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Protocol for assessing neonatal tetanus mortality in the community using a combination of cluster and lot quality assurance sampling

Field test version

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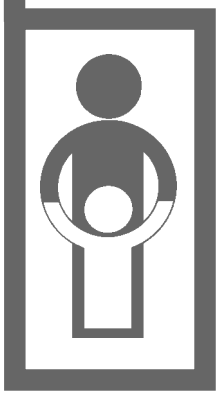

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Contents

Abbreviations ..... *v*

Background 1

Preparation for survey 4
- Review of core indicators 4
- Supplemental data and surrogate indicators 6
- Selecting the highest-risk district or districts for the survey 7

Implementation of survey 12
- Background 12
- Sampling method 12
- Training and supervision 17
- Implementation 18
- Information to be collected 19

Data analysis 21

References 23

Annex 1: District line-list to assess MNT elimination status 24

Annex 2: Checklist of preparations 26

Annex 3: Budget items to consider 27

Annex 4a: Probabilities for of acceptance (i.e. that NT has been eliminated) at any rate of neonatal tetanus mortality, single sampling and double sampling plan 28

Annex 4b: Explanation of probability calculations 29

Annex 5: Form 1 – Household information and live births for first and second samples 32

Annex 6: Form 2 – Live births and mother's TT status 33

Annex 7: Form 3 – Neonatal death investigation form 35

Annex 8: Form 4 – TT coverage status for childbearing aged women who did not give birth 1-13 months before the start of the survey 37

Abbreviations

CBR	crude birth rate
CS	cluster sample
DTP	diphtheria–tetanus–pertussis (vaccine)
LQA	lot quality assurance
MNT	maternal and neonatal tetanus
MOH	ministry of health
NT	neonatal tetanus
NTMR	neonatal tetanus mortality rate
Td	tetanus–diphtheria toxoid
TT	tetanus toxoid
UNFPA	United Nations Population Fund
UNICEF	United Nations Children's Fund

Background

In 2000 the United Nations Children's Fund (UNICEF), the United Nations Population Fund (UNFPA) and WHO set the goal of eliminating maternal and neonatal tetanus (MNT) by 2005 and drew up a strategic plan with this objective. MNT elimination is defined as the achievement of under one case of neonatal tetanus (NT) per 1000 live births annually in every district of a country. In 1990, by which date MNT had been eliminated in 76 developing countries, it was estimated that there were 560 000 cases. By 2000 there were estimated to be 238 000 cases, and 104 developing countries had achieved elimination. The principal strategies for MNT elimination are:

1) routine and supplemental tetanus toxoid (TT) immunization;

2) provision of clean delivery services;

3) effective surveillance to detect and investigate NT cases.

To accelerate the control of maternal and neonatal tetanus, WHO, UNICEF and UNFPA recommend a high-risk approach. This involves the identification of high-risk districts (or areas in such districts), the administration of three doses of tetanus toxoid (TT) to all childbearing women in those districts or areas, the use of auto-disable syringes and proper disposal procedures, the documentation of progress and achievements, and the maintenance of achievements by strengthening the routine system. The latter measure includes the introduction of tetanus–diphtheria (Td) immunization for children of school age, particularly in high-risk districts.

A recommended set of methods and measures (Table 1) for assessing MNT elimination are described in a WHO guide on monitoring and evaluation for MNT elimination. The measures focus on the key strategies required to achieve and sustain elimination in districts. The core measures recommended in the WHO/UNICEF algorithm (Fig. 1) and the surrogate indicators should be reviewed to assess MNT risk/elimination status in each district. Every country should maintain a spreadsheet of the indicators, by district, to allow them to continually monitor progress towards NT elimination.

Figure 1:
WHO-UNICEF recommended algorithm to assess MNT risk/elimination status by district using core and surrogate indicators

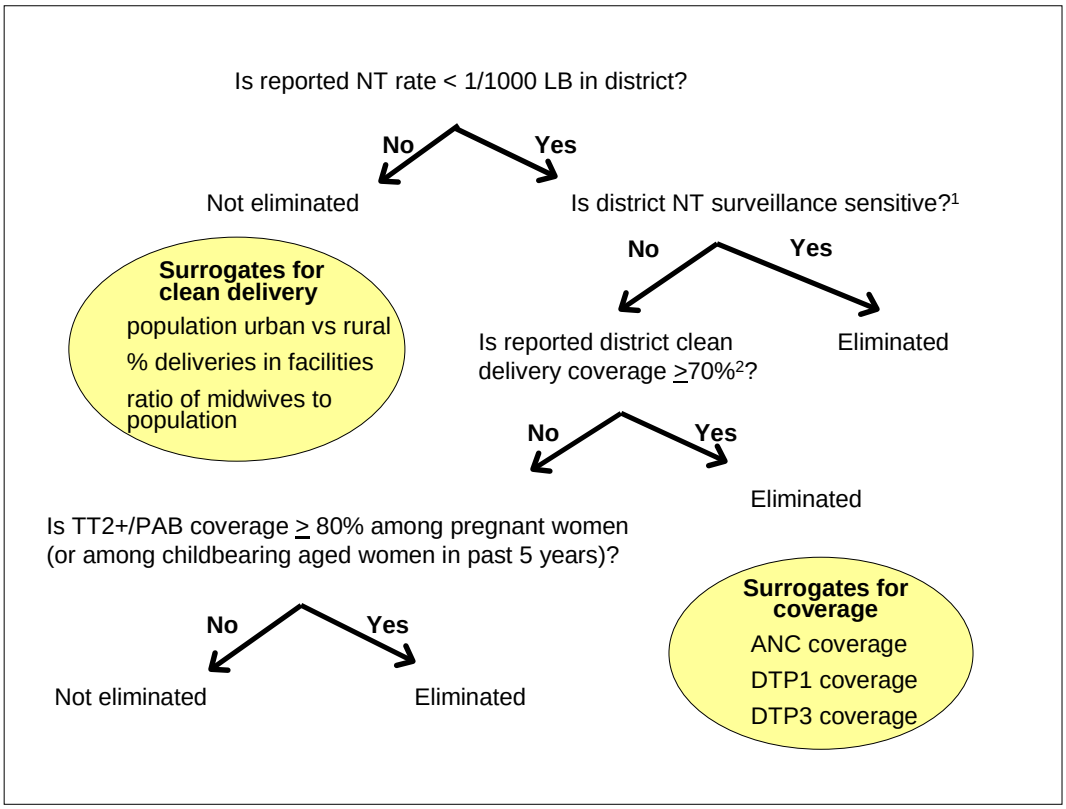


Table 1:
Summary of WHO recommendations on neonatal tetanus monitoring and evaluation

	Protection measures	Impact measures
Core methods	TT2+ coverage monitoring	Facility-based surveillance
	Clean delivery coverage monitoring	
Supplemental methods	Protection at birth (PAB) coverage monitoring	Vital registration
	Immunization coverage surveys	Community-based surveillance
Validation methods	Serosurveys	NT mortality surveys (LQA or cluster)

The validation of MNT elimination is based on a review of data from four sources:

1) core and surrogate information by district using the standard algorithm;
2) impact analysis of supplemental immunization activities;
3) a community-based NT mortality survey in selected high-risk districts;
4) the existence of a feasible plan to sustain MNT elimination.

