Annex 2

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Vaccine-Preventable Diseases

Surveillance Standards

World Health Organization

Tetanus Serosurveys

2.1 BACKGROUND AND RATIONALE

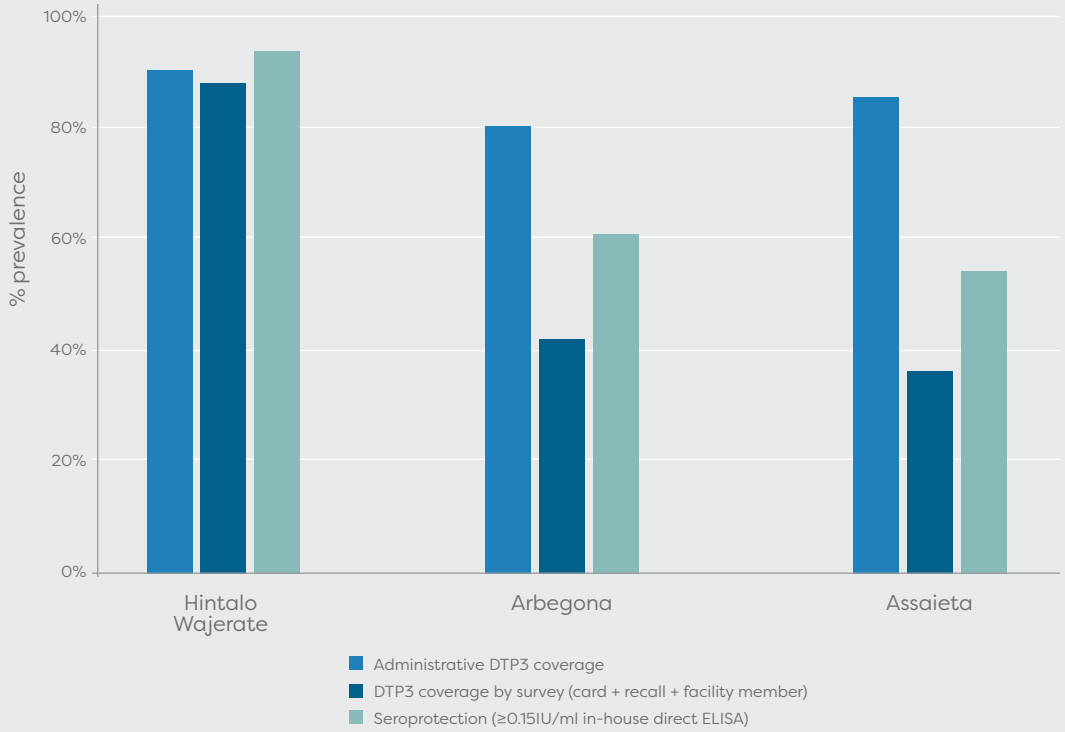
This annex provides guidance on the use of serosurveys to estimate population immunity and monitor disease risk for tetanus. The aims of tetanus vaccination are 1) to achieve and sustain maternal and neonatal tetanus elimination (MNTE) and 2) to ensure lifelong tetanus protection in all people by achieving high coverage with six doses of tetanus vaccine (three primary plus three booster doses) through routine immunization *(1)*. Because tetanus spores persist in the environment, tetanus is not eradicable; 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. The World Health Organization (WHO) recommends the following booster dose vaccination schedule: 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 tetanus-toxoid containing vaccine (TTCV) doses (preferably tetanus-diphtheria vaccine, or Td) are provided to women of reproductive age (WRA) through routine services or campaigns in high-risk areas *(1)*. In some countries, the provision of tetanus-toxoid (TT) 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 (DTPCV3) is a key performance indicator of the routine immunization system. However, countries may encounter challenges with monitoring DTPCV3 coverage through administrative methods due to inaccurate recording and reporting of vaccination doses and outdated target populations, or through surveys with limited documentation of vaccination history or other biases associated with the survey methods (see Figure 1).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 in routine immunization, antenatal care (ANC) and 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.

