

Generic protocol for tuberculin school survey

The generic protocol for tuberculin surveys is developed by KNCV Tuberculosis Foundation. This protocol has been based on the following documents:

- Guidelines for conducting tuberculin skin test surveys in high prevalence countries (1996). Arnadottir T., Rieder HL, Trébuq A, Waaler T. *Tubercle and Lung Disease* 77, Suppl 1-20.
- Estimation of annual risk of tuberculosis infection, generic protocol (APW/SE/05/025811). WHO, Regional office for South East Asia, New Delhi, September 2005.
- The design of multi-stage tuberculin surveys: some suggestions for sampling (2000). Nagelkerke NJD, Borgdorff MW, Kalisvaart NA, Broekmans JF. *Int J Tuberc Lung Dis* 4(4), 314-320.

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The electronic version of this document can be obtained from www.kncvtbc.nl

Rationale for this generic protocol

Tuberculin skin test (TST) surveys in school children are an important means of estimating the trend in risk of infection. Over the years discussion about how to perform a TST survey has resulted in a more or less standardized method of performing school surveys. This has resulted in several guideline documents (see previous page).

This document incorporates relevant information from these different guidelines, guides those who develop a protocol through all the required steps, and provides an outline for a complete protocol for a TST survey in schools. It is strongly advised to involve an epidemiologist in the design of a survey protocol.

How to use this generic protocol

This document describes all components that need to be included in a tuberculin survey protocol. It guides the user past all decisions that have to be made when developing a protocol. Furthermore, it provides the outline and basic text for a complete protocol. After having followed all the steps described in this document and having filled out the results of all decisions, a complete country-specific protocol for a school based TST survey will be ready.

Issues to decide on are presented in highlighted text between brackets, e.g. [xxxxxx].

To facilitate making decisions we have provided background information and considerations in boxes with text in italic, e.g.

xxxxxxxxxxxxxxxx

The person developing the protocol can use this background information for discussions with stakeholders and to guide decisions. After a given decision on the design of the tuberculin study has been made, the person developing the protocol should remove the brackets and highlighted background and instead include the appropriate text for the local setting. If all highlighted areas are replaced with information on the local situation, the document can be used as a protocol for a school based TST survey. The boxes with background information should also be removed from the protocol. So the finalized protocol will not contain any highlighted text between brackets or boxes with background information any more. Lastly, the first three pages up to and including this one can be removed so the finalized protocol starts with the title page of the country-specific protocol.

Protocol for tuberculin school survey in [country], [year(s)]

This protocol has been drawn up on the basis of the generic protocol for tuberculin surveys as developed by KNCV Tuberculosis Foundation. The electronic version of the generic protocol can be obtained from www.kncvtbc.nl

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Summary

To monitor the performance of the TB program and to obtain information about TB epidemiology the NTP in [name country] will perform a tuberculin survey in schools. This will provide information about the annual risk of tuberculous infection (ARTI), which is defined as the average probability of a group of individuals to acquire a new tuberculous infection in the course of one year.

The aim of the survey is to provide information on the magnitude and trend in tuberculosis transmission in order to evaluate TB program performance. Specific objectives are

1. To assess the prevalence of tuberculosis infection in school children.
2. To assess BCG coverage in school children.
3. To estimate the annual risk of tuberculosis infection (ARTI) [and compare this with the findings in [previous / future] surveys].

The study population will consist of primary school children in school class [x to x OR x and x] in [xx] districts selected by probability proportional to population size sampling. In each district [xx] schools are selected by random sampling. A minimum of [xxx] primary school children should be included per district. Thus the total sample size will be [xxxxx] primary school children.

[x] field teams will visit the selected schools and test all children in school class [x to x OR x and x] using the tuberculin skin test (TST) with 2 TU in 0.1 ml PPD RT23/Tween 80. Three days after testing the teams will visit the schools again to read the skin reactions. When testing and reading in a district is finished the survey forms will be sent to a central office for data entry. After finalizing data collection and data entry, the ARTI will be assessed using analysis methods applicable for the data, e.g. cut off levels or the mirror method.

Key persons and institutions involved

Principal investigator:

Other investigators:

Technical support:

Training of tuberculin teams:

Funding agencies:

Abbreviations

ARTI	:	Annual Risk of Tuberculous Infection
BCG	:	Bacille Calmette Guérin
C.I	:	95% Confidence Interval
cm	:	Centimeter
°C	:	Degrees Celsius
DEFF	:	Design effect
DOTS	:	Directly Observed Treatment Short-course
HIV	:	Human Immuno-deficiency Virus
IUATLD	:	International Union against Tuberculosis and Lung Disease
Lab	:	Laboratory
<i>M. Tuberculosis:</i>		<i>Mycobacterium Tuberculosis</i>
mm	:	Millimeter
ml	:	Milliliter
No.	:	Numbers
PPD	:	Purified Protein Derivative
PTB	:	Pulmonary TB
SE	:	Standard Error
SSI	:	Statens Serum Institute, Copenhagen, Denmark
TB	:	Tuberculosis
TST	:	Tuberculin Skin Testing
TU	:	Tuberculin Unit
WHO	:	World Health Organization

1. Background and rationale

To monitor the performance of the TB program and to obtain information about TB epidemiology it is important to assess the epidemiological situation of TB from time to time.

A sensitive indicator of the epidemiological situation of TB is annual risk of tuberculous infection (ARTI), which is defined as the average probability of a group of individuals to acquire a new tuberculous infection in the course of one year. It expresses the overall impact of incidence and average duration of infectious cases in the community, efficiency of TB control programs as well as the environmental and social factors influencing transmission of infection. The ARTI is especially useful for measuring the trend of TB. It is generally computed from the prevalence of infection estimated through well-planned and carefully conducted cross-sectional tuberculin surveys in a representative sample of children.

As tuberculin surveys to estimate ARTI are generally conducted among children, the results indicate the current TB situation in the community. The ARTI is considered to be sensitive to changes in the TB situation in epidemiological terms. One of the aims of TB control programs is to decrease the transmission of infection in the community. Hence, it is important to know whether the risk of infection is decreasing or not and, if so, what is the rate of decline per annum. Therefore, repeat tuberculin surveys are used to assess the impact of TB control programs and epidemiological trends of TB in the community.

2. Country information

[Include general information of the country where the TST survey will be held]

Tuberculosis is a leading public health problem in [Name country]. In [year], about [number of notified cases] new cases of Tuberculosis (TB) occurred. To control TB, the DOTS (Directly Observed Treatment Short Course) strategy was introduced in [year of introduction]. By [year], about [percentage] of the population in the country lived in areas covered by DOTS. The case detection rate was [percentage] and the treatment success rate was [percentage] in [year].

[Include information on previous tuberculin and TB prevalence surveys]

3. Aim and objectives

Aim:

To provide information on the magnitude of [and trends in the magnitude of] tuberculosis transmission in order to evaluate TB program performance.

Objectives:

1. To assess the prevalence of tuberculosis infection in school children.
2. To assess BCG coverage in school children.
3. To estimate the annual risk of tuberculosis infection (ARTI) [and compare this with the findings in previous or future surveys].

4. [To compare trends between geographical areas in order to identify priority areas for strengthening program performance.]

The following important factors should be taken into account when deciding on the objectives of a proposed tuberculin survey:-

- a. *Population size of the country*
- b. *Epidemiological setting*
- c. *Baseline or repeat survey*
- d. *Available resources*

It has to be decided beforehand whether a single estimate of the risk of infection for the entire country will be adequate or separate estimates will be required for different regions in the country. If independent estimates are required, sample size is estimated separately for each region/stratum and the survey in each region is carried out independently of the other regions. However, a uniform protocol should be followed in all regions. Similarly, separate surveys may be planned for different strata (e.g. rural/urban) that are expected to have pronounced epidemiological differences in TB situation. It is suggested that national level surveys may be planned in smaller countries. In larger countries, it is best to plan separate surveys at sub-national levels (regional/provincial).

It should also be decided whether the objective is to obtain a baseline estimate of the risk of infection or to study the trends in risk of infection. To study the trends, repeat tuberculin surveys need to be carried out with an optimum interval of 5-7 years.

4. Methodology

The following information needs to be collected to decide on study population, sample size and to undertake sampling:

1. *Proportion of children enrolled in primary schools, if available by school class.*
2. *BCG coverage and age at vaccination.*
3. *Previous data on prevalence of infection, from reports / published literature.*
4. *Population of all districts (primary sampling units).*
5. *List of schools, addresses and number of pupils in selected districts.*
6. *Number of children enrolled per school in the school classes included in the survey*

Study population

The study population consists of school children in school class [x to x OR x and x] in [name country/name province].

All areas in the [country/province] are accessible and are included in the sampling list.

If there is information available before planning of the survey that areas are not accessible it should be mentioned in the protocol and these areas should be excluded from the sampling frame.

ARTI estimates obtained from young age groups (< 10 year) reflect on relatively recent disease situation. Moreover, the prevalence of infection with environmental mycobacteria is lower in younger age groups although it increases rapidly in the first years of life. Also prevalence of HIV infection, which may affect the reaction to tuberculin, may be lower in primary school children compared to older age groups.

It should be considered whether school enrollment is sufficiently high to make schoolchildren a representative sample for all children in the country. Therefore, enrollment should be assessed in advance. If school enrollment is low, a community tuberculin survey may be considered. Preferably only first school class (or first and second school class) children who are usually between 6-7 years of age may be included in the study population as an increasing number of students may drop out of school in higher school classes. Therefore, tuberculin surveys may be carried out in schools when a high proportion of children in the selected age group is enrolled or enrollment is not expected to be associated with TB prevalence (but it usually is). The survey may be conducted in kindergartens in countries where the proportion of children attending kindergartens is high. However, in countries with infant BCG vaccination, children under the age of 5 years should not be included in a TST survey.

For repeat surveys, a similar study population in respect of age group status should be selected to facilitate valid comparison between the two surveys.

BCG vaccination policy and coverage

It should be considered whether children with BCG scar can be included in the study sample for estimating the prevalence of infection or the prevalence of infection should be estimated exclusively among children without BCG scar.

