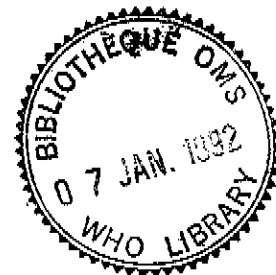




Tuberculosis Surveillance and Monitoring

Report of a WHO Workshop

Geneva, 20-22 March 1991



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INTRODUCTION

An estimated 1700 million people, or one-third of the world's population, are infected with tubercle bacilli, and each year 8 million new cases are thought to occur, of whom 95% live in developing countries. Each year 2.9 million people die from tuberculosis, with nearly 99% of tuberculosis fatalities occurring in developing countries.

Recently, significant changes in tuberculosis incidence have been noted. In industrialized countries declining trends have slowed and, in some cases, reversed. The situation in many developing countries has not improved in the past two decades, and tremendous increases in tuberculosis cases are being observed in countries where HIV infection is highly prevalent, notably in tropical Africa and the Caribbean. In some countries, the tuberculosis case-load has doubled over the last few years and is expected to continue increasing.

Encouraged by the increasing conviction that tuberculosis should not be allowed to remain a serious global problem when effective control measures are available, WHO has launched a new coordinated global strategy. The established targets are to cure 85% of all sputum-positive cases detected worldwide and to detect 70% of all such cases by the year 2000. Programme activities are focused on operations support and research and development. Operations support comprises development of training materials and support of training courses, monitoring and evaluation of country programmes and direct support to countries in planning, implementation and operational research. Programme advocacy, aimed at securing financial support, is included among the activities.

For programme planning and evaluation, and also for advocacy, it is essential that pertinent data are collected and analyzed systematically to quantify the problem and its trend; an activity referred to as surveillance. Some indicators, such as the annual risk of infection or the prevalence of disease, may have to be measured at regular intervals. Others, such as notifications of new cases or deaths from tuberculosis may be generated as part of routine programme activities. Another set of data must be collected and analyzed to measure the performance of the programme, referred to as monitoring. Monitoring makes it possible, for instance, to determine the cure ratio, the defaulter ratio and the case fatality ratio.

The systematic collection of data and reporting are often regarded by programme staff as tedious and time-consuming tasks, especially if the purposes of the activities are not clear. For this reason data collection and reporting must be restricted to a useful minimum. To address this issue and make recommendations for surveillance and monitoring at various levels WHO convened a workshop on 20-22 March 1991. The specific objectives of the workshop were to review current notification systems, to establish a practical case definition for reporting tuberculosis, and to identify the essential information that should be collected and reported.

INFORMATION REQUIRED

The participants fully agreed that a fundamental principle to be followed in the design of an efficient tuberculosis surveillance and monitoring system is to collect only the information that is essential for measuring the problem and evaluating the programme activities. It was emphasized that few data beyond those necessary to manage the patient are required for routine programme management. Good and simple record design and management facilitate both patient management and information extraction, transfer, and analysis by managers at all levels from the local to the national. Three documents, the patient register (usually held at the district level), the treatment card (usually held at the treatment centre), and the laboratory register contain the essential information required for patient and programme management.

Clinic level: Patient management

Peripheral tuberculosis workers have the essential task of managing case-finding and treatment of individual patients. Good patient management, the prescription of the appropriate regimen and treatment follow-up, requires knowledge of the severity and the site of the disease, the age, sex and body weight of the patient, his/her address, previous anti-tuberculosis treatments and smear results. The minimum information that should be obtained for each tuberculosis patient is therefore:

1) diagnostic category, 2) age and sex, 3) body weight, 4) date of registration, 5) address, 6) treatment outcome (including smear results and regularity of drug intake). Other information such as socioeconomic status, race/ethnicity and HIV status may also be useful for differentiating high- and low-risk groups, depending on local social and demographic structures.

