Background document 2.a

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

INTRODUCTION
A major goal of TB surveillance is to provide an accurate measure of the number of new TB cases and deaths from TB that occur each year and to be able to assess trends over time. In some countries, TB surveillance is already meeting the standards necessary to do this, but in others, there are important gaps in TB surveillance that do not make this possible. For example, TB cases that are diagnosed in the private sector go unreported in many settings, and in many countries with a high burden of TB, people with TB may not access health care and be diagnosed at all. Many countries lack vital registration systems with the geographical coverage and quality required to accurately measure deaths caused by TB.

The primary purpose of the TB surveillance checklist in this document is to:

1. Assess a national surveillance system’s ability to accurately measure TB cases and deaths; and
2. Identify gaps in national surveillance systems that need to be addressed.

The results of the national assessment
1 can then be used to identify which countries have surveillance systems that already provide an accurate measure of the number of TB cases and deaths that occur each year, and to define the actions necessary to strengthen surveillance in countries in which gaps are identified. Countries in the former category can be "certified" as having TB surveillance data that provide a direct measure of TB incidence and/or mortality.

The checklist consists of a set of 15 standards and their associated benchmarks. These were developed and revised based on results from two rounds of field-testing in a total of 10 countries, including Brazil, China, Egypt, Estonia, Japan, Kenya, Netherlands, Thailand, UK, USA, as well as feedback provided during expert meetings organized by WHO in September 2011 and May 2012.

The standards are general statements about the characteristics that define a high-performance TB surveillance system; 14 standards are related to measurement of TB cases and one is related to measurement of TB deaths. For a country's TB surveillance system to be certified as providing a direct measurement of TB cases, there are 11 standards that need to be met; of these, 2 are specific to paper-based systems with aggregated data, 3 are specific to electronic case-based systems, and 2 assess system coverage. For a country's TB surveillance system to be certified as providing a direct measure of the number of cases of MDR-TB, the number of HIV-positive cases of TB, and TB in children specifically, there are an additional 3 standards that must be met. For a country's surveillance system to provide a

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1 This checklist may also be used at sub-national level; however, this is not the primary purpose for which the Task Force has developed the checklist.
direct measure of TB deaths, there is one standard that must be met. For each standard, benchmarks define (in quantitative terms wherever possible) the level of performance that is considered good enough to meet the standard. It is recognized that the standards and benchmarks related to health system coverage (B2.2) and vital registration (B3.1) are outside the purview of the TB programme. However, to assess the capacity of the surveillance system to accurately estimate TB burden, these two standards and associated benchmarks are necessary.

The rationale for each standard and associated benchmark(s), and the methods that should be used to assess if the benchmarks are achieved, are explained in the accompanying user guide. Examples are used to illustrate the methods that are described, as well as recommended corrective actions if the benchmarks are not met. The user guide also defines any terms that may not be familiar to those using the checklist.

The checklist is designed for the assessment of the most recent complete calendar year. Depending upon the timeliness of the reporting and finalization of data validation procedures, the lag time may range from no delay to one year. It is anticipated that an assessment of a TB surveillance system using this checklist would take place every 3-5 years.

In a few instances (e.g. B1.4 and B2.1) where compilation of the necessary evidence may be difficult or impossible on a regular basis, to demonstrate that a standard is met it is acceptable to use evidence from the literature or special studies carried out in recent years, provided that the results from assessment of other standards show that data quality within the system has not declined subsequently. This is explained in more detail in the user guide.

The checklist can be used by in-country staff for self-assessment. External peer review and endorsement of the findings by the WHO Global Task Force on TB Impact Measurement will be necessary for a country’s system to be certified.

Part A (below) provides a general description of the TB surveillance system being assessed. The checklist for TB surveillance and vital registration systems is included in Part B, which includes four sections covering data quality (B1), system coverage (B2), TB mortality data from vital registration systems (B3) and surveillance of TB/HIV cases, MDR-TB cases and TB cases in children (B4).
## PART A: CHARACTERISTICS OF THE TB SURVEILLANCE SYSTEM

*Before completing the checklist, it is important to characterize the national TB surveillance system. Please provide answers to the following questions.*

### A1. How are data recorded for individual cases at the service delivery level (e.g. in TB diagnostic units, health centres, clinics)?

