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*Protocol for the Assessment of the
Quality of Surveillance and
Control of EPI Diseases*



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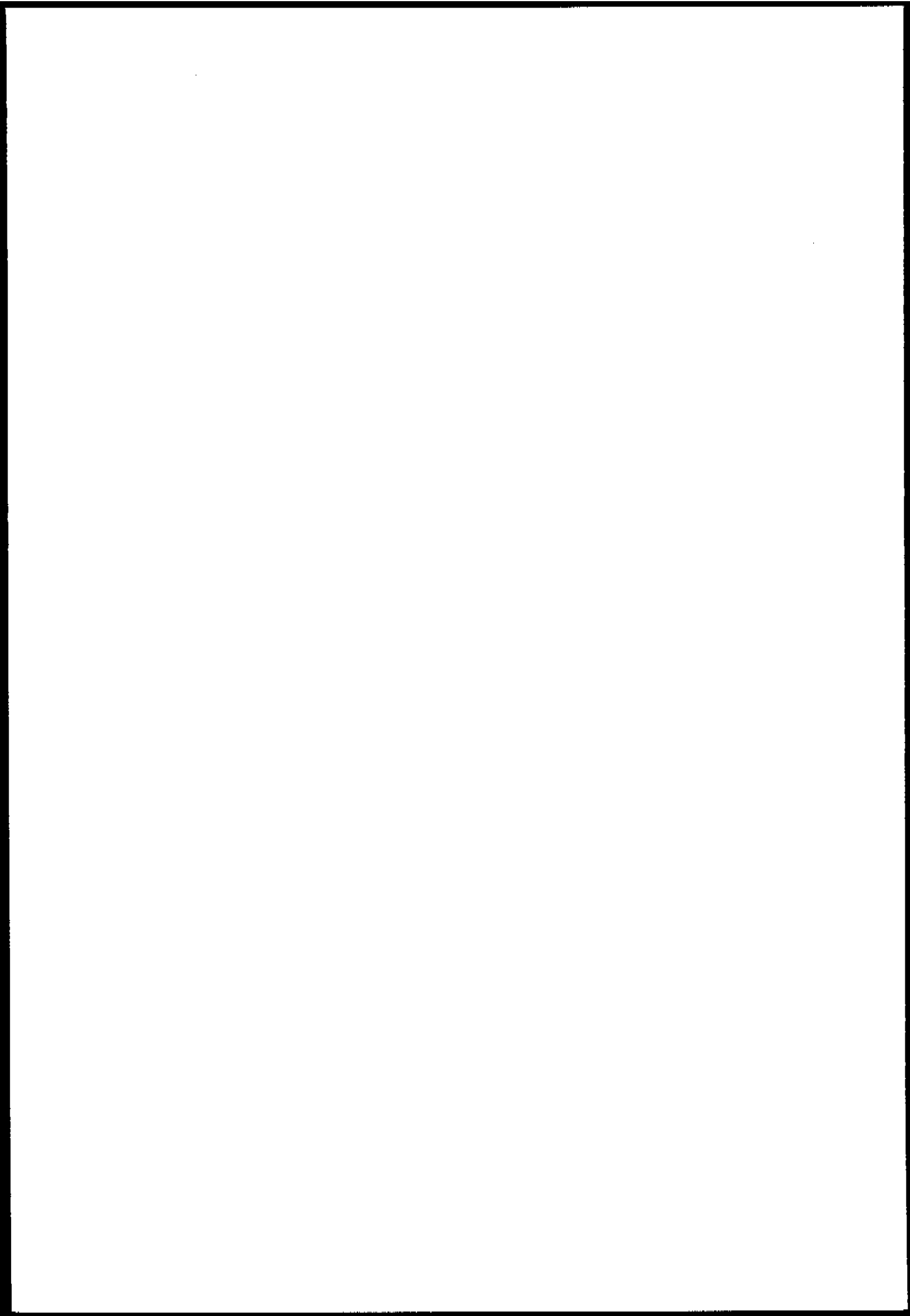
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1. Background

By 1990, it was estimated that 80% of the world's children were receiving all scheduled vaccines in their first year of life. The achievement of this high coverage was quantified by comparing routine reporting of immunizations performed against estimated annual birth cohorts. Assessment using random cluster sampling techniques confirmed estimates of coverage. Independent reviews of national expanded programmes on immunization (EPI) were occasionally conducted to verify both the levels of achievement and the quality of immunization service being provided.

From the very early stages, surveillance for the six target diseases was promoted as an important element of the EPI. Effective surveillance carries the potential to locate high risk areas and populations and to identify programmatic failures. Of equal importance, by determining disease trends, it can help determine the impact of immunization and its cost effectiveness.