District level: Basic programme management

The level from which programme management can be most effectively carried out will vary depending on the organization of the public health system and the case load. However, the level directly above the local health care delivery units may best serve in general as the vantage from which to manage the programme and evaluate performance. As a general model, the several health clinics or dispensaries where treatment is provided to residents of a district should be supervised by a district manager. The manager will monitor the collective achievement of case-finding and treatment and take the appropriate steps to reach and maintain optimum performance. Some of the most important information needed for programme monitoring includes 1) the number of newly diagnosed patients, 2) the proportion with smear-positive sputum, 3) the number of patients treated with the various regimens recommended, 4) treatment outcome (cure ratio) and case fatality ratio.

The periodicity of routine monitoring is dictated by the need for timely corrective action but should capture information on a number of tuberculosis cases large enough to form a statistically stable picture of programme achievement. As a general rule, most routine programme monitoring data at the district level should be collected quarterly.

While managers at the regional or provincial levels will monitor on a broader scale, most responsibility for programme performance should be vested in district level managers.

National level: Surveillance, programme management and advocacy

At the national level information is needed to adapt and develop the control strategies and watch for unanticipated changes in incidence, to evaluate the programme performance and to increase the awareness of the community, governments, and non-governmental and international organizations about the magnitude of tuberculosis and progress in controlling the disease.

Although tuberculosis case notifications are reported to WHO by the majority of Member States, the usefulness of this information for surveillance of the global tuberculosis problem is limited. This is because there is no standard case definition in use, because programme performance is often poor and variable and coverage is incomplete. The development of a good notification system is essential for monitoring and surveillance. Improvements in programme performance will improve the quality and quantity of information available for local, and hence for national and global surveillance of tuberculosis.

A satisfactory information system based on notifications is likely to be established in parallel with improved case-finding and diagnosis. In Argentina, for example, data collected over a 10-year period clearly shows increases in the number of cases notified and in the proportion bacteriologically confirmed associated with improved case-finding. In Tanzania, where a good information system has been set up, the effects of the HIV epidemic are clearly reflected in the rising number of tuberculosis notifications.

DEFINING A CASE OF TUBERCULOSIS

The workshop considered that both for surveillance and monitoring it is essential to have a practical case definition of tuberculosis so that data reported are unambiguous and comparable. It was reaffirmed that smear-positivity would define the most important class of cases but would be too restrictive as the sole criterion. The case definition should be based on available diagnostic techniques and be adaptable to techniques that may be developed. Sensitivity and specificity of diagnostic techniques must be carefully considered in the design of a case definition. Sensitivity is the fraction of persons with active tuberculosis who are correctly found to have tuberculosis. Specificity is the fraction of persons without active tuberculosis who are correctly found not to have the disease. When a test is sensitive, very few cases are missed. When a test is specific, very few persons without tuberculosis are mistakenly judged to have the disease.

Diagnostic criteria

Sputum smear microscopy is the most practical diagnostic technique because all national programmes can achieve adequate proficiency in its use and because it identifies the most infectious and, in general, the most serious forms of

pulmonary tuberculosis. Adequate proficiency depends on following an appropriate protocol for specimen collection, transport and processing. The rule is to collect a spot specimen (i.e. obtained on the spot, when the patient first attends a clinic with symptoms suspicious of tuberculosis), an early morning specimen consisting of all sputum raised within one or two hours after rising, and another spot specimen collected at the time the overnight specimen is brought to the clinic. Because errors in laboratory technique and specimen collection and submission are possible, a single specimen is not considered an adequate basis for defining a tuberculosis case. Moreover, the overall predictive value (the proportion of test results which are correct) of smear examination increases notably up to 3 specimen examination.