**Tick all that apply**

- Data are recorded electronically on a national web-based system
- Data are recorded electronically on a state/provincial/regional-based system
- Data are recorded electronically on a local system
- Data are recorded on paper
- Data are not recorded

### A2. What types of data are available at the national level?

**Tick all that apply**

- Patient level data (that allow multiple episodes of TB in same person to be identified) are available
- Case level data are available
- Only aggregated data (i.e. summaries for groups of cases) are available

### A3. What is the frequency of data transmission to national level?

**Tick all that apply**

- Real-time (web-based)
- More often than monthly
- Monthly
- Quarterly
- Less often than quarterly

### A4. Is a national TB surveillance report routinely produced and disseminated on an annual basis?

- Yes
- No

**Additional description, as needed (e.g. coverage, staffing and human resources):**
## PART B: CHECKLIST FOR TB SURVEILLANCE AND VITAL REGISTRATION SYSTEMS

For each standard, please assess whether the system is able to satisfy the associated benchmark(s), using the methods recommended in the user guide. Indicate ‘Met’, ‘Partially met’, ‘Not met’ or ‘Could not be assessed/not applicable’ in the Results column, and any action recommended to improve the quality of the system in the Corrective Action column.

<table>
<thead>
<tr>
<th>STANDARD</th>
<th>BENCHMARK(S)</th>
<th>RESULTS</th>
<th>CORRECTIVE ACTION</th>
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<tr>
<td>B1. TB SURVEILLANCE SYSTEM DATA QUALITY</td>
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| B1.1 Case definitions are consistent with WHO guidelines | 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 | ☐ Met  ☐ Partially met  ☐ Not met  ☐ Could not be assessed/not applicable | |
| B1.2 TB surveillance system is designed to capture a minimum set of variables for reported TB cases | 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* [Y/N])  
• For case-based systems, a patient identifier (e.g. numeric ID)  
* i.e. by smear, culture or WHO-endorsed molecular test (e.g. Xpert MTB/RIF) | ☐ Met  ☐ Partially met  ☐ Not met  ☐ Could not be assessed/not applicable | |
| B1.3 Scheduled periodic reports (e.g. quarterly reports) are accounted for at national level *(For paper-based systems only)* | • 100% of expected reports from each reporting unit are accounted for at national level | ☐ Met  ☐ Partially met  ☐ Not met  ☐ Could not be assessed/not applicable | |
| B1.4 Data in scheduled periodic reports (e.g. quarterly reports) are complete and internally consistent *(For paper-based systems only)* | Both benchmarks should be satisfied to meet this standard:  
• Sub-totals of the number of TB cases by age group, sex, and case type equals the total number of reported TB cases in >95% of reports from reporting units.  
• >95% of sampled clinics are acceptable in terms of the | ☐ Met  ☐ Partially met  ☐ Not met  ☐ Could not be assessed/not applicable | |
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| B1.5     | Data for each variable in the minimum set are complete for all reported cases *(For electronic systems only)* | Data are recorded for >95% of reported cases for at least each of the following variables:  
- Age or age group  
- Sex  
- Year of registration  
- Geographical location  
- Case type (i.e. new; pulmonary; laboratory-confirmed)  
- For case-based systems, a patient identifier (e.g. numeric ID) | Met  
Partially met  
Not met  
Could not be assessed/not applicable |
| B1.6     | Electronic system has the features required for data consistency and completeness *(For electronic systems only)* | Electronic system has each of the following:  
- Real-time automatic data validation checks during data entry, especially:  
  - Ensuring that the minimum data set is captured for each case (Standard B1.2)  
  - Restricting sex, geographical location, case type, laboratory confirmation, culture, MDR and HIV status variables to pre-specified options or to plausible ranges  
  - Restricting year of registration and age or date of birth variables to plausible ranges  
  - Ensuring numeric fields contain numbers only and date fields contain valid dates  
  - Detecting duplicated patient or case identifiers  
- Automatic batch data consistency and validation checks in place and all specified checks passed  
- Data entry and validation processes documented in SOPs  
- Up-to-date data dictionary available | Met  
Partially met  
Not met  
Could not be assessed/not applicable |
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<tr>
<td>B1.7 Duplicated reports of the same TB episode are identified and removed (For electronic systems only)</td>
<td>• Contingency and recovery plan available and operational</td>
<td>☐ Met ☐ Partially met ☐ Not met ☐ Could not be assessed/not applicable</td>
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| B1.8 Number of reported TB cases is internally consistent (within country) | The first benchmark and at least one of the others should be satisfied to meet this standard:  
• Year to year difference (N2 - N1) in reported cases at national level does not exceed $2\sqrt{N1+N2(1+k)^2}$, where k is the expected rate of change  
• Year to year difference (N2 - N1) in reported cases at first subnational levels does not exceed $2\sqrt{N1+N2(1+k)^2}$, where k is the expected rate of change  
• Year to year change in the national number of reported TB cases consistent with:  
  – year to year change in national TB mortality (HIV-neg, from national vital registration) i.e. trajectories with same direction  
  – year to year change in the national prevalence of HIV i.e. trajectories with same direction  
  – year to year change in national GDP per capita i.e. trajectories with opposite direction | ☐ Met ☐ Partially met ☐ Not met ☐ Could not be assessed/not applicable |  |
| B1.9 TB surveillance data are externally consistent | Two of three benchmarks should be satisfied to meet this standard:  
• Among all TB cases, the sex ratio (M/F) is between 1.2-1.8 when HIV prevalence in TB cases is < 50% and 0.8-1.2 when HIV prevalence in TB cases is ≥ 50%  
• Among new TB cases, the percent of children is between 5-15% in low- and middle-income and 1-10% in high-income countries | ☐ Met ☐ Partially met ☐ Not met ☐ Could not be assessed/not applicable |  |
### B2. TB SURVEILLANCE SYSTEM COVERAGE

