uses it?
Clean birth kit for home delivery without skilled health personnel	Plastic sheet, soap, disposable razor blade, cord tie, cotton cloth 'tetra', gloves, plastic bag for disposal of placenta, pictorial instruction for use leaflet, pictorial leaflet on maternal and newborn danger signs	The person attending birth when there is no skilled health personnel
Essential newborn kit for home delivery by skilled home personnel	The above, plus protective apron and mask, portable weighing scale, essential medicines, bulb syringe or portable suction unit	Skilled health personnel
Essential clean birth and newborn kits for primary health facilities and referral hospitals	Medical devices, delivery set, suture set, sterilization kit, lighting, medicines, treatment guidelines	Skilled health personnel and doctors

Where permitted by local regulations, individual clean birth kits for home delivery may also include:[44]

— The antiseptic chlorhexidine for newborn skin washing and umbilical cord cleaning. In high mortality settings, chlorhexidine has been shown to reduce newborn deaths by as much as 23 percent when applied within the first 24 hours of birth.

— Misoprostol pills, a uterotonic drug which contracts the uterus, can help to prevent excessive bleeding after delivery.

To ensure a high-quality of care of births in health facilities, in 2016 WHO developed quality of care standards which define the requirements. Accompanying these standards are a WHO Safe Childbirth Checklist and an Implementation Guide which are designed as tools to improve the quality of care provided to women giving birth in health facilities (see **Box 17**). All of these materials support the implementation of clean birth and cord care practices.

44 The Partnership for Maternal, Newborn and Child Health (2006). Opportunities for Africa's newborns: practical data, policy and programmatic support for newborn care in Africa. World Health Organization on behalf of The Partnership for Maternal, Newborn and Child Health (http://www.who.int/pmnch/media/publications/oanfullreport.pdf, accessed 22 November 2018).

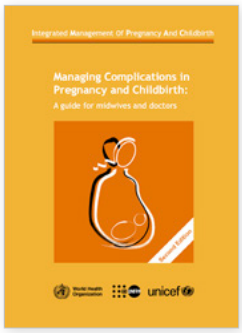
45 UNFPA (2011). Inter-agency reproductive health kits for crisis situations. New York. United Nations Population Fund, Humanitarian Response Branch (https://www.unfpa.org/sites/default/files/resource-pdf/RH%20kits%20manual_EN_0.pdf, accessed 22 November 2018).

Box 17

Resources on pregnancy, childbirth and newborn care

Pregnancy, Childbirth, Postpartum and Newborn Care: A guide for essential practice (2015) – compiles all the updated norms and standards that enable health care workers to provide high-quality, integrated care during pregnancy, childbirth and after birth to both mothers and newborns. The recommendations are specifically for skilled attendants working at the primary health-care level, either at the facility or in the community. The guide can be adapted to local needs and resources.

Available online at: https://apps.who.int/iris/bitstream/handle/10665/249580/9789241549356-eng.pdf.

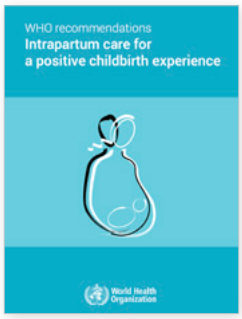


Managing complications in pregnancy and childbirth: a guide for midwives and doctors (2nd edition, 2017) – a manual for midwives and doctors at the district hospital who are responsible for the care of women with complications of pregnancy, childbirth or the immediate postpartum period, including immediate problems of the newborn.

Avalable online at: https://apps.who.int/iris/bitstream/handle/10665/255760/9789241565493-eng.pdf.

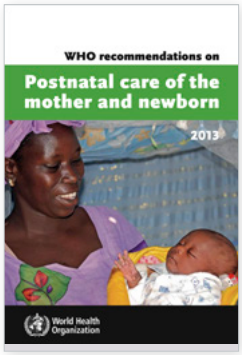
Early essential newborn care clinical practice pocket guide (2014) – is a good example of a user-friendly guide providing evidence-based protocol to essential newborn care focusing on the first hours and days of life, developed in the WHO Western Pacific Region.

Available online at: https://iris.wpro.who.int/bitstream/handle/10665.1/10798/9789290616856_eng.pdf.



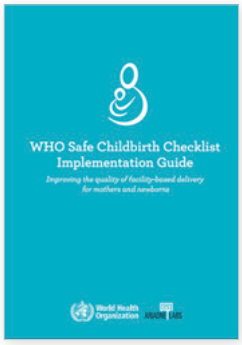
WHO recommendations: intrapartum care for a positive childbirth experience (2018) – consolidated new and existing WHO recommendations, intended to inform the development of relevant national- and local-level health policies and clinical protocols, and to ensure good-quality and evidence-based care irrespective of the setting or level of health care.

Available online at: https://apps.who.int/iris/bitstream/handle/10665/260178/9789241550215-eng.pdf.



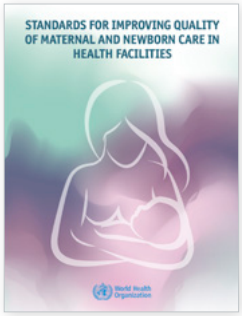
WHO recommendations on postnatal care of the mother and newborn (2013) – guidelines that address timing, number and place of postnatal contacts, and content of postnatal care for all mothers and babies during the six weeks after birth. Primarily intended for health professionals who are responsible for providing postnatal care to women and newborns, but can be included in job aids and tools for both pre- and in-service training of health professionals.

Available online at: http://apps.who.int/iris/bitstream/handle/10665/97603/9789241506649_eng.pdf.



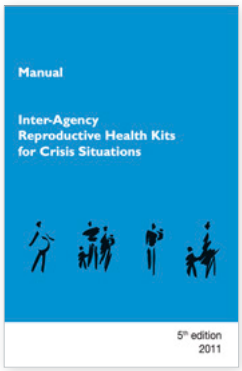
The Safe Childbirth Checklist (2015) – an organized list of evidence-based essential birth practices targeting major causes of maternal and neonatal deaths and intrapartum-related stillbirths. The Checklist may need to be adapted to reflect the local context and/or national guidelines and protocols. An Implementation Guide for health facilities has been developed to help birth attendants and health-care leaders successfully launch and sustain use of the WHO Safe Childbirth Checklist.

Available online at: http://www.who.int/patientsafety/implementation/checklists/childbirth/en/.



Standards for improving quality of maternal and newborn care in health facilities (2016) – include eight domains of quality of care that should be assessed, improved and monitored within the health system.

Available online at: http://apps.who.int/iris/bitstream/handle/10665/249155/9789241511216-eng.pdf.



Inter-Agency Reproductive Health Kits for Crisis Situations (2011) – manual which provides information on procurement procedures and contents of standardized emergency kits designed for worldwide use, pre-packed and kept ready for immediate dispatch in crisis situations.

Available online at: https://www.unfpa.org/sites/default/files/resource-pdf/RH%20kits%20manual_EN_0.pdf.

Newborn health in Humanitarian Settings: Field Guide (2018) – provides essential guidance and tools to health staff involved in designing, managing, monitoring and evaluating newborn health services within humanitarian settings.

Available online at: https://www.healthynewbornnetwork.org/resource/newborn-health-humanitarian-settings-field-guide/.

4

CHAPTER 5

Tetanus surveillance

In this chapter you will learn:

- What is tetanus surveillance and why it is necessary;
- WHO recommended standards for tetanus surveillance.

You can use this information to:

- Establish reliable tetanus surveillance systems;
- Monitor that MNTE is achieved and sustained.

What is tetanus surveillance and why is it necessary?

Tetanus surveillance is the systematic, timely, and continuous collection, analysis and interpretation of epidemiological data on tetanus cases, linked with timely dissemination of the results so that appropriate action can be taken to control or prevent further cases of tetanus.

Many countries have regulations for mandatory reporting of a list of notifiable diseases, tetanus being one of these. Surveillance reports should distinguish and separately categorize cases of neonatal (aged 0–28 days) and non-neonatal (aged >28 days) tetanus (see **Table 10** for case definitions).

Surveillance for neonatal tetanus

A key objective of neonatal tetanus surveillance is to detect cases of NT towards monitoring achievement and maintenance of MNTE, defined as less than one NT case per 1 000 live births annually in every district or equivalent administrative unit.

NT surveillance data (or a lack thereof) are used to identify areas and sub-populations at high-risk for NT and to guide an effective response. High-quality surveillance data, along with other key programme indicators, at the national and subnational (i.e. district) levels, enables monitoring of the impact of interventions, and are necessary to identify areas of increased risk for MNT and to target interventions to maintain elimination.

Surveillance for non-neonatal tetanus

The objective of surveillance for non-NT is to monitor disease burden and changing epidemiology over time in order to assess the impact of vaccination and to identify gaps in the immunization programme and health systems in general.

Information from non-NT surveillance should be used to tailor strengthening of routine immunization services and optimize strategies and vaccination schedules, including introduction and timing of booster doses. It can also be used to identify clustering of tetanus cases warranting investigation. Finally, rapid detection of cases can help save lives, i.e. through initiating receipt of proper treatment, including administration of antitoxin.

Table 10
WHO case definitions for tetanus

Neonatal tetanus (NT), aged 0-28 days	Non-neonatal tetanus (non-NT), aged ≥28 days	Maternal tetanus
Suspected case: —any neonate who could suck and cry normally during the first 2 days of life and developed tetanus-like illness or death between 3 and 28 days of age; **OR** — any neonate who died of an unknown cause during the first month of life.	**Suspected case** is any case with acute onset of at least one of the following signs: — trismus (lockjaw); — risus sardonicus (sustained spasm of the facial muscles); — generalized muscle spasms (contractions).	Tetanus occurring during pregnancy or within 6 weeks after any type of pregnancy termination (birth, miscarriage or abortion).[46]
Confirmed case: any suspected case found to have all three of the following: —normal ability to suck and cry during the first 2 days of life; **AND** —could not suck normally between 3 and 28 days of age; **AND** —developed muscle stiffness and/or spasms (jerking).	**Confirmed case:** suspected case clinically confirmed as tetanus by physician/trained clinician.	

5

46 It includes postpartum or puerperal tetanus resulting from septic procedures during delivery, postabortal tetanus resulting from septic abortion, and tetanus incidental to pregnancy resulting from any type of wound during pregnancy.

Importance of accurate and complete reporting of non-neonatal tetanus (non-NT) surveillance for MNTE

Surveillance for non-neonatal tetanus can detect cases of maternal tetanus. However, in most countries non-NT surveillance occurs through aggregate reporting which lacks specific information (i.e. age, sex, pregnancy status) to distinguish maternal tetanus. If country programmes decide that maternal tetanus is of special priority, reports of maternal tetanus should be handled similarly to those of neonatal tetanus.

What are the WHO recommended standards for tetanus surveillance?

In 2018, WHO published an updated second edition of *Surveillance standards for vaccine-preventable diseases* (see **Box 18**). This document provides surveillance standards (see **Table 11**) and performance indicators for both NT and non-NT surveillance, and detailed guidance for surveillance activities including:

— case detection

— case definitions and final classification

— case investigation, public health response and clinical case management

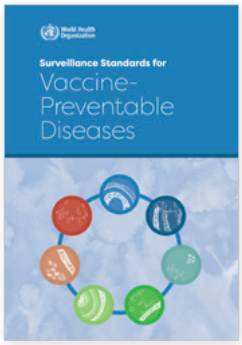
— data elements for collection, as well as reporting, analysis, and use

— surveillance performance indicators.

Countries may adapt these standards based on local epidemiology, policy, disease control objectives and strategies. Relevant extracts are provided in **Annex 7** for NT surveillance and in **Annex 8** for non-NT surveillance.

Box 18

WHO resources on vaccine-preventable disease surveillance



Surveillance standards for vaccine-preventable diseases, second edition (2018) – provides NT and non-NT surveillance standards and detailed guidance for surveillance activities.

Available online at: http://www.who.int/immunization/monitoring_surveillance/burden/vpd/standards/en/.

Neonatal tetanus surveillance standards available at: http://www.who.int/immunization/monitoring_surveillance/burden/vpd/WHO_SurveillanceVaccinePreventable_14_NeonatalTetanus_R1.pdf.

Non-neonatal tetanus surveillance standards available at: http://www.who.int/immunization/monitoring_surveillance/burden/vpd/WHO_SurveillanceVaccinePreventable_15_Non_neoTetanus_R1.pdf.

Making disease surveillance work (2008) – Module 8 of WHO training for mid-level managers series provides the basic concepts of surveillance and explains in practical terms how to manage a surveillance system for vaccine-preventable diseases.

Available online at: http://apps.who.int/iris/bitstream/handle/10665/70184/WHO_IVB_08.08_eng.pdf.

Immunization in practice: a practical guide for health staff (2015 update), Module 6: Monitoring and surveillance – explains how to collect and report data for the monitoring of immunization services and the surveillance of vaccine-preventable diseases.

Available online at: http://apps.who.int/iris/bitstream/handle/10665/193412/9789241549097_eng.pdf.

Table 11
WHO recommended surveillance standards for tetanus

Neonatal Tetanus (NT)	Non-Neonatal Tetanus (Non-NT)
The **minimal** recommended standard: Nationwide, case-based surveillance (meaning every suspected NT case should be investigated and classified as confirmed or discarded).	The **minimal** recommended standard: Nationwide, surveillance with aggregate routine reporting from inpatient facilities and investigation of any unusual disease clusters.
NT surveillance is population-based and includes all neonates aged 0–28 days. Laboratory confirmation is not an aspect of NT surveillance, as the basis of tetanus diagnosis is clinical rather than laboratory-based.	Non-NT surveillance is population-based and includes all persons aged >28 days. Laboratory confirmation is not an aspect of non-NT surveillance, as the basis of tetanus diagnosis is clinical rather than laboratory-based.
	Enhanced surveillance for non-NT: • Case-based surveillance. • Either nationwide or sentinel surveillance is advised depending on the local context (public and private referral hospitals with intensive care capacity located in areas with high non-NT burden).
Linkages to other surveillance • Ideally, NT surveillance is linked with active surveillance for AFP and measles-rubella, and routine aggregate surveillance for "zero reporting" as part of Integrated Disease Surveillance and Response (IDSR). • Linkage to vital event surveillance and neonatal death surveillance[47] may be useful for increasing NT surveillance sensitivity and helping to conserve resources.	**Linkages to other surveillance** • Ideally, non-NT surveillance is linked with aggregate surveillance systems for other diseases through systems such as IDSR and Early Warning, Alert and Response Network (EWARN). • In some cases, HMIS reporting may be used for facility-based aggregate reporting of non-NT cases. • Linkage to maternal death surveillance and response (MDSR) and other maternal child health post-partum surveillance systems may be relevant in some countries.

47 WHO (2016). Making every baby count: audit and review of stillbirths and neonatal deaths. Geneva: World Health Organization (http://apps.who.int/iris/bitstream/handle/10665/249523/9789241511223-eng.pdf, accessed 22 November 2018).

CHAPTER 6

Monitoring & Evaluation (M&E)

In this chapter you will learn:

- What monitoring and evaluation (M&E) is required for tetanus vaccination;
- How to periodically assess if MNTE status is sustained;
- What to do if M&E and/or periodic assessment of MNTE finds that elimination status is at risk.

You can use this information to:

- Design/adapt recording and monitoring tools for tetanus vaccination, including boosters;
- Plan and conduct a post-validation assessment of MNTE to ensure it is sustained.

What monitoring and evaluation is required for tetanus vaccination?

A successful monitoring and evaluation system for tetanus vaccination consists of:

1. continuous **programmatic monitoring** that provides information on implementation performance of tetanus vaccination (i.e. vaccine supply/stock, number of doses administered, coverage of 3 primary infant doses and 3 booster doses, TTCV2+, PAB, AEFI reporting, etc.), and
2. periodic assessment to check that **MNTE status** is maintained.

These two activities are interlinked and will be explained in this chapter. Reliable disease surveillance data (described in **Chapter 5**) provide an important complement to programmatic monitoring and evaluation, as it confirms the impact of the programme.

What is most important is that countries (especially those that achieved MNTE by conducting TTCV campaigns for women of reproductive age in high-risk districts) recognize that even though they validated MNTE, strong surveillance and constant attention to TTCV protection levels (i.e. high coverage) must continue so that elimination status is sustained.

Programmatic M&E: what monitoring tools need to be in place or revised?

Most national immunization programmes are already providing TTCV to pregnant women through ANC contacts, and have an M&E system in place for this. However, as discussed in **Chapter 3**, there may be a need to revise the ANC TTCV recording forms and monitoring processes in order to improve accuracy, particularly for tallying pregnant women who are already fully vaccinated with TTCV. Additionally, the ANC M&E system needs to monitor and report the doses, coverage, and other relevant information (e.g. stock, AEFI, etc.) for the TTCV administered through its services.

As additional child/adolescent TTVC boosters are added, the main recording and reporting tools that are used by the immunization programme will need to be adapted or developed to include the booster doses of TTCV vaccine. These are:

— vaccination register and defaulter tracking system

— tally sheet

— home-based record (vaccination card) defaulter tracking system

— stock record

— integrated monthly report.

Depending on the national schedule and delivery strategy for TTCV booster doses, and given that the administration of these boosters spans several age groups over time, it will likely be necessary to introduce several new monitoring tools and processes for the booster doses given to older children/adolescents.

When there is a pre-existing vaccination contact with the same age group, such as MCV2 or HPV vaccination, then the M&E tools can be adapted to include the TTCV booster. Likewise, if TTCV booster vaccination includes a 4–7 year old target group, then this opportunity (possibly at entry to day-care/crèche/school) can be used to check the vaccination status of these children and catch up missed doses of other childhood vaccines (see **Annex 9** for Job Aid).

Good coordination and collaboration between national ANC and EPI programmes is needed to obtain high-quality TTCV data (e.g. TTCV2+ and PAB coverage is correctly and accurately calculated) so that the TTCV performance information from both programmes can be shared and reviewed to inform any needed corrective actions.

Given the great diversity of approaches and country context, there are no generic M&E tools or processes to recommend for TTCV. Each country will need to design its own system according to its unique programme of service delivery. Those countries that have moved to electronic monitoring systems will have clear advantages as it will be much easier to retain and track the vaccinations given to individuals over the life course.

Helpful general information on immunization programme monitoring can be found in WHO publication *Immunization in Practice: A Practical Guide for Health Staff, Module 6 – Monitoring and Surveillance* (see **Box 18**) and also a forthcoming *WHO resource Handbook on the use, collection and improvement of immunization data* (see **Box 20**).

How to periodically assess if MNTE status is sustained?

It is a proud moment when a country is officially validated[48] as having successfully achieved elimination of maternal and neonatal tetanus. This end to a major public health problem usually represents years of hard work and investment, and is accompanied by much national and international media attention and celebration.

How can we know that MNTE is being sustained?

— Periodically conduct a post-validation assessment exercise. and/or

— Check on MNTE as part of regular programme review opportunities.