This protocol describes and explains a method for implementing a community-based mortality survey to assess MNT mortality in the districts at highest risk. It is best used to validate elimination status. It is in three parts:

1) preparation for the survey, including methods for selecting districts;

2) implementation of the survey;

3) data analysis and interpretation.

The statistical basis of the method is briefly described in the Annexes.

Preparation for survey

During initial communication with the ministry of health (MOH) in the country concerned, the objectives, specific terms of reference and protocol for conducting the survey should be agreed. The preparations that are necessary before the survey should be specified.

Review of core indicators

The MOH should be informed that a team composed of national and international staff will first review and rank districts by using a set of indicators. Table 2 shows what is involved. The indicators are based on the WHO/UNICEF algorithm (Fig. 1) and should be compiled by district in a spreadsheet before the assessment is made (Annex 1).

Table 2:
Sample of core indicators for an assessment of MNT elimination, Zimbabwe, 1998-1999

District	NT cases reported		Clean delivery coverage (%)		TT2+ coverage among pregnant women (%)	
	1998	1999	1998	1999	1998	1999
Buhera	0	0	74	67	58	59
Chimanimani	0	0	74	75	77	63
Chipinge	0	1	63	63	61	60

Some of the common limitations of data compiled for the three core indicators are outlined below. They should be considered as the team reviews the validity of the data during the assessment.

Reported incidence of NT

Most countries where NT has been a problem in recent times have not yet developed uniform nationwide surveillance or vital event registration with medical certification of the cause or causes of death. The least efficient routine surveillance is likely to be in districts with rural populations, although such districts may have recently established active surveillance for NT in their district hospitals. Before accepting low rates of reported NT as the basis for deciding that NT has been eliminated, the sensitivity and reliability of surveillance for NT must be evaluated.

A thorough evaluation of a surveillance system is a major undertaking, not to be attempted by the assessment team. The team should focus on assessing the sensitivity of surveillance and identifying the districts with the least efficient surveillance. Some characteristics of surveillance which should be reviewed in each district are listed below.

- Is there an adequate number of reporting sites and is their distribution representative?
- Is zero reporting mandatory?
- Is a reporting completeness at least 80%?
- Have there been annual hospital record reviews or has there been active surveillance for NT?
- Has a functioning system of community surveillance for NT in rural populations been established to ensure that neonatal deaths are detected and investigated?

If the answers to any of the questions are in the affirmative the team should attempt to ensure that policies are followed and that activities are correctly performed. For example, the team should review samples of records to ensure:

- that, if done, annual hospital record reviews cover all paediatric discharge diagnoses and chart reviews for neonatal deaths that occur in the age range 4-14 days (in which over 90% of NT deaths occur);
- that diagnoses or exclusions of NT are substantiated by the information in the records (e.g. no NT cases are missed);
- that, in rural populations, active surveillance for neonatal deaths is conducted in the major hospital or hospitals in the area concerned, and that there is evidence of community sensitization and involvement in the notification of neonatal deaths.

Percentage of births with clean delivery

The second criterion is whether at least 70% of births have been delivered by a physician, nurse or midwife (in some countries, clean delivery is defined more stringently, e.g. delivery must take place in a health facility). Most developing countries have been disseminating educational information on clean delivery, training traditional birth attendants and/or providing clean delivery kits, all of which contribute to reductions in NT. If a country has achieved uniform clean delivery coverage of at least 70% it is possible that education and training have been extended to population subgroups with limited access to professional care. However, districts with clean delivery coverage below 70%, especially those with large rural, dislocated or slum populations, may not have achieved elimination. These districts will be of particular interest to the assessment team, since deliveries at home are more common in such districts than elsewhere and are more frequently associated with non-sterile conditions at birth as well as with traditional practices in which umbilical stumps are dressed with infectious materials.

Percentage of pregnant women given TT immunizations

The algorithm specifies that at least 80% of pregnant women (or women of childbearing age) should have received an adequate number of TT immunizations to provide them with sufficient antitoxin to produce passive immunity in their newborn offspring. Although immunization with TT is the most practical programmatic means of preventing NT, it is difficult to assess coverage reliably on the basis of reports of TT doses administered. This is particularly true in countries with well-functioning immunization systems that have been established for many years, where administrative reports of TT coverage often underestimate the real achievements.

Because protective antitoxin levels depend on the timing and numbers of TT doses given and because the term TT2+ is commonly used to designate two or more TT immunizations, administrative tallies of immunizations are difficult to associate with appropriate denominators. For example, women who have received five appropriately spaced doses of TT have sufficient protection for their reproductive years. If coverage is calculated from the tallies for women of fertile age, all such women are usually included in the denominator. However, as only women who have received TT during a particular year are included in the numerator, the estimate of coverage can be substantially lower than the actual protective levels. If coverage is calculated for pregnant women the number of live births is the most frequently used denominator to represent them. In countries with well-established immunization systems, however, many women may not have been eligible for a dose during a recent pregnancy either because they have previously been vaccinated or because they have completed the five-dose series. Although such women are protected, the administrative estimate of TT2+ does not include them in the numerator even though they are still included in the denominator as pregnant women, and the consequence is again an underestimation of TT2+ coverage.

If there are supplemental data, such as the results of coverage or serological surveys, which substantiate administrative estimates of coverage, the MOH should have the reports available for review so that the population subgroups and/or districts to which the results apply can be identified.

Supplemental data and surrogate indicators

The MOH should also compile supplemental information and surrogate indicators (Annex 1) by district, in addition to the core indicators. These may also be used to select districts for the survey.

Supplemental information may include:

- completeness of reporting by districts;
- reports on annual record reviews;
- completed forms for investigations of neonatal deaths.

Surrogate information may include:

- the proportion of pregnant women having made at least one visit for antenatal care (these data can complement those on clean delivery);
- coverage with DTP3 (these data can complement those on TT2+ coverage);
- coverage with DTP1 (these data give an indication of access to care);
- drop-out rate from DTP1 to DTP3 (calculated as [(DTP1 – DTP3) x 100%] / DTP1, providing an indication of the management of immunization services).

The surrogate indicators should be incorporated into the spreadsheet with the core indicators (Annex 1).

The most recent population estimates for districts, indicating the numbers of women of fertile age, pregnant women and births, should also be available. Once the districts are selected for the community-based survey the most recent population estimates for the census enumeration units, e.g. wards, blocks and village areas, should be obtained. Arrangements should be made to obtain copies of national, regional and district maps as required.

Selecting the highest-risk district or districts for the survey

It is critical that the MOH consolidate the data and information before assessment begins, for the following reasons.

- The information provides the evidence needed in deciding whether to conduct a community-based survey to validate MNT elimination (i.e. whether the data suggest that MNT elimination has probably been achieved, thereby making it worthwhile to conduct a community-based survey, or whether they clearly indicate that MNT elimination has not been achieved and that the survey should be postponed).
- The information is used to select the highest-risk districts for the survey.

The selection of the district or districts should take place well before the start of the survey so that proper administrative and logistical arrangements to be made. For example, it is necessary to obtain census data and maps of the districts to be surveyed. A budget should be prepared and the funds should be released in time to enable preparation and implementation. Field and supervisory staff have to be recruited and trained. Vehicles, petrol and drivers have to be provided. These administrative and logistical arrangements (Annex 2) should all be resolved by the time the international team members arrive in the country. A sample of the budget items that should be considered for the community-based survey is given in Annex 3.

