Background document 2.c

USER GUIDE FOR CHECKLIST OF STANDARDS AND BENCHMARKS FOR TB SURVEILLANCE AND VITAL REGISTRATION SYSTEMS

This user guide was developed to provide instructions to implement the associated checklist of standards and benchmarks for TB surveillance and vital registration systems in an accurate and standardized way. For each standard and benchmark, the rationale and recommended methods to assess whether the benchmarks are achieved are laid out. Specifically, the user guide provides a description of how data should be collected, what data should be reviewed, and for elements that require reviewing a sample of records, how the sampling should be conducted. Real examples are provided to demonstrate how the proposed methods have been used in other settings. When benchmarks are not met, recommended actions are provided. Definitions of key terms are listed in the back of the guide.

The assessment of TB surveillance and vital registration systems using the checklist is designed for the previous calendar year to ensure sufficient time for the most complete data to be available for review. Certification is based on the review of the system from that period.
Documentation and other information to be used for the assessment:

**TB Program - National Level:**
- Blank data collection forms for TB, MDRTB, TB/HIV (e.g. treatment card, reports forms, registers)
- National guidelines for TB, MDRTB and TB/HIV
- Program manual
- M&E plan
- List and/or total # of all TB facilities in country (that report TB cases)
- Most recent annual TB report
- Any reports on data quality or surveillance evaluations that have been done in past 5 years
- Most recent complete years’ compiled reports of TB cases (paper and/or electronic)
- Data management documentation for surveillance system (e.g. SOPs, reports, data dictionary)
- Surveillance-related training documents
- Surveillance data:
  - Dataset of minimum set of variables (see B1.2) for last complete calendar year
  - # of reported TB cases at national level and first sub-national levels from the last two years
  - # of TB deaths (HIV-neg, from vital registration if possible) from last two years at national level

**External to TB Program:**
- Economic statistics: 1) GDP from last two years & 2) average out-of-pocket health expenditure
- National health statistics: under-5 mortality rate <10 per 1000 population
- National vital registration system information (e.g. description, national coverage and quality)
- National prevalence of HIV from the last two years at national level

**Facility/District Level (paper-based systems only):**
- TB register of a health facility
- Laboratory register
- Treatment cards/medical records
- District register
STANDARD: B1.1 CASE DEFINITIONS ARE CONSISTENT WITH WHO GUIDELINES

BENCHMARKS: ALL THREE BENCHMARKS SHOULD BE SATISFIED TO MEET THIS STANDARD:

- LABORATORY CONFIRMED CASES ARE DISTINGUISHED FROM CLINICALLY DIAGNOSED CASES
- NEW CASES ARE DISTINGUISHED FROM PREVIOUSLY TREATED CASES
- PULMONARY CASES ARE DISTINGUISHED FROM EXTRAPULMONARY CASES

RATIONALE FOR STANDARD AND BENCHMARK

TB case definitions are essential for effective TB surveillance. They are necessary to provide consistent information on epidemiological trends and control programme performance. They are also used to guide treatment selection. Reported TB cases should be standardized to allow meaningful monitoring of differences in rates between geographical areas and monitoring of trends in rates in reported TB cases over time. Case definitions that are unclear and unstandardized, and changes or inconsistencies in case definitions are detrimental to such monitoring. TB case definitions that are not comparable with universally-recommended criteria for categorizing cases (e.g. laboratory vs clinically confirmed, new vs any previous treatment, pulmonary vs extrapulmonary) or are inconsistent over time make the analysis of surveillance data difficult, if not impossible.

METHOD TO ASSESS BENCHMARK

Data sources and data collection methods: Case definitions should be documented in national TB manuals and policies. A review of policy documents is needed to assess this standard. National case definitions should be compared with WHO recommended definitions for logical consistency (as opposed to exact wording). If TB case counts based on national definitions equal TB case counts that would be obtained using WHO definitions, national definitions should be classified as consistent with WHO recommendations. Otherwise, national definitions should be classified as inconsistent with WHO guidelines.

Main limitations: The existence of standard case definitions in national policy documents does not necessarily translate into their adoption at all levels.

Interpretation of results: All three benchmarks should be satisfied to meet this standard.