Clinical findings, culture and radiography: Additionally, the case definition should help in classifying separately cases who cannot be detected by sputum smear microscopy. These cases are potentially infectious or fatal and need to be identified and treated. To diagnose them, clinical judgment and additional diagnostic techniques such as radiography and mycobacterial culture have a important role to play. These techniques may not be universally available but they are expected to increasingly become so, as will new diagnostic techniques currently being developed. A drawback of currently available methods, however, is that, with the exception of sputum culture, they are not as specific as smear examination and are likely to yield a number of false positive cases (especially radiography). Treatment of these patients may be wasteful and lead to unnecessary exposure to drug toxicity. On the other hand, these diagnostic techniques have the potential advantage to identify a number of smear-negative patients who are truly diseased and may become smear-positive and transmit infection. Early detection and treatment of these cases may prevent transmission to other individuals whereas waiting for progression to disease extensive enough to be detected by sputum-smear microscopy may allow transmission to occur, especially to close contacts.

Although smear examination remains the primary diagnostic method and the basis of the case definition, culture and radiography are powerful diagnostic tools for smear-negative patients and should be used if they are available. Radiology can also be used as a screening test in passive case-finding. It reduces the number of smear examinations and, by increasing the pre-test prevalence of truly diseased individuals, it also increases the predictive value of positive test results (the proportion true positive test results among all positive tests).

The tuberculin test has little value in the diagnosis of tuberculosis. It should not be included as a diagnostic criterion in the case definition for surveillance of tuberculosis in many countries for the following reasons: 1) The tuberculin reaction in a BCG vaccinated person who has not been infected with M. tuberculosis cannot be distinguished from a reaction in a person who has been infected with M. tuberculosis. Because the BCG coverage has reached high levels in many countries, there would be a large number of false positive tuberculin skin tests and the predictive value positive of the test will be low. 2) Additionally, false negatives occur among the seriously ill, the malnourished and the HIV infected, altering the negative predictive value of the test (the

proportion of true negative test results among all negative tests) and seriously limiting its usefulness, especially in countries with high prevalence of HIV infection. Nevertheless, the result of tuberculin test is important, in some instances, to diagnose children who are contacts of an infectious case.

The uses of the tuberculosis case definition

The main purposes of a case definition are to help in the choice of treatment for individual patients and to facilitate notification. In addition, because the definition emphasizes the role of smear examination, it should promote the use of this low-cost diagnostic technique. Because smear-positive patients must be given priority and should receive the best treatment and because smear-negative patients may receive a different regimen, the classification of cases according to smear result is essential and must be strongly emphasized.

The challenge in defining what is a case of tuberculosis lies in the fact that the definition should apply in individual case management, in programme management and epidemiological surveillance. The definition specifically should make it possible to:

- identify whom to register in the case management system;
- identify persons who require curative tuberculosis treatment;
- distinguish cases who need special regimens;
- provide a basis for accurate counting of cases;
- identify whom to notify as a case;
- classify notified cases epidemiologically.

The case definition should furthermore categorize cases by smear results because smear-positive cases provide the most pertinent epidemiological information:

- smear-positive cases are the most important in the sense that they are the most infectious and they are usually the most ill and at risk of death;
- cases defined by repeated smear examination provide a highly specific core index of cases diagnosed with great certainty (confirmed cases);
- they are globally comparable and their description in terms of time, place and person, provides the most accurate epidemiological picture of the situation of tuberculosis;
- case-holding and treatment outcome of these patients provides the best measure of programme efficacy;

Further subclassifications should be made according to the status at the time of diagnosis, i.e.

- disease site (pulmonary/extra-pulmonary),
- personal attributes (age/sex);

and according to the past history of disease and anti-tuberculosis treatment, i.e.

- new case,
- relapse,
- treatment failure and returning defaulter
- chronic cases

These characteristics are critical from a patient management perspective because they determine the regimen that should be given (treatment/re-treatment). The matrix presented in Table 1 describes which patients should be registered, treated (and with what regimen) and notified.

In addition, the diagnostic criteria should acknowledge the role of the attending physician and the need to treat all patients, including smear-negative ones. The case definition should be applicable to HIV infected individuals and individuals with AIDS. These patients should be registered, treated and notified like other tuberculosis cases. Because the definition should also include the vast majority of children with tuberculosis, history of exposure to a sputum-positive case and, in some instances, the tuberculin test results may be important additional diagnostic criteria for children.