Suggested method for selecting districts for the survey

The basis for surveying districts at highest risk for NT is the assumption that if NT has occurred in the recent past it will probably have done so in these districts. If NT has been eliminated in the districts at highest risk it is reasonable to assume that the disease has also been eliminated in those at lower risk.

During previous assessments a procedure was developed for identifying districts at highest risk for NT. It is based on three steps:

1) consolidating core and surrogate indicators on every district in a spreadsheet (Annex 1);

2) developing a short list of districts potentially at highest risk by ranking the districts according to the values of the indicators;

3) selecting the districts to be surveyed from the short list on the basis of public health judgement and logistical and administrative considerations.

Since the data on indicators by district should already have been entered on a spreadsheet (Annex 1), the initial ranking and listing of potentially highest-risk districts can be rapidly done by using sort commands. The ranking and listing procedures can also be done manually. The list of districts is repeatedly sorted by level of performance for each indicator and the districts of lower performance from each sorting procedure are copied to a new table of potentially high-risk districts. The table of potentially high-risk districts should contain a row for each district with a rank in the low range for any indicator, and columns for all the indicators being considered. In other words, once a district has been entered in the new table the values for all other indicators for that district should be copied to the same row.

Ranking

Ranking is not performed for reported NT cases. Instead, any district that has reported NT during the preceding two years should be copied to the table of highest-risk districts with the number or rate of reported cases.

For indicators with coverage values the district with the lowest value is ranked as 1, the next lowest as 2, and so on. For example, if the range of reported clean delivery coverage ranges from 20% to 91%, the district with 20% coverage is assigned rank1, that with the next highest level of coverage (e.g.23%) is ranked 2, and the process continues until a practical number of districts with the lowest coverage values have been obtained, ranked and entered in the table with their ranks and coverage levels. The same is then done to identify districts with the lowest values for coverage with TT2+ and DTP3, and for any other indicators used for the ranking of districts.

How many districts to include in the initial list of high-risk districts

The number of districts to be ranked for a particular indicator can be expected to vary in accordance with the numbers of districts in the country and the values of the indicators. For a country with a large number of districts (e.g. over 50) it may be useful to identify and list 10 with the lowest values for each indicator; in a smaller country with fewer districts a smaller number could be ranked. However, the actual values of the indicators may determine how many districts should be ranked. For example, if all but a small number of districts have similar high levels of verified clean delivery coverage a cut-off value may be practical. If such a distribution of values were identified for a particular indicator, only the districts with coverage below the cut-off value would be entered in the table.

Preparing a short list

Table 3 is part of a table of the initial listing of districts with ranked indicator values which was prepared during an assessment in Zimbabwe. The table was reviewed by the assessment team in order to identify districts with multiple low rankings or with an unusually low rank for any particular indicator. The purpose of the review was to develop a short list of probable highest-risk districts. This selection process was not wholly based on the data in Table 3: public health judgement also came into play. For example, in Zimbabwe none of the districts that reported NT cases during the preceding two years, e.g.: Mount Darwin and Guruve, were selected for the short list, because the other indicators for the particular districts suggested a low NT risk and because a review of investigation forms suggested that some reports of NT cases from these districts were erroneous. Table 4 is the short list prepared for the assessment in Zimbabwe.

Table 3:
Initial list of districts with low performance indicator values,
Zimbabwe, 1998-1999

District	Reported NT cases		Clean delivery coverage or ranking*		TT2+ coverage or ranking*		Antenatal care coverage or ranking*		DTP3 coverage or ranking*	
	1998	1999	1998	1999	1998	1999	1998	1999	1998	1999
Guruve	1	1	**5**	**5**	101%	93%	102%	108%	82%	90%
Uzumba Maramba Pfungwe (UMP)	NR	0	NR	**1**	NR	87%	NR	68%	NR	**1**
Mount Darwin	0	1	73%	69%	107%	91%	116%	96%	96%	82%
Zvimba	0	0	65%	**6**	113%	104%	79%	74%	75%	73%
Bindura	0	0	76%	79%	**8**	**6**	72%	71%	67%	79%
Nkayi	0	0	71%	68%	67%	**8**	94%	76%	124%	72%
Chikomba	0	0	84%	82%	80%	56%	74%	**5**	87%	83%
Gweru	0	0	82%	83%	**7**	**3**	**5**	**2**	**5**	**4**

* Ranked values are single digits in bold print.
NR: no report received.

Table 4:
Short list of districts identified as being at highest risk for NT, and reported values of selected indicators, Zimbabwe, 1998-1999

District	NT reported cases		Clean delivery (%)		TT2+ coverage (%)		Antenatal care (%)		DTP3 coverage (%)	
	1998	1999	1998	1999	1998	1999	1998	1999	1998	1999
UMP	NR	0	NR	35	NR	87	NR	68	NR	31
Goromon.	0	0	76	68	35	103	26	58	26	129
Lupane	0	0	58	57	49	54	76	71	65	65
Umguza	0	0	59	62	71	42	38	48	36	34
Umzing.	0	0	58	55	53	49	64	62	61	64
Mutoko	0	0	88	85	24	61	36	79	24	97
Gweru	0	0	82	83	53	47	57	56	52	52

NR: no report received.

Selection from the shortlist

The selection from the short list of the district or districts to be surveyed is more subjective than the preparation of the initial listing of high-risk districts. This selection should be based on public health judgement as well as on a consideration of administrative, financial and logistical realities. In Zimbabwe, for example, a group of three neighbouring districts was selected for survey from the short list. This was done because administrative and financial constraints convinced the assessment team that an initial intention to survey two groups of three neighbouring districts was impractical.

There may be other factors to consider during the final selection of a district or districts for survey. In the State of Rajasthan in India, for example, there were multiple objectives for an MNT assessment. One was to assess the elimination of MNT, another was to measure coverage achieved during recent supplemental immunization activities and to determine their impact on NT, and a third was to survey a district in the desert area for political reasons. The process of ranking districts in Rajasthan was basically the same as that used in Zimbabwe. Because of the several objectives, however, it was decided that the national and international team members should independently select the district to be surveyed. Both groups arrived at the same conclusion.

In summary, there are various ways in which districts can be objectively ranked for inclusion in a survey. The method described in this document is one of them. Some countries have chosen to enhance this method by weighting the indicators. The weighted values can be summed to obtain a score for each district. Although a standardized method for weighting and scoring could be developed, it is recognized that the best way to do this may vary between countries because of programmatic variations and differences in reliability between indicators. In Zimbabwe, for example,

antenatal care coverage was considered a valuable substitute for TT coverage because of the provision of TT immunizations at antenatal care sessions, and therefore could have been given a high weight. In countries in which TT immunizations are provided separately, antenatal care coverage may not be as useful a substitute for TT coverage and therefore should not receive a high weight. If a decision is made to score districts it is probably desirable to allow the assessment team to weight the indicators that are considered most useful and reliable for the country in question.

Good preparation for a survey is essential. Proper logistical and administrative arrangements and the selection of districts well in advance are vital for efficiency and the best possible results.

Implementation of survey

Background

In order to evaluate the neonatal tetanus mortality rate (NTMR) in a community, the survey method described in this document uses the principles of lot quality assurance sampling to judge whether the NTMR has been reduced to less than 1/1000 live births during a recent 12-month interval. This method is appropriate to use at the final stage of MNT elimination when there is evidence to suggest that NT is reduced to less than1/1000 live births and is only occurring sporadically, i.e. not clustering. Using this method in combination with cluster survey sampling, data are collected on clusters of births in order to reduce costs. The assumptions on which this combined approach is based are indicated in Annex 4b.