Tuberculin surveys to estimate the prevalence of infection and ARTI have traditionally been conducted among BCG unvaccinated children. However, in many countries it has now become operationally difficult to obtain an adequate and representative sample of unvaccinated children due to high vaccination coverage. In most countries BCG is given at birth without re-vaccination. The majority of the vaccinated children elicit low levels of tuberculin sensitivity[Menzies, 1992 #66]. However, inclusion of vaccinated children in the 0-4 age group for tuberculin surveys may interfere with the interpretation of survey results. In 5-9 years age group, BCG vaccination during infancy has not been found to influence survey results significantly[Chadha, 2004 #321]. Therefore, in areas of high BCG vaccination coverage, all children irrespective of BCG status should be included in the study sample. The younger age group, where interference may present a problem to interpretation of the tuberculin test, is not included in school surveys anyway.

Inclusion of BCG vaccinated children not only eliminates concerns about the study sample being representative but also makes the survey cheaper and less time consuming. In the analysis it should be assessed whether there is a difference between children with a BCG scar and without. If a difference exists a stratified analysis can be performed.

In communities with low coverage of BCG vaccination, the survey may preferably be conducted among children without BCG scar. In such case the sample size would correspond to only the children without BCG scar. However, all children in the selected age group encountered during the registration process should be tuberculin tested in a given school irrespective of BCG scar status. Children with BCG scar are excluded at the time of analysis for estimating ARTI.

In countries where re-vaccination with BCG is practiced at the time of school entrance, re-vaccination should be deferred in areas selected for the survey until the survey has been completed.

The (estimated) national BCG vaccine coverage was [xx%] in [year(s)]. Children with a BCG scar [will / will not be] included in the study sample.

Children with skin rash, suffering from high fever or receiving anti-TB treatment and whose parents /guardians did not agree for the test are excluded for testing.

Sample size calculation

Tuberculin surveys are most informative if repeated after 5-7 years. It is recommended to calculate sample size for a repeat survey designed to show a predefined change in infection prevalence. This can either be the current survey that is a repeat survey of an earlier survey, or the current survey with a repeat survey planned ahead in several years.

In case an earlier survey has been carried out using similar methods, the prevalence of infection of this survey may be used as an estimate of 'P₁'. In this case the currently planned survey will be the repeat survey.

In case no earlier survey has been carried out using similar methods, the prevalence of infection observed in other characteristically similar areas may be used as an estimate of 'P₁'.

The formula used for sample size calculation for a repeat survey designed to show a predefined change in infection prevalence is as follows:

$$N = \frac{10.5 [P_1 (1 - P_1) + P_2 (1 - P_2)]}{(P_1 - P_2)^2}$$

This formula provides a sample size (N) for a 90% chance of obtaining a significant difference at 5% level [between the present survey and the repeat survey (planned in xxxx or between the previous survey performed in xxxx and the present survey)].

Where:

Alfa (α) = 1.96 (corresponds with a significance level of 5%)

Beta (β) = 1.28 (corresponds with a power of 90%)

$$10.5 = (\alpha + \beta)^2 = (1.96 + 1.28)^2$$

P₁ = expected prevalence of infection in the previous or current survey (as a proportion, so 0.1 instead of 10%)

P₂ = expected prevalence of infection in the current or future survey (as a proportion, so 0.1 instead of 10%)

The sample size required to be able to obtain a difference with a 90% chance at the 5% significance level between prevalence estimates of two surveys can be calculated with the help of the excel Annex 'precision rate of decline'.

To calculate the required sample size we take [xx%] as P_1 (expected prevalence of infection in the [previous/current] survey). And [xx%] as P_2 (expected prevalence of infection in the [current/future] survey). The difference between P_1 and P_2 indicates the minimum difference in infection prevalence (if first and repeat survey have the same average age) that we will be able to identify with this sample size.

The required sample size is estimated so that it will be possible to be able to [assess whether there was a statistically significant difference in the prevalence of infection between the repeat surveys / assess the change in the prevalence of infection between the repeat surveys with a precision of [xx%] at the [xx%] confidence level].

Design effect because of cluster sampling

The tuberculin survey will be carried out in defined clusters/schools (groups of children) rather than in children selected by simple random sampling from the total population of children in the country. This affects the precision, therefore, the sample size is increased by an appropriate factor to correct for this design effect, in order to obtain the prevalence estimate as precise as with simple random sampling. This multiplication factor is called the design effect (DEFF). A multiplication factor of 3 was proposed to correct for the design effect in this tuberculin survey using two-stage sampling for selection of clusters [Nagelkerke, 2000 #70]. Based on [provide information on previous surveys or assumptions made] we assume the design effect to be [x] and we will increase the sample size by this amount.

The design effect 'DEFF' becomes larger with larger differences in infection prevalence between the sampled districts.

The value of 'DEFF' can be estimated from the data of an earlier tuberculin survey using a similar sampling design, as the ratio of cluster sample variance to the variance as if it was a simple random sample (see excel Annex 'calculation design effect').

BCG vaccine coverage

[As children with a BCG scar are not included in the estimation of the prevalence of infection, the estimated sample size is increased by [x] to take into account the proportion of children that has a BCG scar].

Exclusions, dropouts and errors

The estimated sample size is further increased by [10-20%] to arrive at the number of children that are to be registered during the survey. This addition is made to account for exclusions, dropouts and errors that occur during tuberculin testing or reading.

The proportion of children in the sampled study population that will not be included in the actual data analysis may be based on the results of a previous TST survey.

The basic formula for the calculation of N in order to be able to assess [whether there is a difference between the prevalence of infection between two surveys / the difference in prevalence of infection between two surveys with [xx%] precision] is:

$N = [\text{give the appropriate formula for your purpose}] = [xxxxx]$

To arrive at the number of children that need to be included in the study sample, this number is multiplied by the expected design effect [x], [if applicable, the BCG discount effect [x]] and [x] to account for exclusions.

Therefore, to have a 90% chance of obtaining a significant difference at 5% level between the surveys / to be able to give the difference between the prevalence of infection in the two surveys with a precision of [xx%] a sample size of [xxxxxx] schoolchildren is required.

Example:

*If the prevalence of infection in the current survey was 7% (P1), the expected prevalence of infection after 7 years would be 4.5% (P2), assuming a 5% per annum decline in the risk of infection. Substituting the values of P1 & P2 in the above formula, the estimated sample size for the repeat survey after an interval of 7 years is 2956. Considering a design effect of 3, a BCG vaccination coverage of 30% (BCG discount effect = $1 / 0.3 = 3.3$), and 20% exclusions, the total needed sample size would be $2956 * 3 * 3.3 * 1.2 = 35117$.*

Sampling technique

Sampling is used to draw a representative sample of the population without any bias. We use two-stage cluster sampling.

For an example on how to perform two-stage cluster sampling, see excel Annex 'two-stage cluster sampling'

First, we select [xx] districts (i.e. local government areas like provinces) by probability proportional to population size sampling (PPS). See Annex 1 for a list of selected districts.

It is best not to exclude any districts from the sampling frame. However, in some circumstances, it may be necessary to exclude certain districts for reasons of safety of field teams, accessibility or political reasons. Any areas to be excluded should be decided before sampling and should be recorded in the survey report, since populations in such districts may be at different risk of infection.

The number of districts to be selected should neither be too small nor large. If the number is too small, they may not be representative of the total country and the sampling error will be large. If the number of districts is large, sampling error will be reduced but the survey will need much more resources. Similarly, the number of schools and the number of children to be investigated in each district should not be too large. Thus, the number of districts is based on operational convenience & sample size and may be in the range of 5-25% of the total districts. [Nagelkerke, 2000 #70].

The larger the variation in prevalence of infection between districts is expected to be, the larger the number of sampled districts should be. The 'guidelines for measuring national TB prevalence in population-based surveys' currently in preparation under auspices of the WHO-WPRO (Philippe Glaziou) provides an excel Annex on how to estimate the optimal number of districts, taking into account the costs. This requires assumptions on the estimated prevalence, the desired precision, the estimated standard deviation around the mean prevalence among districts, and on the relative cost of starting new districts compared to adding new persons to a district. This worksheet also gives the design effect (based on the assumption that there is no variation within districts). However, it should be used only if one has sufficient insight into the required assumptions.

If stratification is performed with the aim to obtain separate estimates for each stratum, the selection of districts should be carried out independently in individual strata. As a result, a different set of districts may be selected for different strata.

Method of selecting districts by probability proportional to size (PPS) sampling (see excel Annex 'two-stage cluster sampling').

- 1. List all districts with their names in the first column and population size in the second column.*
- 2. Add a third column with cumulative population.*
- 3. Calculate the sampling interval by dividing the cumulative population of all districts by the desired number of districts to be selected.*
- 4. Select the first district by randomly choosing a number between zero and the value of the sampling interval.*
- 5. Add the value of the sampling interval systematically to the randomly selected number for selection of remaining districts (see column 4 in the following example). A district may be selected more than once. If a district is selected twice, the number*

Example of PPS sampling of 10 districts (see also excel Annex 'two-stage cluster sampling'):

Sampling interval $4,305,000/10 = 430,500$

Random number between 0 and 430,400 selected: e.g. 97,439

Column 1 Name of district	Column 2 Population of district	Column 3 Cumulative population	Column 4 Selection of districts
A	556,000	556,000	1, 2
B	125,000	681,000	
C	245,000	926,000	
D	73,000	999,000	3
E	156,000	1,155,000	
F	468,000	1,623,000	4
G	74,000	1,697,000	
H	356,000	2,053,000	5
I	64,000	2,117,000	
J	231,000	2,348,000	6
K	639,000	2,987,000	7
L	123,000	3,110,000	
M	54,000	3,164,000	8
N	185,000	3,349,000	
O	354,000	3,703,000	9
P	568,000	4,271,000	10
Q	34,000	4,305,000	
Total	4,305,000		

The second stage of sampling involves the selection of schools (clusters) within individual districts. Lists of all schools in the sampled districts and the number of pupils in the school in school class [x to x OR x and x] were collected. Schools are selected in each district from the lists by simple random sampling until the required number of [x pupils] per district in school class [x to x OR x and x] is reached. See Annex 2 for the list of selected schools per district, including some fall-back schools. The survey team should aim to include a fixed number of pupils in each district. If the number of pupils included in the sampled schools is too low, or a school can not be included for some reason, one can fall back on the extra schools to reach the required sample size.

A sampling design with PPS sampling of districts followed by simple random sampling of schools and inclusion of all eligible children in the schools until a predefined number of pupils is included per district results in a self weighting survey (i.e. each pupil in the country has the same chance to be included in the survey). With PPS sampling, the national infection

prevalence can be estimated by dividing the total number of infected pupils by the total number of tested pupils[Nagelkerke, 2000].

In the selected schools (clusters), all available children fulfilling the inclusion criteria, who are present on the day of testing are included. No sampling is recommended within the school.