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 U.K. *(3) (4) (5) (6)*, but a case has been made for greater use of serological data for immunization program decision-making in lower and middle-income settings *(7) (8)*. A limitation of serosurveys is that they cannot discriminate the number of vaccine doses received (for example, two versus three doses) or the source of the immunizing event (natural infection for most diseases, routine vaccination or campaign vaccination).

FIGURE 1

Tetanus vaccination coverage and seroprotection among children 12–23 months in linked coverage and serosurveys in three districts in Ethiopia, 2013 *(2)*

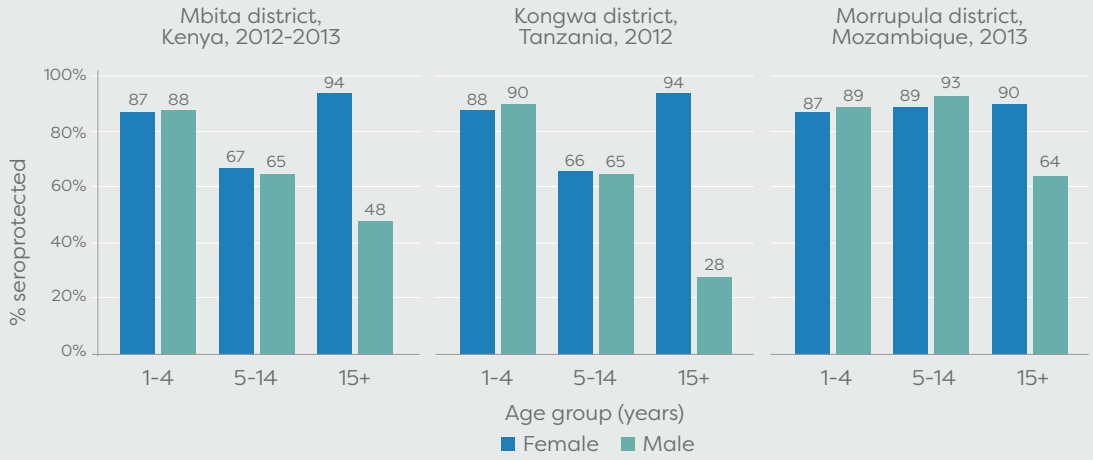


Unlike other vaccine-preventable diseases, natural tetanus infection is not a source of immunity for tetanus, so immunity is an attractive biomarker of vaccination coverage. Tetanus serosurveys are helpful in assessing population immunity resulting from cumulative coverage from vaccine doses, vaccine effectiveness (for example, reduced effectiveness due to freezing TTCV) and waning immunity over time (see Figure 2). Assessment of lifelong 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) *(9) (10)*. 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 TT dose, TT2+, or protected at birth (PAB)[1]. As part of broader tetanus prevention efforts, the Strategic Advisory Group of Experts (SAGE) on Immunization recommends 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 *(12)*.

[1] *Protection at birth (PAB) is a supplemental method of determining tetanus vaccination coverage, particularly where TT2+ is unreliable* (11). *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 the 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.*

FIGURE 2

Seroprotection among individuals in districts in three eastern and southern African countries *(13)*



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 from nationally representative tetanus serosurveys among reproductive-age women

SURVEY	POPULATION	PAB COVERAGE	SEROPROTECTION
Burundi, 1989 *(14)*	Women giving birth in past year	73% (95%CI: 66%-79%)	67% (95% CI: 59%-76%)*
Central African Republic, 1996 *(9)*	Women giving birth in past year	76% (95%CI: 69%-83%)	89% (95% CI: 83%-94%)**
Cambodia, 2012 *(10)*	Women aged 15–39 years Parous women aged 15–39 years	- 83% (95%CI: 79%-86%)	88% (95%CI: 86%-89%)** 97% (95%CI: 95%-98%)**

PAB = protected at birth; 95%CI = 95% confidence interval

* *≥ 0.01 IU/ml in competition ELISA*

** *≥ 0.01 IU/ml in Double Antigen ELISA*

2.2 SURVEY SETTING AND POPULATION

Globally, surveillance for neonatal and non-neonatal tetanus has been documented to be suboptimal *(15) (16)*. 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 DTPCV coverage *(2)*. In WRA, sufficient tetanus immunity can be used to help monitor achievement and maintenance of MNTE. 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 households to visit 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 of reproductive age with protective TTCV doses in every district (17) (18). 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 (12). 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.