The elements sampled in the survey are:

- live births delivered during a recent 12-month interval, completed at least four weeks before the survey data are collected;
- live births in a group of districts with a combined total population of a least 750 000; for smaller populations, alternative plans involving reduced sample sizes are being developed and tested.

All live births that have occurred in the sampled households are assessed, regardless of the normal place of residence of the mother. For example, a birth that has occurred to a mother who has returned to her parents' home for delivery is assessed if the parents' home falls in the sampled cluster.

Sampling method

In general, the cluster selection methods used in the 30 x 7 cluster survey method for assessing immunization coverage is used to select cluster starting points in the population units specified in the preceding section (WHO 1991a, 1991b). A random start and selection interval equivalent to the population divided by the total number of clusters in the survey is used to systematically select population units, e.g. villages or wards, in which clusters fall. The procedure of visiting neighbouring households until a specified quota of live births has been surveyed, as in the above-mentioned 30 x 7 cluster survey method, is also used. This hybrid LQA method for assessing NTMR differs from the 30 x 7 cluster survey method in the number of clusters and the two stages in which the clusters are surveyed. The rationale for the use of a double sampling procedure and the use of smaller clusters has both theoretical and practical bases.

The theoretical bases are as follows.

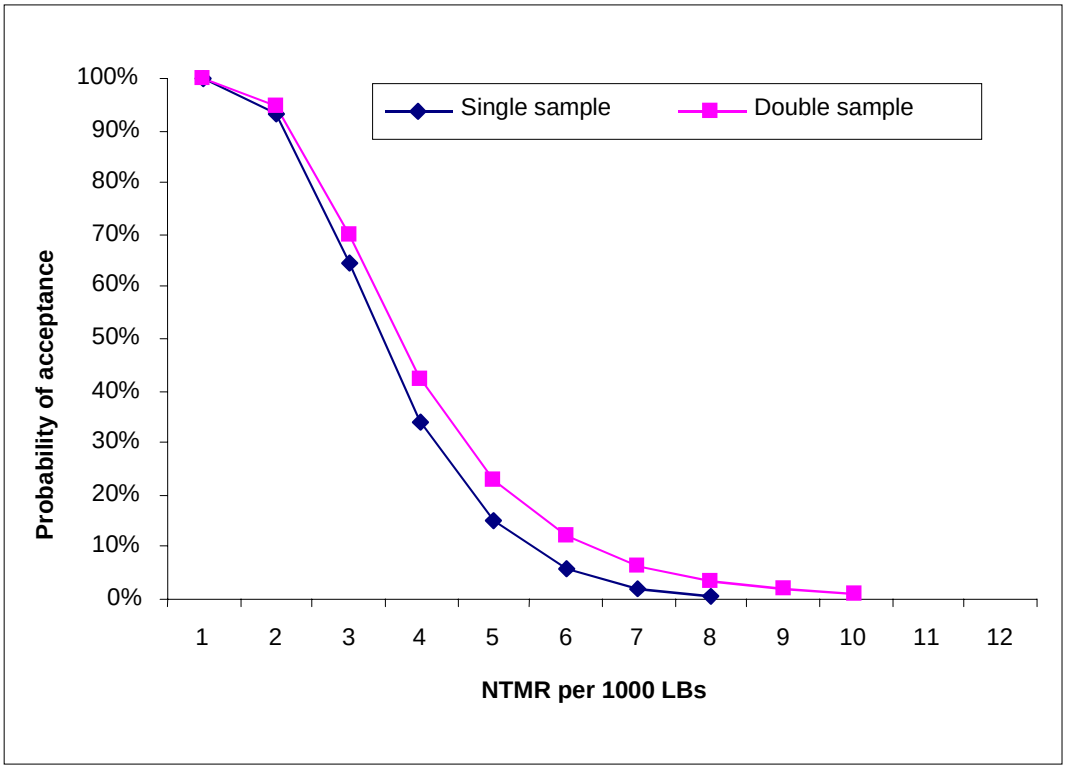
- On average a double sample procedure needs a smaller sample size in order to reach a decision than a single sample procedure with the same total sample size. Annex 4 and figure 2 show the similar probabilities of classifying populations with different rates of NT when single and double sampling procedures are employed.
- A larger number of clusters increases the representativeness of the sample.
- The probability of obtaining a design effect above 1 with a rare event such as an NT death is reduced even further with clusters of smaller size.

The practical bases are as follows.

- A smaller sample size reduces the amount of fieldwork.
- Clusters can be designed to be of a size that can be completed in a single day of fieldwork.
- By having clusters of appropriate size it should be possible to decide on a daily basis whether to:
  - stop the survey and reject the districts (i.e. NT not eliminated);
  - continue the survey and, on completion of the first sample of clusters, decide to stop the survey and accept the districts (i.e. NT eliminated);
  - continue the survey with the second sample.

The sampling frame consists of a list of all the population units, i.e. the smallest units for which population estimates exist, in the districts selected for the survey on the basis of an analysis of core and surrogate indicators as described in the preceding chapter.

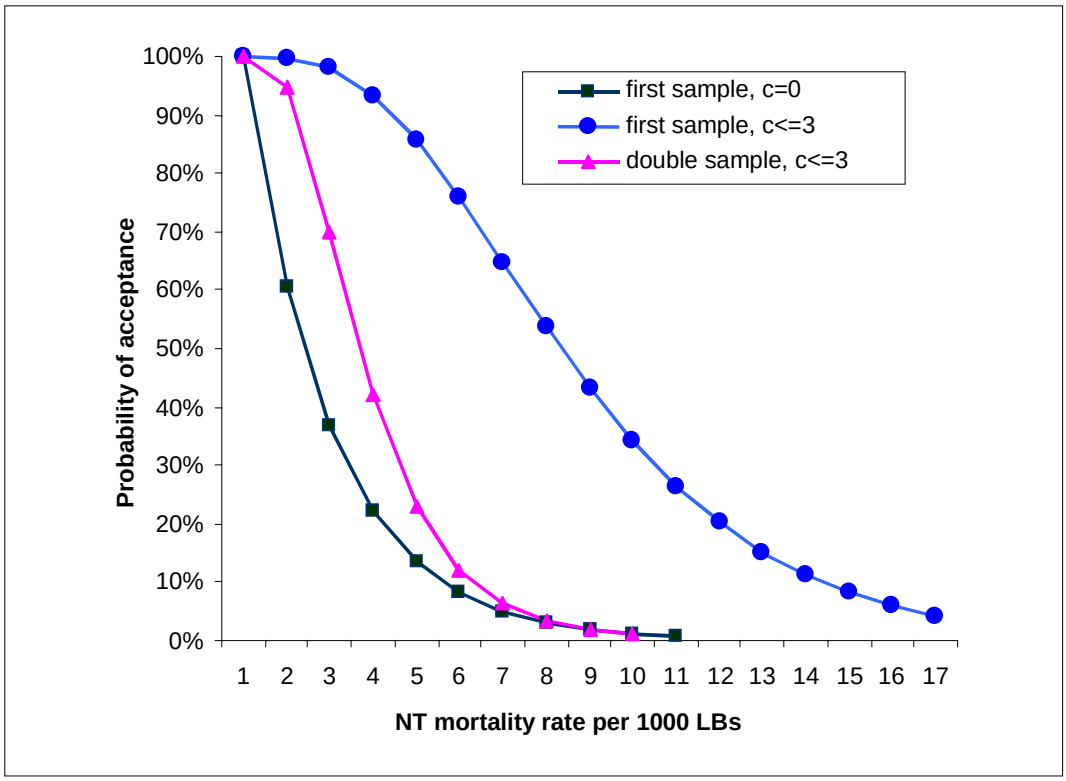
Figure 2:
Operating curves for a single and double sample,
both with sample sizes of 3000 live births and probability
of "acceptance" (i.e. that NT has been eliminated) given that
three or fewer neonatal tetanus deaths were found in the survey sample