In most countries, development of surveillance for the EPI target diseases has been less successful than immunization. One of the key factors has been the difficulty of easily quantifying surveillance performance, thus providing comparators for change over time. In most developing countries, routine reporting of the EPI diseases has been estimated to represent less than ten percent of actual incidence.

The commitment to disease reduction targets, starting in 1985 in the Region of the Americas and globally in 1988-89, made it critical to develop surveillance as the key factor in collecting accurate data, based on which further disease control measures would be developed.

Equally important within the context of the disease reduction targets is the need to assess that surveillance is sufficiently sensitive to promptly detect cases should they occur. Unidentified weaknesses in surveillance will lead to delayed and eventually more difficult control measures, complacency if the disease is thought no longer to exist and failure to develop appropriate immunization strategies.

This protocol provides a means of rapid assessment of surveillance within a country. It is mainly meant for countries with mature immunization programmes and low reported incidence of poliomyelitis and/or neonatal tetanus and/or measles. The assessment is of the surveillance system and, although part of the protocol involves a limited search for disease in high risk areas, it does not, in itself, actually involve surveillance for the target diseases. At the end of the assessment, it will not be possible to say that a disease does not exist in the country, although it may be possible to say that it does. More typically, the assessment will conclude that surveillance in the country is or is not sufficiently sensitive to detect the disease if it occurred and therefore that the reported incidence is or is not credible.

Since assessment of surveillance is more frequently qualitative than quantitative and often involves subjective judgement, it is important that the assessors should be led by an experienced epidemiologist with a team which represents skills in the subjects being assessed.

In addition to the experienced team leader and the specialists in specific subjects to be reviewed, the team should have sufficient members to split into subgroups for field visits. In addition to the team leader, specialists and consultants from the international agencies, the team might include representatives from the bilateral agencies and non-government agencies with interests in supporting EPI activities within the country.

The main approach of the assessment is an audit of practices and records in the disease surveillance system.

By the end of the assessment, it should be possible to answer a number of questions;

- i) Is the surveillance system sufficiently sensitive at all levels that it might be expected to identify cases of the target diseases?
- ii) Is the system sufficiently developed to investigate competently all cases/outbreaks that fall within the case/outbreak definitions of the target diseases?
- iii) Once cases are identified, is the system sufficiently reliable and rapid that they will be reported?
- iv) Is there adequate coordination between all sectors and all parts of the health professions so that detected cases are investigated and reported according to national policy?
- v) Is the surveillance system sufficiently related to control strategies, based on techniques such as line listing, mapping and identification of high risk areas and groups?
- vi) How can the existing surveillance system be further developed to become more efficient and effective?
- vii) What specific additional activities need to be introduced to increase the probability that the three specific disease reduction targets will be achieved?

A list of background documents is appended (Annex 1). It is important to ensure consistency in assessments and in advice being offered by the international agencies to national immunization programme managers. Before attempting to evaluate progress and achievements, team members should be fully conversant with the recommendations made by the WHO Global Advisory Group concerning EPI in general and surveillance in particular.

2. Method of assessment

The process of assessment of surveillance involves several key steps:

Step 1. The country concerned should agree to the terms of reference of the team's visit. The team members should be briefed on the assessment and their role within the team.

Step 2. The responsible officials within the country should, in advance of the team's visit, prepare background documentation relating to surveillance and the specifics of the diseases under investigation.

Step 3. On arrival, the team should review the data, seeking clarifications and additional information where needed.

Step 4. The team, after reviewing the data, should prepare a list of areas and institutions to be visited, possibly specifying individuals to be interviewed, and develop a tour plan with team members investigating technical subjects within their area of expertise.

Step 5. The team will then perform appropriate assessments for each site.

Step 6. When data collection and assessment is complete, the team will reconvene and after discussion and review, will prepare a summary of activities, findings and recommendations.

Step 7. The team will present its findings and recommendations to the health authorities in a debriefing session.

Each of these steps will be considered in greater detail.

Step 1. Agreement on Terms of reference

- The host country should agree, well in advance, the terms of reference of the assessment visit.
 - The officials concerned should have been informed, not only of the objectives of the visit, but also its limitations, e.g. that the team would be unable to confirm whether diseases still existed or whether targets had been met.
 - The Ministry should be invited to hold a debriefing session at the end of the visit and, if appropriate, to convene a workshop for key professionals to help plan the implementation of the recommendations.
 - The country should understand the need and right for the team to visit different geographical areas, ministries, institutions, health units possibly including the private sector. During these visits, it should be agreed that the team could investigate records and have discussions with concerned individuals.
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- Prior to the visit, team members should be briefed, possibly by letter, on the terms of reference of the assessment, their role in the team and the WHO/EPI recommendations on the subject.
- On arrival in the country, the team leader will ensure that, at the earliest possible stage, all team members understand their role, the objectives of the assessment, the WHO/EPI recommendations, the procedures within the team and their responsibilities for data analysis, report writing and debriefing.

