

3. Plan for survey implementation

A successful survey depends on good planning. The survey coordinator leads the planning and is responsible for all aspects of the survey and must establish and maintain good communications with the field and laboratory teams. The coordinator must ensure that all procedures follow the study protocol and monitor the quality controls established in the protocol. If a laboratory is contracted to complete the laboratory work, it is important that the survey coordinator monitor the laboratory specimen handling and testing procedures and data collection integrity and check quality controls to avoid unexpected outcomes at the end of laboratory testing.

3.1. Establish schedule and finalize project plan

Prior to serosurvey implementation, a detailed serosurvey protocol that includes all aspects of survey design and implementation must be written, including SOPs for field data collection and laboratory testing as well as all questionnaires and necessary forms that will be used in the survey. SOPs must be developed in line with the country context, including language(s), capacity and resources available. The SOPs must also specify the tools and materials to be used by the national staff. The protocol serves as the guiding document that defines the study objectives, survey design, sampling methods, analysis plan and staff roles and responsibilities.

The protocol should be reviewed and validated (approved) by the technical and steering committees prior to implementation of the survey. The protocol needs ethical review and approval by the national research review board and, depending on the funding source, by international review boards. A protocol template is provided in Annex 1.

3.2. Partner with relevant health authorities and communities

Serosurvey implementation relies upon collaboration with relevant health authorities and communities participating in the study. Health authorities may represent national, regional and/or district levels. These key stakeholders should be involved in the initial planning and implementation of the serosurvey, particularly the fieldwork in the communities being surveyed.

Often prior to the survey, a letter or circular is issued by the appropriate ministry of health department announcing the survey and asking for support by local authorities. This communication, which includes a summary of the rationale of the project, can also be carried by the field team and supervisors. Prior to implementation in a particular enumeration site, as a matter of courtesy supervisors should visit regional/district/local authorities to explain the programme of work and its benefits to their community.

In regions where civil society is under strain, such as in areas of military or rebel conflict or heightened ethnic or religious tension, a considerably greater effort may be required to explain and gain support for the project. This is especially needed to maintain the safety of the project staff.

The national statistics office should be consulted for sampling frame and enumeration steps. They can aid by:

- providing updated census data and maps of enumeration areas, their population and demographics such as average household size and birth rate;
- supporting the selection of clusters using appropriate probability sampling methods;
- supporting the mapping and listing of households in selected clusters, e.g. by providing a fieldworker with experience in household enumeration to join the survey teams;

- supporting the development of questionnaires, electronic data collection and data management systems; and
- potentially aiding in data analysis.

While experienced in household surveys, national statistics office enumerators need to participate in the specific orientation and training about this serosurvey.

A memorandum of understanding should be prepared and signed between institutions with clear definition of the roles and responsibilities.

3.3. Select assay(s) and develop standard operating procedures

The survey protocol will describe the selection of the testing laboratory and serologic assay(s) to be used. See **Section 4.4** of this document for more information about laboratory testing considerations.

A detailed SOP for all laboratory procedures must be developed and approved by the steering committee. The SOP will detail specimen collection, storage and transport, the assay(s) used, result management and interpretation, data storage, quality control mechanisms and safety procedures. Where necessary, pre-survey activities include:

- commissioning of equipment or instrumentation
- training of collection and testing staff
- establishing specimen transportation and storage processes
- where necessary, validation of the specimen type, assay or testing strategy.

3.4. Select data collection methods

Data can be collected using paper forms or digitally using portable devices such as tablets or smartphones. The survey protocol should justify the reasons for the choice of data collection method and clearly show how quality controls will be done with whichever method is chosen.