Unfortunately, given the ubiquitous nature of *Clostridium tetani* in the environment, if high coverage of vaccination with TTCV is not sustained, in the absence of high rates of clean birth and cord care practices, it is possible that a country could lose its MNT elimination status. For this reason, countries that have been validated need to periodically assess whether MNTE is being sustained. If weaknesses or concerns are identified, corrective actions must be planned and implemented swiftly.

A high-performing and reliable surveillance system for NT[49] provides essential information for MNTE monitoring and is the best method for monitoring programme success and sustaining of MNTE status. However, as described in **Chapter 5**, vaccine preventable disease surveillance systems are not always sufficiently robust and/or adequately funded in some countries to be confidently relied upon.

As a consequence, countries that have validated elimination need to periodically conduct a post-validation assessment of MNTE (a standalone exercise) or include checking on MNTE as part of regular programme review opportunities (such as annual VPD data desk review, or national immunization programme review). There may also be other periodic opportunities, such as serosurveys (see **Annex 10**) or DHS/MICS/ immunization coverage surveys, which can provide information for monitoring MNTE. Nevertheless, surveys rarely provide precise district-level coverage estimates and therefore, if MNTE status is to be reconfirmed as validated, special surveys may need to be designed for selected districts.

48 WHO (2014). Validation of Maternal and Neonatal Tetanus Elimination (including a guide to the use of Lot Quality Assurance – Cluster Sample Surveys to assess neonatal tetanus mortality). Geneva: World Health Organization (https://www.who.int/immunization/documents/MNTE_Validation_survey_WHO_IVB_18.15.pdf accessed 19 March 2019). For further information on the method of validating MNTE see https://www.who.int/immunization/diseases/MNTE_initiative/en/index2.html.

49 Reliable NT surveillance: a) 0 cases notification functioning, b) completeness of district health facility surveillance reporting ≥80%, c) annual review of hospital records at least once a year. The needs: 1. Case definition of NT cases available and known in all health facilities, 2. Case investigation forms for suspected cases available and cases investigated, 3. If rural district, functional community level surveillance.

Countries themselves, with support from partners/stakeholders, can decide which approach(es) to use. The decision will depend on many factors such as overall performance of the immunization programme, consideration of risk factors that might affect MNTE status (e.g. emergencies, natural disasters, civil unrest/conflicts), available time and funding, and the unique opportunities that arise.

Table 12 describes and outlines the pros and cons of various options that countries may consider using to assess if MNTE is sustained after validation. It is possible that countries may use a combination of approaches over time. Guidance for each of the options is described in the following pages.

Table 12
Approaches to assessing if MNTE is sustained after validation

Description	PROs	CONs
Option A. Annual VPD data desk review		
Compile and review key MNTE indicators (fewer) as part of annual process of immunization programme VPD data desk review. If quality district coverage data, especially PAB and health facility deliveries are available, this approach can avoid having to do the more resource-intensive post-validation assessment.	Conducted annually Integrated with performance review of other vaccines No special funds needed More likely to happen as being established as norm Linkage to cMYP and annual planning	Possible tendency to conduct in isolation (need to specifically invite other MCH/ANC programmes to join and share their data). Less focus on tetanus alone (diluted) Good quality data at district level is required for a valid assessment (and this may not be available from low performing districts).
Option B. National immunization programme review		
MNTE sustainability included as a part of periodic national immunization programme review This would require adapting the approach outlined in C below, and visiting the "at risk" districts as part of the fieldwork. The questionnaires/data collection variables used in Approach C could be adapted and imbedded into those used for the Immunization Programme Review.	Gives visibility to sustaining MNTE Partner involvement Field visits Funded Findings linked to action through recommendations and work-plan	Frequency every 3-5 years Availability of other programmes to join High-quality data at district level is required for a valid assessment.

Description	PROs	CONs
Option C. Post-validation assessment of MNTE		
5-step method to review core and surrogate MNT risk indicators which requires planning, and depending on the size of a country, may require 3-4 weeks preparation, a 3-day workshop, and field visits.	Very rigorous Involves EPI, MCH and surveillance programmes Linked to action	Intensive Vertical approach (focus on MNTE only) May be more costly (outsourcing for preparation, workshop and implementation, if no in-house expertise)
Option D. Other opportunities		
Serosurvey DHS/MICS surveys Vaccination coverage surveys	Accurate (if correctly implemented) Integrated	Irregular frequency Usually implemented at national level, rather than focus on districts at high risk for MNTE Costly May require specialized external technical expertise

Option A – Including MNTE sustainability in annual desk review of data

WHO and UNICEF encourage countries that have achieved MNTE to review their surveillance and other relevant datasets annually, with the purpose to identify if any districts are at risk of MNT re-emergence and if necessary, design and implement corrective actions quickly. When undertaken jointly, this annual data review can serve to further improve the synergy of EPI and MNCH programmes.

Beyond MNTE, for all programmes it is good management practice to carry out data desk reviews regularly and at all administrative levels so that data problems can be identified and addressed. The vision is that through the "use of data for action" all countries continuously improve the performance of their national immunization programmes (see **Box 20** for guidance).

WHO recommends, that at a minimum, countries undertake an annual data review as an initial step in compiling and critically analyzing the available information needed for an annual programme performance review. A good time for such a review is after all annual data are collated and before the WHO/UNICEF Joint Report Form is prepared and submitted.

A desk review can be performed by immunization programme staff alone or it can be done in collaboration with ANC and Health Management Information System (HMIS) staff. If MNTE is to be included, a collaborative approach is the preferred option because it will facilitate review of the non-immunization parameters, such as skilled birth delivery data. Full datasets should be reviewed (i.e. full national dataset in the case of a national level review).

In addition to vaccination coverage data, the desk review should include review of reported NT surveillance by district. Silent districts should be identified. The desk review of data does not require additional data collection. It is a review of existing data from routine information systems and selected reproductive health data which focuses on the following domains of data quality:

— completeness of administrative data;
— internal consistency of administrative data;
— external comparisons and consistency of administrative data (i.e. consistency with survey estimates);
— consistency of population data estimates (i.e. target population, the denominator for calculating coverage).

Normally, the desk review requires monthly or quarterly data by subnational administrative area for the most recent reporting year, and annual aggregated data for the last three reporting years, for the selected programmatic indicators.

Through analysis of the selected programme indicators, the desk review process quantifies problems of data completeness, accuracy and consistency, and thus provides valuable information on the adequacy of health-facility data to support planning and annual monitoring.

Increasingly, donors (such as Gavi[50]) are making reviews of data and data quality along with a data quality improvement plan, a requirement for countries to receive funding (see **Box 19**). With very little additional effort, these can also be used as opportunities to verify the sustainability of MNTE.

50 Gavi. Support Guidelines. Geneva: Gavi the Vaccine Alliance (https://www.gavi.org/support/process/apply/, accessed 15 January 2019).

Box 19

Gavi data quality requirements

Gavi requires that countries applying for all types of Gavi support:

1. Undertake routine monitoring of vaccination coverage data through **an annual desk review.**
2. Conduct periodic (once every five years or more frequently where appropriate) **in-depth assessments** of routine administrative vaccination coverage data.
3. Conduct periodic (at least once every five years) nationally representative **vaccination coverage surveys**.
4. Use 1 and 2 to develop a data quality improvement plan, that it is ideally integrated into other EPI plans.

WHO has developed a number of technical guides to support countries in the review of data and data quality (**Box 20**).

Box 20

WHO key resources for data and data quality assessments/reviews

Handbook on the collection, assessment and use of immunization data (to be published in 2019) – provides a framework for the systematic assessment and strengthening of national and subnational immunization data and information systems. This critical information is intended for country decision-makers to improve and use immunization and surveillance data, and enable them to:

1. decide what data are needed for programme improvement, and use them for action;
2. develop efficient tools and information systems to collect those data;
3. assess immunization data and systems, and implement data quality improvement plans.

Available online at: http://www.who.int/immunization/monitoring_surveillance/en/.

Data Quality Review Toolkit Module 2: Desk review of data quality (2017) – This toolkit is the result of collaboration between WHO, The Global Fund, Gavi, and (USAID)/MEASURE Evaluation and integrates and builds upon previous and current tools and methods designed to assess data quality at facility level. It proposes a unified approach to data quality, taking into account best practices and lessons learned from many countries.

Available online at: http://www.who.int/healthinfo/tools_data_analysis/dqr_modules/en/.

Option B – Integrating MNTE sustainability into a national immunization programme review[51]

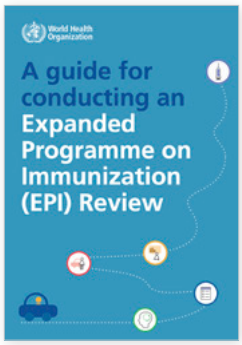
A national immunization programme review (also referred to as an EPI Review), is the comprehensive assessment of the strengths and weaknesses of an immunization programme at national, subnational and service-delivery levels. The purpose of this review is to provide evidence for the programme's strategic directions and priority activities.

With this in mind, an EPI review should be conducted before the immunization programme's strategic planning cycle, such as the cMYP. Review findings are presented formally to the Ministry of Health, other relevant ministries, and often the country's Interagency Coordinating Committee (ICC) for their responses and endorsement for incorporation into the next strategic plan.

Because EPI reviews are comprehensive and look at all aspects of the immunization programme, it is only natural that they include the assessment of MNTE sustainability. WHO recommends that EPI reviews should be conducted every 3–5 years. In 2018 WHO published a new *Guide for Conducting a National Immunization Programme Review* (see **Box 21**).

Periodic post-validation assessment of MNTE could also be included in a VPD surveillance review as it is an exercise that may identify missed NT cases. Guidance on how to conduct a VPD surveillance review is also provided in the *Guide for Conducting a National Immunization Programme Review* (**Box 21**).

Box 21
WHO resource for conducting EPI reviews



A Guide for Conducting a National Immunization Programme Review (2018) – provides guidance to individuals and teams responsible for planning and implementing an EPI Review, with the main objectives to set a benchmark for conducting quality EPI reviews, share best practices in order to increase the efficiency and quality of reviews, including through the integration of assessments as feasible, and to emphasize that EPI reviews should be country-driven and part of a strategic planning process.

Available online at:
http://www.who.int/immunization/documents/WHO_IVB_17.17/en/.

51 Assessment of MNTE sustainability could also be incorporated into Reproductive Health Programme reviews of ANC and skilled birth delivery, these reviews could assess the performance and missed opportunities for TTCV vaccination of pregnant women at ANC contacts and clean delivery practices.

Option C – Conducting a post-validation assessment of MNTE

Annex 11 provides the full details on the methodology for conducting a stand-alone post-validation assessment of MNTE. **Use of MNTE risk assessment data sheet must be the starting point for the post validation assessment.** WHO website contains the MNTE risk assessment data spreadsheet (Excel file format), sample tools, data tables and questionnaires that can be adapted to the local context (https://www.who.int/immunization/diseases/MNTE_initiative/en/).

A post-validation assessment comprises a desk-review of data to determine if MNTE indicator standards are being maintained and to identify any districts that are potentially at risk of not sustaining MNTE. It includes field visits and interviews at both the facility and community level, which in the poorer performing districts (particularly if there is any doubt about the quality of district level data), is critical to cross check the reported coverage of TTCV, ANC and skilled birth delivery. The assessment includes bottleneck analysis and development of a workplan and timeframe for implementing corrective actions, if needed.

The success of a post-validation assessment depends on good preparation and planning, as well as well as the participation of other relevant programmes (particularly MNCH and ANC).

Option D – Using serosurveys[52] to assess MNTE sustainability

In 2016, WHO Strategic Advisory Group of Experts (SAGE) on immunization recommended that tetanus serosurveys be considered where feasible, to validate assessments of disease risk identified using other data sources, and to guide vaccination strategies. In 2018, WHO developed guidance for tetanus serosurveys[53] that references the *Guidelines on the use of Serosurveys in Support of Measles and Rubella Elimination*[54] and the updated *WHO Vaccination Coverage Cluster Survey Reference Manual*.[55]

52 Information on immunization coverage survey methods is available online at http://www.who.int/immunization/monitoring_surveillance/routine/coverage/en/index2.html.

53 WHO (2018). Tetanus Serosurveys. Geneva: World Health Organization (http://www.who.int/immunization/monitoring_surveillance/burden/vpd/WHO_SurveillanceVaccinePreventable_25_Annex2_R1.pdf, accessed 22 November 2018).

54 WHO (2019). Guidelines on the use of serosurveys in support of measles and rubella elimination. Geneva: World Health Organization (http://www10.who.int/immunization/monitoring_surveillance/burden/laboratory/serosurvey/en/, accessed 24 October 2019).

55 WHO (2018). Vaccination Coverage Cluster Survey: Reference Manual. Geneva: World Health Organization (http://apps.who.int/iris/bitstream/handle/10665/272820/WHO-IVB-18.09-eng.pdf, accessed 15 January 2019).

Serosurvey — the collection and testing of blood specimens from a defined population over a specified period of time to determine antibodies against a given etiologic agent as a direct measure of the population's immunity

Seropositivity — serologic evidence of the presence of an antibody of a specific type in the serum

Seroprevalence — the proportion of people in a population who test positive for serum antibodies against a specific disease or pathogen; it is often presented as a per cent of the total specimens tested

Serosurveillance — serosurveys conducted routinely or periodically

Natural tetanus infection is not a source of immunity, so immunity presents an attractive biomarker of vaccination coverage. Serosurveys provide objective measures for estimating population immunity. Tetanus serosurveys can be used by country programmes to provide an immunologic assessment of true protection of mothers and infants, and the correlation between maternal histories and their actual protection. This may be useful for monitoring of disease risk and when assessing the sustainability of MNTE. Routine serosurveillance programmes are however most common in higher-income countries.

Use of tetanus serosurveys for monitoring achievement and maintenance of MNTE

MNTE is defined as a district level goal of <1 neonatal tetanus case per 1 000 live births in every district per year. MNTE strategies include coverage with >80% of women with protective TTCV doses in every district. Conducting tetanus serosurveys in every district to evaluate this indicator would be resource-intensive, and is not recommended.

However, serosurveys performed at the national level or in designated high-risk districts that document >80% seroprotection can provide evidence compatible with elimination. Nationally representative serosurveys may indicate the presence of important immunity gaps, but may not confirm absence of immunity gaps in specific districts, required to validate the sustainability of MNTE status.

Because tetanus is not eradicable and many countries have achieved MNTE through time-limited campaigns, serosurveys should be considered where feasible to monitor population immunity and MNT risk and guide vaccination strategies, especially in high-risk districts.

Integrating the fieldwork with other surveys or laboratory testing efforts is recommended where possible to allow monitoring of impact and sharing of costs across public health programmes.

Before undertaking a tetanus serosurvey, programme-specific questions should be defined so that specific objectives would drive the design of the serosurvey. **Table 13** provides possible objectives of serosurveys by target population.

Population-based cluster surveys are a method for obtaining estimates of seroprevalence representative of the target population. During the planning and design stages, a protocol is developed which defines preparation and implementation activities. More information on survey design and sampling methodologies are available in **Annex 10** and the *WHO Vaccination Coverage Cluster Survey Reference Manual*[56], while considerations for protocol development, budgeting and implementation are included in the *WHO Guidelines on the Use of Serosurveys in Support of MR Elimination*[57].

Given the high cost of serosurveys, opportunities can be explored for integration with other activities and cost savings. These can be generated by integrating tetanus serosurveys implementation with other surveys such as Demographic Health Surveys (DHS), periodically conducted in many countries. DHS often include blood sample collection for children and WRA, and collect information on TTCV coverage, neonatal deaths, deliveries in health facilities and by skilled health personnel, ANC visits, parity, obstetric care, health care access, and socio-demographics that can inform interpretation of serosurvey results.

Table 13
Objectives of tetanus serosurveys by target population

Target population	Objectives of tetanus serosurveys
All ages and both sexes	Assess disparities in seroprotection (examples: adult males vs females, young vs school-age children).
	Determine duration of immunity and need for booster dose introduction or schedule optimization.
	Evaluate impact of catch-up vaccination or campaigns on tetanus immunity (including TT-conjugate vaccines).
Children (e.g. 6–23 months, 12–35 months, 6 months–5 years, 1–15 years)	Evaluate population immunity, compared with vaccination coverage (ages 6–11 and 12–23 months).
	Identify areas and subgroups needing targeted remediation (outreach, school-based immunization, etc.).
	Determine duration of immunity and need for booster doses (for example, at ages 12–23 months, 4–7 years, 9–15 years.)

56 WHO (2018). Vaccination Coverage Cluster Survey: Reference Manual. Geneva: World Health Organization (http://apps.who.int/iris/bitstream/handle/10665/272820/WHO-IVB-18.09-eng.pdf, accessed 15 January 2019).
57 WHO (2019). Guidelines on the use of serosurveys in support of measles and rubella elimination. Geneva: World Health Organization (http://www10.who.int/immunization/monitoring_surveillance/burden/laboratory/serosurvey/en/, accessed 24 October 2019).

Target population	Objectives of tetanus serosurveys
Women of reproductive age before achieving MNTE	Evaluate population immunity, compared with vaccination coverage (e.g.TTCV2+/PAB).
	Monitor impact of targeted campaigns in areas at high risk for neonatal tetanus.
	Identify areas and subgroups needing targeted remediation through campaigns, outreach or another strategy.
Women of reproductive age after achieving MNTE	Monitor population immunity for maintenance of MNTE (e.g. in countries relying on campaigns to achieve MNTE).
	Provide evidence needed for TTCV booster dose introduction as part of sustaining elimination.
	Identify areas and subgroups for targeted remediation such as outreach vaccination or improved ANC and obstetric care.

AIDS Indicator Surveys (AIS) and Malaria Indicator Surveys (MIS) are other periodic surveys that almost always include collection of blood samples. Serosurveys for vaccine-preventable diseases (polio, measles, rubella, diphtheria, etc.) or other diseases (such as parasites, arboviral, or food- and water-borne diseases) may also be options for integration in some countries.

Another widely conducted periodic survey is the Multiple Indicator Cluster Survey (MICS), but it less often includes collection of blood samples.

An additional potential opportunity for integration and cost savings is through the use of multiplex laboratory testing such as bead-based immunofluorescence assays. Tetanus multiplex assays have been demonstrated to have good performance and cost saving compared to other laboratory tests. For more detail on options and cost see **Annex 10**.

Serosurvey findings should be interpreted in the context of current and historic data on immunization programme policies and performance, including any past supplementary immunization activities and disease incidence, if available. Tetanus survey results may differ from administrative vaccination coverage or coverage survey estimates. For interpretation of data, explanations of disparities between seroprotection rates and vaccinations coverage, and use of results see **Annex 10**.

Annexes

Annex 1.
What is tetanus?

Clinical features

Tetanus is an acute infectious disease caused by tetanospasmin, a toxin produced by the spores of bacterium *Clostridium tetani* (*C. tetani*) that grows in anaerobic conditions found in devitalized tissue and decaying matter. Tetanus toxin disseminates to nervous tissue via the blood and lymphatic system or enters the central nervous system along the peripheral motor neurons. The toxin blocks inhibitory neurotransmitters of the central nervous system, resulting in muscular rigidity and prolonged spasms.