If the number of pupils in the selected school classes is unknown the number of schools selected within individual districts needs to be estimated using the average number of children in the selected school classes expected to be available in each school. The number of schools may vary from district to district if it is expected that the number of pupils in the selected school classes differs from district to district.

Sampling for repeat survey

A repeat survey may preferably be carried out in the same districts as in the previous survey(s). Unless the distribution of population size among districts has changed significantly, then new districts should be sampled proportional to their new size.

If the school 'population' in the district has not changed (no closing of schools, merging of schools or opening of new schools) in between two surveys the same schools may be used. The advantage is that school staff may be the same as in the previous survey and this can facilitate cooperation. The researchers should check whether the selected schools are still able to provide the required number of pupils.

If the school 'population' in the district has changed a fresh sample of schools has to be selected by simple random sampling.

Tuberculin

A standardized dose of tuberculin of 2 TU in 0.1ml PPD RT23/Tween 80 (from Statens Serum Institut in Copenhagen) is used for the tuberculin skin testing (TST). Vials opened should be used within 24 hours.

Countries with experience in using 1 TU PPD RT23/Tween 80 or tuberculin produced by other laboratories for tuberculin surveys in recent times may consider to continue using another dose or tuberculin than the recommended 2 TU in 0.1ml PPD RT23/Tween 80 from Statens Serum Institut in Copenhagen. However, using a different dose or type of tuberculin will complicate the comparison of the survey with surveys from other countries.

Important is that the entire quantity of tuberculin is procured from the same manufacturer in the minimum possible number of batches. This is because the antigenicity and stability of PPD have been found to vary from laboratory to laboratory and even from batch to batch in the same laboratory.

The order for procurement of tuberculin must be given well in advance with clear instructions about the numbers and time when required. This is to ensure the usage within expiry period. The quantity required depends upon the sample size and requirement for training. In general one 5 ml vial of tuberculin PPD is enough to test 25 children (see Annex 5)

During supply and transportation of tuberculin the cold chain is maintained. During storage, PPD vials are refrigerated at 2-8 °C and care is taken that they do not freeze. Vaccine carriers are used to transport tuberculin vials. During fieldwork, maximum care is taken to protect the tuberculin from heat and sunlight. It is vital that PPD vials are transported at the right temperature so activity is not lost. The ideal temperature is again 2-8 °C. The vials should at all times be kept under 20 °C and should never freeze, i.e. as a result of direct contact with ice.

Tuberculin skin testing of TB patients

About 150 sputum smear positive cases of PTB will be tuberculin tested with [PPD RT23/Tween 80/other tuberculin used in the survey] by the same persons who perform the TST testing in schools for the survey. The frequency distribution of reaction sizes among the tested cases is plotted as histogram for locating the mode. The mode should be assessed using the information from all smear positive TB patients with an induration size ≥ 3 mm.

Information obtained from the analysis of reaction sizes of smear positive TB patients will be used for analyzing the data of the survey.

As HIV/AIDS is known to affect the reaction to tuberculin, it would be best to use reaction size information from HIV-negative sputum smear positive cases only. If HIV-status is unknown, it should be considered to test these smear positive cases for HIV.

5. Field work

Planning of survey

The survey is planned and conducted under the technical and managerial support of [name institute or organization, i.e., usually the organization running the NTP] which is the central coordinating centre. The co-ordination centre has the overall responsibility of planning and organizing the survey. The co-ordination centre will appoint a survey coordinator who will have the day to day responsibility for the survey (see Annex 3a, 3b and 3c for terms of reference for survey coordinator, team leader and team member).

Before the survey starts, the education and health authorities at national level, and at local level will be informed about the survey. These authorities will all be involved in the implementation phase of the survey. Before the start of the survey sensitization meetings will be organized at district level. Maximum advantage will be taken to utilize the above officers either as effective channels of communication or as direct participants in the survey, especially the school teachers, the local education officers and the district clinical officers. The teams should be provided with a letter of introduction.

A rough draft of the planning of the national survey will be made in advance, but the definitive planning schedules are made per district so progress can be incorporated in the final schedule. See Annex 4 for a work plan that shows the different activities that should be performed at the central level, when they should be finished and the person responsible.

Timeframe

The duration of the field work depends on sample size, average number of children available in each school, the infection prevalence, and local conditions like distances and transportation. In large schools, up to 400 children can be tested per field team each day. The time required in individual districts will be estimated using local information about school sizes, school hours, and transportation time.

A period of 3-4 months should be set aside for planning – collection of necessary data, writing protocol and work instructions, sampling of clusters, informing the sampled districts and get permission for performing the survey, recruitment of staff, procurement of supplies and for obtaining ethical clearance. Additionally, 1-2 months are required for training the field teams and conducting a pilot study.

School holidays, school hours, examination days, major festivals and difficulties in traveling during rainy season should be kept in mind while preparing the time schedule for fieldwork.

In the pilot study performed as part of the training of the field team, the team can get a good feel of the feasible number of tested/read children per time frame.

Procurement and supplies

The materials required for the survey are procured in the planning phase of the survey. Annex 5 contains a complete list of materials and equipment procured for the survey.

Manpower and training

The number of field teams depends on sample size and the number of districts. Each team should contain at least a team leader, two testers/readers, and two assistants (organizing children, preparation of syringes, recording data) (see Annex 3 for example of terms of reference and Annex 6 for criteria for survey team members). We planned for [X] field teams of [X] individuals each.

Training of the survey team is an indispensable element in the success of a tuberculin survey. Training of health workers by experienced trainers and standardization of the test procedures will contribute to high quality survey results. Furthermore, standardization across and within surveys allows for comparison of the survey results with those from previous surveys.

Field personnel will be trained intensively on all tasks involved in the survey, especially tuberculin testing and reading (Annex 6). Training is combined with a pilot study. Therefore, the training/pilot study is carried out under the watchful eye of the central coordinating center. During the training/pilot study the field procedures and study forms are tested. Each field team member participates in the training/pilot study and should strictly adhere to the work instructions.

The performance of the team members on testing and reading is evaluated before deploying them in the survey. This is to obtain maximal quality of the field data collection.

Preparation of district

The [team Leader or XXXX (function of other person)] contacts the selected districts in advance of the fieldwork and prepares, in consultation with local authorities, a tentative district work plan with the dates of the planning visit, and testing and reading for each selected school (Testing or reading should not be planned on festival or holidays and reading should preferably be done 72 hours after testing) (Annex 8).

During the contacts for preparation of the district the team leader seeks co-operation for support in fieldwork, including accommodation of the field team and storage of tuberculin (in refrigerator 2-8 C⁰). Any practical problems likely to be encountered during the fieldwork are assessed. Also a district map that can be used for location of the selected schools is requested for.

Together with the district health authorities a sensitization meeting will be organized for health personnel to inform the health personnel about the survey and how they should respond to inquiries about the survey.

In consultation with district officials it is decided to which health centers children who require further medical assistance [describe what has been decided, e.g. TST result > 10 mm and parent with TB or symptoms] may be referred to by the field team. District officials are requested to ensure the availability of necessary supplies including drugs in these health centers.

A weekly planning schedule for planning, testing and reading visits to schools (see Annex 9) per district is developed by the team leader together with the other team members using the information from the district workplan (see Annex 8).

In short, the following tasks are performed during the planning visit and on the day of testing and the day of reading (for details see further):

Planning visit

Visit of selected schools to inform them about the survey, to distribute information leaflets and to collect information for planning.

Day of testing

1. Calling the names of the children and noting the census information on census form (Annex 7)
2. BCG scar examination
3. Preparing syringes and needles
4. Injection of PPD-RT23

Day of reading

1. Calling the names of the children and noting the results of the test on the census form
2. Reading the test
3. Writing induration size on form

Planning visit

The [team leader/planner/someone else] undertakes a planning visit to each selected school at least one week prior to the date of testing in order to solicit the support and consent of school authorities. They are informed about the dates of testing and reading. The head master and teachers of the school are handed teacher information sheets (see example in Annex 13). Census forms (Annex 7) are handed to the school staff and arrangements are made that for all eligible school classes, the name, sex and age of all children as obtained from the school register is written on the forms (also for those that are not present at the time). For each class a separate form should be used. The census forms are given to the field team on the day of testing.

[Information leaflets for parents (Annex 12) are distributed to the teachers to be sent to the parents through children.]

A visit is also undertaken to the local health centre to inform health workers about the survey. A health worker of the area may be requested to assist the field team on the days of tuberculin testing and reading for liaison with local authorities and eliciting participation of the community.

Testing visit

The field team should carry with them all necessary materials.

Materials for field work:

1	Tuberculin vials in vaccine carrier or coolbox
2	Tuberculin syringes
3	Box for disposing syringes
4	Safe needle disposal container
5	Cotton
6	Alcohol
7	Census forms
8	School summary sheet
9	District summary sheet
10	Transparent plastic rulers
11	Stationary
12	List of selected schools + addresses
13	District map
14	Copy of letter from district authorities
15	Approval letter Ministry of Education

The testing centre is set up at a convenient place near or in the school.

Registration of eligible children

A list of children [enrolled in school class X to X] is obtained from the school register, entered on the census form (Annex 7) by the school staff and presented to the field team on the day of testing. The sex and age are copied from the school register or if not available from school register are filled out by the teacher (after asking the child). This list does also include children who are already known to be excluded from tuberculin testing (see the paragraph 'Tuberculin testing')

Preparation of syringes

Before a vial is used the first time, the date and time of opening is written on the label of the vial. The top of the tuberculin vial should be cleaned using cotton and alcohol before inserting the needle for the first time. One or two team members draw up a little more than 0.1 ml tuberculin into disposable syringes with disposable G.26 needle syringes. Any air accidentally introduced is then removed and the volume subsequently adjusted to exactly 0.1 ml. The vials should be used within 24 hours after opening. The syringes should be used within 1.5 hours after preparation.

BCG scar examination

Each child is examined on the [site of BCG vaccination in the country] for presence/absence of a BCG scar which is a pea-sized (2 to 3mm) hypo-pigmented shiny lesion raised above the skin. If a scar is present but does not have the characteristics of a BCG scar, it is recorded as doubtful. The finding is entered on the census form in the BCG column (Annex 7).

In most countries the site of BCG vaccination is the upper third of the left or right arm.

If a child is absent this is indicated in the column BCG by writing 'A' (=absent), if the child is excluded 'Ex' (=excluded) is written in column BCG and the reason for exclusion is written in column comments. For all children absent during testing day or excluded the column PPD result (in mm) is blocked to prevent induration size being scored with the wrong child.