Sample size

The sample size, i.e. the number of births used to classify populations with NTMRs in the vicinity of less than 1/1000 live births, and the probabilities of the classifications, are shown in Annex 4 and figures 2 and 3. Figure 2 is a set of curves comparing the operating characteristics, i.e. the probabilities of accepting and rejecting a group of districts with any particular NTMR, of single and double sampling plans with a sample size of 3000 live births. The curves illustrate how the use of a double sampling procedure reduces the amount of work. The first sample of 1000 live births can provide results that may eliminate the need to complete the second sample of 2000 live births. If it is necessary to continue with the second sample the survey can be stopped whenever more than three NT deaths have been identified during the first and second sampling combined.

Figure 3:
Operating curve for the double sampling plan.
Shown are the two curves for the first sample
(n=1000 with c=0 and c<=3).
The third curve shows the probabilities for the
entire double sampling plan (n=3000 with c<=3).



c=number of NT deaths identified

The calculation of the number of clusters recommended in this protocol is based on:

1) crude birth rate (CBR);

2) household size;

3) the number of households that can be visited in one day.

If a survey team can travel to and survey about 125 households in a working day in a country with a CBR of 0.039 and an average household size of 5.5, then an average of 25 live births should be found in 117 households in each of 120 clusters. Country variations in birth rates and average household sizes may affect the number of clusters needed. The following method can therefore be used to calculate the number of clusters in the survey if data are available on the CBR, average household size and the number of households that can be visited by a team in a day.

Number of live births needed / CBR = population required to obtain the number of live births needed.

Population required / average household size = average number of households needed to obtain the required number of live births.

Number of households needed / number of households that can be visited by a team in one day = number of clusters required.

The following example relates to a country with a CBR of 39 per 1000 population, and an average household size of 5.5 persons.

3000 live births needed / 0.039 = 76 923 population required to obtain the number of live births needed.

76 923 population required / 5.5 per household = 13 986 households to be visited.

13 986 households / 125 households to be visited in one day = 112 clusters.

Thus 3000 live births should be found in 112 clusters with an average of 26.8 births per cluster, i.e. 125 households x 5.5 per household x 39 live births per 1000 population. Because it would be necessary to assign 26 or 27 live births to different clusters in order to obtain an average of 26.8, the next smallest multiple of births dividing evenly into 3000, i.e. 25, is used, giving a total of 3000/25 = 120 clusters. On average, therefore, each cluster of 25 live births consists of about 117 households containing about 641 people (25 live births x 5.5 persons per household / 39 live births per 1000 = 641 persons).

Forty clusters will then be selected from the 120 clusters. These 40 clusters will be the first sample (to collect information on 1000 live births), and the remaining 80 clusters will constitute the second sample (to collect information on 2000 additional live births).

For assessing TT2+ coverage, TT histories are collected from a sample of 280 pregnant women and a sample of 400 women of childbearing age. The first seven women in the cluster who had a baby aged 1-13 months before the beginning of the survey will provide an estimate of protected LBs for a total sample size of 280. A sample of the first 10 childbearing aged women (CBAW) in each cluster will result in a sample size of 400 CBAWs. These sample sizes should provide estimates with narrower confidence intervals than a 30 x 7 survey because more clusters are surveyed and coverage is usually higher than 50%. The sample sizes can be adjusted in accordance with the precision desired.

Cluster selection

Cluster selection is performed in the manner of the 30 x 7 cluster survey method, except that 120 clusters are selected. The clusters are numbered sequentially, 1 to 120. A random number 1 to 3 will be selected. That random number identifies the first cluster of the first sample. The second cluster in the first sample is the cluster with the sequential number corresponding to the random number plus three. The sum indicates the cluster number of the next cluster in the first sample. The 40 clusters constituting the first sample are identified by continuing to add 3 to the number of each subsequently identified cluster. The remaining clusters constitute the second sample, which may or may not be surveyed, depending on the results obtained from the first sample.

Training and supervision

Interviewers should be selected on the basis of their background in public health and their ability to interact with families, and particularly with women, about sensitive issues such as pregnancy, pregnancy outcomes and the survival of infants. Public health nurses are often ideal candidates. The training session should be as practical as possible and should include demonstrations and practice in the completion of each survey form. Written guidelines should be provided on completing the forms and on asking lead-in questions about past pregnancies and signs of life at birth, in order to increase the ability to detect and record live births that have occurred during the period of eligibility for the survey. The characteristic symptoms associated with the development of NT should be described and discussed so as to ensure optimal sensitivity and specificity of NT diagnosis by the verbal autopsy method. Special attention should be given during training to demonstrations on eliciting and recording information from respondents about neonatal deaths, with a view to minimizing bias among both respondents and interviewers. If data on TT coverage or protection at birth are to be collected during the survey the interviewers should understand the immunization schedule and should be aware of the duration of protective immunity given by TT. If a woman does not have an immunization card a verbal history should be taken. In this connection the following questions are recommended.

1) Did you receive any injections during your pregnancy with this baby? If so, were they of TT and how many were you given?

It is important to know the national policy concerning the site of TT injection, which is usually in the muscle of the upper arm. It is also necessary to know whether other injections are routinely given during pregnancy, and, if so, the site of other injections. For the purpose of quality control, a question can then be asked about the sites of any reported injections. If a woman describes an injection given in the gluteals, it probably was not TT.

2) Did you receive any TT vaccination doses during any preceding pregnancies? When were those pregnancies?

The accuracy of the response can be expected to decline with increasing recall time. Nevertheless, the question should be asked since serological studies have shown rather good concordance between a mother's ability to recall TT injections associated with special events such as pregnancy and her serological status.

3) Did you receive any TT doses during other special events (e.g. supplemental TT immunization activities, school immunization events)? When were those events?

Again, accuracy can be expected to decline with increasing recall time. However, the questions are worth asking since there is evidence that women, especially younger women, can recall school immunization events and supplemental immunization activities. Questions on whether doses were administered by auto-disable syringes (ADs) can help to differentiate between routine and supplemental immunization activities. ADs are often used only in the SIAs.

In general, one supervisor should be assigned to every five interviewers or interviewer teams, although the optimal ratio may vary between countries. The supervisors should participate in the initial review of district data, the planning for the survey and the training. During the survey the supervisors should continually visit interviewers in the field and periodically accompany them on household visits. The supervisors should ensure that household selection and visits are conducted according to the protocol and that the forms are completed and tallied properly.