A possible shortcoming in settings where diagnosis is limited to sputum smear microscopy is that some patients who need treatment may not meet the criteria for being defined as a case. This may result in a delay of diagnosis and treatment. Some of these patients will return later to be diagnosed and treated only after having become infectious and others may be cured without treatment. In some instances, however, some patients may die of tuberculosis because diagnostic facilities are not available.

Table 1: Classification of tuberculosis for treatment, registration, notification and cohort analysis

Site\History		New	Transferred in	Relapse	Failure		Chronic
					True failure	Returning Defaulter	
Pulmonary	Smear +	R/N/T/C	R/T	R/N/Tr/Cr	R/Tr/Cr	R/Tr/Cr	R/T*
	Smear -	R/N/T	R/T	NA			
Extra-pulmonary		R/N/T	R/T				

- (R) Register (all cases)
 (N) Notify (all new and relapse cases)
 (T) Treat (all new and transferred in cases)
 (Tr) Treat with re-treatment regimen (relapse and failure cases)
 (C) Cohort analysis of new smear positive cases (new smear positive cases)
 (Cr) Cohort analysis of re-treatment cases (relapse and failure cases)
 (NA) Not applicable
 * Chronic cases should be treated with second line drugs

The case definition

The following is the definition proposed by the Workshop for application in all national settings.

A case of active tuberculosis is a patient with disease from Mycobacterium tuberculosis complex (M. tuberculosis, M. africanum, or M. bovis) who therefore requires treatment with anti-tuberculosis chemotherapy. The vast majority of cases present with symptoms. Patients with tuberculosis should be characterized by site of disease and history of prior tuberculosis therapy.

A. Site of disease

Cases of active tuberculosis are classified as either pulmonary or extra-pulmonary. Cases of pulmonary tuberculosis are further subdivided into smear-positive and smear-negative.

A.1 Pulmonary tuberculosis

A.1.1 Smear-positive tuberculosis:

A patient with at least two specimens smear-positive for acid fast bacilli (AFB),

OR with one sputum specimen smear-positive for AFB in conjunction with one sputum specimen culture positive for M. tuberculosis.

OR with one sputum specimen smear-positive for AFB and radiographic abnormality consistent with active pulmonary tuberculosis¹;

A.1.2 Smear-negative tuberculosis:

A patient with at least two sputum specimens negative for AFB and radiographic evidence consistent with active pulmonary tuberculosis¹ and the decision by a physician to treat with a full curative course of anti-tuberculosis chemotherapy,

OR a patient with AFB smear-negative sputum which is culture-positive for M. tuberculosis.

A patient should not be considered a case of pulmonary tuberculosis if three sputum specimens are smear-negative for AFB and there is a normal chest radiograph or a suspicious radiograph which clears with non-specific treatment.

A.2 Extra-pulmonary tuberculosis

A case of extra-pulmonary tuberculosis² is a patient with at least one mycobacterial culture-positive for M. tuberculosis from an extra-pulmonary site

¹ Such as radiograph which worsens without treatment.

² Includes pleural effusion and mediastinal adenitis without evidence of parenchymal involvement.

OR radiological, histological and/or clinical evidence consistent with active tuberculosis in conjunction with the decision by a physician to treat with a full curative course of anti-tuberculosis chemotherapy (excluding preventive chemotherapy).

B. History of prior tuberculosis therapy

A tuberculosis patient should be defined further by history of previous anti-tuberculosis treatment as:

B.1 A new case:

A patient who has never received anti-tuberculosis treatment for more than one month.

B.2 A relapse case:

A patient who was declared cured in the past and again has disease meeting one of the above definitions (A.1.1, A.1.2, A.2).

B.3 A treatment failure case:

A patient who is still sputum smear-positive at five months or more after the start of chemotherapy for a newly diagnosed case of tuberculosis OR a patient who interrupted the treatment for more than 2 months after completing the first month of chemotherapy, returned to treatment and was found to be smear-positive (also referred to as a returning defaulter).