3.4.1. Designing the questionnaires

A well designed survey form is required to collect accurate and complete data. The survey should be thorough but avoid using excessively long questionnaires. Only essential information used for data analysis should be included in the questionnaire. The layout of the questionnaires should facilitate data recording and minimize transcription errors. The principles of designing a good questionnaire form are presented in Box 3-1. Pretesting, translating and back-translating of the questionnaires can provide clarity as to what information needs to be collected and therefore, increase the data quality. See WHO Tetanus Serosurvey Guideline Annex 2.11 (1) for an example of a questionnaire in a serosurvey that aims to estimate seroprevalence.

Because probability samples are recommended, data analysis will be weighted so that the information which each individual in the survey contributes to the overall result reflects the probability that each individual had of being selected into the survey. It is therefore critical to carefully record the following information:

- the probability that each cluster was selected (this is recorded during the sampling procedure)
- the probability that each household in each cluster was selected
- the probability that a given individual in each household was selected

- the probability of missing information (refusals, absentees).

See World Health Organization Vaccination Coverage Cluster Surveys: Reference Manual (2) Annexes E and F for an example of mapping and listing households in the clusters (enumeration areas) selected for the survey.

Box 3-1: Principles of good form design

Below are some tips to consider when designing survey forms:

- Leave adequate spaces for clear, legible handwriting.
- Make the layout of the form clear and clean so it is obvious to detect when the forms are incomplete.
- Pre-print as much information as possible, including geographic stratum and cluster identifications.
- use pre-printed labels with laboratory identification numbers, with enough copies for the questionnaire, tubes, laboratory request form and specimen containers. If possible, pre-printed labels should include a barcode that can be read by a scanner up reduce data transcription. Codes should identify the cluster, household and the selected individual.
- Include space to note the data collector's name and/or identification number, as well as date and time of the survey interview. These fields may be useful in resolving incomplete or incorrect data variables.
- If including skip patterns (e.g. If response to this question is 'no' skip down to question #22) ensure the form is clearly designed to maximise success. People tend not to implement these well in practice and their use should be minimized.

Eligible respondent data collection form

For each household, each selected eligible individual will be interviewed using a standard questionnaire. The information collection form should include:

- The geographic stratum, the cluster number and the household identification. The household identification should be unique within each cluster. This can be accomplished with a team-specific prefix, e.g. A001, A002, and B001, B002; or by assigning different ranges of numbers to different teams, for example Team A uses 100 through 199 and Team B uses 200 through 299.
- A respondent identification within the household (01, 02, etc.).
- A large space for applying sticker(s) with identification code(s) that match those on blood specimen tubes.
- A large space for data collectors to record respondent's comments important to the survey and not captured by the survey questionnaire. These comments should not only be recorded on the paper forms, but also entered at the time of data entry and reviewed by the analysis staff to determine whether the comment warrants special attention or the discarding of the respondent from the dataset (e.g. the respondent was clearly intoxicated during the interview).

Informed consent form

Templates for a range of informed consent and assent forms for specimen collection have been developed by WHO and are available online (3). Translate the selected informed consent form(s) into the languages spoken in the areas participating in the survey.

The forms for informed consent and assent should help field staff to explain, in plain language, the expected benefits and potential risks of participation and the procedures in place to maintain data confidentiality, clarify the right to non-participation without fear of reprisals and provide contact information for the ministry of health and/or the principal investigator of the survey.

Once the process is explained and questions answered, the selected individual is required to sign an informed consent form. See World Health Organization Vaccination Coverage Cluster Surveys: Reference Manual (2) Section 3.3 and elsewhere (4) for details on obtaining ethical clearance.

Cluster summary form

As part of quality control, the supervisor completes a Cluster Summary Form when collection of data within the cluster is completed. Information included on the cluster summary form includes:

- cluster identification
- total number of households selected in cluster
- number of households visited and outcome of the visits
- by age groups:
 - number of persons absent
 - number of persons refused
 - number of persons consented to participation in the questionnaire
 - number of blood specimens collected.

Stratum summary form

This form is completed by the stratum coordinator when the stratum is completed.