Tuberculin testing

Children with skin rash, suffering from high fever or receiving anti-TB treatment and whose parents /guardians did not agree for the test are excluded from tuberculin testing. Exclusion is recorded in the BCG column and reason for exclusion is recorded in the comments column of the census form.

The tuberculin tester injects 0.1 ml of tuberculin intra-dermally on the dorsal aspect of left forearm. It is not necessary to sterilize clean skin before injection. The needlepoint is inserted lengthwise with the bevel upward in superficial layer of the skin of the forearm while the skin is lightly stretched. The syringe is held by the barrel only and the plunger is not touched until the needle point has been satisfactorily inserted. 0.1 ml volume is slowly injected and the finger is removed from the end of the plunger before the needle is withdrawn. A correct injection will raise a flat anaemic round weal of 8-10 mm. In case of injury or scar on left forearm, the test may be given on the right forearm; this should be recorded in the comments column of the census form (Annex 7). If the test is not performed satisfactory, i.e. no flat

anaemic weal with clearly detectable pits is visible, or there is leakage of tuberculin, the test should be repeated on the right forearm and this should be recorded in the comments column of the census form.

Before leaving the school all forms are checked for correctness and completeness of all entries by the team leader.

Reading visit

Reading of tuberculin reactions

Reading of reactions is done 72 hours after testing. If this is not possible it should be ensured that it is performed between 48 to 96 hours after testing. If the proportion of tested children available for reading is low, then home visits may be undertaken to supplement the coverage. First the identity of the tested child is verified using the census form. Reading should be done under sufficient light. The reading concerns a single aspect of the reaction: the induration. The reader locates the induration by slowly palpating the area of the testing spot. The margins of the indurations are easily recognizable when firm and well circumscribed but in case of soft ill-defined swelling, the margins are required to be identified very carefully. The size of the induration is measured by carefully palpating the edges of the induration with the index finger, and assessing the transverse diameter of the induration with a flexible transparent ruler. The maximum transverse (perpendicular to long axis of the forearm) diameter of induration is measured. Care is taken not to measure the erythema. The result is recorded on the census form in the PPD result column (as well as any comment if applicable, i.e. complications like bulla, vesicles, necrosis and lymphangitis). If there is no induration, '0' is recorded on the census form in the PPD result column. If the child is absent from class on the day of reading and, hence, its reaction is not read, 'A' will be noted in the PPD result column. If the child had to be excluded from reading (e.g. because it fainted) 'Ex' is written in the PPD result column and the reason for exclusion is written in the comments column. BCG scar status of the child should not be revealed to the reader before he/she has read the reaction. This can be guaranteed by using one person for reading and another person for recording the results.

Procedure for reading of indurations of ≥ 8 mm

If the first reader finds an induration of ≥ 8 mm, the second reader repeats the reading, without being informed of the exact reading result of the first reader.

If readings of the readers are within a difference of 2 mm, the reading result of the first reader is recorded.

If the difference is 3 mm or more between the two readers, both readers read a second time. If a compromise is found, this reading will be recorded. If no compromise is found, the reading of the first reader is recorded.

After completing reading in a school, and before the team leaves, all forms are examined for correctness and completeness by the team leader. If data are missing, these can be xxxxxaangevuld

6. Management of positive reactors

As the probability of infection differs for different settings e.g. because of different prevalence of non tuberculous mycobacteria, the cut off value for regarding a child as infected should be discussed with the stakeholders and/or be based on the guidelines of the TB program.

The manner of follow-up of positive reactors should be described in the protocol. It should be decided beforehand which children are regarded as infected and will be referred to the health care sector. All individuals involved in the tuberculin survey should be aware that a positive reactor does not necessarily develop tuberculosis disease. If latent tuberculosis infection will not be treated, there may be no use in referral for the child.

Although the chance is small that a child with TB disease will be identified during the survey, the protocol should also describe how these children will be managed by the field team. Describe also whether treatment of patients is free of charge or not.

One could use a referral letter for positive reactors (see Annex 9 for an example letter) that can be given to the child to take home. In addition to a referral letter, the district health authorities may be given a list with information on all children with a positive reaction (see Annex 10). Recommended management of positive reactors includes:

- Children with a TST > the cut-off point who are household contacts of a TB case and have symptoms of TB will be treated with anti-tuberculous treatment according to the NTP guidelines.*
- Children with a TST > the cut-off point without a household contact but with symptoms of TB will be investigated further and treated if necessary.*

Individuals with a TST result of > [xx] mm are regarded as potentially infected. These children [will / will not] be referred for clinical evaluation. Children with signs of active TB will be referred for clinical evaluation.

[Include here detailed information on how positive reactors and children with signs of active TB will be managed during the survey].

7. School and district summary report

After completion of testing and reading the team leader fills the school summary sheet (Annex 14) and part of the district summary sheet (Annex 15) and if applicable part of the list with referred children (Annex 11). If portable computers are available the district summary sheet can be prepared in an Excel sheet that automatically generates graphs and pie charts. These graphs and charts can be shared with the local authorities at the end of the field work period.

8. Data management

Data entry will be done during data collection (i.e. start after field data collection of first district has finished) and continue after the last district is visited by the field team to allow the data entry clerks to finish data entry and checking of the data. The data analysis and report writing will be finished [x with a maximum of 6] months after the data files of the tuberculin survey became available.

After verification of completeness of the raw data (i.e. check of every data collection form after completion), the team leader will forward them to the data entry unit at periodic intervals.

Data will be entered in a [EPI-info/Access/other] data entry file. [Data will be double entered and the two files will be compared to identify data entry mistakes / A random sample of [x%] of the data will be double entered and compared to the original data file to identify data entry mistakes. If more than [x%] of the data contains data entry mistakes all data will be double entered]. Any inconsistencies identified during data entry will be discussed with the survey coordinator and decisions about how these inconsistencies were handled will be carefully noted.

Each pupil will get a unique number by combining the form number and the number on the census form. A form number always consists of 3 numbers and a pupil number of 2 numbers (e.g. form number 001, 012, or 145 and pupil number 04, or 22). A pupil on form 304, and with number 10 on the census list will have unique number 30410 and a pupil on form 012 and with number 2 will have unique number 01202.

The data entry unit will perform adequate file management and regularly make back ups of the data entry files.

9. Data analysis

The [biostatistician/epidemiologist] involved in the survey will use [SPSS/EPI Info/STATA/other] for analysis.

Presence of digit preference (propensity to measure reactions in even numbers or preference for digits ending with zero or 5) will be assessed. If present, data will be analyzed with and without smoothing. Smoothing of the data is undertaken to reduce the influence of digit preference on the estimate of prevalence of infection[Eilers, 2004 #335]. This involves calculating the expected frequency at each mm of induration as the average of three or five frequencies including one/two before and one/two after the induration of interest. Calculations of prevalence of infection can then be based on this new set of frequency distribution.

The method of estimating the prevalence of infection will depend on the frequency distribution of the reaction sizes. If there is a bimodal distribution a specific cut off level (e.g. 10mm, 15 mm or the cut off level that was used in previous surveys) can be used. In case there is no bimodal distribution (due to a specific reaction as a result of infection with mycobacteriae other than tuberculosis or BCG vaccination) but a clear mode, the mirror method can be used[Rieder, 1995 #60]. The mirror method assumes that tuberculin reactions due to infection with tubercle bacilli are normally distributed around the mode. With this technique, the number of reactions above the mode is doubled and added to the frequency of the mode to arrive at the estimated total number of tuberculin positive children.

The mode of the reaction sizes of smear positive cases will be used to assign or confirm the size of the mode of the children in the TST survey. In case that no clear mode is visible we will

assume that the mode of the smear positive patients is similar to that of children with a history of infection.

We will assess the precision of the prevalence estimate by varying the threshold for infection (in case of a clear bimodal distribution) or by varying the mode (in case the mirror method is used).

We will assess whether there is a difference in the distribution of TST results in children with a BCG scar and without a BCG scar. If there is no difference all data will be included in one analysis. If there is a difference we will stratify the results by BCG scar present and BCG scar not present in the analysis.

Alternatively, mixture analysis has been proposed as a method to assess the infection prevalence but experience with this advanced statistical method is sparse and this method should be applied only by a very experienced statistician. For more in-depth literature on this subject, we refer to:

- *Neuenschwander BE, Zwahlen M, Kim SJ, Engel RR, Rieder HL. Trends in the prevalence of infection with mycobacterium tuberculosis in Korea from 1965 to 1995: an analysis of seven surveys by mixture models. Int J Tuberc Lung Dis. 2000 Aug;4(8):719-29.*

The difference between the prevalence as estimated in this survey compared to other surveys will be calculated.

Next, the annual decline in prevalence will be estimated from the results of this and previous surveys. The mean annual decline in prevalence between two surveys can be calculated as:

$$\text{Annual decline} = 1 - (P_2/P_1)^{1/T}$$

where:

P_1 = prevalence of tuberculous infection in first survey*

P_2 = prevalence of tuberculous infection in second survey*

* Prevalences are given as proportions (so 0.2 instead of 20%)

T = years between the first and the second survey [Cauthen, 1988 #323]).

An estimate of the Annual Risk of Tuberculosis Infection (ARTI) of the children that have participated in the survey will be calculated using the following formula:

$$\text{ARTI} = 1 - (1 - P)^{1/A}$$

where:

P = Prevalence of Infection at the time of the survey

A = Mean age of the children (0.5 years must be added to the mean age calculated from the survey data if age was recorded in full years at the last birthday)

The estimated ARTI is the average of the annual risks of infection experienced by the study sample from birth to the time of survey. However, this risk may not have been constant over the period. Thus, it is assumed that for a decreasing or increasing risk of infection, the estimated ARTI would correspond most closely to the mid-point of the average lives of the individuals included in the study sample. This mid-point is estimated by dividing the mean age by 2 and subtracting from the year of the survey. For example, if the survey were to be conducted in the year 2006 among school children 6 years of age, the estimated ARTI would correspond to the year 2003.

10. Ethical approval and consent

The survey will start only after receipt of written ethical clearance from an official medical ethical committee. The central and local health and education authorities will be informed about the survey through the normal channels. The survey team will present a letter from the Minister of Education to the head master when preparing the field work in a school. Local leaders will be informed and sensitized in the preparation phase of the survey.