B.4 A chronic case:

A patient who is still discharging AFB after having completed a re-treatment regimen under supervision.

C. Information base

Once diagnosed, all cases should be treated and registered with information on age and sex, weight, place of residence and date of registration. They should be classified and notified in the following categories:

Site of disease: Pulmonary, extra-pulmonary, or both

Sputum smear: Positive or negative

Mycobacterial culture: Positive, negative, or unknown

Previous anti-tuberculosis treatment: Yes (if one or more months of treatment was received) or no

Previously declared cured: Yes or no

Cases who were previously treated and notified but who were not cured such as chronic cases, treatment failures including returning defaulters and transfers "in" should not be notified again.

Case registration (usually in a district register) is the foundation of tuberculosis surveillance and programme monitoring. Registered cases are classified and enumerated at regular intervals, in general every 3 months at the district level and reported to the upper level (Province or Region). The total

number of newly registered cases represents the overall case finding activity of the programme. The proportion of smear-positive cases reflects, at least in part, the quality of the case-finding and diagnostic activities.

DISEASE SURVEILLANCE

Data used for disease surveillance may be generated by routine programme activities or obtained with special surveys. Case notification may provide a valid approximation of incidence. Tuberculosis mortality data may be obtained from vital statistics and case fatality from the analysis of treatment results. Data on primary and secondary drug resistance and the reported incidence of tuberculous meningitis may be available as part of normal programme activities. On the other hand special studies are needed to measure disease prevalence and the annual risk of infection.

Programmatic information

Case notifications

In many industrialized countries, case notifications provide a useful indicator of the tuberculosis problem because the number of cases closely reflects the incidence. In many developing countries this is not so because often the notification system is deficient, diverse criteria are used for defining a case, and only a fraction of all cases is detected. Also, cases are detected from a large prevalence pool so that the numbers or rates reflect the performance of the tuberculosis control programme rather than the true incidence. It is not unusual that strengthening of the programme results in an immediate increase in the case notification rate (the number of cases of tuberculosis notified per 100 000 population).

The Workshop extensively discussed a global overview of the tuberculosis situation that included an analysis of recent notifications from developing countries. Despite shortcomings, notification data at the national level, particularly those of well operated national tuberculosis control programmes, is of great value for surveillance of the epidemiological situation. In some African countries, a rapid rise in the detection rates in the last few years was observed and was not readily explained by increased case-finding activities. Analysis of the trend by age revealed that the increases occurred in the age groups in which HIV infection was most prevalent. Moreover, the increases for smear-negative and extra-pulmonary tuberculosis were higher than for smear-positive pulmonary tuberculosis. HIV testing of tuberculosis patients confirmed that the observed increase could be explained largely from increases in incidence attributable to HIV infection. This surveillance information gave an early warning of the potential impact of HIV infection and was instrumental in planning future needs.

Case fatality and mortality

The case fatality ratio is the proportion of patients (usually, smear-positive patients) who died of any cause during the course of the treatment.

It is an indicator of the performance of the treatment programme but obviously also provides information on the tuberculosis problem. In this respect, however, it should be interpreted with care. A small proportion of patients must be expected to die from tuberculosis at the beginning of treatment, especially if there is some delay before diagnosis is made. Another fraction of the patients may be found to die after their sputum has converted bacteriologically to negative, and death during the treatment period may be particularly frequent among tuberculosis patients with other diseases, notably AIDS. Carefully interpreted the case fatality ratio should be used for programme monitoring to compare trends over time within a district or a country and for district and regional comparisons.

Although tuberculosis mortality reflects to some extent morbidity, the value of mortality data as an epidemiological indicator of the tuberculosis problem is limited in industrialized countries since the introduction of effective chemotherapy. Whereas the collection of mortality data is not feasible in most developing countries, it may have some value for the assessment of case finding activities. Complete multiple cause coding is needed, however, to avoid misinterpretation.