2.3 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**

TARGET POPULATION	OBJECTIVE
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 or 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, TT2+/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

2.4 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*, while details on cluster survey design and sampling methodologies are found in the *WHO Vaccination Coverage Cluster Survey Reference Manual (19) (20)*. Close attention should be paid to survey sampling and laboratory methods to ensure that results are valid and interpretable *(12)*.

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 delivery and cord care for the last pregnancy.

Care should be taken to document 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 vaccine 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 form for serosurveys**, below).

2.5 SAMPLE COLLECTION

Serum or dried bloodspots (DBS) are the specimens of choice for tetanus 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 finger prick 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 labor 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 *(19)*.

2.6 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 seroprotection (≥ 0.01 IU/mL) include modified ELISAs, such as the competition ELISA, double-antigen ELISA (DAE), and toxin-binding inhibition (ToBI) assay, as well as bead-based immunofluorescence assays such as the 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 *(21)(22)*. Before serosurvey use, newly established tetanus assays should be validated against a reference test and calibrated with the tetanus international reference serum (TE-3) *(19)*.

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 cutoff; antitoxin concentrations of ≥ 0.1–0.2 IU/mL are usually defined as seroprotective when indirect ELISA is used (ideally determined by validation against a 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 cutoff for indirect ELISA, documented variation in the sensitivity and accuracy of individual commercial ELISA tests leads to important disparities in final results *(23) (24)*. 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 *(25)*. Point of care tetanus IgG testing is also not recommended for serosurveys *(21)(22)*.

2.7 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, which is < 10% of the volume required for ELISA). Tetanus multiplex assays have been demonstrated to have good performance *(10) (26)* 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 *(27)*.

2.8 SUGGESTED DATA ANALYSES

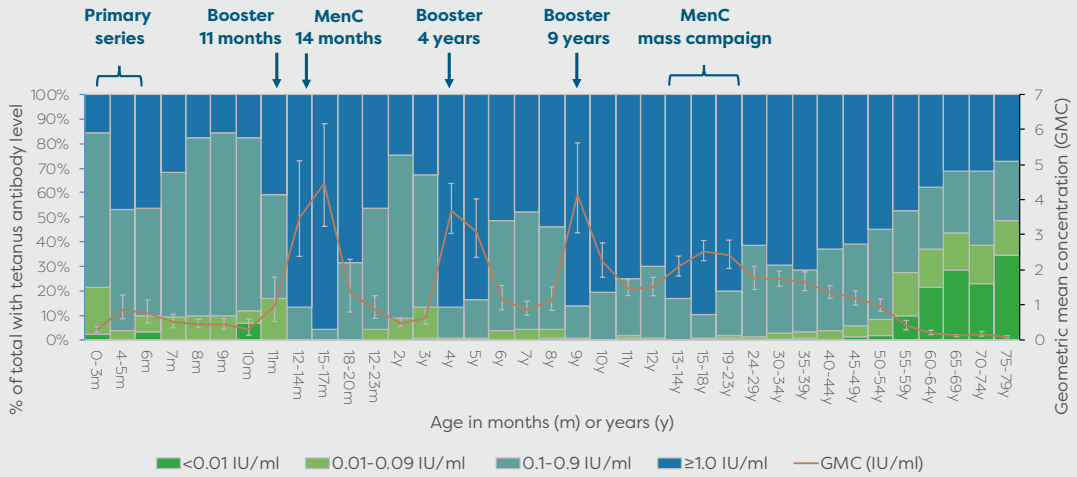
During data analysis, survey methods should be used to account for cluster survey design elements including strata, cluster and survey weights. Survey methods should also be used to calculate point estimates and 95% confidence intervals for the overall target population and survey strata. When estimating 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 IU/ml for modified ELISAs, and bead-based immunoassays)
  - When reporting tetanus IgG results, the test method and cutoff used should be stated, as well as the correlation with a neutralization assay or other validation process, if known *(21)(22)*.
- 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 delivery with a skilled birth attendant 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 *(28)*



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 antibody 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.