Three clinical types of disease are often described.

1. **Localized tetanus** is uncommon and consists of spasms of muscles surrounding the site of injury. Although generally mild, localized tetanus may progress to generalized form of disease.
2. **Cephalic tetanus** is rare, associated with head or face lesions and/or with chronic ear infections. It presents as cranial nerve palsies and may progress to generalized tetanus.
3. **Generalized tetanus** is most common (>80% of cases) and presents as a generalized spastic disease. The common first sign is muscular stiffness in the jaw (trismus or lockjaw), followed by stiffness in the neck, difficulty in swallowing, rigidity of abdominal muscles, and spasms. Typical features are the facial expression resembling a forced grin known as "*risus sardonicus*", and the position of backward arching of the head, neck and spine (ophisthotonus). Generalized spasms are initially induced by sensory stimuli, but they occur spontaneously as the disease progresses. During spasms the limbs are drawn up and flexed, fists are tightly clenched, and toes are hyper-flexed. Intense spasms can lead to convulsive fits. Ultimately, breathing becomes difficult as spasms become more frequent and prolonged, leading to respiratory failure. Spasm of the glottis can result in immediate death.

   Neonatal tetanus (NT) is a form of generalized tetanus occurring in newborn infants, most often as a result of an infected umbilical cord stump. It is characterized by a newborn infant who sucks and cries for the first few days after birth, but who subsequently develops excessive crying and progressive difficulty to suck and breastfeed. Death occurs as a result of paralysis of the respiratory muscles and/or inability to feed.

Depending on age, quality of care available, and the length of the incubation[1] period, the case-fatality rate of tetanus ranges from <1% for localized, 15–30% for cephalic, and 10–70% for generalized, including neonatal, tetanus. Higher mortality rates are associated with shorter incubation periods.

1 The incubation period of non-neonatal tetanus usually varies 3-21 days, although it may range from 1 day to several months. The median interval to onset of symptoms is 7 days. In general, shorter incubation periods are associated with more heavily contaminated wounds, more severe disease, and a worse prognosis. For neonatal tetanus, the average incubation period is about 7 days, with a range from 3 to 14 days after birth in 90% of cases.

Tetanus can occur at any age and case-fatality rates are high. In the absence of medical intervention, the case-fatality rate approaches 100%. Even with intensive care, case-fatality rates are high (10–20%).

Reservoir and transmission

The spores of *C. tetani* are found everywhere in the environment, particularly in soil, ash, intestinal tracts/faeces of animals and humans, and on the surfaces of skin and rusty tools like nails, needles, barbed wire, farm implements, etc. Being very resistant to heat and most antiseptics, the spores can survive for years.

Tetanus is not transmitted from person to person. Rather, *C. tetani* enters the human body through contaminated wounds or tissue injuries, including those resulting from unclean deliveries, burns, dental extractions and surgical procedures such as abortions and circumcision performed under unhygienic conditions. Cases can occur in patients unable to recall a specific wound or injury and may follow inapparent wounds or those considered trivial.

Neonatal tetanus usually occurs through introduction of tetanus spores via the umbilical cord during the delivery through the use of an unclean instrument used to cut the cord or after delivery by 'dressing' the umbilical stump with substances contaminated with tetanus spores (see **Chapter 4**).

A person who recovers from tetanus does not develop immunity and must receive or complete a tetanus vaccination series to prevent future disease.

Risk groups

Anyone who has not received a complete vaccination series against tetanus and who has greater than usual risk of traumatic and puncture injury is at risk of contracting tetanus. This includes un- or under-vaccinated women of reproductive age and their newborn delivered by untrained birth attendant where delivery conditions and postpartum cord care practices are unclean.

Diagnosis

The diagnosis of tetanus is primarily based on clinical features, secondarily supported by epidemiologic setting, and does not depend on laboratory confirmation. There are no reliable confirmatory laboratory tests. WHO definitions for tetanus cases are summarized in the **Table 11**, **Chapter 5**.

Clinical case management of neonatal tetanus

NT is a medical emergency requiring hospitalization, immediate treatment with human tetanus immune globulin (TIG), agents to control muscle spasm (preferred choice benzodiazepines), and antibiotics (preferred choice metronidazole or penicillin G). A single intramuscular dose of human TIG is recommended as soon as possible to prevent further progression of the disease. If TIG is not available, equine-derived antitoxin tetanus serum (ATS), can be given in a single intravenous dose, after testing for hypersensitivity. Alternatively, intravenous immune globulin (IVIG) may be used. Supportive care should be provided including keeping patients in a dark and quiet environment to reduce the risk of reflex spasms, and nasogastric feeding for newborn infants. If muscle spasms are occurring, it is critical to maintain a safe airway. If mechanical ventilation is not available, patients should be carefully monitored in order to minimize spasm and autonomic dysfunction while avoiding respiratory failure.

Clinical case management of non-neonatal tetanus

Non-NT is a medical emergency requiring hospitalization and immediate treatment with TIG, drugs to control muscle spasm (preferred choice benzodiazepines), wound care, and antibiotics (preferred choice metronidazole or penicillin G). A single intramuscular dose of human TIG is recommended as soon as possible to prevent further progression of the disease. If TIG is not available, equine-derived anti-tetanus serum (ATS) can be given in a single intravenous dose after testing for hypersensitivity. Alternatively, intravenous immunoglobulin (IVIG) may be used.

Supportive care should be provided; patients should be kept in a dark and quiet environment to reduce the risk of reflex spasms. If muscle spasms are occurring, it is critical to maintain a safe airway. If mechanical ventilation is not available, patients should be carefully monitored in order to minimize spasm and autonomic dysfunction while avoiding respiratory failure. Finally, before discharge, age-appropriate tetanus toxoid containing vaccines (TTCV) should be administered to prevent future disease.

Health burden of tetanus

The health burden of tetanus is almost completely preventable through immunization with TTCV which are included in routine immunization programmes globally, and administered during antenatal care contacts (ANC) in many countries.

In many countries tetanus disease surveillance is not well established and its incidence is not known accurately. WHO estimates that in 2015, the latest year for which estimates are available, approximately 34 000 newborns died from NT, which represents a 96% reduction from the situation in the late 1980s. However, in 2017, a total of 12 476 tetanus cases including 2266 neonatal cases were reported through the WHO/UNICEF Joint Reporting Form[2] indicating the low reporting sensitivity and uncertainty about the true disease incidence. However, WHO/UNICEF global and regional summary data reflect the changing picture of tetanus with decreasing NT and persistent burden of non-NT.

In settings where high TTCV coverage has not been achieved, immunity gaps exist. The immunity gaps in women of reproductive age (WRA) and in their newborn infants who

2 WHO. Global and regional data and statistics [online database]. Geneva: World Health Organization (http://www.who.int/immunization/monitoring_surveillance/data/regions/en/, accessed 15 January 2019).

are not protected against birth-associated tetanus contribute to continuing maternal and neonatal tetanus burden in low-income countries. Immunity gaps have also been identified in school-aged children and adolescents and notably adolescent/adult males in low income countries who did not receive booster doses following the primary series given in infancy,[3] and who also need sustained protection against tetanus following injuries and surgical procedures (e.g. motorbike accidents, voluntary male circumcision as part of the programme for HIV/AIDS prevention, etc.). Because non-NT is beginning to predominate globally, further reductions in disease incidence can be gained as countries are able to ensure and maintain high coverage of the complete vaccination series (3 primary and 3 booster doses prior to adolescence). Ultimately, the most equitable and sustainable approach is to ensure tetanus protection over the life course **for all** members of the population.

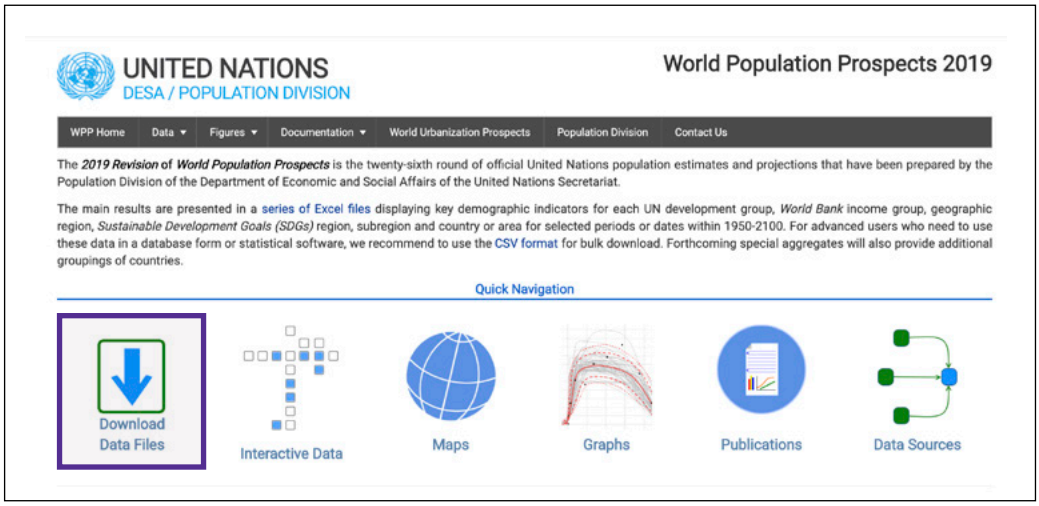
3 WHO (2017). Tetanus vaccines. WHO Position Paper. Weekly Epidemiological Record. 92:53–76 (http://www.who.int/immunization/policy/position_papers/tetanus/en/, accessed 22 November 2018).

Annex 2.
Estimating target populations using UN Population Division estimates and projections

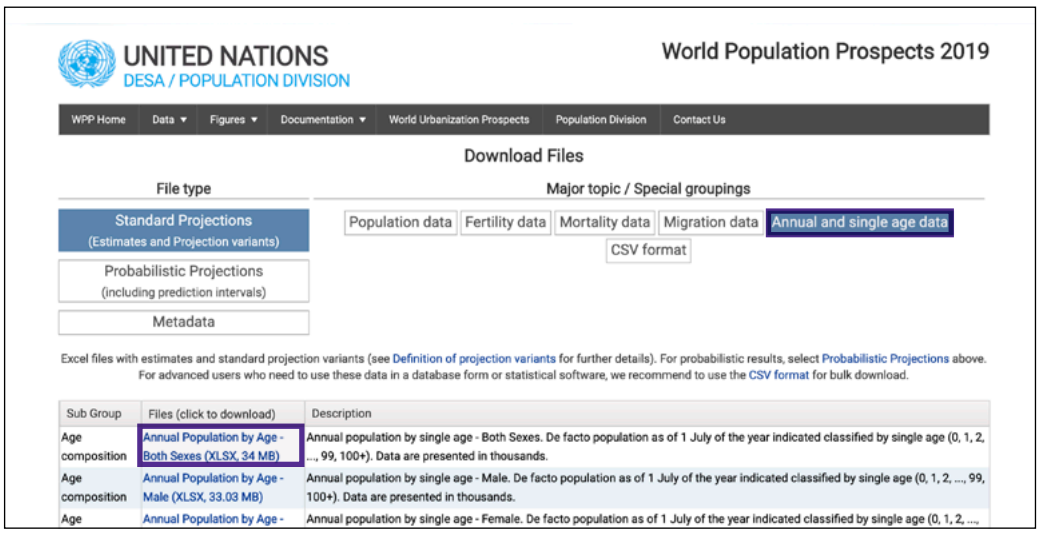
Official United Nations population estimates and projections have been prepared by the UN Population Division and are available in the series of Excel files that can be downloaded from the following link: https://population.un.org/wpp/ . A new Revision is issued every two years and the 2017 Revision provides population projections for the period 2015-2100. The next Revision is due in the first half of 2019.

To obtain the single age cohort estimates, do the following:

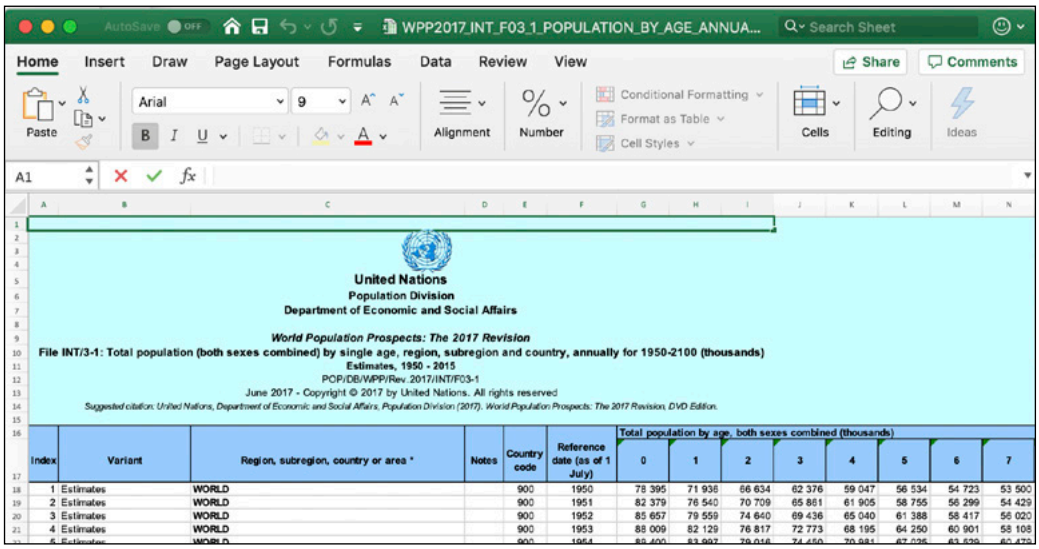
1. Open the UN Population Division home page (https://population.un.org/wpp/) and select 'Download Data Files'.



2. Under Major topic/Special Groupings select 'Annual and single age data' and the subgroup and files you are interested in (e.g. in 'Age composition' subgroup select file 'Annual Population by Age - Both Sexes').



3. Download the Excel file and filter the year and the country you are looking for.



United Nations
Population Division
Department of Economic and Social Affairs

World Population Prospects: The 2017 Revision

File INT/3-1: Total population (both sexes combined) by single age, region, subregion and country, annually for 1950-2100 (thousands)
Estimates, 1950 - 2015
POP/DB/WPP/Rev.2017/INT/F03-1
June 2017 - Copyright © 2017 by United Nations. All rights reserved
Suggested citation: United Nations, Department of Economic and Social Affairs, Population Division (2017). World Population Prospects: The 2017 Revision, DVD Edition.

Index	Variant	Region, subregion, country or area *	Notes	Country code	Reference date (as of 1 July)	Total population by age, both sexes combined (thousands)							
						0	1	2	3	4	5	6	7
1	Estimates	WORLD		900	1950	78 395	71 938	66 634	62 376	59 047	56 534	54 723	53 500
2	Estimates	WORLD		900	1951	82 379	76 540	70 709	65 861	61 905	58 755	56 299	54 429
3	Estimates	WORLD		900	1952	85 657	79 559	74 640	69 436	65 040	61 388	58 417	56 020
4	Estimates	WORLD		900	1953	88 009	82 129	76 817	72 773	68 195	64 250	60 901	58 108

Annex 3.
Determining the number of TTCV doses to be administered to a pregnant woman at ANC contact or health facility – health worker training scenarios

At a pregnant woman's first contact with the health facility, health personnel enquire about her previous vaccination history and examine her vaccination cards/records to determine the number of Td doses required. A pregnant woman is deemed fully protected against tetanus upon receipt of 6 doses of a tetanus-containing vaccine, with the last dose being received in the adolescent period.

The following scenarios are used to determine the number of doses of tetanus-containing vaccines to be administered to pregnant women when they visit the health facility.

If a pregnant woman visits the health facility for the first time and this is NOT her first pregnancy her vaccination status must be reviewed against the schedule to ensure that she has been appropriately vaccinated. Efforts are usually made by health workers to complete vaccination schedules post-pregnancy.

If a pregnant woman received:

No TTCV doses or has unknown vaccination status	she will need	a) 1 Td dose as early as possible b) 1 Td dose at least 4 weeks later c) 1 Td dose at least 6 months later d) 1 Td dose at least 1 year later e) 1 more Td dose at least 1 year later (to obtain long-term protection)
Only 3TTCV doses in childhood	she will need	a) 1 Td dose at the first ANC visit b) Another Td dose 4 weeks later (to be protected for that pregnancy) c) 1 more Td dose at least 1 year later (to obtain long-term protection)
4 TTCV doses in childhood	she will need	a) 1Td dose at that visit (to be protected for that pregnancy) b) 1 more Td dose at least 1 year later (to obtain long-term protection)
3 TTCV doses in childhood and 1Td or 1 DT dose later	she will need	a) 1Td dose at that visit (to be protected for that pregnancy) b) 1 more Td dose at least 1 year later (to obtain long-term protection)
4 TTCV doses in childhood and 1 Td dose later	she will need	a) 1Td dose at that contact (no further doses required)
4 TTCV doses and 2 Td boosters	she will need	No vaccination, the woman is fully protected

Annex 4.
How to implement the protection at birth (PAB) method in practice?

Introduction of the PAB method may require a modification of vaccination cards/home-based records, tally sheets, and immunization registers as well as an inclusion of this indicator in the HMIS at all levels, along with quality training and supervision of workers at immunization sites for it to be successful.

Mothers need to bring their ANC or maternal immunization card to facilitate the process, otherwise the health worker will have to rely on the mother's recall to assess the number of TTCV doses received in the past and their timing.

Materials required:

— revised child vaccination cards/home-based records with space to record PAB;

— revised immunization tally sheets that include a space for recording PAB status;

— revised immunization reporting forms adapted to include PAB totals;

— the PAB calculator (**Figure 1**), available from WHO, can facilitate the process for health workers when they assess infants until they are confident with the method;

— availability/retention of long lasting immunization cards for mothers and children to prevent the need to take and rely on mother's recall of TTCV doses (which can be difficult given other injections received by the mother during pregnancies or outside of pregnancies).

Method to assess PAB:

When mothers bring their children for their first vaccination[1] of Penta/DTP1:

1) If the mother has a card

a. Ask to see it and check the number of Td doses given during the last pregnancy and during previous pregnancies if indicated on the card (1 to 5 doses).

b. Note when the last Td dose was administered.

c. Tally PAB (birth protected against tetanus) if the mother has received:

— 2 properly spaced Td doses while pregnant with the child, OR

— 1 Td doses while pregnant with the child and 1 TT/Td doses at any time before the pregnancy in the past, OR

— NO dose of Td while pregnant with the child BUT 3 or more doses at any time during her reproductive years before that pregnancy.

— NO dose of Td while pregnant BUT 5 (if tetanus vaccination started during adolescence or adulthood) or 6 TTCV doses previously which provides long-term protection.

1 There are other contacts that can be used to assess PAB. Refer to **Table 8** for implementation options.

2) **If mother does not have a card ask her questions about her Td immunization history:**

   a. How many doses of Td did she receive while pregnant with the child? If she received 2 doses, the birth was protected (PAB).