Other programmatic information

The incidence of tuberculous meningitis is difficult to measure reliably as all cases may not be hospitalized and diagnosed. In addition, it is liable to, perhaps, be significantly influenced by increased BCG vaccination coverage of the new-born. Nevertheless, when it can be measured, the incidence of tuberculous meningitis under 5 years of age provides a useful indicator of the intensity of M. tuberculosis transmission in the community and thus of the effectiveness of case finding and treatment.

Drug sensitivity testing for primary and acquired resistance may also provide useful information not only on the epidemiological situation, but also on the effectiveness of the treatment programme and the efficacy of the treatment regimen.

Special surveys

Risk of infection

The annual risk of infection represents the probability for an individual to become infected with M. tuberculosis in a one-year period. The average annual risk of infection for a given period of time can be calculated from the prevalence of infection among children at a given age. In countries with high BCG coverage, it is often difficult to measure as many children have positive skin test due to their BCG vaccination and un-immunized children may not be representative of the general child population.

The annual risk of infection, however, is extremely informative because 1) it reflects the prevalence of individuals currently most prone to transmit disease, 2) it can be used to project the number of new cases of tuberculosis

- that can be expected unless the risk has become very low,
- 3) it allows the prediction of the proportion of the population that will remain at risk of developing tuberculosis in the years to come, and
 - 4) changes over time reflect the long-term trend of the tuberculosis problem.

Prevalence of active tuberculosis

The prevalence of tuberculosis disease represents the burden of tuberculosis at a given point in time, including the case-load that requires antituberculosis treatment. Most patients who have pulmonary tuberculosis can be identified by bacteriological examination of sputum. They are the most infectious cases and therefore are responsible for spreading most tuberculosis infections in the community. For this reason and because their identification is relatively easy and reliable, these patients are most relevant to tuberculosis surveillance.

The prevalence of pulmonary tuberculosis can be measured by conducting nationwide prevalence surveys in which cases of pulmonary tuberculosis are identified using radiography screening and sputum smear and culture examination. These surveys, however, are not recommended because they are expensive and require a large sample size, which makes them especially inappropriate for poor countries.

MONITORING TUBERCULOSIS CONTROL PROGRAMMES

Case detection ratio

The case detection ratio is the proportion of all cases that are detected and it is estimated by the proportion of expected cases that were reported, expressed as a percentage. This calculation requires prior knowledge of the annual risk of infection. It is based on the assumptions that all cases identified are being notified and that the general model for calculating the expected number of cases is applicable to the particular population considered. The method used to project the expected incidence is not valid when the annual risk of infection is low and may not be appropriate in countries with a high prevalence of HIV infection.

The case detection ratio is an important programme indicator because it reflects the intensity and the extent of the case-finding activities.

Treatment results

Cohort analysis of case-holding and treatment outcomes is the most informative technique for evaluating the case-holding and treatment programme. It is based on the analysis of data summarized from the tuberculosis patient register. It requires all newly diagnosed patients to be registered along with individual patient information on diagnostic results, adherence to treatment, and treatment outcome. Follow-up information on smear result and attendance to appointment for drug collection must be recorded until the end of treatment. Cohort analysis of treatment outcome is usually done for smear-

positive patients only, but the technique may be adapted for other types of patient if deemed useful. It avoids biases attendant upon retrospective and cross-sectional methods.

A cohort consists of all patients registered during a given time interval (usually a quarter). The duration of the interval between the registration of cases and the analysis is chosen in such a way that all patients can have completed the prescribed treatment and follow-up information has become available in the district register (i.e. the duration of the treatment regimen plus another three months). The analysis should be carried out for each district usually every quarter and provide immediate feedback to the staff responsible for the programme. Patients registered during the quarter being evaluated are identified in the district register and classified in one of the following categories:

1) cured, 2) treatment completed, 3) died of any cause, 4) treatment failure, 5) default, 6) transferred out. The number of patients in each outcome group is computed separately for each regimen used and for new and retreatment cases. The total number of new cases included in the analysis should equal the number notified in the report on new cases for the quarter concerned (Table 1). The following indicators can then be computed:

Cure ratio

In the cohorts registered in a given time interval, the proportion who completed treatment and had at least two negative smears with an interval of at least 1 month, one of which was obtained at the end of treatment.