2.9 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 data, if available. This approach will give context to serosurvey results and may help highlight areas for potential improvement *(19)*.

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 *(19)*. Considerations for the use of serologic data to assess vaccination history have been summarized elsewhere *(29)*. It is important to recognize that serological data are not necessarily a gold standard for assessing vaccination 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 TT2+ 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 *(10)*. 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, TT and MenAfriVac campaigns doses, doses following injury) » Partial series of multidose vaccine (such as DTPCV2) 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

2.10 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).

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2.11 SAMPLE QUESTIONNAIRE FORM FOR SEROSURVEYS

INSTRUCTION

Fill one form for each survey participant and blood sample collected. It is important to collect written documentation of vaccination status from all home-based records (e.g., infant/child, school, maternal and campaign vaccination cards). In some settings with poor availability of home-based records, it may be valuable to review facility records in order to document vaccination status. Because tetanus vaccine doses may be received from a variety of sources, and available documentation may be incomplete, collect recall of vaccination history from all participants regardless of available documentation.

***Note**: This sample questionnaire is generalized for use for serosurvey participants of all ages and both sexes. An important difference between questionnaires used for serosurveys and vaccination coverage surveys is that serosurveys should attempt to collect information on all vaccine doses containing tetanus toxoid from different sources up until the time of the survey, while coverage surveys are usually concerned with TTCV doses provided at specific routine immunization opportunities (for example, DTPCV3 in infancy or Td doses during last pregnancy). For each survey, the questionnaire should be adapted to the local context (for example, adjust the vaccine card section to match cards in use in country). If the survey population is restricted to a certain group (such as women of reproductive age or children), remove questions that are not applicable. If including multiple participants from one household, consider including the household-level questions in a separate questionnaire linked with individual level forms for each household member.*

SECTION 1 DEMOGRAPHIC INFORMATION

NO.	QUESTIONS AND FILTERS	CODING CATEGORIES	SKIP	NOTE ON QUESTION
D01	Identification number	_____		*Must allow linkage back to serum sample*
D02	Sex	Male 1 Female 2		
D03	Is date of birth known/ available?	Yes 1 No 0	**If no, skip to D05**	
D04	Date of birth	DD/MM/YY: ___ ___ / ___ ___ / ___ ___ (fill "99" for missing parts of the date)		
D05	Age in years	Age in years _____		*For children < 12 months, collect "age in months" separately.*
D06	Ethnic group	_____		*Coded choices preferred for analysis*
D07	Province of residence	_____		*Coded choices preferred for analysis*
D08	District of residence	_____		*Coded choices preferred for analysis*
D09	Village of residence	_____		

NO.	QUESTIONS AND FILTERS	CODING CATEGORIES	SKIP	NOTE ON QUESTION
D10	Are you/your child living in the same province of birth?	Yes 1 No 0 Don't know/refused to answer 99		
D11	Highest year of completion in school	_____		*Coded choices preferred for analysis*
D12	Do you/your child have records available that show which vaccinations were received?	Yes 1 No 0 Don't know/refused to answer 99	**If no/ don't know, skip to W01 for women, C01 for child, or M01 for men.**	*Training should emphasize accurate recording of documented vaccination history.*