All parents may be sent a leaflet (Annex 12) with information about the survey through the teacher. Passive consent will be obtained: in case no objection is received from the parents at testing day, consent may be assumed as given. Any parents who decline to give consent to participate for their children for any reason will have their decisions respected and their pupils excluded from the testing. Information about the age and sex of the child will be included on the data collection form.

The survey involves no significant invasive procedures except for minor discomfort at injection sites. In case of side effects caused by the survey the costs will be covered. All syringes and needles used in the survey will be sterile and disposable. Any pupil suspected to have TB or any other medical problem will either be attended to by the survey team or appropriately referred for further medical care as described in the former paragraph. Data will be handled anonymously after data is entered electronically as each child will be coded with a unique number.

11. Budget

The budget required to perform this tuberculin survey is described in Annex 16.

Budget components for the school-based TST survey are listed in excel Annex 'budget components'. This excel sheet can be used to make a complete budget overview.

Annexes

Annex 3: Terms of Reference

Annex 3a: Terms of Reference survey coordinator

Objective: To carry out within [x] months, the tuberculin survey according to the [name protocol] protocol referred to after this as the protocol.

Output: The tuberculin survey data of around [xxxx] students from the selected primary schools in the [xx] districts as specified in the protocol.

Accountability: The survey coordinator is in charge of securing the necessary resources and technical assistance for the field teams to carry out the tuberculin survey in line with the protocol in the assigned districts. He is accountable to the Principal Investigator for all technical and administrative matters.

The tasks of the survey coordinator:

1. Coordinate overall planning of the survey: The survey coordinator will in consultation with the principal investigator and team leaders ensure that the composition of the field teams and the assignment and allocation of districts to the teams is in line with the protocol. Each team will be assigned the task of surveying part of the districts. The survey coordinator will work through the details of each team district plans with the team leader. The survey coordinator will attend the complete training course of the field teams.

Note that whether a district is accessible or not should be decided by the principal investigator and the steering committee (not by the field teams or team leader). The survey coordinator plays a facilitating role in making this decision.

2. Troubleshooting any issues regarding resource allocation and resource transfer to the field teams carrying out the tuberculin survey: The survey coordinator is responsible for ensuring that the team leaders have the necessary resources and technical assistance for their team to carry out the tuberculin survey in their assigned districts including the availability of the following items: tuberculin vials, cool box, ice packs, tuberculin syringes, box for disposing syringes, cotton, alcohol, census forms, school summary sheets, district summary sheets, referral sheets, list with referred children, information leaflets, transparent plastic rulers, stationary, list of selected schools + addresses, district maps, copy of letter from district authorities and copy of letter from ministry of education.

The survey coordinator ensures that the team leader has and utilizes the resources to purchase crayons and notebooks (or other incentives as agreed with the survey coordinator) that are distributed to all the school children in the classes that participate in the survey.

3. Ensure that the survey is carried out in line with the protocol: monthly report. The survey coordinator is responsible for ensuring that the schools selected in the protocol are the ones visited by the teams. To support this, the survey coordinator will produce a one page "Tuberculin Survey Update Report" monthly, with electronic and hard copy. This report will contain updates of the activities of the field teams, names of schools visited and progress of the survey. The hard or soft copies will be distributed to the principal investigator, the person who will perform data analysis and other stakeholders. The survey coordinator needs to ensure that the team leaders are familiar with the protocol and are implementing this strictly. The coordinator needs to draw immediate attention of the principal investigators if the protocol is not being adhered to. In addition this it needs to be noted in the monthly reports and remedial action initiated by the survey coordinator.

4. The survey coordinator is responsible for the supply and safe handling of tuberculin from national to district level: During transportation and storage of tuberculin vials from the point of manufacture to the point of usage in the field the cold chain has to be maintained. PPD vials should be refrigerated at 2-8° C and not allowed to freeze. Vaccine carriers or cool boxes should be used to transport tuberculin vials, which must be used within the expiry period as specified.

The survey coordinator is responsible for supplying the team leaders with tuberculin as and when required. For this very close coordination between the team leaders and survey coordinator is essential. The survey coordinator needs to ensure that the cold chain indicators which accompany the tuberculin from the central depot to the peripheral centres do not show any excesses in temperature and their duration.

5. Perform monthly supervision of each team: The survey coordinator will visit each team every month and also as necessary when needing to 'troubleshoot' logistic problems such as communication with district, supplies and equipment, funding, transport, security, etc. These visits should include seeing the team in action at the schools on each occasion whenever possible.

6. The survey coordinator will be responsible for data management and data entry into the data entry system: S/he needs to re-check all data forms for completeness and consistency and ensure that they arrive at the data entry unit at least after each district has been completed and if possible more frequently, and s/he will also review school and district summary reports. The survey coordinator will be responsible for collection and storage of the raw data and to follow up and retrieve any missing data from any of the field teams. S/he will forward the data to the data entry unit as soon as it has been received and checked, and will make sure that [these/a xx% random sample of the data] are double-entered and verified into the data entry system provided for this purpose. The survey coordinator ensures that the data entry files are sent to the person performing data analysis at least once a month. The survey coordinator will ensure that s/he receives a complete set of the following forms from each district. This will include ensuring completeness and accuracy of the following forms: census form and district summary form.

The survey coordinator will make him/herself available for questions from the person performing data analysis after data collection and data entry has finished.

7. The survey coordinator during his/her supervision trips will check that the activities mentioned in the protocol are carried out on the day of testing and the day of reading as described in the protocol: S/he will also periodically check with schools already visited to see if specific parts of the protocols were followed (eg clearing away of syringes, informed consent, crayons and notebooks for students issued, TB suspected children referred and followed up)

Annex 3b: Terms of Reference team leader

Objective: To carry out within [x] months the tuberculin survey according to the [name protocol] referred to after this as the protocol.

Output: The tuberculin survey data of around [xxxx] students from the selected primary schools in the [xx] districts as specified in the protocol.

Accountability: The team leader is accountable to and reports to the survey coordinator to secure the necessary resources and technical assistance for his team to carry out the tuberculin survey in the assigned districts. Through the survey coordinator (s)he is accountable to the principal investigator for all technical and administrative matters.

The tasks of the team leader:

1. Participate in overall planning: The team leader will be assigned as the in charge of a field team. The allocation of districts to each team will be assigned at the beginning of the survey in line with the protocol at national level in consultation with the survey coordinator and Principal Investigator. The team leader is accountable to the survey coordinator for the advanced planning of the tuberculin work of his team in the districts.

Note that whether a district is accessible or not should be decided by the principal investigator and the steering committee (not by the field teams or team leader).

2. Manage team resources and budgets: The team leader is responsible for organizing the overall work and conduct of his/her team. S/he needs to liaise with the survey coordinator in order to secure the necessary resources and technical assistance for his team to carry out the tuberculin survey in their assigned districts including the availability of the following items: tuberculin vials in cool box, tuberculin syringes, box for disposing syringes, cotton, alcohol, census forms, school summary forms, district summary forms, transparent plastic rulers, stationary, list of selected schools + addresses, district maps, copy of letter from (district) authorities.

S/he will arrange transportation for the whole team using funds allocated to him/her for this purpose. The team leader will also ensure availability of crayons and notebooks (or other incentives as agreed with the survey coordinator) that are distributed to all the school children in the classes that participate in the survey.

3. Check and ensure team knowledge of protocol: It is the responsibility of the team leader to ensure that all team members familiarize themselves with the protocol and carry it with them at all times during field work.

4. Team field work: The team leader is responsible for the division of tasks within the team (e.g. who draws up the tuberculin, who checks the BCG etc) as described in the protocol.

5. The team leader is responsible for the handling of tuberculin: During transportation and storage of tuberculin vials from the point of manufacture to the point of usage in the field the cold chain has to be maintained. PPD vials should be refrigerated at 2-8° C and not allowed to freeze. Vaccine carriers or cool boxes should be used to transport tuberculin vials, which must be used within the expiry period as specified. During fieldwork, maximum care should be taken to protect the tuberculin from heat and sunlight. Vials opened must be used on the same day or latest by the following day.

6. The team leader is in charge of making district contacts: Before and while entering a district the team leader is responsible for informing the Ministry of Health and the Ministry of Education persons in charge within the district. S/he is also responsible for making all other contacts as necessary to ensure as far as possible safe passage and support for the tuberculin survey at local level.

7. The team leader is in charge of making district workplans (strict adherence to protocol's school selection, tuberculin storage and arranging medical assistance for TB suspects): The team leader contacts the selected district in advance of the fieldwork and prepares, in consultation with local health workers, a tentative district work plan with the dates of the planning visit, and testing and reading for each selected school (Testing or reading should not be planned on festival or holidays).

During the preparation of the district the team leader seeks co-operation for support in fieldwork, including accommodation of the field team and storage of tuberculin (in refrigerator 2-8 C⁰). Also a district map that can be used for location of the selected schools is requested for.

In consultation with district officials it is decided to which health centers children who require further medical assistance (see protocol) may be referred to by the field team. District officials are requested to ensure the availability of necessary supplies including drugs in these health centers.

8. The team leader ensures that his team makes a planning visit to each school according to the following protocol: The team leader decides whether (s)he her/himself will of a team member will be the planner. The planner undertakes a planning visit to each selected school at least one week prior to the date of testing in order to solicit the support and consent of school authorities. They are informed of the dates of testing and reading.

A visit is also undertaken to the local health centre to inform the health workers about the survey. A health worker of the area is requested to assist the field team on the days of tuberculin testing and reading. A school planning sheet (see protocol) is filled for guidance of the field team. The teachers of the school are handed teacher information sheets (see protocol). Information leaflets for parents (see protocol) are distributed to the teachers to be sent to the parents through children.

9. The team leader will be responsible for data management which includes checking all data forms for completeness and consistency, and preparing school and district summary reports and distributes them to the schools and district authorities: The team leaders will verify completeness and consistency of the raw data (i.e. check every data collection forms after completion) and forward them to the data entry unit at periodic intervals (at least after each district is completed). The team leader will also make him/herself available for questions from the survey coordinator or person who performs data analysis after data collection has finished.

10. The team leader is responsible for the supervision of the team (e.g. quality of injection, reading indurations, recording data, preparing syringes etc) and ensures that all the activities mentioned in the protocol are carried out on the day of testing and the day of reading as written in the protocol

Annex 3c: Terms of Reference team member

Objective: To carry out within [x] months the tuberculin survey according to the [name protocol] referred to after this as the protocol.

Output: The tuberculin survey data of around [xxxx] students from the selected primary schools in the [xx] districts as specified in the protocol.