Step 2. Collection and presentation of background data

The team will be provided with an overview of the national surveillance of EPI target diseases and its accomplishments.

These data will be specific for the situation in the country, but should include:

- summary of existing policies on immunization, surveillance and disease control, including targets, strategies, plans of action, field guides and directives for health staff;
 - demographic detail, access to health care, minority populations and lifestyles, urbanization, high risk areas, level of privatization of health care;
 - description of the immunization programme, including the schedule, cold chain, training, supervision, coverage data by political unit (e.g. district), supplementary immunization activities;
 - description of the surveillance system, including the reporting network, reporting procedures, designated personnel, existence of laboratory support and directives on its use, data collection methods, level and status of data analysis, use of computers, feedback and training in surveillance. The results of any previous evaluations which included surveillance;
 - the use of surveillance performance indicators. The basis for these data should be at least the three key indicators presented in chapter 6 in the document "An integrated approach to high coverage, control of measles, elimination of neonatal tetanus, eradication of poliomyelitis - introducing the high-risk approach" (WHO/EPI/GEN/93.21). These three indicators focus on reporting timeliness/completeness, the rate of investigated cases/outbreak and the rate of cases/outbreak response and are listed in Annex 3. In countries with advanced programmes (e.g. >80% coverage), which are the main target for the present protocol, more indicators are needed to ensure that programme activities are effective and sustainable on a routine basis. Such indicators are shown in table 1, "Data needed at national level" and are copied from table 7.1 in the above-mentioned document.
 - review of special surveillance studies, e.g. NT surveys, lameness surveys, serological studies, outbreak investigations and vaccine efficacy studies.
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Table 1. Data needed at national level

DATA NEEDED AT NATIONAL LEVEL		
MEASLES	NEONATAL TETANUS	POLIOMYELITIS
<ul style="list-style-type: none"> - Coverage * - No. cases* - Immunization status of cases (from outbreak investigation) - Age breakdown (from outbreak investigation) - No. reports received on time compared to expected reports* 	<ul style="list-style-type: none"> - Coverage* - No. cases* - No. NT deaths (only where NT is rare) - % of districts reporting cases* - Immunization status of mothers of cases (from case investigation) - No. reports received on time compared to no. of expected reports* - % neonatal deaths investigated - % NT deaths investigated within 1 month of detection (at health facility) or reporting (to district) - % NT cases followed by corrective activities within 2 months of investigation - % pregnant women attending antenatal care (x 1,2 etc) - No. maternal deaths (from maternity hospitals) 	<ul style="list-style-type: none"> - Coverage* - No. cases* - No. acute flaccid paralysis (after case investigation) - % of districts infected (i.e. one case within previous 12 months)* - Immunization status of cases (from outbreak/case investigation) - Age breakdown (from outbreak/case investigation) - No. reports received on time compared to no. of expected reports* - % of cases reported within 1 week, 2 weeks and > 2 weeks of onset of paralysis - % of cases investigated - % of cases investigated within less than 48 hours of detection - % cases with outbreak response - % cases with outbreak response within 24 hours of investigation - % cases investigated that has 1 or 2 stool specimens taken - Rate of AFP detected per 100,000 children aged under 5 years

* indicates national data, at a minimum, that should be routinely reported to WHO. Regions may decide on additional data to be reported.

Step 3. Clarification of basic data

On the first day after arrival, the international team will meet with its national counterparts and, having either studied the basic data previously prepared or having heard a presentation on the data by programme staff, will seek specific clarifications. The team will be expected to identify apparent strengths and weaknesses, hear and understand concerns of the programme staff and will identify those parts of the programme that merit practical investigation or verification.

It is important for the assessment team not to be negatively critical of existing practices and progress in the country. However, as well as noting the successes, it is necessary to identify weaknesses and defects if subsequent recommendations are to be useful and practical.

Step 4. Identify sites to be visited

The number of sites to be visited will be constrained by the time available, the number of team members, distances and the ease of travel. Also, the depth of investigation will be influenced by the national stage of achievement in developing surveillance.