SECTION 2

VACCINATION CARD

NO.	VACCINE DOSE	CODING CATEGORIES	DATE	SKIP
V01	DTP1/Pentavalent 1	Yes 1 No 0	If yes, date: DD/MM/YY: ___ ___ / ___ ___ / ___ ___ (fill "99" for missing parts of the date)	
V02	DTP2/Pentavalent 2	Yes 1 No 0	If yes, date: DD/MM/YY: ___ ___ / ___ ___ / ___ ___ (fill "99" for missing parts of the date)	
V03	DTP3/Pentavalent 3	Yes 1 No 0	If yes, date: DD/MM/YY: ___ ___ / ___ ___ / ___ ___ (fill "99" for missing parts of the date)	
V04	DTP4/Pentavalent 4	Yes 1 No 0	If yes, date: DD/MM/YY: ___ ___ / ___ ___ / ___ ___ (fill "99" for missing parts of the date)	
V05	DTP5/ Pentavalent 5/ DT/Td (5th dose)	Yes 1 No 0	If yes, date: DD/MM/YY: ___ ___ / ___ ___ / ___ ___ (fill "99" for missing parts of the date)	
V06	Td (6th dose)	Yes 1 No 0	If yes, date: DD/MM/YY: ___ ___ / ___ ___ / ___ ___ (fill "99" for missing parts of the date)	
V07	MenAfrivac *[or other TT-conjugate vaccine in schedule]*	Yes 1 No 0	If yes, date: DD/MM/YY: ___ ___ / ___ ___ / ___ ___ (fill "99" for missing parts of the date)	**For women, continue to V08. For children, skip to C01. For men, skip to M01.**
V08	For women only: TT1/ Td1	Yes 1 No 0	If yes, date: DD/MM/YY: ___ ___ / ___ ___ / ___ ___ (fill "99" for missing parts of the date)	
V09	For women only: TT2/ Td2	Yes 1 No 0	If yes, date: DD/MM/YY: ___ ___ / ___ ___ / ___ ___ (fill "99" for missing parts of the date)	
V10	For women only: TT3/ Td3	Yes 1 No 0	If yes, date: DD/MM/YY: ___ ___ / ___ ___ / ___ ___ (fill "99" for missing parts of the date)	

NO.	VACCINE DOSE	CODING CATEGORIES		DATE	SKIP
V11	For women only: TT4/ Td4	Yes No	1 0	If yes, date: DD/MM/YY: ___ ___ / ___ ___ / ___ ___ (fill "99" for missing parts of the date)	
V12	For women only: TT5/ Td5	Yes No	1 0	If yes, date: DD/MM/YY: ___ ___ / ___ ___ / ___ ___ (fill "99" for missing parts of the date)	
V13	For women only: 1st TT/Td campaign dose	Yes No	1 0	If yes, date: DD/MM/YY: ___ ___ / ___ ___ / ___ ___ (fill "99" for missing parts of the date)	
V14	For women only: 2nd TT/Td campaign dose	Yes No	1 0	If yes, date: DD/MM/YY: ___ ___ / ___ ___ / ___ ___ (fill "99" for missing parts of the date)	
V15	For women only: 3rd TT/Td c cxsw4x campaign dose	Yes No	1 0	If yes, date: DD/MM/YY: ___ ___ / ___ ___ / ___ ___ (fill "99" for missing parts of the date)	

SECTION 3

WOMEN'S BIRTH AND VACCINATION HISTORY

NO.	QUESTIONS AND FILTERS	CODING CATEGORIES		SKIP	NOTE
W01	Have you ever given birth?	Yes No Don't know/refused to answer	1 0 99	**If yes, skip to W04**	
W02	Have you ever received any tetanus injection, such as at school, after injury or as part of a campaign?	Yes No Don't know/refused to answer	1 0 99	**If no or don't know/ refused, end the interview. Thank the participant.**	*For non-parous women only.*
W03	How many times did you receive a tetanus injection?	_____ doses *(range 0-4, mark "99" if don't know)*		**Skip to W16**	*For non-parous women only.*
W04	How many births have you had?	Number of births: _____			
W05	What year was your last child born?	Year (YYYY): _____			*Can use as analysis filter for births in last X years.*
W06	Where was your last child born?	Health facility Home Other	1 2 3		
W07	Who assisted with the birth of your last child?	Doctor Nurse/midwife Community health worker Traditional birth attendant Family member Neighbor/friend Other No one	1 2 3 4 5 6 7 8		*Delivery by doctor, nurse or midwife is defined as "skilled birth attendant"*
W08	Was any substance applied to the umbilical cord of your last child?	Yes No Don't know/refused to answer	1 0 99	**If no or don't know/ refused, skip to W10**	