Implementation

The completion of the first sample may require only one day if there are enough field staff to go simultaneously to 40 different clusters. Each team should go to the location of its assigned cluster, randomly select and survey the first household in the cluster, and then survey neighbouring households until the required information has been collected on all households visited. This information includes the survival status of 25 live births, TT coverage of a sample of their mothers, and other women of childbearing age, and the epidemiological features and clinical signs associated with neonatal deaths. Data collection instruments are indicated in Annexes 5-8. If no NT deaths have been identified on completion of the 40 clusters the survey can be stopped and NT can be judged to have been eliminated in the surveyed districts, i.e. pass status is achieved. If, more than three deaths attributable to NT have been identified the survey can be stopped, the conclusion can be drawn that NT has not been eliminated, and failed status is assigned.

The second sampling must be started if above zero and under four NT deaths are found in the first. For the second sampling, issues of efficiency and logistics should be considered in deciding which clusters to cover first and the order in which they are to be surveyed. For example, where the first sample has produced three NT deaths in a particular population subdivision, and if there are second sample clusters in that subdivision, it would be practical to cover them first. If, in this example, one additional NT death is found the survey can be stopped and a failed status is assigned.

In general, in a second sample it is practical to look first at the clusters in which there is a higher probability of NT. If, however, there has been only one NT death in the first sample and if none of the second sample clusters are suspected to be at higher risk of NT, the order in which the clusters are surveyed should be based on practical matters such as cost, travelling time and logistics.

During the second sampling the survey can be stopped whenever the number of NT deaths of the first and second sample combined exceeds three. Plans should therefore be made for obtaining daily information on the findings of the field teams.

In summary, the rules for determining the pass or fail status of the survey during the first or second sampling and for stopping the survey are as follows.

During the survey of the first sample of clusters:

- if more than three NT deaths have been found on completion of the 40 clusters in the first sample the survey can be stopped and FAIL status is assigned to the district or districts surveyed;
- if no NT deaths have been found on completion of the 40 clusters in the first sample the survey can be stopped and PASS status is assigned to the district or districts surveyed;
- if one, two or three NT deaths have been found on completion of the 40 clusters in the first sample a survey of the second sample clusters should begin.

N.B.: If data are being collected only to evaluate NT, the survey can be stopped whenever more than 3 NT deaths are found. However, if other variables, such as TT coverage are being assessed, all clusters in the first sample must be completed to obtain a representative result.

During the second sampling of clusters:

- if more than three NT deaths, including the deaths found in the first sample clusters, are found at any time, the survey can be stopped and FAIL status is assigned to the surveyed district or districts;
- if no more than three NT deaths, including deaths found in the first sample clusters, are found on completion of the second sample clusters, PASS status is assigned to the surveyed district or districts.

Information to be collected

Sample data collection instruments and instructions to interviewers are given in Annexes 5-8. For maximum efficiency and the best possible data quality the information collected during the survey should focus on what is essential for the purposes of evaluating the NTMR, the TT status of mothers and women of childbearing age, and other epidemiological factors related to the risk of NT. Data on a few additional variables, e.g. the number of residents in each household visited, should also be collected as an aid to assessing whether the survey is being well implemented. Such information provides data for calculating average household size, verifies the actual number of household visits needed to complete each cluster, and provides an estimate of the CBR. These estimates can then be compared with other sources of data in order to validate the quality of the survey data.

For each live birth encountered, a line on form 2 should be completed that provides information on date of birth, sex , whether the baby is still alive and, if not, whether it died before 29 days of age. In addition, form 2 should be used to collect TT status at the time of birth from a sample of mothers of these live births. Additional variables may be appropriate for particular settings but they should be limited to critical issues about MNT elimination so as to ensure an efficient focused survey that provides data of high quality.

For any neonatal death, i.e. between 0 and 28 days of age, that has occurred in a baby born 1-13 months before the survey dates, form 3 should be used to record information needed to complete the standard verbal autopsy questions for NT.

Form 4 may also be completed to obtain an estimate of the TT coverage of women in a sample of childbearing age women.

In summary, the interviewers should carry the following four forms shown in Annexes 5-8.

- Form 1 (Annex 5). Tally grid on households visited and household size for first sample.
- Form 2 (Annex 6). Live births occurring 1-13 months before survey and TT coverage status of a sample of their mothers.
- Form 3 (Annex 7). Characteristics of neonatal deaths.
- Form 4 (Annex 8). TT coverage status of a sample of women of childbearing age.

Data analysis

The interpretation of the survey results has been described in the preceding section. If no NT cases are identified among the 1000 live births surveyed in the first sample, NT can be considered to have been eliminated in the district or districts surveyed. The same conclusion is reached if fewer than four cases have been found on completion of the first and second samples. If more than three cases are identified during the survey, however, the conclusion should be that NT has not been eliminated.

A point estimate may be calculated for NT if fewer than four cases are found, in which instance both the first and second samples will necessarily have been completed. However, it should be recognized that the upper limit of a 95% confidence interval exceeds 0.001, the elimination threshold, if even a single NT case is found, and the lower limit extends below 0.001. Consequently, the calculation of a confidence interval for the NT rate in these surveys is largely an academic exercise. One can readily refer to the operating characteristic curves for this sampling plan in the Annexes to find the statistical probabilities of a pass status for any rate of NT in a population. However, if one wishes to calculate a confidence interval, the design effect resulting from the cluster sampling method must be included. A practical approach is to assume that the design effect is very close to unity and to use the quadratic or another formula that accounts for the skewness of the confidence interval with incidence rates for rare events.

If more than three cases of NT are identified during the survey it is generally impractical to calculate a point estimate and a confidence interval. If more than three cases are encountered in the first sample only, the confidence interval is wide because only 1000 live births have been sampled. If a fourth case is identified in the second sample and the survey is stopped, i.e. the second sample is not completed, the results are unrepresentative.

In order to obtain point estimates for TT coverage of mothers and women of childbearing age the procedure is straightforward. The proportion of women immunized with a particular dose is calculated by dividing the number of women who have received the dose by the number of eligible women who have been sampled. Let us assume, for example, that the first five mothers of live births encountered in the first sample, that is 200 mothers in all, are asked about their TT status. If 182 of them have received TT1, the point estimate for coverage with TT1 among mothers who delivered a live birth during the period of eligibility is 182/200 or 91%; if 178 have received TT2, 89% is the point estimate for TT2 coverage. The calculations of point estimates for TT coverage among women of fertile age, or for any other subsample and parameter measured, e.g. place of birth for a subsample of live births, in households visited during the first sampling, is performed as described above for TT doses.

The data in this type of survey are collected from people living in groups of neighbouring households, i.e. clusters. There is a strong probability that people living near one another are more alike than people who live in different clusters. For example, TT coverage among women who live in households in a cluster near a health centre may be higher than that among women who live in a cluster distant from a health centre. The calculation of a confidence interval for variables measured in cluster surveys should take into account that the data are gathered in the clusters by calculating a design effect. The LQA-CS survey method approximates a single stage cluster sample with a census of elements; the formula for calculating the variance for this type of cluster survey, i.e. incorporating the design effect, is used to estimate the confidence interval for the variables included in the survey.