3.5. Budget and procurement

3.5.1. Budget

Once the study design has been accepted by the steering committee, health authorities and any funding bodies, a detailed budget must be developed. The budget should encompass all aspects of the study protocol including, but not limited to, human resources, consumables, software and data analysis tools, consultant fees (expert advice, legal, financial, statistical), printing and communications, ethics and authorization costs, laboratory costs (reagents, consumables, capital equipment, service and maintenance agreements, quality control and external quality assessment, waste disposal, personal protective clothing, assay and testing strategy validation processes, external testing), specimen storage and transport fees. Professional help by an accountant or finance team would be useful. If the cost of the proposed budget exceeds the funds available, the steering committee may be required to modify the protocol accordingly or seek additional funding.

See World Health Organization Vaccination Coverage Cluster Surveys: Reference Manual (2) Section 2.9 for more details on preparation of budgets, and Annex C of the same document for a survey budget template.

3.5.2. Work plan creation

With the protocol and the budget documented and approved by the steering committee and the funding body, a schedule of work should be developed. Some key considerations when planning the

schedule are detailed in Box 3-2. The scheduling of work can be done using a range of off-the-shelf project planning tools. The greater the detail of planning, the less likely unexpected situations will arise. The work plan will document each step of the project, detailing which activities rely on other activities being completed. The plan details each step in chronological order, with the time required for the completion of each activity identified. In this way, the supervisors can maintain an overview of the progress of the project and intervene when the project falls behind schedule.

Critical to successful implementation is identifying what consumables and equipment are required and having them purchased and delivered prior to implementation. Ensure sufficient time for any commissioning of equipment, validation of assays or testing strategies, and training of staff to be completed. Allow contingency for items being out-of-stock, damaged or delayed in transit or at customs.

The overall work plan can be segmented for each cluster and the expected timelines communicated to each cluster team. The overall work plan should be approved by the steering committee, and each level of supervision should have periodic and structured reports of progress against the plan. Critical time points should be included in the plan and, if not met, should trigger involvement by the steering committee. This oversight is especially required for time-critical project activities, e.g. those that must be performed within six months of an outbreak.

Box 3-2 Considerations when planning survey schedule

- Avoid seasons with adverse weather conditions
- Avoid collecting data during religious and cultural events
- Avoid certain agricultural seasonal cycles
- Determine what time of day to do the survey
- Allow sufficient time for revisits or rescheduling work to respond to unexpected delays.

3.6. Determine data management strategy and select data analysis tools

The steering and technical committees must decide on how both interview data and specimen data will be transported or transmitted, stored and analysed. Analysis software that can perform all the require analyses should be selected if appropriate for the situation. An experienced data manager is a valuable resource at this stage of planning. See WHO Vaccination Coverage Cluster Surveys: Reference Manual (2) Section 3.5 and elsewhere (4) for more information on data management and analysis.

3.6.1. Managing interview data

Decide how the interview data will be sent from the field to a central database. If data are collected digitally, decide how these data will be quality checked, securely transmitted to the database and cleaned before analysis. It is also important to decide how the interview data will be linked to the specimen data for each participant. Matching bar code labels on both the specimen and the interview form (or are scanned into a digital form) are an ideal linking mechanism.

3.6.2. Managing specimen data

The specimen ideally will have a label with a barcode that links it to the paper or digital survey data. Otherwise, at least three identifiers (e.g. name, date of birth, gender or cluster identification) should be used to confirm traceability of data. Labels intended for laboratory specimens should be

waterproof, durable and, ideally, validated for the purpose. A form that accompanies the specimens to the laboratory should include the name of the serosurvey and a summary reminder of the instructions for processing the samples, which is detailed in **Section 4.3.3** below.

Create SOPs for the receipt, processing, testing and storing of specimens. The laboratory supervisor should monitor the quality of specimens received from the field teams and communicate any issues to the field supervisor.