Two generalizations can be made which might assist in making optimal use of the time available:

- i) Many sites likely to benefit from investigation will be located in the capital city or other major urban areas. These will include the central surveillance unit, statistical departments, major hospitals, including infectious diseases and paediatric rehabilitation centres, diagnostic and research laboratories, academic centres for epidemiology, surveys and research.
- ii) Sites selected by risk assessment, the principle being that it will probably prove most useful to examine surveillance performance in areas where high levels of achievement are most critical. Such sites can be selected in cooperation with national staff, who, in all probability, will be well aware of areas of low coverage, high disease incidence, high proportions of minority groups or where surveillance is poor.

Although the reasons for site selection will probably be country specific, WHO has offered guidelines by characterizing high risk areas according to the target diseases:

Measles

- below average coverage
- below 90% coverage with measles vaccine
- densely populated areas
- refugee sites
- urban slums
- areas where cases cluster
- areas or groups where cases occur

Neonatal tetanus

- areas where cases cluster
- groups with high incidence
- areas or groups with recurrent cases
- districts with reported NT rates $> 1/1000$ L.B.
- Areas with lowest clean delivery rates
- districts with unknown or low coverage with TT2
- districts with risk factors:
 - rural
 - livestock near living area
 - poor health access / infrastructure

Poliomyelitis

- areas with any polio cases in the last three years
- areas of low coverage with OPV3
- areas where the epidemiology of polio, in general, suggests a high risk of wild poliovirus transmission persisting, for example:
 - urban slums
 - newly developed urban slums
 - areas of poor hygiene

High risk areas for different diseases may overlap. Areas where surveillance is thought to be poor merit the highest priority for investigation. It is recommended that teams should concentrate on the thorough investigation of a limited number of high risk areas, rather than a more superficial examination of a greater number of sites.

Within the identified high risk areas, the team should expect to assess the surveillance performance in institutions at the provincial, district and sub-district levels, including health centres, and community health posts. Other sites may include hospitals, the private sector, traditional healers and schools and day care centres.

Step 5. Perform appropriate assessment at each site

The team will have identified the particular characteristics that have made it an appropriate site for an assessment visit, in high risk areas including identification of the risk factor.

The assessment will always include discussion with local staff for their own ideas and experience on disease incidence, trends, completeness and quality of reporting. Each level of the surveillance system will have responsibilities and characteristics to which the assessment will be addressed. Annex 2 lists some proposed activities for each level of institution or site.

In general, the suggested activities should include:

- Assessment of the use of surveillance and disease reduction indicators.

These indicators should always monitor the completeness and timeliness of reporting. To identify effectiveness, completeness and trends, it may be necessary to review surveillance records. If surveillance indicators are being used, the team should assess their accuracy, whether they are being correctly calculated and whether they are being used to correct identified defects in the system.

The surveillance indicators recommended by WHO are those presented in Step 2 above.

- Assessment of routine surveillance policies.
The team will assess whether national / WHO recommended policies are being correctly implemented.
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The WHO recommended principles of surveillance for the EPI target diseases are

- use of standard case definitions
- monthly or weekly reporting of cases
- immediate reporting of diseases under special surveillance
- zero reporting, where no cases have been seen
- line listing of cases
- active surveillance for additional cases
- mapping of cases
- feedback to reporting staff
- laboratory surveillance where indicated
- expert committee to classify final diagnoses.

- **Case investigation and outbreak response.**

Case investigation and outbreak response are fundamental components of the EPI disease reduction strategies. The team should assess whether these are being done and whether they are being done correctly, thoroughly and consistently. The team should review records of recent outbreak investigations and match these to national instructions on the subject.

- **Review clinical or case discharge records.**

In reviewing these records, the team should look for records of recent cases, identifying whether recent cases had been adequately investigated and reported within national reporting guidelines.

- **Review special studies.**

The team should review any special studies that have recently been conducted in the country, including epidemiological analysis, intervention studies, NT or lameness surveys. The quality and the results identified should be assessed to identify their consistency with reports for the same period.

- **Active case search.**

Active case searches can be time consuming and, if the diseases are rare in the area, will need a large sample size to have a reasonable chance of identifying cases. No attempt should be made to randomize the search. Instead the team should concentrate on high risk areas and focus on hospitals, health centres, rehabilitation units rather than on the community. Active searches should not be undertaken if conducting them seriously reduces the effectiveness of surveillance assessment based on health institutions.

Step 6. Preparation of assessment summary and recommendations

On reconvening at the end of the phase of data collection, the team should discuss and review its findings. These discussions may lead to an awareness of the need to collect additional data or seek further explanations from national staff.