Recommended actions: Convene a national advisory group to review current case definitions, followed by edits to national guidelines, adaptation of recording and reporting systems (paper forms and registers and/or electronic databases) and updates to curriculum and training materials.
In Kenya, the Division of Leprosy, Tuberculosis and Lung Disease has developed and distributed Guidelines on the Management of Leprosy and Tuberculosis. To assess whether the definitions are consistent with those recommended by WHO, guidelines were reviewed. Case definitions were clearly defined in the guidelines for TB management and recording and reporting of TB case data, differentiating lab confirmed vs clinical cases, new and re-treatment cases (including relapses, failures and returnees after default), and pulmonary and extra-pulmonary cases. Furthermore, a review of the curriculum and TB training manual for health workers demonstrated that these case definitions were a part of routine training for TB management. The definitions in Kenya are consistent with those recommended by the WHO (http://www.who.int/tb/publications/global_report/2008/table_a2_1/en/index.html), and the surveillance system in Kenya meets this standard.
STANDARD B1.2 TB SURVEILLANCE SYSTEM IS DESIGNED TO CAPTURE A MINIMUM SET OF VARIABLES FOR REPORTED TB CASES

BENCHMARK: DATA ARE ROUTINELY COLLECTED FOR AT LEAST EACH OF THE FOLLOWING VARIABLES:

- AGE OR AGE GROUP
- SEX
- YEAR OF REGISTRATION
- GEOGRAPHICAL LOCATION (FIRST SUB-NATIONAL LEVEL, E.G. PROVINCE, STATE, REGION)
- CASE TYPE (NEW [Y/N], PULMONARY [Y/N]; LABORATORY-CONFIRMED\(^1\) [Y/N])
- FOR CASE-BASED SYSTEMS, A PATIENT IDENTIFIER (E.G. NUMERIC ID)

RATIONALE FOR STANDARD AND BENCHMARK

Surveillance systems need to collect data for a set of well-defined variables. It is important to collect uniform data to improve the comparability, consistency and relevance of surveillance information. The minimum set of data elements selected represents the fundamental attributes necessary to assess data quality such that TB data can measure TB incidence and trends. For example, data on all cases disaggregated by age, sex, year, geographical location and case type (new [Y/N], pulmonary [Y/N]; laboratory-confirmed[Y/N]) are needed to assess whether standards B1.2, B1.8, and B1.9 in Table B are met. In case-based systems, a unique patient identifier (e.g. TB registration number) is needed to match and remove duplicate cases. However, this does not preclude national TB programs from collecting additional data to meet their own specific needs.

METHOD TO ASSESS BENCHMARK

Data sources and data collection methods: This standard specifically targets data collected by providers within the national tuberculosis control network, including providers under the National TB Programme and other public and private providers engaged with the Programme. If an official national annual TB report from the previous year for which data are complete is available for review and demonstrates all of the essential data elements are collected from reporting units the report itself is sufficient to assess whether the minimum set of data elements are available. Alternatively, if either a standardized electronic system or a set of paper data collection tools is used to capture each of the minimum set of elements, then the benchmarks can be considered to have been met. If this is not the case, a review of the national surveillance database or, for paper-based systems, the TB quarterly reports can be undertaken to check if all the minimum data elements are captured.

\(^1\)i.e. by smear, culture or WHO-endorsed molecular test (e.g. Xpert MTB/RIF)
Main limitations: This standard will miss providers that do not report to the national TB program and/or are outside the reporting network. Paper-based systems following the 2006 WHO Recording and Reporting guidelines will fail both age and sex benchmarks, which are intended for smear-positive cases only.

Interpretation of results: For all benchmarks to be met and to meet the criteria to satisfy the standard, data should be routinely captured by program recording and reporting for each of the following variables for all cases: age or age group, sex, year of registration, geographic location, and all three case types (new, pulmonary and lab-confirmed). For case-based systems, a patient identifier is also needed.

Recommended actions: New program recording and reporting forms can be developed and related training conducted to take into account the collection of the minimum set of data needed to assess trends and to look at internal and external consistency.

EXAMPLE(S)

In Uganda, the surveillance system is paper-based. Patient data are collected at the facility level and then recorded in facility and district TB registers. Then aggregated reports are compiled at the district level and sent via the province to the national program office. A national annual TB report is routinely disseminated and standardized data collection forms were distributed and used in reporting units nationally. To assess whether at least the minimal data elements were captured for all TB cases in Uganda, the annual and quarterly reports were reviewed. Data are collected on sex, year of registration, district and disease site (pulmonary vs extrapulmonary TB), along with other variables prioritized by the national TB program. The age of each patient is collected in unit and district TB registers but is only routinely reported for new smear positive cases. Laboratory confirmation is only collected for pulmonary cases. Based on the assessment, only some of the variables were captured for all cases, so this standard was partially met.
STANDARD B1.3: SCHEDULED PERIODIC REPORTS (E.G. QUARTERLY REPORTS) ARE ACCOUNTED FOR AT NATIONAL LEVEL (FOR PAPER-BASED SYSTEMS ONLY)