Accountability: The team member is accountable to and reports to the team leader to secure the necessary resources and technical assistance for his team to carry out the tuberculin survey in the assigned districts. Through the team leader (s)he is accountable to the principal investigator for all technical and administrative matters.

The tasks of the team member:

1. Tasks during field work: The team member is responsible for all tasks as assigned or delegated by the team leader. The main different tasks are introducing the team and the purpose to the children, preparing syringes, injection of tuberculin, BCG scar reading, reading indurations, recording data.

2. Work according to protocol: It is the responsibility of the team member to stay familiarized with the protocol, and work according to the protocol (e.g. with all tasks assigned, maintenance of cold chain, etc). All team members will carry the protocol with them at all times during field work.

3. The team member is responsible for the equipment, goods, etc. that have been provided to him/her in order to conduct the survey.

4. The team member should always maintain a polite and respectful attitude in his contacts with authorities, teachers, parents, children etc.

Annex 3d: Terms of Reference of data manager

Objective: To carry out within [x] months, the tuberculin survey according to the [name protocol] protocol referred to after this as the protocol.

Output: The tuberculin survey data of around [xxxx] students from the selected primary schools in [xx] districts as specified in the protocol.

Accountability: The data manager reports to the national coordinator on a daily basis. He is accountable through the survey coordinator to the Principal Investigator for all technical and administrative matters.

Tasks of the data manager:

1. Familiarize him/her self thoroughly with the data entry package and the census form of the tuberculin survey (Annex 7). Any queries uncertainties must be discussed with survey coordinator.

2. Ensure that completed data forms are sent to him/her regularly by the team leaders. Data should be coming to the data unit at least after every district is completed. The data entry coordinator needs to receive the census forms from the team leaders and check every data collection form for completeness and consistency.

In case of failure to send data to the data unit or in case data is incomplete or inconsistent he/she will liaise with the survey coordinator and team leaders to ensure that a complete set of data is obtained. The data manager will keep a log book of data received against schools chosen in the protocol. If there are unexplained discrepancies between schools tested and schools listed in the protocol he/she needs to find out why and also notify the survey coordinator and principal investigator immediately for further follow-up.

3. Conduct concurrent entry of all data and ensure double entry of [part of the] data using a second person. The data manager is responsible for entering all the data into the data entry file simultaneously with data collection (e.g. starting after data collection in the first district is completed). [A random selection of xx% of the] data will be double entered by a different person and the two files will be compared to identify data entry mistakes. If more than xx% of the double entered data contain typing errors all data are double entered.] The double entry files will be checked and the discordant pairs will be rechecked manually from the hard copies and the correct data will be entered to arrive at a final master copy.

4. Give every pupil a unique number in the database by combining census form number + number on the census list. To facilitate checking for data entry mistakes each pupil will get a unique number by combining the form number and the number on the census form. For example, a pupil on form 304, and with number 10 on the census list will have unique number 30410

5. Discover, note and discuss inconsistencies in the data. Any inconsistencies identified during data entry will be discussed with the survey coordinator and decisions about how these inconsistencies were handled will be carefully noted.

6. Conduct file management and make back-ups of all data entry files. The data manager will perform adequate file management and regularly make back ups of the data entry files.

7. Sends monthly copies of data master files to the person who will perform data analysis. The data manager (under the guidance of the survey coordinator) sends copies of the master data entry files (post double entry and verification) to the person who will perform the data analysis at least once a month, for external quality control. For this the data manager has access to the internet facilities.

The data manager, as well as the survey coordinator, will make him/herself available for questions from the person performing data analysis after data collection and data entry has finished.

Annex 4. Central work plan

The central work plan below shows the different activities that should be performed at the central level, the time when they should be finished and the person responsible.

Date completed	Activity	Responsible person
[xx/xx/xxxx]	Appointment of principal investigator	[name person]
[xx/xx/xxxx]	Development of tuberculin survey protocol	[name person]
[xx/xx/xxxx]	Get lists of population size per district	[name person]
[xx/xx/xxxx]	Sampling of districts	[name person]
[xx/xx/xxxx]	Get lists of schools per sampled district	[name person]
[xx/xx/xxxx]	Sampling of schools within sampled districts	[name person]
[xx/xx/xxxx]	Obtaining ethical clearance from a designated ethical review committee in conformity with the laws and regulations of the country	[name person]
[xx/xx/xxxx]	Procurement of survey materials (especially tuberculin) (Annex 5)	[name person]
[xx/xx/xxxx]	Contact and inform all relevant authorities (e.g. Health department, School education department, Civic administration) at national/provincial/district level about the purpose of the survey and the methods	[name person]
[xx/xx/xxxx]	Selection of survey coordinator, field team leaders, and members of field teams (TOR see Annex 3)	[name person]
[xx/xx/xxxx]	Selection of data entry manager (TOR see Annex 3d)	[name person]
[xx/xx/xxxx]	Development of data entry file	[name person]
[xx/xx/xxxx]	Training of field teams	[name person]
[xx/xx/xxxx]	Pilot study (Annex 5)	[name person]
[xx/xx/xxxx]	Field data collection (Annex 6)	[name person]
[xx/xx/xxxx]	Data entry	[name person]
[xx/xx/xxxx]	Data checking	[name person]
[xx/xx/xxxx]	Data analysis	[name person]
[xx/xx/xxxx]	Report writing	[name person]
[xx/xx/xxxx]	Dissemination of results	[name person]

Annex 5: Materials and equipment required for survey

Required for the field work:

1. Tuberculin vials. The amount of vials needed for the survey can be calculated after the school sampling is completed. In general: 5 ml vial tuberculin PPD covers 25 tests (= 25 children), i.e. for 1000 (children): 25 (doses) = 40 vials are needed. Losses of tuberculin are included in the estimation. If the schools tested during the training are not included in the survey, extra tuberculin for training needs to be ordered
2. Disposable 1 ml syringes, graduated in millimetres with separate 26 gauge 10 mm long needles of short bevel. Order additional syringes as there will be losses especially during training, e.g. 10% extra
3. Transparent rulers 10 cm in length and calibrated in mm (for measuring induration)
4. Cotton wool, alcohol, plasters
5. Vaccine carriers and icepacks for transportation of tuberculin (Can sometimes be borrowed from EPI authorities).
6. Waste buckets
7. Containers for used needles
8. Printed study forms. Forms for information to general population/parents of children should be printed in local language.
9. Stationary, e.g. files to keep the forms, pens, pencils, notebooks, writing boards, stapler or punching machine
10. Calculator
11. T shirts and caps for survey teams
12. Leaflets for teachers
13. [If the national TB programme does not provide free treatment] Drugs for management of children suspected to be suffering from TB and referred by field teams

Required at central level:

1. Computer
2. Printer
3. Data storage devices (e.g. external hard disk, rewritable CDs, removable disc)
4. Printing paper and other stationary

Annex 6: Training of Tuberculin Survey Teams

Introduction

Training is an indispensable element in the success of a tuberculin survey.

Training of health workers by experienced trainers and standardization of the test procedures will contribute to a high quality of the survey results. Furthermore, standardization across and within surveys allows for comparison of the survey results with results from previous surveys or with surveys performed in other countries. In this respect, also recruitment of the members of the survey team is of importance.

1. Recruitment of the survey team

Preferably a survey team comprises only health staff (medical and/or para-medical staff).

In the process of selecting the survey team, the following criteria can be applied:

- Previous experience with intra-dermal injections and/or TB
- Attitude and social skills (Responsible, efficient, thinking along, flexible, polite and friendly attitude, good communication skills)
- Language (Does the team member speak the language of the selected areas?)
- Eye-sight (Good eye-sight is important for TST techniques)
- Willingness to be separated from family for longer periods
- Good writing and registration skills
- Basic computer skills may be required for part of the team

2. Contents and methodology of the training

Training of tuberculin survey teams involves both theory and practical skills. Often the members of the tuberculin team do not normally work for the National Tuberculosis Programme. Therefore the training also includes basic theory on TB infection and disease, and epidemiology.

The didactic methodology to provide this theoretical framework includes lectures, group work, videos, practical exercises and role plays. The second part of the training covers the development of practical skills for tuberculin testing (BCG scar reading, injection techniques, reading of indurations), registration, and the logistics of a tuberculin survey. These practical skills are best learned by supervised application of the intracutaneous injection and reading of test results (indurations). For that purpose, schools (can be part of the survey sample) will be visited. Each participant will gain experience in all aspects of the test. Therefore, a minimum of 2,000 children need to be tested during the training.

During the skills training the trainees will receive individual feed back on their practical performance of the test. Certificates are provided following satisfactory performance. The best testers and readers are selected through an objective assessment by the trainer. Assignment of tasks will be decided on according to the best fitting profile of the team members.

In summary, training of the tuberculin survey teams includes the following aspects:

- basic knowledge of TB infection, epidemiology, TST and the tuberculin survey;
- writing a work plan for a TST survey;
- informing and motivating local authorities, teachers and parents;
- planning and organization of the field work
- information to the pupils;
- checking of BCG scars;
- preparation and application of the TST;
- reading the test results;
- data registration;
- data management

Follow up training

Often training is only performed in the initial phase of the survey. As field data collection of tuberculin surveys in some cases may take years to complete, it is recommended that training is repeated, preferably at least once a year. If training is not repeated, testing and reading methods may gradually diverge from those learned during the initial training. Some readers may tend to read lower values while others tend to read higher values, making comparisons among readers and regions difficult. Repeated standardization with an outsider trainer should therefore be part of quality management and control of the survey.

3. Preparation of the training

The success of the training (and consequently of the survey) does not only depend on the content of the training course or the quality of the trainer. It also depends on the planning and the preparation of the field situation which enables the trainees to gain practical experience. Below some issues are presented that should be taken into consideration in the planning process.

3a. Duration of the training

To ensure adequate training, which includes theoretical as well as practical training, 3 weeks should be allowed in case of a new tuberculin survey. For follow-up training and re-standardisation of the team, 1-2 weeks will suffice.

During the training, a minimum of 2,000 children need to be tested, divided over 4 - 5 testing days.

Below an example of a training schedule:

DAYS	ACTIVITY
1. Saturday	Introduction, theory
2. Sunday	Day off
3. Monday	Theory
4. Tuesday	Testing day 1
5. Wednesday	Theory
6. Thursday	Theory

7. Friday	Reading day 1
8. Saturday	Evaluation
9. Sunday	Day off
10. Monday	Testing day 2
11. Tuesday	Testing day 3
12. Wednesday	Evaluation/theory
13. Thursday	Reading day 2
14. Friday	Reading day 3
15. Saturday	Evaluation
16. Sunday	Day off
17. Monday	Testing day 4
18. Tuesday	Testing day 5
19. Wednesday	Evaluation/theory
20. Thursday	Reading day 4
21. Friday	Reading day 5, closure

It is important that at least two days of theory are planned before the first school visit during the training.