The confidence intervals for TT coverage, and for other variables for which data may be collected during the survey, are calculated with the aid of a spreadsheet. It is necessary to enter the number of clusters in the survey and an estimate of the number of clusters in the population. The latter is arrived at by dividing the population in the sampling frame by the average cluster size, which may vary between variables. For each variable the number examined and the number with a particular attribute should be entered for each cluster. In many instances the number examined is the same for several variables and only the number with the particular attribute needs to be entered in order to obtain the confidence interval for the attribute. The spreadsheet provides the point estimate, the 95% confidence interval, and the values of the variance, the design effect, and a corrected sample size for each variable. Instructions on the use of the spreadsheet are included in the spreadsheet file.

References

1) UNICEF, WHO, UNFPA. Maternal and neonatal tetanus elimination by the year 2005: Strategies for achieving and sustaining elimination. November 2000 (UNICEF publication).

2) World Health Organization, 1991a. *Training for mid level managers. The EPI coverage survey* (unpublished document WHO/EPI/MLM/91.10; available from Vaccines and Biologicals, World Health Organization, CH-1211 Geneva 27, Switzerland).

3) World Health Organization, 1991b. *Training for mid level managers. Facilitator guide for the EPI coverage survey* (unpublished document WHO/EPI/MLM/91.11; available from Vaccines and Biologicals, World Health Organization, CH-1211 Geneva 27, Switzerland).

Annex 1:

District line-list to assess MNT elimination status

			Algorithm - core indicators					Surrogate indicators						
District name	Province name	Reported NT cases	Live births	Reported NT rate per 1000 LBs	Good NT surveillance	Clean delivery rate	TT2+ coverage	ANC (≥1 visit)	DTP1	DTP3	Drop out	Urban or rural (majority of population)	Other indicators (add columns as needed)	NT risk
		number	number	rate	yes, no, unknown	%	%	%	%	%	(DTP1-DTP3) DTP1			high, low, unknown
National summary (total)														

Annex 2:
Checklist of preparations

Checklist of preparations	Date completed	Name of person responsible
Preparations to be completed well in advance		
Protocol, objectives, and expected outcome shared with national staff		
Terms of reference, objectives, and dates agreed upon with Ministry of Health		
Necessary district-level data (core & surrogate indicators) consolidated for review and district selection		
Population data obtained from selected districts		
Clusters selected		
Detailed maps obtained of selected clusters		
Number of needed staff (interviewers and supervisors) calculated		
Interviewers, supervisors, drivers identified		
Interviewers, supervisors, drivers agree to dates, responsibilities, conditions for work		
Vehicles/source of petrol identified and reserved		
Budget calculated		
Financial resources identified		
Financial resources mobilized so that they can be rapidly accessed		
Date of training set?		
Place of training identified?		
Interview forms prepared (i.e. adapted to the local situation, translated) & field tested		
Clearance obtained from districts where the survey will be conducted		
Preparations to be completed just before the start of the survey		
Staff recruited (both interviewers and supervisors)		
Staff trained (including a field exercise or role play to practice interviews and completing forms)		
Money accessed to pay perdiems and petrol		
Interview forms and other stationary prepared for each interview team		
Means and frequency of communicating with survey teams established		

Annex 3:

Budget items to consider

Budget items to be considered	Amount in local currency	Amount in US$	Comments on how calculation was made
Rental of training site			
Equipment for training (projectors, flipcharts) - rental			
Perdiem for trainers			
Perdiem for interviewers			
Perdiem for supervisors			
Perdiem for drivers			
Rental of vehicles			
Petrol for vehicles			
Stationary			
Communications			
Administrative support (printing, photocopies,			
recruiting of staff)			
Consultant costs (or payment of local firm/experts to help or oversee survey)			

Annex 4a:

Probabilities for of acceptance

(i.e. that NT has been eliminated) at any rate of neonatal tetanus mortality, single sampling and double sampling plan

	Single sample, n=3000	Double sampling plan		
NTMR/1000LBs	c<=3	n1, c=0	n1, c<=3	n1+ n2, c<=3
0.0	1.000	1.000	1.000	1.000
0.5	0.934	0.607	0.998	0.947
1.0	0.647	0.368	0.981	0.7
1.5	0.342	0.223	0.934	0.421
2.0	0.151	0.135	0.857	0.228
2.5	0.059	0.082	0.758	0.12
3.0	0.021	0.05	0.647	0.064
3.5	0.007	0.03	0.537	0.035
4.0		0.018	0.433	0.02
4.5		0.011	0.342	0.011
5.0		0.007	0.265	
5.5			0.202	
6.0			0.151	
6.5			0.112	
7.0			0.082	
7.5			0.059	
8.0			0.042	

* where:
LB = live births
c = the number of NT deaths identified;
n = number sampled (after completion of single sampling)
n1 = completion of first sample of 1000 live births (of a double sampling plan)
n1+ n2 = completion of 1st and 2nd sample (for a total of 3000 live births) of double sampling plan

Annex 4b:

Explanation of probability calculations

Assumptions on which the combined lot quality assessment (LQA)/cluster sampling (CS) are based and a brief statistical explanation of probability calculations for operating characteristic curves

Assumptions

The survey design combines quality assurance sampling of the industrial type with cluster sampling. The survey method was designed to be similar to the 30 x 7 cluster survey method for assessing immunization coverage. Field staff familiar with the latter method should have no difficulty in applying the present method.

The quality assurance sampling approach allows a population to be classified as acceptable or not acceptable in respect of a particular attribute. The decision to accept or not accept is based on the mathematical probabilities of obtaining fewer than a specified number of units with a particular attribute in a random sample of predetermined size drawn from the population to be classified.

The major advantage of using a quality assurance sampling design is that smaller sample sizes are needed than in conventional sample surveys in which point estimates with designated precisions are desired. A disadvantage is that the method calls for a simple random sample to be drawn from the population.

The advantages of a cluster sampling design include the reduction in work to develop a survey sampling frame and the reduced logistical complexity associated with measuring units in groups, as opposed to measuring individual units scattered among the population. A usual disadvantage of a cluster sampling design is loss in precision. For a specified precision the number of individual units to be measured with cluster sampling has to be increased as a multiple of the ratio of the variance of the particular design not involving simple random sampling to the variance of a simple random sample, i.e. the design effect.

When an attribute to be measured in a population is rare or is homogeneously distributed, the design effect for single-stage cluster sampling is close to 1, i.e. the precision of the estimate from a cluster sample is identical to that for a simple random sample with the same total number of individual units in the samples. This observation, made on previous conventional cluster sample surveys conducted to obtain point estimates of NT and lameness attributable to polio, led to computer-based tests in which a quality assurance sampling approach was combined with cluster sampling. The results of the tests confirmed the predicted outcomes, and the method was then field-tested to confirm its feasibility.

In summary, this method was considered the most practical for assessing whether MNT elimination has been achieved; if districts at highest risk are surveyed and "pass", it is reasonable to assume that other districts (at lower risk) have also achieved MNT elimination.

Community-based conventional surveys are impractical for this purpose because they would require very large sample sizes (e.g. tens of thousands of live births) to measure a low rate of NT mortality.

Because a single sample of 3000 live births still comprise a relatively large sample, a double sampling plan with the same total sample size was chosen with similar operating characteristics (Fig. 2 and Annex 4a, column 4). The double sampling plan allows a decision to be made on completion of the first sample (of 1000 live births). Other characteristics (e.g. TT2+ coverage) can also be measured during the process of completing the first sample.