   If she received one dose or no Td doses ask:

   b. Did she receive any doses of Td before this pregnancy? If yes, how many doses of Td did she receive while not pregnant during Td/TT SIAs (special event when all women of reproductive age, including pregnant and non-pregnant, received an injectable vaccine)?

   c. Did she have previous pregnancies? If yes, ask her the number of Td/TT doses she received during last 3 pregnancies.

Estimate if the infant was PAB based upon number of doses received and timing of last Td/TT doses and tally accordingly (PAB or not PAB) using criteria listed above.

How to introduce the PAB method at district and health facility level

— Start implementing the PAB method in 1–2 districts or in health centres with high coverage ANC1 (over 80%) to understand and optimize the process of implementing this new method. Training, vaccination cards/home-based records, recording and reporting forms are required.

— Prepare materials for training health staff to use the PAB method.

  — Adapt vaccination cards/home-based records, tally sheets, recording and reporting forms and make enough available for use during the training

  — Distribute the list of questions to ask mothers to each trainee. Adapt question to local context if needed.

— Prepare training agenda topics for each category of staff to be trained, district supervisors and health facility staff.

— Make sure health facilities use the recommended 5-dose Td schedule for maternal vaccination.

— Conduct practical training for supervisors, vaccinators, and other health facility staff with hands-on skills that are required, such as history taking, correctly assessing PAB, and correctly recording on the tally sheet, etc.

— Make sure district supervisors master the method, and can effectively detect and correct mistakes.

— After 2–3 months compare administrative maternal Td coverage rates and the coverage assessed by PAB method. Determine if you can extend the method nationally.

Example of reporting form for assessing protection at birth
(adapted from Ghana reporting form)

Section A: Health facility information

1. **Health Facility/District/Region:** _____
2. **Type of service:** a) Health facility ☐ b) Community outreach ☐
3. **Date of visit:** _____

Section B: Mother information

1. **Age of mother in years** _____
2. **Gravida** (total pregnancies so far) _____
3. **Parity** (total deliveries of number of children so far) _____
4. **Have you ever received any TTCV vaccination** (before or during last pregnancy)**?**
   - ☐ a) Yes
   - ☐ b) No If No, skip to question 9.
5. **If Yes in question 4, total number of TTCV vaccinations**
6. **Source of information:**
   - ☐ a) Maternal health record
   - ☐ b) History/recall (___)
7. **Did you receive TTCV vaccination in last pregnancy (this child)**
   - ☐ a) Yes
   - ☐ b) No If No, skip to question 9.
8. **If Yes in question 7, what is the total number of TTCV vaccinations received?** _____

Decision point (use NT protection calculator if available)

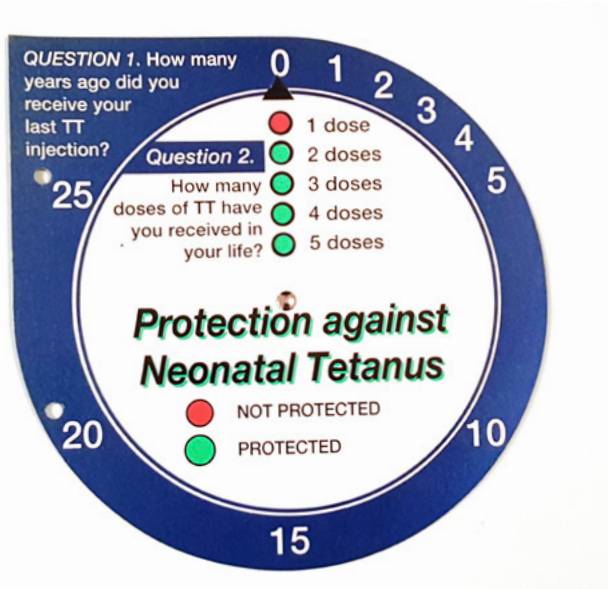
Was the child protected from tetanus at birth?

	Decision rule:
☐ a) Yes	If mother received 2 or more valid doses of TTCV – tick 'yes'
☐ b) No	If mother received less than 2 doses of TTCV – tick 'no'

An easy to use tool for assessing PAB can be developed and used at the health facility, like the NT protection calculator featured in **Figure 1**. It is used to assess PAB at the Penta1/DTP1 contact as indicated in the instructions below.

Figure 1

NT protection calculator



Instructions for use of NT protection calculator:

Question 1: Ask the mother how many years ago she received her last dose of TTCV vaccine. Check her vaccination card if available. Rotate the disk until it points to the indicated number of years. If the answer is less than one year, assume one year.

Question 2: Ask the mother how many doses of TTCV vaccine she has received in her life. Check her vaccination card if available. Look at the colour in the window corresponding to the number of doses received.

Answer: If the colour in the window is green, the child was protected at birth by maternal antibodies. If the colour in the window is red, the child was not protected by maternal antibodies at birth, but may have been protected by clean birth practices. If the mother is eligible for TTCV vaccination, vaccinate her.

Annex 5.
Example of national tally sheet for TTCV2+ (or Td2+) for pregnant women

Proper recording of TTCV2+ coverage in pregnant women is important for NT prevention and should be emphasized to health workers. When assessing vaccination status, health workers must check whether a pregnant woman was fully vaccinated **prior** to pregnancy and vaccinate her if needed. Such monitoring of TTCV vaccination status prevents the unnecessary vaccinations of pregnant women. The example below is a national aggregate tally sheet for TTCV2+vaccination coverage in pregnant women, and can be adapted to the specific country context.

Region/ District	Target	Inade-quately vaccinat-ed	Fully vaccinated for this pregnancy				Fully vacci-nated prior to the preg-nancy	Total TTCV2+ g=b+c+d+e+f	%TTCV2+ coverage for pregnant women = g/target x 100
		a (1st dose)	b (2nd dose)	c (3rd dose)	d (4th dose)	e (5th dose)	f		
Region/ District 1									
Region/ District 2									
Region/ District 3									
Region/ District 4									
Region/ District 5									
Region/ District 6									
Region/ District 7									
Region/ District 8									
Region/ District 9									
Region/ District 10									
Region/ District 11									
Region/ District 12									
Region/ District 13									
Private Sector									
Total									

Annex 6.
Five moments for hand hygiene

Hand hygiene is the primary measure to reduce infections. Cleaning hands at the right times and in the right way makes most health care-associated infections preventable. In 2009, WHO developed guidelines for hand hygiene in health care which provides a thorough review of the evidence on hand hygiene in health care and specific recommendations to improve practices and reduce transmission of pathogenic microorganisms to patients and health care workers. These guidelines are complemented with a guide for implementation and an implementation toolkit which contain many ready-to-use and field-tested practical tools (see http://www.who.int/gpsc/5may/tools/en/).

The approach 'My 5 Moments of Hand Hygiene' explains five situations when cleaning the hands properly is recommended.

	When?	Why?
1 **Before touching a patient**	Clean your hands before touching a patient when approaching him/her.	To protect the patient against harmful germs carried on your hands.
2 **Before clean/ aseptic procedure**	Clean your hands immediately before performing a clean/ aseptic procedure.	To protect the patient against harmful germs, including the patient's own, from entering his/her body.
3 **After body fluid exposure risk**	Clean your hands immediately after an exposure risk to body fluids (and after glove removal).	To protect yourself and the health-care environment from harmful patient germs.
4 **After touching a patient**	Clean your hands after touching a patient and her/his immediate surroundings, when leaving the patient's side.	To protect yourself and the health-care environment from harmful patient germs.
5 **After touching patient surroundings**	Clean your hands after touching any object or furniture in the patient's immediate surroundings, when leaving – even if the patient has not been touched.	To protect yourself and the health-care environment from harmful patient germs.

Annex 7.
WHO Recommended Surveillance Standards for Neonatal Tetanus (NT)[1]

Effective NT surveillance is a key component of the MNTE strategy.

Rationale and objectives of surveillance

Every NT case is an event that marks the failure of multiple levels of the health system. The key objective of NT surveillance is to detect cases of NT towards monitoring achievement and maintenance of MNTE, defined as less than one NT case per 1 000 live births annually in every district. NT surveillance data (or a lack thereof) are used to identify areas and subpopulations at high-risk for NT and guide effective public health response for MNTE. High-quality surveillance data and other key programme indicators should be used at the national and subnational (district) levels to monitor the impact of interventions and achievement and maintenance of MNTE.

Type of surveillance recommended

The minimal recommended standard for NT surveillance is nationwide, case-based surveillance, meaning that every suspected NT case should be investigated and classified as confirmed or discarded. NT surveillance is population-based and includes all neonates aged 0–28 days. Laboratory confirmation is not an aspect of NT surveillance, as the basis of tetanus diagnosis is clinical rather than laboratory-based.

Case detection

— **Facility-based.** Conduct facility-based surveillance by sensitizing surveillance focal points and key clinical staff (such as paediatric ward and special care nursery staff) at designated reporting sites to immediately report every suspected NT case to the designated surveillance staff. The network of reporting sites should include both public and private facilities.

— **Passive surveillance.** Report the number of suspected NT cases seen at designated reporting sites at a specified frequency (weekly or monthly) to the next higher level, even if there are zero cases (referred to as "zero reporting"). Health facility reports should be regularly monitored and verified by surveillance staff.

— **Active surveillance.** Make regular visits to reporting sites that are most likely to admit NT patients (weekly at major health facilities), or as part of active search for acute flaccid paralysis (AFP) and measles-rubella. During visits, review facility registers for unreported NT cases and ask key clinical staff whether any new NT case has been identified since the previous visit. At a minimum, every facility should review registers for NT cases annually. Active surveillance can also be conducted in the community during outreach visits, SIAs or case investigations.

— **Community-based surveillance**. Community-based surveillance should be done in high-risk areas through a network of traditional birth attendants, community leaders, traditional healers or other community members that are sensitized to report suspected NT cases and deaths to health authorities. In these cases, lay case definitions may be used in order to ensure that all suspected NT cases and deaths are detected and reported.

1 Excerpt from Neonatal tetanus surveillance standards (2018) available at: http://www.who.int/immunization/monitoring_surveillance/burden/vpd/WHO_SurveillanceVaccinePreventable_14_NeonatalTetanus_R1.pdf.

Linkages to other surveillance

Ideally, NT surveillance is linked with active surveillance for AFP and measles-rubella and routine aggregate surveillance for zero reporting as part of the Integrated Disease Surveillance and Response (IDSR). Linkage to vital events surveillance and neonatal death surveillance may be useful for increasing NT surveillance sensitivity and helping to conserve resources.

Case definitions and final classification

All suspected NT cases should be investigated. The basis for case classification is entirely clinical and does not depend on laboratory confirmation.

Suspected NT case		
A case that meets either of the following two criteria: • any neonate who could suck and cry normally during the first two days of life and developed tetanus-like illness or death between 3 and 28 days of age; OR • any neonate who died of an unknown cause during the first month of life.		
Final case classification		
Confirmed	**Discarded**	**Not investigated**
Any suspected NT case found to have all three of the following: — normal ability to suck and cry during the first two days of life; AND — could not suck normally between 3 and 28 days of age; AND — developed muscle stiffness and/or spasms (jerking).	The suspected NT case that has been investigated and does not satisfy the clinical criteria for confirmation or has an alternate diagnosis.	Any suspected NT case not investigated or without information available on age and symptoms to confirm the case.

Case investigation

— Ideally, every NT case should be investigated. However, before achieving MNTE, the emphasis should be on implementing SIAs and community interventions to reduce NT burden in known high-risk areas.

— Once MNTE has been achieved, each suspected NT case or death should be investigated by trained staff to confirm or discard the case, ideally within seven days of notification. The sooner the mother and persons who attended the birth are visited, the more likely they are to be available and remember relevant details.

— All reported cases or deaths should be investigated using a standard case investigation form to confirm the NT diagnosis based on case history and symptoms. The investigation should determine why the infant contracted tetanus, such as lack of maternal vaccination, birth unattended or attended by unskilled staff, use of unhygienic cutting tools or application of substances to the umbilical stump. A simplified algorithm can be used to determine if the mother and infant were

protected at birth (PAB) against tetanus, based on maternal vaccination history (see **Box 1** below).

— As NT diagnosis is entirely clinical, misdiagnosis can occur due to lack of training or lack of exposure to NT cases in low-incidence settings. Misdiagnosed cases of NT are most commonly meningitis, sepsis (including umbilical sepsis) or birth defects. Trismus (lockjaw) is absent in these illnesses. In addition, there is no bulging of the fontanelle in NT. During tetanus spasms, the child is conscious, and the spasm is often brought on by stimuli such as light and sound, unlike other convulsions from other causes such as high fever where the child is unconscious. In addition to clinical presentation, details from the case investigation (such as lack of maternal vaccination, unskilled birth attendant or application of unhygienic substances to the cord) may support the NT diagnosis.

Ensure that the filled case investigation form details the findings and actions taken or recommended, and is sent to the next level. Also give written feedback to the reporting facility and community.

Box 1

Simplified protection at birth (PAB) method

During case investigations, surveillance staff can use a simplified PAB method to determine whether a birth is protected against tetanus based on written maternal immunization records and questioning the mother about the number TTCV doses she received during the last pregnancy and the number of doses she received during school-age, previous pregnancies, or campaigns/outreach occurring any time before the last pregnancy. A birth is protected if the mother received:

— two TTCV doses while pregnant with the last child (with second dose delivered at least two weeks before birth);
OR

— one TTCV dose while pregnant with the last child (delivered at least two weeks before birth) and one or more doses at any time before that pregnancy;
OR

— no dose while pregnant with the last child and three or more adolescent/adult doses at any time before that pregnancy.

Public health response

— The mother of the suspected NT case and any other unprotected woman of reproductive age in the community should receive TTCV as indicated (two doses separated by four weeks) to protect her and infants during future births. If possible, the mother should be provided a TTCV dose before leaving the hospital, as part of outreach vaccination organized in conjunction with case investigation, or within six months of confirming the NT case.

— Identification of a confirmed NT case may indicate a more systematic problem. A rapid community assessment should be conducted to determine the need for interventions.

- Starting from the house where the confirmed NT case occurred, move house to house to interview 10–15 other mothers of the community who delivered in the last two years about their vaccination status, delivery place and attendant, application of substances to the umbilical cord, and the survival and vaccination status of their last born child.
- If at least 80% of mothers are protected (either through clean birth, including delivery by a skilled birth attendant and hygienic cord practices, or PAB status), the response can be limited to vaccination of the mother of the NT case and promotion of hygienic cord care practices.
- If less than 80% of mothers are protected, determine the cause of non-protection and formulate an appropriate intervention. If less than 80% of mothers are protected through vaccination, assure that this community is added to the microplan for routine vaccination sessions, including outreach sessions that should include vaccination of pregnant women with TTCV. Make a return visit with a basket of interventions, including providing TTCV to pregnant women.
- If less than 90% of last-born children received DTP3, strengthen routine immunization services in the area (e.g. incorporate community in outreach microplans, reduce missed opportunities at outreach sessions, ensure vaccination at antenatal care visits and sick child visits).
- Complete corrective actions based on the factors that placed the infant at risk for NT. Corrective actions may include maternal vaccination, education on correct delivery or cord care practices and better coordination with maternal and child health services.

Specimen collection

No specimens are collected for NT cases, as there is no laboratory diagnosis of NT.

Laboratory

Tetanus diagnosis is entirely based on clinical features and does not depend on laboratory confirmation. *C. tetani* is recovered from microbiologic culture of wounds in only about 30% of cases, and the organism is sometimes isolated from patients who do not have tetanus. As non-toxigenic strains of *C. tetani* also exist, definitive laboratory diagnosis is not currently possible.

Data collection, reporting and use

Recommended data elements

(* designated core variable required to be completed as part of an adequate case investigation)

Case notification

— Name (if confidentiality is a concern the name can be omitted so long as a unique identifier exists)*

— Unique case identifier

— Date of notification*

— Source of notification (health facility location, name of person)

— Date of case investigation*

Geographic information

- Place of residence (city, district, and province)
- Reporting health facility

Demographics

- Date of birth*
- Sex*

Clinical

- Age of baby in days at onset of symptoms
- Date of onset (date of onset of lockjaw/inability to suck)*
- Date of hospitalization
- Signs and symptoms, including at minimum:
  - Ability to suck and cry during the first 2 days of life*
  - Between 3 and 28 days of age, cannot suck normally*
  - Muscle stiffness and/or spasms (jerking)*

Neonatal outcome

- Final outcome of child's illness: alive, dead, unknown*
- Final classification: confirmed, discarded, not investigated, unknown
- Date of discharge/death

Maternal and perinatal risk factors

- Age of mother
- Ethnic group
- Migrant status
  (mother's length of residency in locality where delivery took place)
- Number of live births delivered (including this most recent one) by the mother
- Number of previous births with similar symptoms and whether child(ren) survived
- Number of antenatal care (ANC) contacts the mother had with a trained healthcare worker during this last pregnancy
- Location of ANC (for follow-up regarding missed vaccination opportunity)
- PAB status of last birth (see **Box 1**)*
- Place of birth: hospital, health centre, home, other, or unknown*
- Assistance during childbirth: health staff (skilled birth attendant), traditional birth attendant, family member/alone, other, or unknown*
  - If not health staff, ask if clean surface and hands were used for delivery
- Tool(s) used to cut umbilical cord and sterilization of tool (cleaned and boiled)*
- Substance put on umbilical cord*
- Maternal outcome (dead, alive; cause of death)

Public health response

- Mother given TTCV (such as Td) dose(s) at the time of case detection/investigation, or as soon as possible afterwards (yes, no, not needed/already protected, unknown/unavailable)
  - If given protective dose, record date that TTCV dose was given

Reporting recommendations and requirements

The number of NT cases should be reported separately from non-NT cases by designated reporting sites weekly, monthly or at another specified frequency, even if there are zero cases (zero reporting). Copies of case investigation forms or electronic data from these forms should be forwarded to the national level.

Cases of NT (0–28 days of age) should be reported annually to WHO-UNICEF, and separately from non-NT (>28 days of age), through the WHO/UNICEF Joint Reporting Form available online at http://www.who.int/immunization/monitoring_surveillance/routine/reporting/en/. Reporting of NT is not required by International Health Regulations (IHR).

Recommended data analyses

— Number and incidence of confirmed NT cases per 1 000 live births, by month, year, sex, and district

— Percentage of confirmed NT cases that were PAB by maternal vaccination (see **Box 1**)

— Percentage of confirmed NT cases whose mother received ANC, and among those who received ANC, those not vaccinated (for analysis of missed opportunities)

— Percentage distribution of confirmed NT cases by

- Place of birth (health facility or home delivery)
- Type of birth assistance
- Type of cord-cutting tools used
- Type of umbilical cord dressing used
- Mother's age
- Mother's parity (first birth vs. multiple births)

— Distribution of outcomes (death, left against medical advice, survived, unknown) among confirmed NT cases

— Percentage of confirmed NT cases whose mother received a TTCV dose(s) after the NT case occurred, as a result of the case detection/investigation or soon after

— Percentage of neonatal deaths attributable to NT (if part of neonatal death surveillance)

— Risk assessments (see section *Using data for decision-making* below)

As with other diseases, surveillance data should be triangulated with data from the immunization programme, such as vaccination coverage, history of SIAs, ANC coverage, and skilled birth attendance (SBA) coverage to understand the entire picture of the disease when formulating conclusions and new policies or strategies.