**B2.1 All diagnosed cases of TB are reported**

One of three benchmarks should be satisfied to meet this standard:

- ≥90% of TB cases identified in a national-level investigation (e.g. inventory study) conducted in last 2-3 years were reported
- TB reporting is a legal requirement that is strongly and systematically enforced, with penalties (financial and other) for non-reporting or incentives for reporting
- Distribution of anti-TB drugs is restricted to national TB programme

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**B2.2 Population has good access to health care**

Both benchmarks should be satisfied to meet this standard:

- <25% total health expenditure is out-of-pocket
- Under-5 mortality rate <10 per 1000 population

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### B3. QUALITY AND COVERAGE OF VITAL REGISTRATION SYSTEM

**B3.1 Vital registration system has high national coverage and quality**

Both benchmarks should be satisfied to meet this standard:

- Cause of death documented in >80% of total deaths recorded in a) a national VR system OR b) sample VR system
- <20% of deaths have garbage codes (A15-A19 in ICD-10 or 010-018 in ICD-9)

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### B4. STANDARDS SPECIFIC TO SURVEILLANCE OF DRUG RESISTANT TB, TB/HIV, AND TB IN CHILDREN

**B4.1 Surveillance data provide a direct measure of drug resistant TB in new cases**

Both the first and second benchmarks or just the third benchmark should be satisfied to meet this standard:

- ≥80% of pulmonary cases have a culture or equivalent test result
- ≥75% of culture or equivalent positive cases with rifampicin susceptibility status documented
- Rifampicin susceptibility status documented for a nationally representative sample of new TB

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| B4.2  Surveillance data provide a direct measure of HIV in TB cases | One of two benchmarks should be satisfied to meet this standard:  
- HIV status (Positive/Negative) documented for ≥80% of new and recurrent TB cases  
- HIV status available from a nationally representative sample from new and recurrent TB cases | ☐ Met  
☐ Partially met  
☐ Not met  
☐ Could not be assessed/not applicable | |
| B4.3  Surveillance data for children reported with TB (defined as ages 0-14 years) are reliable and accurate or all diagnosed childhood TB cases are reported | Two of three benchmarks should be satisfied to meet this standard:  
- Data on age and TB case type recorded for >95% of reported cases aged 0–14  
- Ratio of age groups 0-4 to 5-14 years is in the range 1.5-3.0  
- ≥90% of childhood cases identified in a national investigation (e.g. inventory study including paediatricians) conducted in last 2-3 years were reported | ☐ Met  
☐ Partially met  
☐ Not met  
☐ Could not be assessed/not applicable | |