3b. Planning of the training period

Preferably, the training should take place shortly before the start of the survey. Thus, the newly trained team can continue without interruption with the implementation of the survey. If the schools visited during the training are part of the overall survey sample, data acquired during the training can be included in the survey. It is important that the survey routine, established during the training, can be maintained.

Before the planning of the training one should consider as well:

- school holidays
- climate (e.g. accessibility during rainy season).

3c. Place of the training

The venues of the training should be planned carefully. Not only should be looked into the location for the theoretical part of the training, but also the practical part of the training should be planned and considered.

Preferably the training takes place in an area which includes schools that fall in the sample of the survey.

Issues to take into consideration are:

- size of the schools (for training purposes a minimum of 300 pupils per school should be included. However, it is recommended to include several schools instead of one big school to ensure different experiences in the planning and coordination and practical organization of school visits)
- distances and traveling time (should not exceed more than 3 hours per day)
- availability of training location for theoretical instruction (group sessions)
- availability of audio-visual equipment

- availability of (basic) lodging accommodation

Preferably the whole team stays together in one location. Experience learns that sharing evenings increases team cohesion, facilitates group discussions on the work, provides opportunities for short training sessions, and therefore contributes to a higher output of the training. A (semi) rural environment is preferred.

3d. Size of the group of trainees

As part of the training, individual assessment of the trainees takes place to measure the quality of each team member in various aspects of the TST. Therefore the size of the training team should be limited. No more than 8 - 10 trainees (so maximum 2 school teams) should be selected. Exceptions should be discussed beforehand with the trainer.

Is it advisable that a limited pool of field workers is trained to replace those who drop out, or allow team members to take time off.

All survey team members should participate in the training.

Only the persons that are selected to participate in the survey should take part in the training.

3e. Planning of materials, vehicles, equipment to be used during the training

Transportation:

- Vehicles (+ fuel) with drivers should be available

Materials for the school visits:

- Tuberculin vials
- Disposable 1 ml syringes
- Transparent rulers
- Cotton wool, alcohol, plasters
- Vaccine carriers and icepacks
- Waste buckets or plastic bags
- Containers for used needles
- Printed study forms
- Stationary
- Calculator
- Shoulder bags, t shirts and caps for survey teams
- Leaflets for teachers and parents

Materials and equipment for training sessions

- Video or DVD player
- Beamer
- White board or flip-over, white board markers
- Notebooks and pens (and/or pencils) for participants

3f. Forms/copies

At the start of the training the following forms should be available:

- Planning schedule of the school visits during the training (including date of visit, morning or afternoon visit, name school, number of children to be tested)
- Sufficient copies of school lists, summary sheets, reporting forms for the schools, follow up reporting forms for the TB program

3g. Planning of activities

A draft planning should be discussed with all institutes / programmes involved e.g. MOH/NTP, Ministry of Education, EPI (cold chain facilities) etc. The target group should be explained well (only school class 1 and 2? All pupils from class 1 and 4? Etc.)

An example of a week's plan can be found in Annex 12.

3h. Communication with authorities

Prior to the start of the training, the Health and Education Authorities should be informed. Schools need to be informed about the planned dates of the school visits, and will be requested to fill in the school list with registered children to be tested (name, age, sex). School lists are prepared per class.

3i. Communication with trainer

A minimum of four weeks before the start of the training communication with the trainer should take place about the following issues:

- Provide a list with names participants, previous experience in tuberculin survey, current position, language (how many participants speak English?)
- Location of the training
- Programme of the school visits, including number of schools to be visited, number of pupils to be tested per school, morning and afternoon school visits? Saturday school visits?
- Need to provide a translator. Preferably, translators should be familiar with TB and/or tuberculin surveys (but translation skills come first!).

3j. Budgeting and ordering

The central level / MOH is responsible for financial and logistical arrangements for the teams and the driver during the training and during field data collection (per diem, purchase of equipment, stationary, transport- and running costs etc.).

If the tested schools during the training will not be included in the survey data, extra tuberculin for training purposes needs to be ordered.

4. Example of timetable prior to a training course

Timely preparation of the training is indispensable. A timetable can be helpful. An example of a timetable is given below. Naturally, this timetable should be adapted for each survey, as local circumstances vary.

Activities	Time before start training
------------	----------------------------

Coordination and Consent	
Information letters to Regional Authorities (Health, Education)	3 months
Invitation letters to the selected team members / trainees	3 months
Information letters to District Authorities in selected training district	1 month
Information letters to the EPI Program	1 month
Training and / or standardisation	
Confirmation letter to trainers	2 months
Information to trainer about names trainees, programme etc	1 month
Budgeting and ordering	
Tuberculin: coordinate with KNCV Tuberculosis Foundation or regional WHO office to calculate/order tuberculin	4-5 months
Tuberculin ordering at SSI	4-5 months
Ordering syringes and needles	4-5 months
Ordering rulers, cool boxes, sharps containers, alcohol, cotton, plasters, waste buckets etc	1 month
Designing and ordering t-shirts and caps for team	3 months
Designing and ordering information leaflets for schools (example can be provided by KNCV Tuberculosis Foundation)	3 months
Prepare data collection forms etc	2 months
Arrangements for car, driver, fuel	6 weeks
Ordering rulers, cool boxes, sharps containers, alcohol, cotton, plasters, waste buckets etc	1 month
Ordering office materials (paper, pens/pencils etc)	1 month
Arrangements accommodation team during training	1 month
Arrangements payment team (per diem etc)	1 month
Preparation of the field work per district	
Confirmation use of local car, cool box etc.	1 month
Photocopying of forms /school lists	2 weeks

5. Preliminary budget training course

Below an example of a budget. Costs vary per country/region. If the tested schools during the training are part of the survey sample, it is not necessary to order extra tuberculin and syringes for the training.

Assumptions:

- 3 training weeks with one trainer
- Four-wheel drive cars and telephone are available from NTP

Testing:

- 400 children per day i.e. total 2000
- two testing days per week and two reading days per week
- total 5 testing days x 400 children = 2000

5a. Estimated budget for training course 3 weeks

1. Supplies	Euro (approximately)
Tuberculin PPD RT 23 2TU in 5 ml. vial /25 doses (incl. losses) e.g. 2500/25 = 100 vials. (Box/10 vials = DKK 690,- / USD 110,-) excluding airfreight, cool container and insurance	1100
1ml syringes and needles 2700 ex. (plan for some additional, especially during the training you will have losses)	270
Rulers, pencils, notebooks etc	50
Cotton. spirit, plasters	10
Stationary (paper, printing forms, copy costs, cards)	350
Calculator	15
Cool boxes, 1 x big size, 1 x small size	70
Waste buckets, sharps containers	PM
T shirts, caps, shoulder bags for survey teams	PM
Leaflets for teachers	PM

2. Travel and per diem	Euro (approximately)
Petrol	PM
Per diem team members/drivers	PM
Supervisor 5 days visit to each area	PM
Travel costs trainer	2,500
Housing and allowance trainer 21 days	PM

3. Personnel	Euro (approximately)
Salary team leaders / members	PM
Salary drivers	PM
Trainer	

6. References

- WHO Standard Tuberculin Test': WHO/TB/Tech. Guide 3, 1963
- Arnadottir T. et al. Guidelines for conducting TST surveys in high prevalence countries. IUATLD, Tubercle and Lung Disease 1996; 77 suppl. 1-20.
- Rieder H.L. Methodological issues in the estimation of the TB problem from tuberculin surveys. Tubercle and Lung Disease, 1995; 76: 114-121
- Bleiker M.A. et al. Guidelines for estimating the risk of tuberculous infection from tuberculin test results in a representative sample of children. Bull. Int. Union of Tuberculosis and Lung Disease 1989;64:7-12
- Video with guidelines to conduct TST surveys, developed by KNCV.

7. Information

Training courses in the conduct of tuberculin surveys:

KNCV Tuberculosis Foundation
P.O. Box 146, 2501 CC The Hague, The Netherlands
Tel. +31 70 416 7222
e-mail: info@kncvtbc.nl

Tuberculin PPD RT 23:

Staten Serum Institute (SSI); Mr. Peter Christensen, e-mail pec@ssi.dk

Annex 7: Census form Tuberculin Survey

Form N°:

District (N°):
School (N°):
Class:

Testing date:
Reading date:

Tested by:
Read by:

[Batch number:]

N° of pupils registered:	N° tested:	N° read:
--------------------------	------------	----------

NR	NAME	SEX F/M	AGE In years	BCG*	PPD result# in mm	Comments
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						
11						
12						
13						
14						
15						
16						
17						
18						
19						
20						

* If the child is absent on testing day enter A (=absent) in the BCG column
 If the child is excluded from testing enter Ex (=excluded) in the BCG column and write reason for exclusion in the comments column
 # If the child is absent on reading day enter A (=absent) in the PPD result column
 If the child is excluded from reading enter Ex (=excluded) in the PPD result column and write reason for exclusion in the comments column

Reverse side form

Form N°:

NR	NAME	SEX F/M	AGE In years	BCG*	PPD result# in mm	Comments
21						
22						
23						
24						
25						
26						
27						
28						
29						
30						
31						
32						
33						
34						
35						
36						
37						
38						
39						
40						
41						
42						
43						
44						
45						

* If the child is absent on testing day enter A (=absent) in the BCG column

If the child is excluded from testing enter Ex (=excluded) in the BCG column and write reason for exclusion in the comments column

If the child is absent on reading day enter A (=absent) in the PPD result column

If the child is excluded from reading enter Ex (=excluded) in the PPD result column and write reason for exclusion in the comments column