Using data for decision-making

— Monitor achievement and maintenance of MNTE (<1 NT case per 1 000 live births in every district) and document evidence towards validation and /or sustainability of elimination.

— Input data such as NT rates, TT protection, ANC and SBA coverage into annual risk assessments to identify high-risk geographical areas for targeting improvements in antenatal, obstetric, and vaccination services and conducting targeted SIAs for women of reproductive age.

— Identify with results of case investigations NT risk factors such as place/type of delivery, cord care, age and parity of mother, migrant status and ethnicity, in order to design appropriate messaging and interventions.

— Monitor impact of interventions, including SIAs.

— Identify missed opportunities for maternal immunization with TTCV, such as ANC visits, child visits and outreach vaccination sites.

— Document evidence needed for immunization policy or strategy change (for example, introduction of WHO-recommended booster doses and school-based immunization if first-time mothers are not being reached with vaccination at ANC visits).

— Rapidly identify cases for appropriate case management (refer NT cases for medical care and provide TTCV dose to mother).

— Monitor surveillance performance indicators and identify areas that need targeted surveillance reviews or strengthening (this may be needed when surveillance data appears unreliable when compared with NT risk).

Surveillance performance indicators

— Evaluate NT surveillance through periodic national reviews approximately every five years, integrating with other VPDs and including triangulation of aggregate and case-based NT reports as well as a review of facility records for missed cases.

— Conduct retrospective review of facility registers in hospitals and large health clinics at least annually to identify previously unreported NT cases alongside other VPDs and other diseases.

— As part of the quarterly EPI data review meetings, review surveillance, coverage, and programme performance data at national and subnational level to help identify potential areas where surveillance gaps might exist or surveillance needs to be strengthened.

— At least annually, review the indicators listed in **Table 1**.

Table 1
Neonatal tetanus surveillance performance indicators

Surveillance indicator	Description	Target	Formula	Notes
Completeness of reporting	Percentage of designated sites reporting NT data, even in the absence of cases (zero reporting)	≥ 90%	# sites reporting NT/# designated reporting sites for NT surveillance x 100 (for given time period)	
Timeliness of reporting	Percentage of designated sites reporting NT data on time, even in the absence of cases (zero reporting)	≥ 80%	# of surveillance units in the country reporting by the deadline/ # of designated reporting sites for NT surveillance x 100	At each level reports should be received on or before the requested date.
Completeness of investigation	Proportion of neonatal tetanus suspected cases that have been investigated (only among cases reported from health facilities)	≥ 90%	# of NT case investigations/ # of suspected NT cases reported x 100	If case-based database only includes data on case investigations performed, this indicator can be calculated as: # suspected cases in the case-based dataset/# suspected cases in the aggregate report x 100 This indicator will reflect the representativeness of case-based surveillance and efficiency of case investigations.
Timeliness of investigation	Percentage of all suspected cases investigated within 7 days of notification	≥ 80%	# suspected NT cases investigated within 7 days of notification/ # suspected NT cases investigated x 100	
Adequacy of investigation	Percentage of investigated suspect cases with complete information for all core variables	≥ 80%	# of suspected NT cases for which an adequate investigation was completed with collection of 12 core variables/ # of suspected NT cases investigated x 100	1) The core variables are: case identification, date of birth, sex, place of usual residence, date of illness onset, date of notification, date of investigation, symptoms in case definition, outcome (alive/dead), maternal vaccination history, place/type of delivery, tool for cutting cord, and material applied to cord. 2) For any case, if information on any of the core variables is missing, the investigation will be considered inadequate.
Achievement and maintenance of MNTE	Percentage of districts with <1 NT case per 1 000 live births	100%	# districts with <1 NT case per 1,000 live births/ total # districts x 100	Ideally, this indicator should be calculated using confirmed NT cases. If the completeness of investigating suspect cases is <90%, the indicator can be calculated using suspect cases to highlight districts needing targeted interventions and programme strengthening.
Adequate case response	Percentage of confirmed NT cases for which the mother received a TTCV dose in conjunction with case detection or investigation	100%	# of mothers of NT cases that received a TTCV dose in conjunction with case detection or investigation/total # of NT case investigations x 100	

Contact tracing and management

As tetanus is not contagious, no contact tracing is needed.

Surveillance, investigation and response during outbreaks

Tetanus is not considered an outbreak-prone disease. In general, NT outbreaks do not occur, but clusters linked to a single source of substandard clinical care have been observed. For disease clusters occurring in countries where MNTE has already been achieved, every case should still be investigated and there should be no change in the surveillance process. Before achieving MNTE, disease clusters should be investigated to determine risk factors, but the primary emphasis should be on implementing SIAs in known high-risk areas to reduce NT burden.

Special considerations in surveillance of neonatal tetanus

— **Risk assessments.** NT risk assessments are used to identify high-risk areas for targeted SIAs, programme improvement, and field evaluation during MNTE validation. For countries yet to achieve MNTE, NT risk assessments should be performed at least every one to three years, triangulating district-level data on NT cases and rates, skilled birth attendance (SBA), TT/PAB coverage from routine and SIAs, and other proxy indicators. For countries that have already achieved MNTE, regular risk assessments using the same inputs should be done (Annex 11).

— **Ethical and equity issues.** Discussion of neonatal deaths may be a sensitive topic, especially among some cultures and ethnic groups. NT may occur most frequently among marginalized groups missed by the immunization programme, such as migrants, the homeless and residents in urban slums, who may be sensitive to questioning by outside government officials. Use guidance from local health staff on how best to address these challenges.

— **Neonatal death surveys.** The relative contribution of NT to neonatal mortality can be assessed through audits of neonatal deaths at health facilities or in community settings, as described in the document called *Making every baby count: audit and review of stillbirths and neonatal deaths*[1] and implemented in some countries as part of the Every Newborn Action Plan. In some countries, activities in sentinel communities may approach or achieve real-time reporting of neonatal deaths and attempts should be made to link NT case detection to investigation through case-based surveillance. Of note, neonatal mortality cluster surveys (with verbal autopsies) are also conducted in the districts determined to be of highest risk for NT during MNTE validation exercises.[2]

— **Serological surveys or serosurveillance.** Where feasible, serosurveys of tetanus IgG among adult women should be considered as a complementary tool for monitoring MNT risk and guiding vaccination strategies. Because immunity does not result from natural infection, tetanus seroprotection reflects population immunity from vaccination. Close attention should be paid to the survey objective, sampling strategies and laboratory methods to ensure that results are valid and interpretable. Serosurveillance should not replace NT surveillance.

1 WHO (2016). Making every baby count: audit and review of stillbirths and neonatal deaths. Geneva: World Health Organization (http://apps.who.int/iris/bitstream/10665/249523/1/9789241511223-eng.pdf, accessed 22 November 2018).

2 WHO, UNICEF. Pre-validation assessment guidelines [for maternal and neonatal tetanus elimination]. Geneva: World Health Organization; 2013 draft. Available upon request from the World Health Organization.

Annex 8.
WHO Recommended Surveillance Standards for Non-NT[1]

Rationale and objectives of surveillance

The need for improved tetanus surveillance is underscored by the absence of reliable global estimates of non-NT cases and deaths, including maternal tetanus (see **Box 1**). A key objective of surveillance for non-NT is to monitor disease burden and changing epidemiology over time in order to assess the impact of vaccination and to identify gaps in the immunization programme. This information should be used to inform targeted strengthening of routine immunization services and optimize strategies and immunization schedules, including introduction and timing of booster doses. Another key objective is detecting and investigating unusual disease clusters. Finally, rapid detection of cases can help save lives and allow for proper treatment, including antitoxin, to begin.

Box 1

Maternal tetanus

Maternal tetanus is defined as tetanus occurring during pregnancy or within 6 weeks after pregnancy ends (with birth, miscarriage or abortion) and has the same risk factors and means of prevention as neonatal tetanus. For this reason, NT elimination (<1 case per 1 000 live births) is considered a proxy for maternal tetanus elimination.

If country programmes decide that maternal tetanus is of special priority, reports of maternal tetanus could be handled similar to reports of neonatal tetanus, including case investigation, rapid community assessments and public health response (see **Annex 7**). When feasible, serosurveys of tetanus immunity among women of reproductive age can be a complementary tool for monitoring MNT risk and guiding vaccination strategies (see **Annex 10**).

Type of surveillance recommended

The minimal recommended standard for non-NT surveillance is nationwide, aggregate surveillance with routine reporting from inpatient facilities and investigation of any unusual disease clusters. Non-NT surveillance is population-based and includes all persons ≥28 days of age. Laboratory confirmation is not an aspect of non-NT surveillance, as the basis of tetanus diagnosis is clinical rather than laboratory-based.

Enhanced surveillance for non-NT consists of case-based surveillance to aid understanding the epidemiology of the disease and causes of infection and to allow monitoring of treatment practices and disease outcomes. Either nationwide or sentinel surveillance would be advised, depending on the burden of disease, health-seeking behaviours and resources available in the country (sentinel surveillance requires fewer resources).

1 Excerpt from Non-neonatal tetanus surveillance standards (2018) available at: http://www.who.int/immunization/monitoring_surveillance/burden/vpd/WHO_SurveillanceVaccinePreventable_15_Non_neoTetanus_R1.pdf.

Case detection

— Establish a formal surveillance network of inpatient facilities designated for non-NT reporting and sensitize surveillance focal points and key clinical staff (such as ICU staff) to recognize and report non-NT cases per national guidelines.

— Report the aggregate number of inpatients with a final diagnosis of non-NT at designated reporting sites at a specified frequency (weekly or monthly), even if there are zero cases (referred to as zero reporting). Health facility reports should be regularly monitored and verified by surveillance staff. Unusually high numbers reported in a given month may represent a data entry error that needs to be corrected, or a disease cluster that needs investigation.

— For countries deciding to establish case-based surveillance for non-NT, public and private referral hospitals with intensive care capacity located in areas with high non-NT burden should be prioritized as sentinel sites to capture the majority of non-NT cases. Later, surveillance can be expanded to include additional sites that represent a larger extent of the population.

Linkages to other surveillance

Ideally, non-NT surveillance is linked with aggregate surveillance systems for other diseases through systems such as IDSR and EWARN. In some cases, HMIS reporting may be used for facility-based aggregate reporting of non-NT cases. Linkage to maternal death surveillance and response (MDSR) and other maternal child health post-partum surveillance systems may be relevant in some countries.

Suspected non-NT case		
Any person >28 days of age with acute onset of at least one of the following: - trismus (lockjaw) - risus sardonicus (sustained spasm of the facial muscles) - generalized muscle spasms (contractions).		
Final case classification		
Confirmed	**Probable**	**Discarded**
A suspected non-NT case clinically confirmed as tetanus by a physician/ trained clinician.	A suspected non-NT case **without** clinical confirmation by a physician/trained clinician.	A case that has been investigated and does not satisfy the clinical criteria for confirmation or has an alternate diagnosis.

Note: The basis for case classification is entirely clinical and does not depend on laboratory confirmation. In low incidence settings, many clinicians may have never seen a tetanus case, making clinical diagnosis more challenging. During tetanus spasms, the patient is usually conscious, and the spasm is often brought on by stimuli such as light and sound, unlike other convulsions where the patient may be unconscious. Although tetanus diagnosis usually includes a history of injury or wound, tetanus may also occur in patients who are unable to recall a specific wound or injury. The most common differential diagnoses for tetanus are hypocalcemic tetany, drug-induced dystonias (from drugs such as phenothiazines), meningoencephalitis, strychnine poisoning, and trismus due to dental infections.

Case investigation

In countries conducting aggregate surveillance, information should be collected at designated health facilities from inpatient records for cases with a final diagnosis of non-NT, and reported to the next higher level based on national surveillance guidelines. No further investigation is needed except in the case of unusual disease clusters.

In countries conducting case-based surveillance, each suspected tetanus case should be investigated using a standard case investigation form, ideally within seven days of notification, to confirm the diagnosis and determine the cause of infection. Send filled case investigation forms detailing findings and actions taken or recommended to the next level and give written feedback to the reporting facility and community.

Tetanus immunoglobulin (TIG) or antitoxin tetanus serum (ATS) should be given immediately, even if investigation cannot be performed in a timely manner.

Specimen collection

No specimens are collected for non-NT cases, as there is no laboratory diagnosis.

Laboratory

Same as for NT, non-NT diagnosis is entirely based on clinical features and does not depend on laboratory confirmation.

Data collection, reporting and use

Recommended data elements

Aggregate surveillance

— Age group (optimal for tetanus epidemiology are 29 days–4 years, 5–14, 15–44, 45–64 and 65+ years, but can be aligned with needs of integrated surveillance system)
— Sex
— Month
— Geographical area
— Immunization status (if possible)

Case-based surveillance

— Case notification
  - Name (if confidentiality is a concern the name can be omitted so long as unique identifier exists.
  - Unique case identifier (such as EPID number)
  - Date of notification
  - Source of notification (health facility location, name of person)
  - Date of case investigation

Demographics

— Sex
— Date of birth (or age if date of birth not available)
— Race/ethnicity (if relevant)
— Migrant status
— Educational status
— Place of residence (city, district, province)

Clinical

— Date of onset
— Date of hospitalizations
— Signs and symptoms (at a minimum)
  - Trismus
  - Risus sardonicus
  - Muscle spasms

Vaccination status

— Number of tetanus vaccine doses (preferably by documentation, by recall if documentation not available)
— Date of vaccine doses, especially the last dose
— Receipt of tetanus conjugate vaccines (such as Hib, MenA, MenC, Pneumo, Typhoid, depending on formulation)

Risk factors

— Occupation
— History of wound or injury (including chigger/jigger infestation and intravenous drug use)
— History of surgery or medical procedure (e.g. male circumcision)
— History of dental or ear infection
— Maternal tetanus
  - Current or recent pregnancies (within the last 6 weeks)
  - Number of antenatal care (ANC) contacts during pregnancy
  - Pregnancy outcome (live birth/healthy child, live birth/NT case, still birth, miscarriage, or abortion)
  - Information on birth/pregnancy termination (date, location, who attended, clean surface/hands/tools)
  - Parity
— Application of unhygienic substances to wounds

Treatment

— Tetanus immunoglobulin (TIG), antitoxin tetanus serum (ATS), intravenous immune globulin (IVIG) given
  - Date of administration
— Antibiotics given (type)
  - Date of administration (starting date)

Outcome

— Outcome (patient survived, died, unknown)
— Final classification (confirmed, probable, discarded)
— Date of discharge/death

Reporting recommendations and requirements

The number of non-NT cases should be reported separately from NT cases by designated reporting sites weekly, monthly or at another specified frequency, even if there are zero cases (zero reporting). Case investigation forms or electronic data from these forms should be forwarded to the national level.

For the purpose of case counts, tally only confirmed inpatient cases for national reporting because non-NT is managed on an inpatient basis. Including outpatients would likely result in overestimation because of problems like misdiagnosis, reporting errors from smaller facilities or double-counting of outpatients referred for inpatient admission.

Cases of non-NT should be reported annually to WHO-UNICEF and separately from NT, through the JRF (http://www.who.int/immunization/monitoring_surveillance/routine/reporting/en/). Reporting of NT is not required by International Health Regulations (IHR).

Recommended data analyses are:

— number of non-NT cases and incidence rates by month, year and geographical area;

— incidence rates by sex and age group (29 days–4 years, 5–14, 15–44, 45–64, and 65+ years);

— trends in the sex ratio of non-NT cases over time;

— proportion of cases protected against tetanus (see **Table 1**);

— proportion of cases by risk factor;

— proportion of cases receiving TIG/ATS/IVIG;

— case-fatality ratio (number of non-NT deaths / number of non-NT cases x 100);

— proportion of maternal tetanus cases.

As with other diseases, surveillance data should be triangulated with data from the immunization programme, such as coverage and historic vaccination schedules, to understand the entire picture of the disease when formulating conclusions and new policy.

Table 1
Expected duration of protection provided by valid tetanus toxoid containing vaccine (TTCV) doses

(A valid dose is defined as a dose administered after the minimum time interval required. TTCV doses received by adolescents and adults during childhood are only included if verified by reviewing written records such as infant or school vaccination records).

Cumulative no. of TTCV doses if vaccination began in infancy	Cumulative no. of TTCV doses if vaccination begun >1 year of age	Minimum interval between doses to be considered valid	Duration of protection from receipt of last dose
TTCV1	TTCV1	—	None
TTCV2/TTCV3	TTCV2	4 weeks	3 years
TTCV4	TTCV3	6 months	5 years
TTCV5	TTCV4	1 year	10 years
TTCV6	TTCV5	1 year	20–30 years

Using data for decision making

— Monitor disease burden and impact of vaccination, including TTCV campaigns targeting women of reproductive age or wide-age range campaigns for both sexes with TT-conjugate vaccines such as MenA.

— Identify and investigate non-NT disease clusters to determine risk factors and appropriately design risk mitigation strategies such as provision of vaccine and improved hygiene practices.

— Identify gaps in the immunization programme (areas with low coverage, cold chain issues resulting in frozen TTCV, etc.) to inform targeted strengthening of routine immunization services or need for catch-up vaccination.

— Identify groups at higher risk for tetanus infection (women of reproductive age, school-age children, male adults, elderly) to inform changes in policy or strategy such as introduction of booster doses or optimization of schedule.

— Monitor maternal tetanus to strengthen MNTE strategies and reduce missed opportunities for vaccination such as ANC, sick visits, and outreach.

— Periodically assess tetanus risk factors (occupation, road accidents, unclean deliveries/surgeries, migrant status, ethnicity) to appropriately design and implement messaging and interventions.

— Rapidly identify cases for appropriate case management, including provision of TIG/ATS/IVIG.

— Monitor surveillance reporting to identify areas that need targeted surveillance reviews or strengthening, where surveillance data appear unreliable.

Surveillance performance indicators

Evaluate non-NT surveillance through periodic national reviews approximately every five years, integrating with other VPDs and including triangulation of aggregate and case-based NT reports as well as a review of facility records for missed cases. Targeted subnational reviews and data quality assessments can be conducted more frequently. As part of the quarterly EPI data review meetings, review surveillance, coverage and programme performance data at national and subnational level to help identify potential areas where surveillance gaps might exist or surveillance needs to be strengthened. Regular monitoring of surveillance indicators could help identify specific areas of the surveillance system and reporting network that should be targeted for improvement (**Table 2**).

Contact tracing and management

As tetanus is not contagious, no contact tracing is needed.