Brief statistical explanation of probability calculations for operating characteristic curves

The operating characteristic (OC) curves in figures 2 and 3 were generated with Poisson probabilities. The OC curves show the probabilities of finding fewer than, or exactly, the numbers of NT deaths specified in the sampling plans for any rate of NT mortality in the populations tested. The curves shown are for a single sampling plan of 3000 LBs and <4 NT deaths (n=3000, c<4) and for a double sampling plan with a total of 3000 LB (n1 =1000 LBs, c1=0; n2=2000, c2<4).

The probabilities shown in columns 1, 2 and 3 of annex 4a are readily calculated with the Poisson formula for c=0 or c<4, as each of these probabilities are just the sums of the individual probabilities for each number of NT deaths that is acceptable. The calculations to obtain the probabilities in column 4 are more complex. The probabilities in column 4 are the sums of the products of several probabilities which can occur with a double sampling plan. For example, in the 4th column, the probabilities are calculated for all of the ways in which c1 is >0 and <4 in the first sample, and with the results of the second sample c2 can result in a sum <4. The probabilities are only shown in the table for the particular instance in which the NTMR = 1 per 1000 live births.

For example for an NTMR of 0.001, the probabilities of finding a certain number of NT deaths (c1) in the first sample (n1) are shown in the following table:

Number of NT cases (c1) in the first sample (n1)	0	1	2	3
Probability of c1 in n1 given NTMR = 1 per 1000 LBs	0.368	0.368	0.184	0.061

If in n1, c1 = 1, then need to calculate the probabilities in n2 of c2 = 0, 1 and 2, which are: 0.135, 0.271 and 0.271, respectively, which sum to 0.677.

If in n1, c1 = 2, then need to calculate the probabilities in n2 of c2 = 0 and 1, which are: 0.135 and 0.271 and sum to 0.406.

If in n1, c1 = 3, then need to calculate the probabilities in n2 of c2 = 0, which is: 0.135.

Then, it is also necessary to calculate and sum the combined probabilities as follows:

c1	c2	Probabilities of c1 * c2 given an NTMR of 1 per 1000 LBs	Product of probabilities
0	-	0.368	0.368
1	0,1 or 2	0.368 *0.677	0.249
2	0 or 1	0.184 * 0.406	0.075
3	0	0.061 * 0.135	0.008
Sum of the products of the probabilities	0.7		

* See column 4 in the annex 4a for the NTMR = 0.0010.

Annex 5:

Form 1 – Household information and live births for first and second samples

Cluster No.: _____ Location 1st household _____ Interviewer _____

Instructions for interviewers on using this grid and Forms 2, 3 and 4 for the first sample

In the squares of the grid below, enter the number of residents in each household visited. When visiting each household, ask whether there are any women in it between the ages of 15 and 49 years. If there are, ask if any of them were pregnant during the preceding three years. If any were, ask about the outcomes of the pregnancy or pregnancies. Circle the corresponding household cell if a woman in the household delivered a live birth between the two dates corresponding to 13 months and 1 month before the survey respectively. Complete a line in Form 2 for each live birth found. If the baby died at under 29 days of age, complete Form 3. If there are any other women in the household between 15 and 49 years of age, put brackets ( ) around the appropriate household cell and complete a line in Form 4 for each eligible woman.

Instructions on using this grid and Forms 2 and 3 for the second sample

In the squares of the grid below, enter the number of residents in each household visited. When visiting each household, ask whether there are any women in it between 15 and 49 years of age. If there are, ask if any of them were pregnant in the preceding three years. If any were, ask about the outcomes of the pregnancy or pregnancies. Circle the corresponding household cell if a woman in the household delivered a live birth between the two dates corresponding to 13 months and 1 month before the survey respectively. Complete a line in Form 2 for each live birth found. If the baby died at under 29 days of age, complete Form 3. There is no need to collect data on immunization coverage for the second sample.

Annex 6:

Form 2 – Live births and mother's TT status

Instructions:

For the first sample, complete parts A, B, and C of this form. Complete part B for live births occurring 1-13 months preceding the start of the survey.

Complete part C for the first seven mothers with a live birth. For the second sample, complete parts A and B only.

Cluster No: _____ Interviewer's name: _____

	Part A. Identifier	Part B. Baby's information				Part C. Mother's TT status					
Line No	Mother's/father's name	Date of birth	Sex of baby	Alive? (yes/no)	Died when <29 days old? (yes/no)	Card? (yes/no)	TT1	TT2	TT3	TT4	TT5
1											
2											
3											
4											
5											
6											
7											
8											
9											
10											
11											
12											
13											
14											
15											
16											
17											
18											
19											
20											
21											
22											
23											
24											
25											

Annex 7:

Form 3 – Neonatal death investigation form

Cluster No.: ___ Line No.: ___ Interviewer name: _____
Investigation date:___/___/___

Case identification and household location

Name of respondent: _____ Relationship to baby: _____
Address of respondent: _____
Baby's date of birth: ___/___/___ Baby's date of death: ___/___/___
Age at death in days: _____ Sex of baby (circle): M F
How many pregnancies has the mother had (regardless of outcome, including this one)? _____

Mother's immunization status

Did the mother have an immunization card (circle)? Yes No
Immunization history by: _____ card _____ memory _____ both _____ unknown
How many doses of TT has the mother received in total: _____
How many doses of TT has the mother received during this pregnancy: _____
If by card, give dates: 1.__/__/__ 2. __/__/__ 3. __/__/__ 4. __/__/__ 5. __/__/__

Mother's antenatal care history

How many antenatal care visits were made during this last pregnancy? _____

Delivery practices

Place of delivery? _____ hospital _____ health centre _____ home _____ outside _____ other
Attendant? _____ trained attendant _____ untrained attendant _____ without attendant
On what surface was the baby delivered? _____
What was used to cut the cord? _____
Was any substance put on the cord stump (circle)? Yes No
If yes, specify _____

Baby's symptoms

Baby suckled normally for at least the first two days of life?	_____yes	_____no	_____unknown
Baby stopped sucking after the first two days of life?	_____yes	_____no	_____unknown
Baby's age when illness was first suspected by the mother/informant		_____days	_____unknown
Did the baby have the following signs (circle the response that corresponds):			
Spasm when stimulated by touch, sound or light?	_____yes	_____no	_____unknown
Become rigid or stiff as illness progressed?	_____yes	_____no	_____unknown
Had tremors or fits?	_____yes	_____no	_____unknown
Developed "pursed lips" and/or clenched fists?	_____yes	_____no	_____unknown

Ask the mother to describe the baby's illness; record her description on the back of this form

Treatment and outcome

Was the sick baby taken to a health facility? _____yes _____no _____unknown

If yes, give name of health facility: _____

What was the final outcome for the baby? _____alive _____dead _____unknown

Conclusion

What does the respondent say was the cause of the baby's death? _____

Based on evidence, was this a case of neonatal tetanus?

_____Confirmed case _____Suspected case _____Discarded case _____Unable to classify

Comments: _____

_____

_____

_____

_____

Annex 8:

Form 4 – TT coverage status for childbearing aged women who did not give birth 1-13 months before the start of the survey

Instructions:

Complete the tetanus toxoid vaccination status for women 15-49 years of age (at least 10 per cluster)

Cluster No: _____ Interviewer's name: _____

Line No.	Name of woman	Age in years	Card (yes, no)	TT Doses				
				TT1	TT2	TT3	TT4	TT5
1								
2								
3								
4								
5								
6								
7								
8								
9								
10								