3.6.3. Managing locations using GPS

Global positioning systems (GPS) can be used to identify households, record coordinates of houses visited and enumerate area boundaries. Coordinates can be overlaid on to Google Earth. The use of smartphones has enabled GPS and the recording of images of houses and individuals (where ethics and protocol allow) (5). Use of phones and GPS require identification of a single receiver and multiple backups. The receivers must be validated to ensure correct settings, and staff must be trained in their use, including collecting and storing data and marking waypoints. Some objections may be encountered to the use of GPS, as it has the potential to link data with households. The GPS coordinates can locate a defined geographical region rather than a specific site, thereby limiting the objections.

3.7. Select and train field teams

Selection of individuals for the field and laboratory teams should be based on the candidate's previous experience and skills. When selecting field team members, consider cultural sensitivities and languages of the local communities. Field team composition will vary depending on country context, but should include at least the following personnel:

- experienced enumerators to conduct mapping and household listing of selected clusters – often this is done in a preliminary phase before field teams conduct interviews;
- a person responsible to identify eligible household members, obtain consent and collect data from selected individuals;
- one phlebotomist/sample collector;
- local guide to locate the selected households and introduce the field team to the enumeration area; and
- one field supervisor for every two to three teams.

Roles and responsibilities of the survey coordinator, field supervisor and laboratory supervisor are included in Annex 2.

Hiring, training and supervision

When interviewing potential survey workers, develop a method to score each candidate's suitability in an objective manner. Select the highest scoring candidates first and then select additional individuals for training so they can be available on stand-by as an alternate trained field team member in case there is a need to replace a field team member. The implementing agency may be responsible for the selection and training of the staff or may just require oversight of the process.

A training plan should be developed. Each activity requiring training should be identified, including the level of staff requiring training in that activity. The trainers for each activity should be selected based on both their competence in the activity and their ability to communicate and provide training. Train-the-trainer sessions may be required. The ideal number of individuals within each training session should be determined based on the facility and the type of training required. For example, training in general procedures may be achieved in a classroom style facility whereas specimen collection training may require one-on-one training. Training of field staff must include

practical experience in the field to assess the competency of trainees to obtain informed consent appropriately, administer questionnaires and record data accurately. A curriculum for each training activity should be developed and a standardized training provided if different individuals are training in different locations. External help in developing the training may be required.

Training for field and laboratory staff must be completed prior to the start of data collection and should include pilot testing of the data collection tools to assess and verify competency of the staff. Training should also include practice with the specimen collection SOPs, including specimen labelling and transporting requirements. The survey coordinator, field supervisor and laboratory supervisor should participate in the field and laboratory training to understand all aspects of the serosurvey and establish a supervisory plan for the fieldwork.

See World Health Organization Vaccination Coverage Cluster Surveys: Reference Manual (2) Section 3.9 and elsewhere (6) for more details on training staff.

Hiring contractors

In some situations, the steering committee may choose to contract with a private organization to complete the serosurvey activities, including laboratory testing. In these circumstances, the steering committee will be responsible for validating the choice of implementing agencies and overseeing contractual arrangements. The steering and technical committees should provide adequate oversight and ensure the contract contains a clear and appropriate statement of work to be completed, expected deliverables, access to data, and storage and sharing of the results, data and specimens. The steering committee should clearly communicate the level of oversight that will be provided by the steering and technical committees during the development of the serosurvey protocol and SOPs, as well as the planning and implementation of the work. The contract with the private organization must protect the confidentiality of the individuals. A comprehensive risk assessment should be undertaken, significant risks identified and processes for mitigating these risks documented. Contingencies in case of a failure by the private organization should be in place. The management of the contractor should be through a legally binding agreement, including ownership of data and specimens, termination clauses, and milestones and deliverables to be completed before payment.