Treatment completion ratio (without bacteriological evidence of cure)

In the cohorts registered in a given time interval, the proportion of patients who completed treatment but sputum examination results are not available.

Treatment failure ratio

In the cohorts registered in a given time interval, the proportion who are still sputum smear-positive at five months or more after the start of chemotherapy, or who interrupted treatment for more than 2 months after completing one month of chemotherapy, returned to treatment and were found to be smear-positive.

Defaulter ratio

In the cohorts registered in a given time interval, the proportion who did not collect drugs for two consecutive months or more.

Proportion of transferred out

In the cohorts registered in a given time interval, the proportion recorded as having moved out of the health facility catchment area.

Case fatality ratio

In the cohorts registered in a given time interval, the proportion recorded as having died of any cause during the course of treatment.

Cure ratio is the best and most accurate indicator because it represents the proportion of patients whose cure was bacteriologically documented. It should be as high as possible, indicating that patient bacteriological follow up was properly done and sputum conversion occurred.

Treatment completion ratio is also an important and very useful indicator because it reflects the ability of the programme to, at least, ensure that patients did receive or collect a full course of anti-tuberculosis chemotherapy. In programmes where the intensive phase of treatment is fully supervised, patients who complete treatment are likely to be smear-negative and cured, although a few may still be smear-positive. However, if the initial phase of treatment is unsupervised, treatment completion ratio does not represent the ability of the programme to render smear-positive patients non infectious. For this reason, treatment completion ratio should always be interpreted in light of cure ratio and every effort should be made to, first, increase cure ratio. High treatment completion ratio, with sub-optimal cure ratio, indicates a lack of bacteriological follow up of patients and the need to emphasize patient supervision.

As defined here, treatment completion and cure ratio are mutually exclusive. Their addition represents the proportion of patients who are likely to have been cured and it is a fair approximation of the overall performance of the treatment programme.

Within the cohort analysis methodology, additional indicators may be developed that can be computed for all newly registered cases or that can be used in different programme conditions. Every effort should be made to obtain a sputum specimen, especially at the end of treatment. Even if the specimen is of poor quality or is likely to be saliva, it should be sent to the laboratory. It is the laboratory's responsibility to examine the specimen, determine its quality and report smear results.

Cohort analysis is most useful at the district level where treatment results are evaluated over time or against set targets. Additionally, they are compared with those from other districts and compiled into regional and national reports by the staff at these levels.

EVALUATION AND VALIDATION OF SURVEILLANCE AND MONITORING INFORMATION

Both cost and accuracy of any surveillance system should be assessed periodically. The purpose of data collection must be justified continuously and the surveillance method used must be the best available alternative. The priority for validating case-finding and diagnosis is the routine measurement of the positive predictive value of smear examination. This should be part of the standard laboratory quality control activities.

Accuracy of smear examination can be evaluated by periodically reviewing the diagnosis of a sample of routinely diagnosed cases. The false positive ratio, defined as the proportion of smear-positive results that were in fact smear-negative, is estimated this way. The false negative ratio defined as

the proportion of smear-negative results that were in fact smear-positive is harder to determine because it requires at least re-checking a representative sample of negative smears.

Accuracy of case-finding is also difficult to measure because it requires a comparison of the cases diagnosed with the general population from which cases originated. It depends on the coverage, the accessibility of health services and the quality of diagnostic services. Large differences in case detection rates between physically adjacent, but administratively distinct areas or over time, would indicate differences in case finding performance that require attention.

Although there is no tested methodology for assessing the correctness of treatment results information, it is possible to confirm sputum results with the reference laboratory. Informal evaluation is usually conducted as a part of the routine supervisory visits to districts. Information in the district register is compared to information available in the treatment card and quarterly reports are also verified against the district register.

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