Surveillance, investigation and response in outbreak settings

Definition of outbreak
For non-NT, traditional communicable disease outbreaks do not occur because there is no person-to-person transmission, but cases may cluster together in time and space as a result of the same environmental exposure. A specific threshold has not been defined for the number of non-NT cases that should trigger investigation, but any substantial increase compared with previous reporting from the same area within a comparable timeframe should be investigated. A cluster of non-NT cases could include those occurring within the same geographic and time proximity, or multiple cases determined to be linked to the same source or event. Clusters of non-NT cases have been documented after natural disasters (earthquakes, tsunamis, typhoons), after male circumcision and from injection drug use.

Changes to surveillance in an outbreak setting
Even in countries with aggregate surveillance, data should be regularly monitored to identify potential clusters of non-NT disease. Clusters should be followed up with investigation to determine if there is a common cause. If a cluster is identified, consider line listing of cases with a limited set of variables so that more detailed analysis of cases can be performed (by age, sex, vaccination status, risk factors, treatment, etc.). This information can be used to inform risk mitigation efforts, including provision of vaccine and promotion of improved hygiene practices, both for individuals and for healthcare settings.

Special aspects of investigation
If there is a non-NT cluster, it is important to identify environmental exposure risk factors (nosocomial, occupational, accident).

Table 2
Performance indicators for non-NT surveillance

Surveillance attribute	Indicator	Target	How to calculate (numerator/denominator)	Notes
Completeness of reporting	Percentage of designated reporting sites reporting non-NT data, even in the absence of cases	≥90%	# designated sites reporting non-NT / # designated reporting sites for non-NT surveillance x 100 (for given time period)	Designated reporting sites for non-NT surveillance might only include hospitals or referral hospitals, rather than all health facilities.
Timeliness of reporting	Percentage of designated sites reporting non-NT data on time	≥80%	# designated sites reporting non-NT on time / # designated reporting sites for non-NT surveillance x 100	At each level reports should be received on or before the requested date.
Completeness of investigation (case-based surveillance only)	Percentage of suspected non-NT cases that have been investigated, only among cases reported from health facilities included in case-based surveillance	≥90%	# of non-NT case investigations / # of suspected non-NT cases reported x 100	If case-based database only includes data on case investigations performed, this indicator can be calculated as: # suspected cases in the case-based dataset/# suspected cases in the aggregate report x 100 This indicator will reflect the representativeness of case-based surveillance and efficiency of case investigations.
Timeliness of investigation (case-based surveillance only)	Percentage of all suspected non-NT cases investigated within 7 days of notification	≥80%	# suspected non-NT cases investigated within 7 days of notification /# suspected non-NT cases investigated x 100	

Special considerations in surveillance for non-neonatal tetanus

— **Serological surveys or serosurveillance.** Serological assessments of tetanus IgG antibody levels in a survey setting may be useful for evaluating protection against tetanus. Because immunity does not result from natural infection, tetanus seroprotection reflects population immunity from vaccination. However, the role of serological investigations should always be complementary to surveillance and other assessment methods, and the survey objective and outcomes should be well defined (see **Annex 10**).

— I**mmunity gaps resulting from lack of booster doses.** Investigations have documented immunity gaps and higher burden of disease in school-aged children and adult men in countries not providing the WHO-recommended six TTCV doses to both sexes. All immunization programmes should review programme data and adjust routine immunization schedules to ensure tetanus protection over the life course (three primary doses in infancy and three booster doses in childhood/adolescence).[2]

— **Humanitarian emergencies.** Non-NT should be considered for inclusion in surveillance systems set up during humanitarian emergencies because of the documented outbreaks after earthquakes and tsunamis.[3]

2 Dalal S, Samuelson J, et al. (2016). Tetanus disease and deaths in men reveal need for vaccination. Bulletin of the World Health Organization. 94:613–21 (http://www.who.int/bulletin/volumes/94/8/15-166777/en/, accessed 22 November 2018).

3 WHO (2017). Vaccination in acute humanitarian emergencies: a framework for decision making. Geneva: World Health Organization (http://apps.who.int/iris/bitstream/10665/255575/1/WHO-IVB-17.03-eng.pdf, accessed 22 November 2018).

Annex 9.
Illustrative example of job aid on screening for vaccine eligibility

Example from *Establishing and strengthening immunization in the second year of life* guidance, available online at http://apps.who.int/iris/bitstream/handle/10665/260556/9789241513678-eng.pdf, adapted from Timor Leste and based on their vaccination schedule (up to 2 years of age). This example can be adapted to match local vaccination schedules.

WHICH VACCINES CAN BE GIVEN TODAY?

Use this chart to determine which vaccines should be given to a child at or after a specific age.

"It is better to vaccinate late than never!"

		WHEN TO GIVE	WHEN TO NOT GIVE
BIRTH	HepB BD, BCG	**HepB BD:** As soon as possible after birth, ideally **within 24 hours**, and up to 6 weeks **BCG:** As soon as possible after birth	**HepB BD:** Not after 6 weeks
6 WEEKS	OPV 1, PCV 1, Penta 1, RV 1	At **6 weeks** (or as soon as possible thereafter)	**RV1:** Not after 2 years of age
10 WEEKS	OPV 2, PCV 2, Penta 2, RV 2	At **10 weeks** (or as soon as possible thereafter), and at least 4 weeks after dose 1	Not before 4 weeks has passed since previous dose **RV2:** Not after 2 years of age
14 WEEKS	OPV 3, PCV 3, Penta 3, RV 3, IPV	At **14 weeks** (or as soon as possible thereafter), and at least 4 weeks after dose 2	Not before 4 weeks has passed since previous dose **RV3:** Not after 2 years of age
9 MONTHS	MCV 1	At **9 months** (or as soon as possible thereafter)	Not before 9 months of age (except where indicated)†
18 MONTHS	DTP4 (or Penta4), MCV 2, MenA	At **18 months** (or as soon as possible thereafter), and at least 4 weeks since previous dose	**MCV2:** Not before 4 weeks has passed since MCV1 **DTP4:** Not before 4 weeks has passed since Penta3 **MenA:** Not before 9 months of age (except where indicated)
2 YEARS			

Even if a long time has passed between doses, there is no need to restart the series from the beginning.
There is no upper age limit for most vaccines (except rotavirus <2yrs and hepatitis B birth dose <6 weeks)

Annex 10. Serosurveys[1]

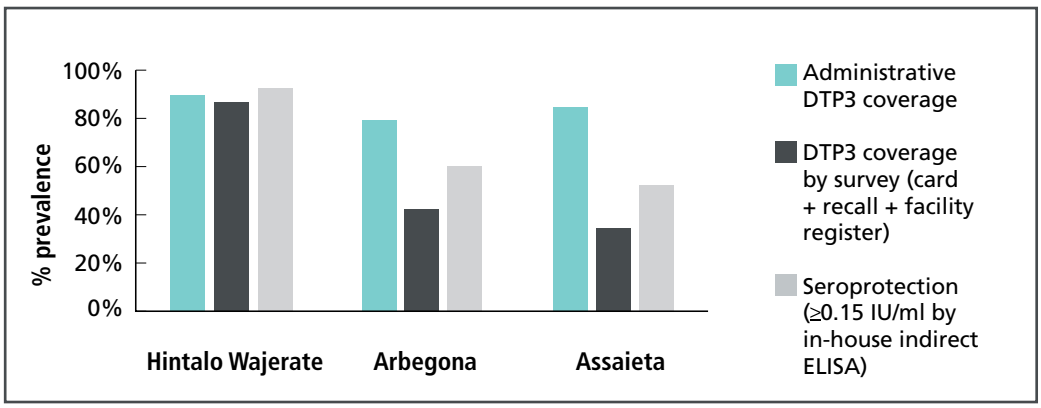
Background and rationale

Tetanus is not eradicable because tetanus spores persist in the environment. Continued high and uniform vaccination coverage is needed to protect the population. Tetanus immunity from infant vaccination wanes with age, so booster doses are given at optimal ages to provide continuous protection across the lifespan (at 12–23 months, 4–7 years, and 9–15 years). In countries where childhood booster doses are not provided and maternal and neonatal tetanus is a public health problem, five TTCV doses (preferably tetanus-diphtheria vaccine, or Td) are provided to women of reproductive age (WRA) through campaigns in high-risk areas and pregnant women through routine services. In some countries, the provision of tetanus-toxoid conjugate vaccines (such as Hib, meningococcal, pneumococcal and typhoid conjugate vaccines) may boost tetanus immunity, but these vaccines are not counted towards the TTCV doses required in the schedule.

Coverage with three doses of diphtheria, tetanus and pertussis containing vaccine (TTCV3) is a key performance indicator of the routine immunization system. However, countries may encounter challenges with monitoring TTCV3 coverage through administrative methods due to inaccurate recording and reporting of vaccination doses and outdated target populations, significant migration from rural areas or through surveys with limited documentation of vaccination history or other biases associated with the survey methods (see **Figure 1**).

Countries that have yet to introduce the recommended three TTCV booster doses beyond infancy may desire evidence to make the decision for introduction. Some countries have achieved or will achieve MNTE through TTCV campaigns without accompanying health systems improvements such as routine immunization, antenatal care (ANC) or obstetric care. Continued monitoring is needed to ensure that MNTE is sustained. Even in countries that include six TTCV doses in their vaccination schedules, evidence may be needed to optimize schedules and close immunity gaps.

Figure 1
Tetanus vaccination coverage and seroprotection among children 12–23 months in linked coverage and serosurveys in three districts in Ethiopia, 2013[2]



1 Excerpt from Tetanus Serosurveys (2018) available online at: http://www.who.int/immunization/monitoring_surveillance/burden/vpd/WHO_SurveillanceVaccinePreventable_25_Annex2_R1.pdf.
2 Travassos MA, et al. (2016). Immunization coverage surveys and linked biomarker serosurveys in three regions in Ethiopia. PLoS One. 11(3):e0149970 (https://doi.org/10.1371/journal.pone.0149970, accessed 15 January 2019).

In general, serosurveys provide objective biological measures for estimating population immunity and monitoring disease risk. Data from serosurveys are increasingly desired to guide policy and strategy, from supporting vaccine introduction to verifying disease elimination. Periodic cross-sectional serosurveys, or *serosurveillance*, can help document challenges with suboptimal programme implementation and changes in epidemiology resulting from accelerated disease control efforts. Routine serosurveillance programmes are most common in higher-income settings, such as Australia, the Netherlands and UK, but a case has been made for greater use of serological data for vaccination decision-making in lower and middle-income settings.

A limitation of serosurveys is that they cannot discriminate the number of vaccine doses received (for example, two or three doses) or the source of the immunizing event (natural infection for most diseases, routine vaccination or campaign vaccination). Unlike other vaccine-preventable diseases, a natural tetanus infection is not a source of immunity for tetanus, so immunity is an attractive biomarker of vaccination coverage.

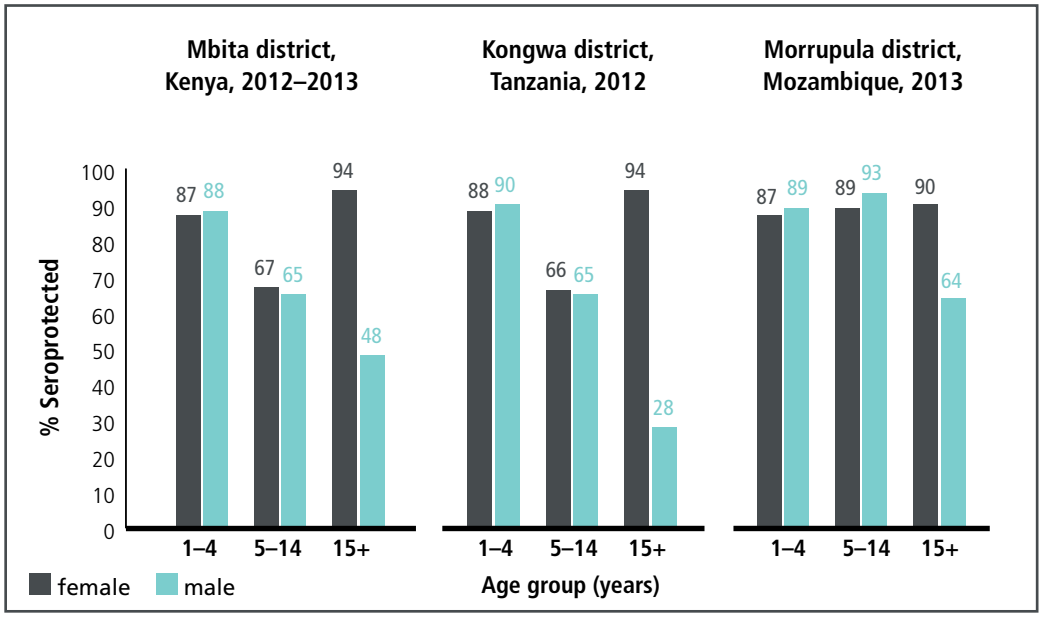
Tetanus serosurveys are helpful in assessing population immunity resulting from cumulative coverage from vaccine doses, vaccine effectiveness (for example, reduced effectiveness due to freezing TTCV) and waning immunity over time (see **Figure 2**). Assessment of tetanus vaccination history for older children and adults is particularly challenging due to missing documentation, inability to recall infant doses and other doses received, and doses from sources not recorded on cards (such as during campaigns or after injury). In fact, tetanus serosurveys among adult women have shown vaccination coverage to be underestimated compared with tetanus seroprotection (see **Table 1**).

As immunization programmes mature and increasing proportions of adult women receive protective TTCV doses during infancy, school, campaigns and other places outside antenatal care, the disparity between seroprotection and maternal vaccination coverage is expected to grow. Indicators for maternal vaccination coverage include a second or subsequent TTCV dose (TTCV2+) or protected at birth (PAB).[3] As part of broader tetanus prevention efforts, the Strategic Advisory Group of Experts (SAGE)[4] on Immunization recommended that, where feasible, tetanus serosurveys should be considered to validate assessments of disease risk identified by other data sources, and to guide vaccination strategies, especially in high-risk districts.

3 Protection at birth (PAB) is a supplementary method of determining tetanus vaccination coverage, particularly where TT2+ is unreliable. PAB can be routinely monitored by surveying maternal vaccination status during infant DTPCV1 visits, and can also be assessed during vaccination coverage surveys that ask about maternal vaccination status during the last pregnancy occurring with a specified time period (1, 2, or 5 prior years). PAB is defined as having received 2 TTCV doses during the last pregnancy, ≥2 total TTCV doses with the last dose ≥3 years prior to the last birth, ≥3 doses with the last dose ≥5 years prior, ≥4 doses with the last dose ≤10 years prior, or ≥5 prior doses. A simplified PAB definition has also been proposed as mothers who received: (i) 2 TTCV doses while pregnant with the last child (with second dose delivered at least 2 weeks before birth), or (ii) 1 TTCV dose while pregnant with the last child (delivered at least 2 weeks before birth) and 1 or more doses at any time before that pregnancy, or (iii) no dose while pregnant with the last child and 3 or more adolescent/adult doses at any time before that pregnancy.

4 WHO (2016). Meeting of the Strategic Advisory Group of Experts on immunization, October 2016 – conclusions and recommendations. Weekly Epidemiological Record. 90: 561–584 (http://apps.who.int/iris/bitstream/handle/10665/251810/WER9148.pdf, accessed 15 January 2019).

Figure 2
Tetanus seroprotection among individuals at district level in Kenya, Tanzania and Mozambique[5]



Seroprotection was defined as ≥0.01 IU/ml by a tetanus bead-based immunofluorescence assay. Immunity gaps in older children and adult males exist because of waning immunity and provision of booster doses only to women of reproductive age. Of the three countries, only Mozambique provides two TTCV boosters to both sexes in first and second grades.

Table 1
Summary of vaccination coverage and seroprotection results of nationally representative tetanus serosurveys among reproductive-age women

Survey	Population	PAB coverage	Seroprotection
Burundi, 1989	Women giving birth in past year	73%	67%*
Central African Republic, 1996	Women giving birth in past year	76%	89%**
Cambodia, 2012	Women aged 15–39 years	—	88%**
	Parous women aged 15–39 years	83%	97%**

PAB = protected at birth
* ≥0.01 IU/ml in competition ELISA
** ≥0.01 IU/ml in Double Antigen ELISA

5 Scobie HM, et al. (2017). Tetanus immunity gaps in children 5-14 years and men ≥15 years of age revealed by integrated disease serosurveillance in Kenya, Tanzania, and Mozambique. The American Journal of Tropical Medicine and Hygiene. 96(2):415-20 (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5303047/, accessed 15 January 2019).

Survey setting and population

Globally, surveillance for neonatal and non-neonatal tetanus has been documented to be suboptimal. Serosurveillance complements disease surveillance but does not replace it. Tetanus serologic data can provide helpful information for monitoring population immunity and disease risk. It should be considered, where feasible, to guide vaccination strategies. Tetanus serosurveys can be useful in settings where reported vaccination coverage is high or where vaccination coverage data is known to be unreliable and independent verification of population immunity is desired. However, serosurveys are resource-intensive and not recommended for every country.

Across a broad age range, tetanus serological data can be used to assess immunity gaps and inform evidence-based remediation (catch-up vaccination or campaigns, optimization of schedules or addition of booster doses, etc.). In children, tetanus immunity has been identified as a potential biomarker for monitoring TTCV coverage. In WRA, sufficient tetanus immunity can be used to help monitor achievement and maintenance of MNTE (see **Box 1** below). Depending on the country, WRA may be defined as 15–39 years, 15–45 years, 15–49 years or another similar age range. Women giving birth in the last year, two years or five years may be specifically targeted in order to assess recent changes in maternal vaccination programme performance. Restricting the survey population to include individuals targeted for vaccination within the last one to two years may improve recall of vaccination doses received and comparability between vaccination coverage and seroprotection. However, the number of household visits required to identify an eligible survey cohort with a narrow age range or birth period (such as one year) will be larger than the number of households required for a wider age range or birth period (such as five years). This has important resource implications.

Box 1

Use of tetanus serosurveys for monitoring achievement and maintenance of MNTE

MNTE is defined as a district level goal of <1 neonatal tetanus case per 1 000 live births in every district per year. MNTE strategies include coverage with >80% of women with protective TTCV doses in every district. Conducting tetanus serosurveys in every district to evaluate this indicator would be resource-intensive, and is **not** recommended. However, serosurveys performed at the national level or in designated high-risk districts that document >80% seroprotection can provide evidence compatible with elimination.

Because tetanus is not eradicable and many countries have achieved MNTE through time-limited campaigns, serosurveys should be considered where feasible to monitor population immunity and MNT risk and guide vaccination strategies, especially in high-risk districts. Integration of fieldwork for surveys or laboratory testing is recommended where possible to allow monitoring of impact and sharing of costs across public health programmes.

Objectives of tetanus serosurveys

Serosurveys assess population immunity rather than directly assessing vaccination coverage. For tetanus, the proportion of the population with demonstrated seroprotection is related to vaccination coverage as well as vaccine effectiveness and duration of vaccine-induced immunity. Before undertaking a tetanus serosurvey, it is

important to define the questions the programme hopes to answer and how the data will be used to guide policy, strategy or programme improvement. The specific objectives should drive the design of a tetanus serosurvey (see Table 2).