3.8. Obtain ethical clearance

As serosurveys involve the collection of biological specimens and possible storage of specimens for future testing, the proposed processes require review and approval by one or more ethical review committees. Be sure that there is enough time to gain required approvals in the planning process. At the time of application for ethics clearance, it is important to specify how data and/or specimens may be used in the future and include these activities in the application. Noting that specimens may be tested for additional markers in the future may be helpful to other programmes.

The proposal submitted for ethical clearance will need to specify whether there is any plan to vaccinate (a) those who are found to have no history of vaccination against measles and rubella and/or (b) those who are found to lack immunity to either infection once laboratory results are available. When survey participants lack a history of vaccination, vaccination with measles–rubella vaccine could be offered as a potential benefit to participants and their families. Vaccination by survey teams would not be recommended in household surveys, but individuals could be referred to local vaccination clinics. Field teams that identify individuals during the interview that have missed vaccination can advise mothers to take their children to the health centre for vaccination. Alternatively, individuals found to be seronegative to measles or rubella could be invited to attend a local vaccination clinic for vaccination. In many instances it will only be possible to offer, at most, a single dose of vaccine, but a component of the follow-up process could include referral of participants to local health services for additional doses. These aspects of serosurvey fieldwork must

be considered well in advance of starting the survey, and mechanisms put in place to support decisions as well as relevant information included in the consent form. See World Health Organization Vaccination Coverage Cluster Surveys: Reference Manual (2) Section 3.3 for details on obtaining ethical clearance.

Informed consent

Whether specimens are new collections, existing unlinked anonymous specimens with minimal demographic information, or specimens previously collected for surveillance, the protocol should indicate whether informed consent will be obtained and how this will be achieved. Adhere to local and national ethical requirements, as well as any additional ethical clearance required by partner and funding agencies. Include forms for recording informed consent in the survey protocol.

To obtain informed consent during the interview, the field team should:

- create a safe environment;
- carefully explain the purpose of the survey and procedures for data and blood collection;
- explain the benefits of participating, emphasizing that measles and rubella are serious and that the survey results aim to help prevent these diseases and access to any follow-up information and notifications from the blood test (if you have a way to follow up, e.g. to vaccinate those found to lack immunity);
- explain procedures for maintaining confidentiality;
- explain that the person can withdraw consent and stop the interview at any time, or do only the interview and not consent to blood collection;
- answer any question or concerns that arise;
- obtain written informed consent from each respondent (or their guardian in the case of a minor) in the household before starting the interview; and
- obtain separate written informed consent for specimen collection.

3.9. Establish fieldwork procedures and quality controls

Fieldwork is the key to getting accurate results from the survey, so it is important to take the time to create and document clear and specific fieldwork SOPs. See World Health Organization Vaccination Coverage Cluster Surveys: Reference Manual (2) Section 4.3 for recommendations about interview fieldwork SOPs and Box 3-3 below for a list of considerations to be included in fieldwork SOPs.

Box 3-3: Considerations for inclusion in the fieldwork standard operating procedures as specified in the protocol

- Method of household selection
- Work schedules
- Days of the week visits take place (e.g. Do visits occur on weekends?)
- Number and frequency of revisits
- Length of time spent in each cluster
- GPS logging and tracking of field teams and supervisors
- Specimen collection and storage process
- Specimen transportation to laboratory
- Data storage and transfer to central database
- Data entry and checking
- Responsibilities of field, cluster and stratum supervisors
- Quality control mechanisms and the persons responsible
- Checks for data completeness, legibility and accuracy
- Links to vaccination programmes or public health facilities
- Logistics for supplies and consumables, including purchase and storage.

References for Chapter 3

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5. Oh DH, Dabbagh A, Goodson JL, Strebel PM, Thapa S, Giri JN, Shakya SR, Khanal S. 2016. Real-Time Monitoring of Vaccination Campaign Performance Using Mobile Phones - Nepal, 2016. MMWR Morb Mortal Wkly Rep 65:1072-1076.
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