BENCHMARK: 100% OF EXPECTED REPORTS FROM EACH REPORTING UNIT ARE ACCOUNTED FOR AT NATIONAL LEVEL

RATIONALE FOR STANDARD AND BENCHMARK

This standard uses report completeness as a proxy for completeness of data within the national tuberculosis control network. Subsequently, this information can be used to evaluate the extent of underreporting and monitor progress in reducing it. This standard specifically focuses on the routine periodic (e.g. quarterly) reports on tuberculosis data channeled from the reporting units or Tuberculosis Management Units (TBMUs) and other public and private providers engaged with the National Tuberculosis Programme to the national level. The benchmark indicates that the National Tuberculosis Programme should receive 100% of the expected periodic reports on TB data from all reporting units (i.e. TBMUs and engaged public and private non-NTP providers) from all over the country during the year under evaluation.

METHOD TO ASSESS BENCHMARK

Data sources and data collection methods: Reports of TB cases sent to the National Tuberculosis Programme from reporting units over the period of one year are the main data sources. The assessment can be done as part of an in-depth review mission of the Programme or specific missions for either a data quality audit or an assessment of the surveillance system. The process consists of counting the number of reports on TB cases received at the central level during the designated evaluation period. This should be over the past year; however, in very large countries with many reporting units, the evaluation period could be a single quarter. The number of expected reporting units is the total number of reporting units (TBMU and other engaged providers). This number is updated on a regular basis depending on the efforts of the Programme to engage other providers in reporting TB cases.

Calculations: Number of routine periodic reports on TB cases submitted from the reporting units (TBMUs/Non-NTP) to the central unit for the evaluation year divided by the number of reports expected to be received from all these units at the central level for the same period (Number and Percentage).

Main limitations: 1) The tendency of the reporting units is to not submit reports of zero cases. The importance of zero case reporting should be emphasized. 2) This standard does not quantify the extent of underreporting of cases within the submitted or non-submitted reports. Routine cross-checking of TB registers against reports during supervisory visits and meetings are crucial to minimize this source of data incompleteness. 3) This standard is limited to the
units reporting to NTP and therefore does not account for the units that should be submitting reports to NTP (e.g. non-engaged private or public providers that treat TB cases) but do not.

**Interpretation of results.** If less than 100% of reports are accounted for at national level, then the system does not meet the standard

**Recommended actions:** Investigations should be undertaken to identify the sources and causes of underreporting and take correctives measures. Report completeness should be included as an indicator in the national M&E framework and plan, which are integral components of the countries’ national strategic plans. The performance of the system can be routinely compared against this benchmark on an annual basis to evaluate the progress made compared to the baseline.

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**EXAMPLE(S)**

The table below shows that out of 513 expected reports in 2010, Egypt has received 495 (report completeness of 96%). Therefore Egypt does not meet the standard.

<table>
<thead>
<tr>
<th>Reporting units</th>
<th>Number of expected reports</th>
<th>Number of submitted reports</th>
<th>Frequency</th>
<th>Level</th>
<th>Data sources</th>
</tr>
</thead>
<tbody>
<tr>
<td>TBMU</td>
<td>157</td>
<td>157</td>
<td>Quarterly</td>
<td>District</td>
<td>Quarterly reports on TB cases</td>
</tr>
<tr>
<td>Health insurance organization</td>
<td>68</td>
<td>68</td>
<td>Quarterly</td>
<td>Central</td>
<td>Quarterly reports on TB cases</td>
</tr>
<tr>
<td>Military</td>
<td>1</td>
<td>1</td>
<td>Quarterly</td>
<td>Central</td>
<td>Quarterly reports on TB cases</td>
</tr>
<tr>
<td>Prisons</td>
<td>3</td>
<td>3</td>
<td>Quarterly</td>
<td>Central</td>
<td>Quarterly reports on TB cases</td>
</tr>
<tr>
<td>Universities</td>
<td>14</td>
<td>5</td>
<td>Quarterly</td>
<td>Intermediate</td>
<td>Quarterly reports on TB cases</td>
</tr>
<tr>
<td>Private clinics, hospitals</td>
<td>27**</td>
<td>27</td>
<td>Monthly or quarterly according to case load</td>
<td>Intermediate</td>
<td>Quarterly reports on TB cases</td>
</tr>
</tbody>
</table>

*Public providers non-affiliated to the national TB control programmes (e.g. universities, military, prisons)

** Varies according to governorate coordinators efforts to engage private providers in their governorates