Usually, nationally representative estimates of seroprotection are desired, but subnational estimates in high-risk areas may suffice depending on the objective and the country situation. Inclusion of age, sex or regional/subnational strata in national surveys allows greater insight into variation in seroprotection, but can greatly increase the cost of the survey. Surveys of residual sera from ANC clinics or other convenience surveys are the most economical option, but the results of these surveys are not generalizable to the rest of the population and are subject to selection bias. For example, ANC coverage is low in many countries and those attending ANC are more likely to receive tetanus vaccination.

Table 2
Objectives of tetanus serosurveys by target population

All ages and both sexes	Assess disparities in seroprotection (examples: adult males vs females, young vs school-age children)
	Determine duration of immunity and need for booster dose introduction or schedule optimization
	Evaluate impact of catch-up vaccination or campaigns on tetanus immunity (including TT-conjugate vaccines)
Children (e.g. 6–23 months, 12–35 months, 6 months–5 years, 1–15 years)	Evaluate population immunity, compared with vaccination coverage (ages 6–11 and 12–23 months)
	Identify areas and subgroups needing targeted remediation (outreach, school-based immunization, etc.)
	Determine duration of immunity and need for booster doses (for example, at ages 12–23 months, 4–7 years, 9–15 years)
Women of reproductive age before achieving MNTE	Evaluate population immunity, compared with vaccination coverage (for example, TTCV2+/PAB)
	Monitor impact of targeted campaigns in areas at high risk for neonatal tetanus
	Identify areas and subgroups needing targeted remediation through campaigns, outreach or another strategy
Women of reproductive age after achieving MNTE	Monitor population immunity for maintenance of MNTE (for example, in countries relying on campaigns to achieve MNTE)
	Provide evidence needed for TTCV booster dose introduction as part of sustaining elimination
	Identify areas and subgroups for targeted remediation such as outreach vaccination or improved ANC and obstetric care

Survey methods

Population-based cluster surveys are a method for obtaining estimates of seroprevalence that are representative of the target population. General considerations for protocol development, budgeting and implementation of serosurveys are included in the *WHO Guidelines on the Use of Serosurveys in Support of Measles and Rubella (MR) Elimination (2018)*,[6] while details on cluster survey design and sampling methodologies are found in the *WHO Vaccination Coverage Cluster Survey Reference Manual*.[7] Close attention should be paid to survey sampling and laboratory methods to ensure that results are valid and interpretable.

During survey implementation, provide adequate training, supervision, and monitoring to ensure that survey staff follow the established protocol for selection of survey participants. Consent should be collected from all survey participants and parents of selected children; assent may also be needed for older children. The most important variables to collect for detailed analysis of seroprotection across subpopulations are age, sex, area of residence, education and vaccination status. For WRA, it is also important to collect data on parity, ANC attendance, clean birth and cord care for the last pregnancy.

Care should be taken to document the history of all received TTCV doses on home-based and health facility records, and by recall of doses received. TTCV doses may be documented on infant/child, school, maternal and campaign vaccination cards. Questions for recall of vaccination history should prompt survey participants about receipt of vaccines from all relevant sources (clinic/outreach, school, military, campaigns, etc.), and such questions should be asked of every participant in case the recorded history is incomplete. In settings where TT-conjugate vaccines are given (such as MenAfrivac campaigns), those doses should also be recorded separately (see sample questionnaire).

Sample collection

Serum or dried bloodspots (DBS) are the specimens of choice for serosurveys. Serum specimens prepared from whole blood (5 mL for older children and adults, 2.5 mL for infants and young children) are used most widely in serosurveys. DBS prepared from fingerprick blood may be more acceptable for participants and have the advantage of not requiring immediate cold storage and cold shipment. However, drying DBS completely may be challenging in humid climates, and the additional step required to elute serum from filter papers increases the labour required in the laboratory. Oral fluid specimens have been used for research, but are not recommended for regular use in tetanus serosurveys. Protocols for specimen preparation and storage are summarized elsewhere.[6]

Serologic testing of tetanus immunity

The accepted minimum level of IgG antibody required for protection against tetanus is 0.01 IU/mL, as measured by the in vivo neutralization assay (gold standard). However, the antibody level required to achieve absolute protection against tetanus disease has been shown to vary based on individual exposure, including anatomical site and severity of infection. In vitro tests currently validated as accurate at the threshold for

6 WHO. Guidelines on the use of serosurveys in support of measles and rubella elimination. Geneva: World Health Organization (http://www10.who.int/immunization/monitoring_surveillance/burden/laboratory/serosurvey/en/, accessed 24 October 2019).

7 WHO (2018). Vaccination Coverage Cluster Survey: Reference Manual. Geneva: World Health Organization (http://apps.who.int/iris/bitstream/handle/10665/272820/WHO-IVB-18.09-eng.pdf, accessed 15 January 2019).

seroprotection (≥0.01 IU/mL) include modified ELISAs, such as competition ELISA, double-antigen ELISA (DAE), and toxin-binding inhibition (ToBI), as well as bead-based immunofluorescence assays such as multiplex bead assay (MBA). Though not commercially available, DAE, ToBI and MBA have all been successfully established in developing country settings and used in large serosurveys. Before serosurvey use, newly established tetanus assays should be validated against a reference test and calibrated with the tetanus international reference serum (TE-3).

A number of commercial options exist for tetanus indirect ELISAs, making these tests the most commonly used. However, indirect ELISAs have issues with non-specific binding in the low seroprotective range (≥0.01–0.20 IU/mL) requiring a higher cut-off; antitoxin concentrations of ≥0.1–0.2 IU/mL are usually defined as seroprotective when indirect ELISA is used (ideally determined by validation against reference test). None of the commercial indirect ELISAs have been validated against in vivo or in vitro tests accurate at the 0.01 IU/mL threshold for seroprotection. In addition to concerns of misclassification bias related to using a higher cut-off for indirect ELISA, documented variation in the sensitivity and accuracy of individual tests leads to important disparities in final results. For these reasons, use of indirect ELISAs is not generally recommended for tetanus serosurveys without confirmatory testing of samples with ELISA results <0.2 IU/ml by in vivo neutralization, DAE, ToBI or bead-based assays. Point of care tetanus IgG testing is also not recommended for serosurveys.

Opportunities for integration and cost savings

The largest cost savings for tetanus serosurveys can be generated by integrating field implementation with other planned vaccination coverage or serosurveys. Demographic Health Surveys (DHS) are periodically conducted in many countries and often include blood sample for children and WRA, in addition to collecting information on TTCV coverage, neonatal deaths, deliveries in health facilities and by skilled birth attendants, ANC visits, parity, obstetric care, health care access and socio-demographics that can inform interpretation of serosurvey results. The Multiple Indicator Cluster Survey (MICS) is also a widely conducted periodic survey, but less often includes collection of blood samples. AIDS Indicator Surveys (AIS) and Malaria Indicator Surveys (MIS) are other periodic surveys that almost always include collection of blood samples. Serosurveys for vaccine-preventable diseases (polio, measles, rubella, diphtheria, etc.) or other diseases (such as parasites, arboviral or food- and water-borne diseases) may also be options for integration in some countries.

Another potential opportunity for integration and cost savings is through multiplex laboratory testing. Bead-based immunofluorescence assays can be multiplexed to measure antibodies to multiple viral, parasitic or bacterial antigens simultaneously from the same small volume of serum (1–5 µL, or <1/10 of the volume required for ELISA). Tetanus multiplex assays have been demonstrated to have good performance with a relative cost savings over other laboratory tests. In one serosurvey, the cost of adding tetanus to a multiplex assay with 19 other antigens was 0.30 USD per sample, and the total cost of the 20-plex assay was less than the reference tetanus test (DAE) at 30 USD per sample. In costing of other serosurveys, the marginal cost of a 20-plex bead assay performed in-country is less than 20 USD per sample — similar in cost to separate ELISAs for measles and rubella.

Suggested data analyses

During data analysis, survey methods should be used to account for cluster survey design elements including strata, cluster and survey weights. Survey methods should also be used to calculate point estimates and 95% confidence intervals for the overall target population and survey strata. When estimating within subpopulations

not included in the original survey design (for example, those with three or more documented doses), the analyst should first evaluate whether the available sample size for each subpopulation is adequate, and whether the subsample is spread across many clusters or is from only a few clusters representing a narrow segment of the overall sample. The analyst should also consider the impact of the survey weights if the subsample is small. The following data analyses and visualizations are suggested if sufficient data is available:

— Proportion of target population with tetanus seroprotection (binary outcome using defined antibody level threshold, ≥0.01 for modified ELISAs, and bead-based immunoassays)

  - When reporting tetanus IgG results, the test method and cut-off used should be stated, as well as the correlation with a neutralization assay or other validation process, if known.

— Proportion of tetanus seroprotection by vaccination status (number of doses received) and data source (card, recall or card + recall).

— Proportion of tetanus seroprotection by subpopulation, such as age, geographic area, parity or education.

— Statistical comparisons of differences in seroprotection across subpopulations, noting that sample size may be insufficient to detect true differences among subpopulations.

— Median antibody levels by vaccination status and subpopulation.

— Proportion by antibody level category (0.01–0.09 IU/mL, 0.1–0.9 IU/mL, ≥1.0 IU/mL, with higher antibody levels generally correlating with higher probability and duration of tetanus protection).

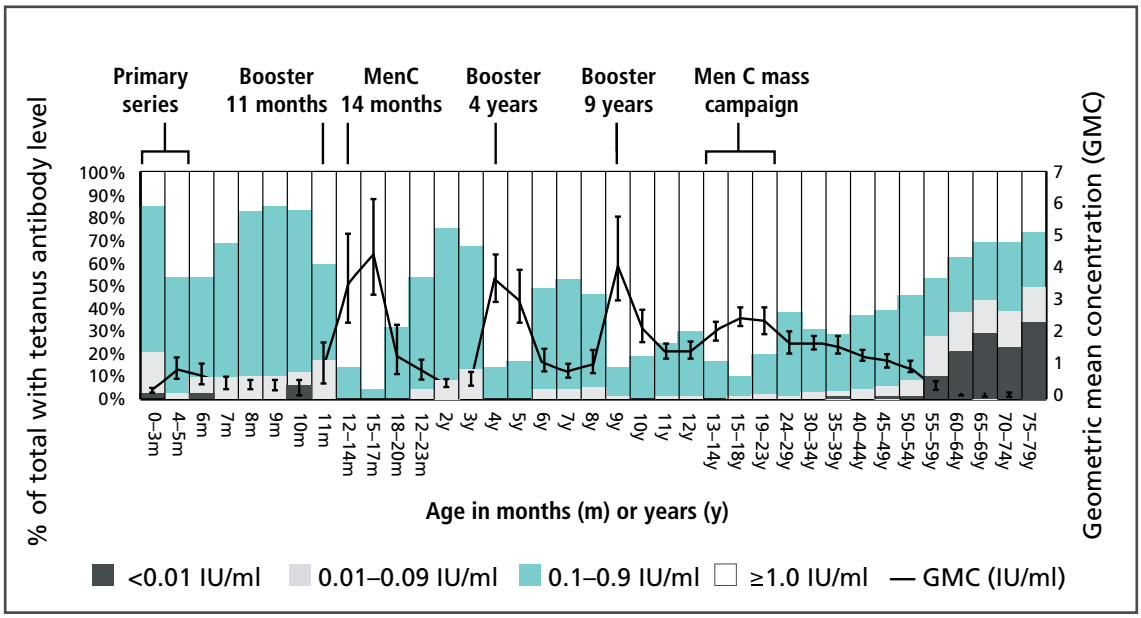
  - It is unnecessary and technically inaccurate to give a qualitative assignment of duration of protection such as "short" or "long". Instead, report the numeric category ranges.

— For parous women unprotected by vaccination, proportion with clean birth with skilled health personnel and clean cord care for last birth.

— Suggested data visualization:

  - stacked bar chart of proportions of antibody level categories by subpopulation (**Figure 3**);
  - if geographic strata are included, a choropleth map of seroprotection by subnational area;
  - for wide age range surveys, bar chart of proportion seroprotected (primary y-axis) and line chart of median antibody level (secondary y-axis) by age cohort (x-axis) (**Figure 3**).

Figure 3
Tetanus antibody levels by age group in national serosurvey of the Dutch population, 2006[8]



Tetanus antibody levels were assessed using a tetanus bead-based immunofluorescence where seroprotection was defined as ≥0.01 IU/ml. The proportions of individuals by age groups and antibody level categories (<0.01 IU/ml, 0.01-0.09 IU/ml, 0.1-0.9 IU/ml, ≥1.0 IU/ml) are depicted with stacked bars and the geometric mean concentrations as a black line with 95% confidence intervals. Higher antibody levels generally correlate with higher probability and duration of tetanus protection and are noted following tetanus vaccination opportunities (depicted above the graph). The "MenC mass campaign" was a meningococcal C tetanus-toxoid conjugate catch-up vaccination campaign that occurred in 2002 as part of vaccine introduction into the routine immunization program at 14 months of age.

Interpretation of results

Tetanus antibody levels generally correlate with the robustness and duration of immunological protection against tetanus resulting from vaccination. Serosurvey findings should be interpreted in light of current and historic data on immunization programme policies and performance (schedules, coverage, etc.), including any past supplementary immunization activities and disease incidence, if available. This approach will give context to serosurvey results and may help highlight areas for potential improvement.

Limitations of the serosurvey should be included in any presentation of results, including selection bias (exclusion or non-random selection of participants), information bias (systematic bias from misclassification error of test or vaccination history) and non-response bias. Considerations for the use of serologic data to assess vaccination history have been summarized elsewhere.[9] It is important to recognize that serological data are not necessarily a gold standard for assessing vaccination

8 Steens A, et al. (2010). High tetanus antitoxin antibody concentrations in the Netherlands: a seroepidemiological study. Vaccine. 28(49):7803-9. doi: 10.1016/j.vaccine.2010.09.036.
9 MacNeil A, Lee CW, Dietz V (2014). Issues and considerations in the use of serologic biomarkers for classifying vaccination history in household surveys. Vaccine. 32(39):4893–900. doi: 10.1016/j.vaccine.2014.07.005.

status, and that serosurveys performed using tests with poor accuracy (inability to correctly classify seroprotection) have a substantial limitation.

Tetanus serosurvey results may differ from reported vaccination coverage or coverage survey estimates (Figure 1), and have the potential to indicate that immunization services are more or less effective than previously appreciated. Possible explanations for these differences are summarized in Table 3. Administrative TTCV2+ coverage of pregnant women is known to underestimate true protection against tetanus, as it excludes women unvaccinated during their current pregnancy but already protected through previous vaccination, or who received one dose in pregnancy and had undocumented previous doses. PAB coverage can also be underestimated due to residual immunity from infant doses in some women, or from booster doses provided outside routine services and misclassification of PAB status due to poor availability of documented vaccination history and recall bias.

Table 3
Possible explanations for differences in tetanus seroprotection and vaccination coverage

Result	Possible explanations
Tetanus seroprotection higher than vaccination coverage	inaccuracies in reported TTCV coverage data (numerator and/or denominator)
	immunity from TTCV doses not documented/recalled (examples: infant/childhood doses for adult participants, TTCV and MenAfriVac campaigns doses, doses following injury)
	partial series of multidose vaccine (such as TTCV2) results in immunity
	suboptimal specificity of laboratory testing, especially in areas with low immunity
Tetanus seroprotection lower than vaccination coverage	inaccuracies in reported TTCV coverage data (numerator and/or denominator)
	reduced vaccine effectiveness from substandard vaccine administration or freezing of TTCV
	age-group affected by waning tetanus immunity
	suboptimal sensitivity of laboratory testing, especially in areas with high immunity

Use of results

Results from tetanus serosurveys have important potential use for monitoring population immunity and disease risk, as well as guiding policy, strategy and targeted improvements for the immunization programme. Triangulation of serosurvey results with current and historic immunization schedules and policies, coverage data, past campaigns and available data on disease incidence will help highlight any challenges with data quality as well as areas for potential improvement. For broader tetanus control, serosurveys can be used to:

— document evidence needed for tetanus immunization policy or strategy change (Td campaigns, introduction of recommended booster doses, school-based immunization, etc.);

— monitor impact of tetanus vaccination programmes, including changes in policy and strategies for greater effectiveness, such as catch-up vaccination, vaccination campaigns and strengthening ANC;

— verify adequate tetanus population immunity needed for disease control goals, and compare with other programme data (such as coverage and surveillance) as a means of independent validation;

— identify areas and subgroups (sex, age group, parity status, migrant status, ethnicity) with low tetanus seroprotection to appropriately design interventions (outreach, catch-up vaccination, campaigns, school-based vaccination).

Annex 11.
Methodology for a post-validation assessment of MNTE

(The forms/questionnaires are available to be downloaded from WHO website https://www.who.int/immunization/diseases/MNTE_initiative/en/)

A post-validation assessment of MNTE is an in-depth exercise to check that elimination status is being maintained. It can be undertaken periodically in any country that has achieved MNTE elimination status, but in particular, it is relevant for those who have concerns about the sustainability of their programme performance (e.g. declining EPI immunization coverage, implementation and management problems, humanitarian crisis or natural disaster, etc).

A post-validation assessment of MNTE requires sufficient time to plan and complete the following:

— conduct a comprehensive desk review;
— synthesize the findings of the desk review;
— undertake district risk categorization;
— complete a root cause analysis or field assessment (if needed);
— identify corrective actions and develop/endorse a MNTE priority action plan and budget for the implementation of proposed activities.[1]

It is essential that the national EPI, MNCH and surveillance managers, together with partner representatives, are involved throughout the post-validation assessment of MNTE. Regional and district EPI, MNCH and surveillance managers participate once the districts are identified.

In order to conduct the post-validation assessment of MNTE, it is critical that reliable NT surveillance[2], vaccination and SBA coverage data, along with expert knowledge, are available to enable the accurate district categorization of potential risk for NT. Data for the past three years need to be compiled so that coverage trends can be reviewed.

There are five steps to complete a post-validation assessment of MNTE which are described below.

Five steps to complete a post-validation assessment of MNTE:

Step 1: Determine risk indicators (core, surrogate, additional).

Step 2: Collect and compile data for each district. Review data and adjust risk cut off points if needed.

Step 3: Review each district and classify them into risk categories ('**low risk**', '**high risk**', or '**at risk**') based on their level of performance and expert input.

Step 4: Conduct in-depth analysis for selected districts to identify corrective actions.

Step 5: Create a MNTE action plan for implementation of proposed activities.

1 All activities should be detailed and budgeted in country annual plans, which can then form the basis for local plans of action.
2 Reliable NT surveillance: a) 0 cases notification functioning, b) completeness of district health facility surveillance reporting 80%, c) annual review of hospital records at least once a year. This requires the following: 1. Case definition of NT cases is available and known in all health facilities, 2. Case investigation forms for suspected cases are available and cases are investigated, 3. In rural districts, there is functional community level surveillance.