Guidelines for filling out the census form

Variable name	Explanation
Form N°	Unique number, i.e. only one form has a specific number. The form N° can be written on the form after the forms are returned to the national level by the field teams and before data entry
District (N°)	Name of district and number of district in Annex 1 List of districts
School (N°)	Name of school and number of school in Annex 2 List of selected schools per district
Class	School class children are in
Testing date	Date TST testing was performed (dd/mm/yy)
Tested by	Name of the person who performed the TST testing
Reading date	Data reading of TST result was performed (dd/mm/yy)
Read by	Name of the person who performed the TST reading
[Batch number]	Batch number of the tuberculin that was used. Should only be filled if more than one batch is used in the survey
N° of pupils registered	Total number of pupils registered on the form
N° tested	Total number of pupils tested on the form
N° read	Total number of pupils read on the form
NAME	Name of pupil
SEX	F = female M = male
AGE in years	Age of the pupil in years
BCG	+ = the child has a BCG scar - = the child does not have a BCG scar D = doubtful whether the child has a BCG scar or not A = the child was absent during testing day Ex = the child is excluded from testing, please write reason for exclusion in the comments box (refused, skin disease, etc.) If a child is absent during testing day, block this field and the rest of the row so it will not inadvertently be filled out for another child RA: if a child is tested in the other arm, write RA in the corner of the PPD results, so the correct arm will be checked for an induration.
PPD result in mm	Measured induration size in mm 0 = no induration A = the child was absent during reading day Ex = the child is excluded from reading, please write reason for exclusion in the comments box If a child is absent during reading day, block this field and the comments field.
Comments	Specific issues, i.e. reason for exclusion, presence of bullae or vesicle etc

Example:

	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
Date	2/11	3/11	4/11	5/11	6/11	7/11	8/11
Name school	School 1	School 2	School 3 and 4	School 1	School 2		
Travel time to school	1 hour	1.5 hour		1 hour	1.5 hour		
Agreed time of arrival at school	9.00 h.	9.30 h.		9.00 h.	9.30 h.		
Activity	Testing	Testing	Planning visit	Reading	Reading		
Estimated number of children (obtained during planning visit)	100	120		100	120		
Number of PPD vials	5-6	6-7					

Annex 10: Referral letter

Dear parent(s) of [redacted],

Your child has participated in the national tuberculin survey. In this survey we have tested your child for infection with tuberculosis. The result of this test was a swelling of [redacted] mm. This result may indicate that your child has been in contact with tuberculosis. This does not necessarily mean that your child will have symptoms now. To find out whether your child has tuberculosis, we advise you to go to a health care facility, e.g. [redacted] with your child to have the child evaluated for tuberculosis. [If your child appears to have tuberculosis disease, (s)he will be treated without costs to you]

If you have questions please contact [name and contact information].

Name of team leader

Signature

Date

Annex 11: List with referred children

Dear district health authorities,

The principal investigator, the survey coordinator and the members of the field teams of the national tuberculin survey like to thank you for your cooperation with the national tuberculin survey.

Please find below a list of children with a TST result > [xx] mm. The children were referred to a health care facility for clinical evaluation.

Name child	Name school	School class

Kind regards,

Name of team leader

Signature

Date

Annex 12: Information leaflet for parents

[Name of survey]

Investigators	Role in Project	Phone

Dear parents,

We are performing a survey that will give us information about how many school children are infected with tuberculosis. The methods that we use have been applied in other countries without harmful effects for many years. We are not testing new medicines.

The school that your child is attending is selected for our survey. All children in class [x to x ór x and x] are invited to participate in our survey. We would like your son/daughter also to participate in our survey.

If your child participates in the survey:

- He/she will be asked to have his/her [left/right] fore arm examined for the presence of BCG scar. The outcome will be recorded.
- He/she will be given a little injection of tuberculin on his/her [right/left] arm. There will be no risk, though a very minimal discomfort at the time of the injection can be experienced. This injection may cause a slight swelling which will give us information about whether your child has been in contact with tuberculosis or not. The swelling itself is harmless and will disappear within a few days without treatment.
- Three days after the injection the investigators will come back to the school to read the results. On this day the pupils will have their arms examined for a swelling.
- The outcome of the reading will be recorded against each pupil's name. If the swelling is greater than a certain measure, your child will be referred to the general health services for evaluation.

Your child's participation in this survey is entirely voluntary. If you do not want your child to participate in the survey please inform the school teacher within 3 days of receiving this information leaflet.

Name of Principal Investigator

Signature

Date

For any questions about the survey please contact the field manager or any of the investigators in the field or ring any of the principal investigators whose names appear in the table above.

Annex 13: Example of information for teachers

Introduction

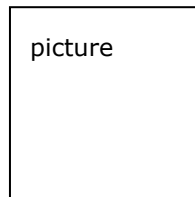
Your school has been visited by a team of the National Tuberculosis Control Program of the Ministry of Health, to conduct a tuberculin survey. In this leaflet we will give some information about the tuberculin survey and Tuberculosis (TB). It may help you to understand why this study is conducted. Also it may help you to answer questions from pupils or their parents.



1. What is a tuberculin survey?

A tuberculin survey is a study about TB infection. A number of schools are randomly selected in different districts, and the children who attend these schools receive the tuberculin test. Your school is one of the selected schools.

TB is big health problem in the world. Each year 2 million people die from TB. Also in [country] many people die from TB. Therefore close monitoring of the TB problem is necessary. The results of the study will help the National TB Program to understand whether the TB problem in [country] is increasing or decreasing. It will also help the TB program to better plan its activities to combat TB.



2. How is the survey conducted?

Each school is visited twice. On the first day the names of the children are registered, their arms are checked for a BCG scar, and they receive the tuberculin skin test. After three days the team returns to read the test results. Each tested child will be checked. The teachers will be asked to assist in writing the names of the children who are registered in the class on a form. Also, the teachers may be asked to assist the team in checking if the name of the child corresponds with the child.

It is very important that all tested children will be present three days later for the reading of the result.



3. What is a tuberculin skin test?

A tuberculin skin test is a small injection in the skin of the arm of the child. A very little amount of tuberculin is injected in the skin. If the child has been in contact with TB bacteria, a swelling may appear within 3 days. This swelling will be measured by the team on their return after three days. The swelling will be measured with a ruler.



4. Is there any harm for the children?

Tuberculin tests are given in many countries in the world and have been used for decades. The test is entirely harmless. It has no side effects. It is NOT a drug or vaccine that is tested. There is *no harm* for the children.

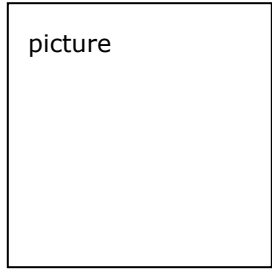


5. Some children are developing a swelling in the days after the test. Do they have TB?

A swelling indicates that there is a chance that the child has been in contact with the TB bacteria. It does NOT mean that the child has active TB. A swelling can also occur after BCG vaccination, or can be caused by other bacteria.

It depends on the size of the swelling whether a child will need a medical follow up to investigate the cause of the swelling. [If the child will need treatment, the drugs will be provided for free by the national TB program.]

There is no need for the school to isolate these children.



7. Does the Ministry of Education approve of the tuberculin survey?

Before the start of the survey the Ministry of Education has been informed about the survey. The Ministry of Education is in full support of the survey. The team carries the copy of a letter with the consent of the Ministry of Education.

8. What is TB?

TB is an infectious disease that usually affects the lungs, although it can affect any part of the body. Without treatment, TB can be a deadly disease. Fortunately, medicines exist that can kill the TB bacteria. Most people who take the drugs well during the whole period of treatment will recover and become healthy again.

9. How is TB spread?

TB germs are spread from person to person through the air. When a person with contagious TB coughs or sneezes, the TB germs escape from his body and float into the air. By inhaling the germs in the air one can become infected.

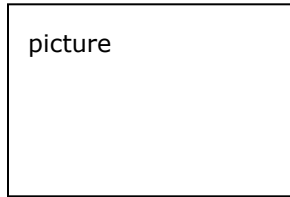
In many infected people the TB bacteria remain 'asleep', and these people will never become ill. Others do get ill with TB and therefore will need treatment.

Also children can be infected and get the disease. But children are usually NOT

contagious for others. It is not necessary to isolate pupils with TB infection or TB disease from the other pupils. They should not be treated differently.

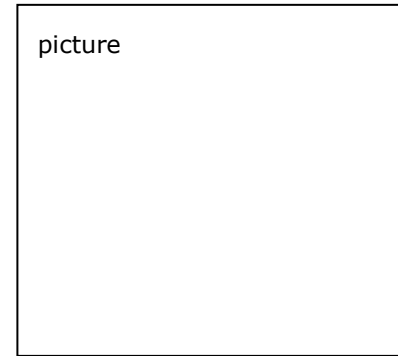
10. What are the symptoms of TB?

People with TB disease often feel weak or sick, lose weight, have fever, and have night sweats. If the TB is in their lungs, they may also cough and have chest pain. If children have TB, the disease is usually located in other parts of their body than the lungs. Therefore they are not infectious. Anyone with symptoms of TB should visit a health clinic. It is very important for the child that TB is treated.



Information for Teachers

What is a Tuberculin Survey



National Tuberculosis Program
Ministry of Health
(logo)

Annex 14: School summary sheet

Dear teachers and head master of [name school],

The principal investigator, the survey coordinator and the members of the field teams of the national tuberculin survey like to thank you for your cooperation with the national tuberculin survey.

We have visited your school to examine the pupils in school class [x to x OR x and x] for the presence of a BCG scar on the [left forearm/other place]. Thereafter, all pupils in school class [x to x OR x and x] were injected with a small quantity of tuberculin. Several days later the field team visited your school again to examine the arms of the pupils that received an injection for a swelling on the site of injection. We perform these examinations to find out the magnitude of tuberculous infection among pupils in the schools in the country.

In your school we have registered pupils in school class [x to x OR x and x]. of the registered pupils were tested and pupils were examined to see if they had an induration and to measure the size of the induration. pupils had an induration of > [xx] mm. This indicates that these children may have been in contact with tuberculosis. [They were referred to a health care facility for clinical examination.]

Presence of an induration of > [xx] mm indicates that the child may have been in contact with a person with tuberculosis. It does not imply that the child has tuberculosis. To ensure that the child does not have tuberculosis clinical evaluation by a health worker is necessary. Therefore, the children with an induration of > [xx] mm are referred to a health centre for clinical evaluation.

If you have questions please contact the [principal investigator/survey coordinator].

Kind regards,

[Name principal investigator/survey coordinator and contact details]

Annex 15: District Summary Sheet

1. District Name _____

2. Code of district _____

3. Details of schools surveyed:

N° of school	School name	N° registered	N° tested	N° read*	N° referred to Health Centres
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					
Total					

*(Out of satisfactorily tested)

Signature of Team Leader

Annex 16: Budget overview

[include here the list of budget components with prices as described in excel Annex 'Budget components', complemented with other costs where necessary.]