NO.	QUESTIONS AND FILTERS	CODING CATEGORIES	SKIP	NOTE
W09	What type of substance?	Mud/earth 1 Dung 2 Ash 3 Spider webs 4 Wasp nest 5 Traditional herbs 6 Oil 7 Soap and water 8 Other 9		*Responses need customization based on local practices.*
W10	When you were pregnant with your last child, did you receive any injection to prevent tetanus (an injection at the top of the arm or shoulder)?	Yes 1 No 0 Don't know/refused to answer 99	**If no or don't know/ refused, skip to W12**	
W11	How many times did you receive this tetanus injection during your last pregnancy?	_____ doses *(range 0-4, mark "99" if don't know)*		
W12	Did you receive any tetanus injection at any time ***before*** your last pregnancy? (previous births, at clinic, after injury, during campaign)	Yes 1 No 0 Don't know/refused to answer 99	**If no or don't know/ refused, skip to W15**	
W13	***Before*** your last pregnancy, how many times did you receive a tetanus injection?	_____ doses *(range 0-9, mark "99" if don't know)*		
W14	Did you receive any tetanus injection at any time ***after*** your last birth? (at clinic, after injury, during campaign)	Yes 1 No 0 Don't know/refused to answer 99	**If no or don't know/ refused, skip to W16**	*Not included for PAB, but included in total doses received.*
W15	***After*** your last birth, how many times did you receive a tetanus injection?	_____ doses *(range 0-4, mark "99" if don't know)*		*Not included for PAB, but included in total doses received.*
W16	In what year did you receive the most recent tetanus injection?	Year (YYYY): _____ *(If don't know year, enter "9999")*	**If year is given, skip to W18. If don't know, go to W17.**	
W17	How many years ago did you receive your most recent tetanus injection?	_____ years *(if unknown, enter "99")*		
W18	Have you ever received a MenAfriVac injection? (during campaign)	Year (YYYY): _____ *(If don't know year, enter "9999")*		*Or other TT-conjugate vaccine in schedule.*
W19	How many years ago did you receive the MenAfriVac injection?	_____ years *(if unknown, enter "99")*	**End of interview. Thank participant.**	

SECTION 4

CHILDREN'S VACCINATION HISTORY

NO.	QUESTIONS AND FILTERS	CODING CATEGORIES	SKIP	NOTE
C01	Did your child receive an injection in their left upper thigh to protect against tetanus, whooping cough, and diphtheria (Penta or DTP), in the first several months of life?	Yes 1 No 0 Don't know/refused to answer 99	**If no or don't know/ refused, skip to C03**	
C02	How many times did your child receive Penta/DTP injection?	_____ doses (range 0-4, mark "99" if don't know		
C03	Did your child receive a Penta/DTP injection in the arm during the second year of life?	Yes 1 No 0 Don't know/refused to answer 99		
C04	Did your child receive any tetanus (TT), or tetanus and diphtheria (DT or Td) injection during school age? (possibly at school or after injury)	Yes 1 No 0 Don't know/refused to answer 99		
C05	How many times did your child receive TT/DT/Td injection during school age?	_____ doses *(range 0-4, mark "99" if don't know*	**If no or don't know/ refused, skip to C08**	
C08	Did your child receive a MenAfriVac injection? (at clinic or during campaign)	Yes 1 No 0 Don't know/refused to answer 99	**End of interview. Thank participant.**	*Or other TT-conjugate vaccine in schedule.*

SECTION 5

MEN'S VACCINATION HISTORY

NO.	QUESTIONS AND FILTERS	CODING CATEGORIES	SKIP	NOTE
M01	Have you ever received any tetanus injection, such as at school, after injury, for military service, or as part of circumcision for HIV prevention?	Yes 1 No 0 Don't know/refused to answer 99	**If no or don't know/ refused, skip to M05.**	
M02	How many times did you receive a tetanus injection?	_____ doses *(range 0-4, mark "99" if don't know)*		
M03	In what year did you receive the most recent tetanus injection?	Year (YYYY): _____ *(If don't know year, enter "9999")*	**If year is given, skip to M05. If don't know, go to M04.**	
M04	How many years ago did you receive your most recent tetanus injection?	_____ years *(if unknown, enter "99")*		
M05	Have you ever received a MenAfriVac injection? (during campaign)	Year (YYYY): _____ *(If don't know year, enter "9999")*		*Or other TT-conjugate vaccine in schedule.*
M06	How many years ago did you receive the MenAfriVac injection?	_____ years *(if unknown, enter "99")*	**End of interview. Thank participant.**	