The approach uses core and surrogate risk indicators for MNT (see **Table 1**) over the past three years which are compiled and reviewed to identify and classify districts at risk. Additional indicators of interest may be added to extend the review of district performance beyond MNT.

The review process is complemented by the use of expert knowledge of the potential risk for NT before the final classification of the districts' risk status. The assessment exercise can be completed as a desk review or it may include field assessments to selected districts.

STEP 1 (2 to 3 weeks): Determine risk indicators, collect and compile data for each district

Using **Table 1** the post-validation assessment team leader should gather all the administrative data, as well as from surveys (e.g. MICS, DHS, coverage surveys) to cross-check reported coverage data and guide any adjustments that need to be made (see **Step 2**). Data for each district over the past three years should be compiled in a concise and easy to read format. An example template spreadsheet is available at WHO website (https://www.who.int/immunization/diseases/MNTE_initiative/en/).

Table 1
Indicators for MNT risk assessment

Core indicators	Surrogate indicators	Additional indicators of interest (examples)
reported number of NT cases	ANC1 coverage	urban vs. rural district
reported NT rate/1000 LB per district	ANC 4 coverage	geographic accessibility
skilled birth attendance (SBA) coverage	DTP1/Penta1 coverage	health infrastructure
district level data for coverage TTCV2+ and PAB	DTP3/Penta 3 coverage	other human development indicators
TTCV2+ coverage (for calculation see **Chapter 3**): — For pregnant women (routine EPI) — For WRA (age group as defined by the country) by TTCV SIAs and year of implementation	MCV1 coverage	percentage, absolute number and clustering of un- or under- vaccinated infants
	TTCV booster coverage	% pregnant women never attending ANC1, and/or delivering in absence of a SBA
	survey based coverage estimates (EPI-CES/MICS/DHS) by years, for comparison with reported data (HMIS or EPI or WUENIC data)	

Data can be found from the following sources:

— **Health management information system (HMIS)**
HMIS data may show an over- or underestimate of performance indicators compared to survey data due to incomplete and/or untimely reporting, inaccurate numerators and denominators (e.g. outdated census, internal migrations, etc.), and the classic under- or over- reporting of NT cases (i.e. not reaching reporting sites and/or cases not confirmed by case investigation).

— **WHO and UNICEF Estimates of National Immunization Coverage (WUENIC)**
WUENIC estimates[3] which are revised annually, can serve to assess if reported national coverage data are under- or overestimated. Local knowledge or coherence between ANC coverage and reported TTCV2+, as well as DTP3/Penta3 coverage, may provide additional information for the review of district performance.

— **Recent (within the past 3 years) population health surveys (vaccination coverage surveys, MICS, DHS, etc.)**
Although population health surveys assess national/regional and rarely district coverage performance, information obtained from these surveys, along with expert knowledge, may be helpful for the review and adjustment of under- or overestimated reported coverage for TTCV2+, other antigens, PAB, and SBA.

STEP 2 (1 day workshop): Review and adjust risk cut-off points if needed

In a one-day workshop, the collected data compiled in the spreadsheet should be carefully reviewed and analysed by the assessment team. If there is a discrepancy between any very recent MICS/DHS/immunization coverage surveys and WUENIC data, the cut-off points for indicators in districts can be adjusted if supported by evidence and upon consensus of all team members.

Practical experience conducting post-validation MNTE assessment has found that it is often necessary to make cut-off adjustments in order to make the exercise manageable and focus on the districts likely at highest risk. Some further explanation and guidance regarding possible adjustments is provided below.

— **NT rate cut-off point adjustment**
By definition, if there is <1 NT case per 1 000 live births reported in a district[4], in the presence of reliable NT surveillance system, the district will be classified as 'low risk'. In the presence of unreliable/weak NT surveillance, the cut-off point may be lowered to 0.5 cases per 1 000 live births or as agreed.

— **SBA coverage cut-off point adjustment**
To attain MNTE status, the MNTE validation survey uses a Lot Quality Assurance Cluster Sample (LQA-CS)[5] to assess that at least 70% of reported deliveries were in the presence of a SBA. However, for the post-validation assessment exercise, if needed this risk cut off-point can be adjusted to 60%. This is because reported SBA coverage remains a conservative estimate of the extent of clean birth practices due to the following reasons:

1. Deliveries in private clinics and home deliveries in presence of a SBA are often not accounted for in the HMIS reports. This underestimates urban SBA coverage.
2. A portion of home deliveries may not be attended by SBA (as defined by the country), but still adhere to the principles of Six Cleans (see **Chapter 4**).

3 WHO. Data, statistics and graphics [online database]. Geneva: World Health Organization (http://www.who.int/immunization/monitoring_surveillance/data/en/, accessed 15 January 2019).
4 In very large districts it may be necessary to consider sub-district analysis to verify clustering.
5 WHO (2014). Validation of Maternal and Neonatal Tetanus Elimination (including a guide to the use of Lot Quality Assurance – Cluster Sample Surveys to assess neonatal tetanus mortality). Geneva: World Health Organization (https://www.who.int/immunization/documents/MNTE_Validation_survey_WHO_IVB_18.15.pdf accessed 19 March 2019).

— **TTCV2+ coverage cut-off point adjustment**
Major differences may be noted in some countries between administrative reported TTCV2+ coverage (e.g. included in the WHO/UNICEF Joint Reporting Form) and TTCV (PAB) protection from coverage surveys. These coverage surveys take into account all TTCV doses ever administered through routine or SIAs and not just TTCV2+ of a given year. However, TTCV (PAB) protection from coverage surveys may still underestimate the true level of protection, as it excludes routine doses of TTCV administered during infancy.

When compared with survey results (EPI-CES, DHS, MICS), TTCV2+ administrative coverage at national and subnational levels can differ. This may be due to the following reasons:

- Pregnant women who completed the five-dose schedule are not eligible for another TTCV dose and often are not accounted for in the TTCV2+ coverage in the administrative reports (see **Chapter 3** for correct formula to be used for TTCV2+ calculation)
- Pregnant women often receive a dose of TTCV vaccine in each pregnancy without taking previous history into account, especially in the absence of documented history such as through vaccination cards (as a result TTCV1 doses are de facto TTCV 2, 3, 4 or 5).
- TTCV doses administered during TTCV SIAs are not counted in the routine administration of TTCV doses at ANC contacts (i.e. history of past TTCV SIA doses is rarely asked at ANC, therefore these doses are not included in the routine administrative reporting of TTCV2+ coverage).

For the above reasons, although the TTCV2+ coverage of at least 80% is compatible with MNTE status, the TTCV2+ district coverage cut-off point to be used in the post-validation assessment may be adjusted to 70% if agreed/justified. However, the rationale for making this adjustment should be based on country and district specificities.

STEP 3 (same 1 day workshop):
Review each district and classify them into the following risk categories 'low risk', 'high risk', or 'at risk', based on their level of performance.

Following the WHO algorithm (**Figure 1**):

— Review the NT rate for each district, based on the agreed cut off point (1/1 000 LB or adjusted 0.5/1 000 LB):

- If reported NT rate is higher than the cut-off point, classify the district as 'high risk'.
- If the reported rate is lower than the cut-off point, further evaluate the district, based on the reliability of the NT surveillance system.

— Evaluate the reliability of the NT surveillance:

- If the surveillance system is reliable, classify the district as 'low risk'.
- If deemed unreliable, continue evaluation of the district using SBA coverage.

— Review the district for SBA coverage:[6]

- If SBA coverage in the district is equal to or greater than the agreed upon cut-off point (i.e. ≥60%), classify the district as '**low risk**'.
- If the district SBA coverage is lower than the cut-off point, evaluate the district further for TTCV2+ or PAB coverage.

— Review TTCV2+ or PAB coverage:

- If the TTCV2+ coverage in the district is equal to or greater than the agreed upon cut-off point (i.e. ≥70%), classify the district as '**low risk**'.
- If the district TTCV2+ coverage is lower than the cut-off point, classify the district as 'at risk'.

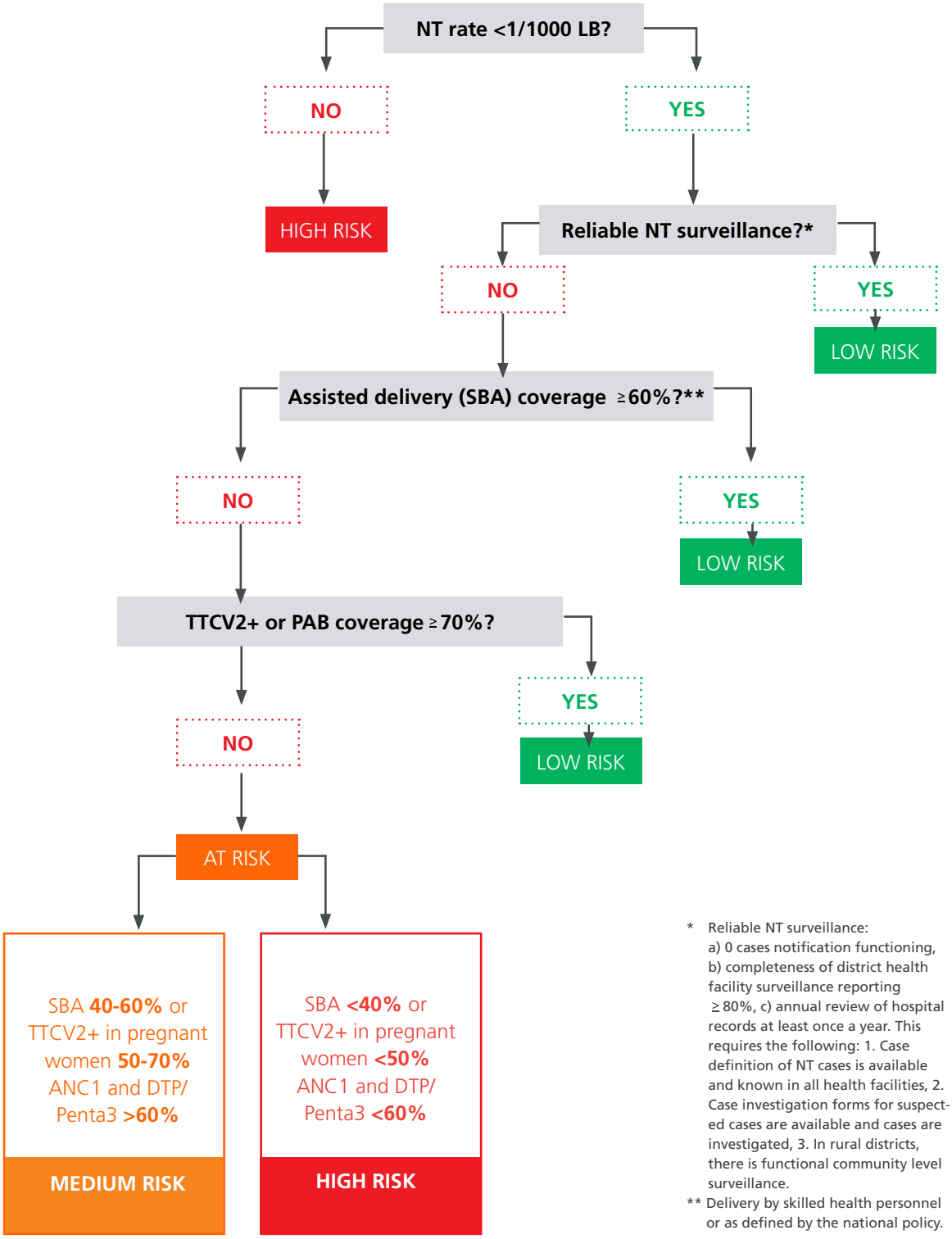
— Review 'at risk' districts and further classify them into '**medium risk**' or '**high risk**'.

- Classify '**at risk**' districts into '**medium risk**' if any of these criteria apply:
  - Reported SBA coverage: 40–60%, or
  - Reported TTCV2+ coverage: 50–70%, or
  - Reported both ANC1 and DTP/Penta3: 60%–85%.
- If none of the above applies, classify remaining '**at risk**' districts as '**high risk**'.

Where risk is unidentified because of lack of data (i.e. silent areas) the district should be deemed as '**high risk**' as it is likely to have unreported NT cases.

6 Delivery by a skill health personnel or as defined by the national policy (see Chapter 4)

Figure 1
WHO algorithm to classify potential risk of NT in districts
(Step 3 of MNT risk assessment)



* Reliable NT surveillance: a) 0 cases notification functioning, b) completeness of district health facility surveillance reporting ≥80%, c) annual review of hospital records at least once a year. This requires the following: 1. Case definition of NT cases is available and known in all health facilities, 2. Case investigation forms for suspected cases are available and cases are investigated, 3. In rural districts, there is functional community level surveillance.

** Delivery by skilled health personnel or as defined by the national policy.

STEP 4 (1 week):
Conduct in-depth analysis for selected districts to identify corrective actions

Based on findings from the desk review and district classifications, two approaches can be undertaken to conduct in-depth analysis for selected districts.

1. Conduct field assessment using standardized tools

The field assessments should be conducted using standardized tools (e.g. district assessment forms, available at WHO website https://www.who.int/immunization/diseases/MNTE_initiative/en/) in one '**low risk**' (e.g. high performing) district, to document best practices, and two '**at risk**' (e.g. lower performing) districts, to document possible weaknesses and recommendations for improvement.

The standardized tools for the field visits are designed to confirm if the districts have been able to sustain MNTE status since the country achieved its elimination. The field assessment evaluates the current risk of MNT through visits to district health offices; referral hospitals; health facilities, and communities with women who had a child in the previous two years.

Activities during field assessments include:

— review of registers, microplans, vaccine stock records to assess whether TTCV2+ is over or underestimated;

— examination of reports of NT cases to see if there have been misdiagnoses, or if the cases belonged to other districts (e.g. referral cases);

— review of the NT surveillance procedures, including if and how referral hospitals record reviews are performed, if there is active/community-based surveillance and community sensitization in rural areas;

— discussions with local health workers and authorities, including hospital paediatric ward staff, to get an impression of the general state of health services in the area and to obtain any additional reports and information;

— review of earlier reports on district performance (surveys, service or surveillance evaluations, etc.);

— interviews with a sample of women who had a child in the previous two years to assess their level of TTCV2+ protection based on history of all TTCV doses ever administered during past TTCV SIAs and during past pregnancies, their frequency of missed opportunities for TTCV administration, use of ANC services, PAB, typical delivery conditions, cord care practices, and perceptions about service availability and reliability.

All evidence gathered from the field assessments should be compiled and analyzed, with findings summarized, including key indicators: number of women interviewed, TTCV2+, TTCV5+ coverage, proportion of births in health facilities, proportion putting traditional substance on cord, proportion of women and deliveries protected against tetanus by combined TTCV and skilled birth attendance.[7]

The assessment team, comprising of EPI, MNCH, surveillance managers and partner representatives, should consider again whether it is likely that MNTE elimination has been sustained, and if weaknesses have been identified, how they should be addressed (see **Step 5**).

7 Debriefing slide set example available online at: https://www.who.int/immunization/diseases/MNTE_initiative/en/.

2. Root-cause analysis (RCA)

As an alternative to conducting field visits, an in-depth analysis can also be done by completing a root-cause analysis (RCA) of '**at risk**' districts to further assess and identify causes for low performance. To facilitate the RCA, certain indicators relating to EPI and MNCH programme components e.g. TTCV2+ vaccination, focused antenatal care, and SBA need to be examined for programme and related management issues (see Table 2).

Table 2
Examples of indicators to be examined in the root cause analysis (RCA) per programme component

Programme component	Indicator
Vaccination coverage with TTCV and PAB coverage	**Commodities:** — Proportion of facilities reporting stock-outs of TTCV vaccine for more than 7 days in the previous 3 months
	Human resources: — Proportion of facilities without trained nurses and midwives
	Access: — Existence of RED/REC plan (fixed/outreach/mobile teams) — Proportion of outreach and mobile sessions conducted in last 3 months
	Quality: — Proportion of pregnant women who were protected for tetanus (TTCV2+) and/or PAB — If implementing child or adolescent TTCV booster doses, percentage of children who received 6 TTCV doses by adolescence
Focused antenatal care (ANC coverage)	**Access:** — Proportion of pregnant women who had at least 1 ANC visit — Proportion of health facilities providing TTCV vaccination at ANC visits
	Utilization: — Proportion of pregnant women who had at least 4 ANC contacts
	Quality: — Proportion of pregnant women who attended ANC within the first trimester
Skilled birth attendance (SBA coverage)	**Human resources:** — Proportion of facilities with skilled health care workers (doctors, nurses, midwives)
	Access and utilization: — Proportion of live births delivered in a health facility
	Quality: — Proportion of deliveries who received postnatal visit within 24 hours.

It is essential to document and summarize the findings on issues and barriers to allow for their prioritization and to determine the necessary corrective actions (Step 5).

Step 5 (1 day workshop): Create a MNTE priority action plan for implementation of proposed activities for action

For each of the issues identified through the in-depth analysis (Step 4), proposed corrective interventions should be consolidated into a MNTE priority action plan (see example of an outline in Table 3) during a workshop attended by EPI, MNCH, surveillance managers and partner representatives.

The MNTE priority action plan should also include immediate next steps, timeline for completion, and should identify the responsible person/organization, budget requirements and source of funding (if needed).

Table 3
Outline of MNTE priority action plan with examples of identified issues and proposed interventions

Main issues identified	Proposed interventions for action
Example Underutilization of TTCV vaccination services due to: — Insufficient number of outreach teams — Limited access to ANC services — Poor mobilization and under-vaccination of pregnant women at outreach sites (with or without ANC) — Insufficient involvement of CHWs — TTCV vaccine stock out — Underestimation of TTCV2+ coverage due to monitoring deficiencies — Weak and unreliable NT surveillance due to poor health worker understanding — Etc.	*Example* — Map unreached and revisit RED/REC microplanning to ensure all pregnant women are within 5km of a vaccination site — Ensure at least 6 vaccination sessions per year for outreach — Consider 2-4 PIRI per year for very hard-to-reach populations — Include additional interventions in PIRI based on community needs — Community-level identification and tracking of eligible women and infants, with defaulter tracing — Organize periodic review meetings with health facility workers and community representatives and CHWs — Allocate required additional resources to reach all target population — Distribute case definition of NT cases to all health facilities and provide refresher training via supportive supervision — Ensure that case investigation forms for suspected cases are available in all facilities and cases are investigated

Immediate next steps	Timeline for completion	Budget/funding source (if needed)	Responsible person/ organization

This document was published by the Expanded Programme on Immunization (EPI) of the Department of Immunization, Vaccines and Biologicals and is available at: www.who.int/immunization/documents.

Copies of this document, as well as additional materials on immunization, vaccines and biologicals may be requested from:

World Health Organization
Department of Immunization,
Vaccines and Biologicals
CH-1211 Geneva 27
Switzerland
Email: vaccines@who.int
Web: www.who.int/immunization/en

ISBN 978-92-4-151561-0