The team leader must ensure that all team members' opinions are solicited and considered with respect to disease surveillance included in the terms of reference were considered. It will be important that the review identifies both successes and problems. With the problems, it is critical to identify causes, e.g. do they result from local inadequacies or do they reflect national shortcomings. The team leader will need to use judgement to identify which of the recommendations are essential, which are important and which can or should be discarded, on the basis that implementing the more important recommendations will encompass the minor ones. There may be greater impact and understanding with the national authorities to have a few key recommendations than a long list including many that are less important. It is important that the recommendations are developed in full consultation with national counterparts.

The report itself will include an evaluation of the team's findings incorporating an assessment of disease control in the country. This should, as far as possible, be quantified, including graphs, tables, maps and with specific attention directed to disease and surveillance indicators. A key focus is whether the level of disease reported by routine surveillance is consistent with the surveillance efficiency identified by the team.

Step 7. Presentation of findings and recommendations

Before leaving the country, the team, headed by its leader will present findings and recommendations to the national authorities, ideally, emphasizing those factors that most importantly or urgently need correction and offering the means and a timetable through which progress might be achieved.

The recommendations should focus on how surveillance and disease control might be improved. They will include recommendations on how existing policies can be better implemented and whether changes in policies are required.

Specific recommendations, when needed, should focus on the development and use of surveillance indicators.

The team will need to make recommendations, based on their assessment, on whether and how control strategies for specific diseases can be introduced or improved. The team may wish to recommend the conduct of further surveys or research aimed at the further definition of surveillance performance and potential, outbreak investigations and vaccine efficacy studies.

Annex 1

Recommended reading

The following were used for the preparation of this document and may be useful to the assessment teams, particularly with respect to current WHO/EPI policies on surveillance and disease control. Many are available as draft or unpublished documents from EPI/HQ or EPI/AFRO.

- Guidelines for improvement of routine systems for surveillance of infectious diseases, including EPI target diseases. WHO/EPI/TRAM/93.1.
 - An integrated approach to high coverage, control of measles, elimination of neonatal tetanus and eradication of poliomyelitis. WHO/EPI/GEN/93.21.
 - Report of the Third Consultation on the Eradication of Poliomyelitis. WHO/EPI/POLIO/90.3.
 - Global Poliomyelitis Eradication by the year 2000. Plan of Action - Revised 1992. WHO/EPI/POLIO/92.2.
 - Neonatal Tetanus Elimination by 1995. (GAG Presentation). WHO/EPI, October 1992.
 - EPI TECHCOM. The Eradication of Poliomyelitis. WHO/EPI/POLIO/92.1.
 - Measles control in the 1990s. Plan of Action for Global Measles Control. WHO/EPI/GEN/92.3.
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Annex 2

Suggested activities for each site

Sites/ Areas /Persons	Interview responsible person	Review surveillance indicators	Review surveillance policies	Review case investigation and outbreak response	Review clinical case records	Review summary records or line listing	Review special studies	Do active case search
Central level surveillance units	X	X	X	X		X	X	
Hospitals	X		X		X	X		
Rehabilitation centres	X		X		X	X		X
Diagnostic/Research laboratories	X		X				X	
Epidemiology/Research centres	X						X	
Schools/Day care	X							
Recent reported cases	X		X	X				X
High Risk Areas								
Provincial, District, sub-district	X	X	X	X		X		
Health Centre	X				X	X		
Hospitals	X		X		X	X		
Sentinel sites	X	X	X	X	X	X	X	
Private Practitioners	X		X		X			
Traditional Healers	X		X		X			X

ANNEX 3

6. Monitoring of Surveillance Effectiveness: Quality Indicators

The three main indicators of quality of reporting and of effective use of reported data are:

1. **Timeliness/completeness** of reporting measured as the number of monthly (or weekly) reports received on time at district, state/provincial and national levels compared to the number of health facilities designated to report. What "on time" means needs to be defined by national authorities depending on local conditions for communication; for monthly reporting, the deadline for peripheral health facilities' reports is often 2 weeks into the following month and at least before the end of the following reporting period. In most countries, eight weeks should be enough for the reports to be processed from the peripheral to the national level.
2. The number of **investigated cases/outbreaks** compared to the number of reported cases/outbreaks. For NT and polio in low endemicity countries, this parameter should relate to reported cases. For polio in high endemicity countries and for measles this parameter should relate to reported outbreaks/clusters of cases.
3. For NT and polio: The number of **cases/outbreak response** compared to the number of cases/outbreaks investigated.

For indicators number 2 and 3 various time limits can be built in, for example how many polio cases were investigated within 48 hours after receipt of reports. For the various diseases other indicators can be monitored on the quality or effectiveness of different operational aspects as indicated in the following section.

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