# Use of high burden country lists for TB by WHO in the post-2015 era

Discussion paper initially prepared in April 2015 to facilitate feedback, and finalized after the June 2015 meeting of WHO's Strategic and Technical Advisory Group for TB (STAG-TB).

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### Summary

During the period 1998 to 2015, the concept of a "high burden country" (HBC) became familiar and widely used in the context of TB. In 2015, three lists – for TB, TB/HIV and MDR-TB - were in use. The TB HBC list (22 countries) had remained unchanged since 2002, and the HBC lists for TB/HIV (41 countries) and MDR-TB (27 countries) had not been updated since 2009 and 2008, respectively. With 2015 marking the end of the Millennium Development Goal (MDG) era and its replacement with a set of Sustainable Development Goals (SDGs) for 2016–2030, as well as the last year of the Stop TB Strategy 2006–2015 and its replacement with the End TB Strategy 2016–2035, it was an ideal year to revisit the three HBC lists and consider their future.

A draft discussion document (a first version of this document) was developed in April 2015, circulated across the WHO TB network and to external partners for feedback and updated accordingly. An online survey to solicit input from a wide range of stakeholders was run for two weeks in May 2015. An updated version of the document including results from the survey was prepared for consideration at the June 2015 meeting of WHO's Strategic and Technical Advisory Group for TB (STAG-TB), alongside a presentation at this meeting. This final version, which includes definition and explanation of the three lists to be used by WHO post-2015, was prepared in October 2015 according to the recommendations from the STAG-TB meeting and using the latest TB burden estimates published in the 2015 global TB report.

Three new HBC lists have been defined and they will be used for the period 2016–2020 (Figure 1). Each list contains 30 countries, defined as the top 20 in terms of absolute numbers of cases plus the additional 10 countries with the most severe burden in terms of case rates per capita that do not already appear in the "top 20" and that meet a minimum threshold in terms of absolute numbers of cases (10 000 per year for TB, and 1000 per year for TB/HIV and MDR-TB). Each list accounts for 85–89% of the global burden. Given overlap among the lists, there are 48 countries that are in at least one list. There are 14 countries (see central diamond in the figure and the countries highlighted in bold below) that are in all three lists.





The 30 TB HBCs (those in all 3 lists in bold) are: **Angola**, Bangladesh, Brazil, Cambodia, **China**, Congo, Central African Republic, DPR Korea, **DR Congo**, **Ethiopia**, **India**, **Indonesia**, **Kenya**, Lesotho, Liberia, **Mozambique**, **Myanmar**, Namibia, **Nigeria**, Pakistan, **Papua New Guinea**, Philippines, Russian Federation, Sierra Leone, **South Africa**, **Thailand**, the United Republic of Tanzania, Viet Nam, Zambia and **Zimbabwe**.

Changes compared with the lists in use in 2015 can be summarized as follows:

- TB HBC list. Two countries are no longer in the list: Afghanistan and Uganda. Ten new countries are included: Angola, Central African Republic, Congo, DPR Korea, Lesotho, Liberia, Namibia, Papua New Guinea, Sierra Leone and Zambia.
- TB/HIV list. Fourteen countries are no longer in the list: Burkina Faso, Burundi, Cambodia, Côte d'Ivoire, Djibouti, Haiti, Mali, Russian Federation, Rwanda, Sierra Leone, Sudan, Togo, Ukraine and Viet Nam. Three new countries are included: Guinea-Bissau, Liberia and Papua New Guinea.
- MDR-TB list. Six countries are no longer in the list: Armenia, Bulgaria, Estonia, Georgia, Latvia and Lithuania. Nine new countries are included: Angola, DPR Korea, Kenya, Mozambique, Papua New Guinea, Peru, Somalia, Thailand and Zimbabwe.

<u>Important note</u>: This is a background paper originally prepared in April 2015 as a basis for discussion among and input from a wide range of stakeholders. Following input from across the WHO network and external partners, and following an online survey that was widely advertised to all stakeholders, an updated version including a proposal for three updated HBC lists was prepared by the Global TB Programme for consideration by WHO's Strategic and Technical Advisory Group for Tuberculosis (STAG-TB) at their June 2015 meeting. This version of the document was updated to account for STAG-TB recommendations, and finalized in October 2015. It was published online in association with the launch of WHO's 2015 global TB report on 28 October 2015. It defines and provides the rationale for the three HBC lists of 30 countries each that will be used by WHO during the period 2016–2020.

### Introduction

During the period 1998–2015, the concept of a "high burden country" (HBC) became familiar and widely used in the context of TB. The initial list of HBCs was defined in 1998, based on the burden of TB in absolute terms. Its purpose was to allow focused interventions in the countries responsible for 80% of the global burden, with the rationale that progress in these countries would translate into global impact. The concept was subsequently applied to TB/HIV (in 2005) and MDR-TB (in 2008).

At the beginning of 2015, the list of 22 HBCs had remained unchanged since 2002, and the HBC lists for TB/HIV and MDR-TB had not been updated since 2009 and 2008, respectively. In this context, WHO was increasingly being asked about the three lists of HBCs, including whether they would be updated or discontinued.

The year 2015 was an ideal time to revisit the lists and consider their future. It marked the end of the era of Millennium Development Goals (MDGs) and their replacement with a set of post-2015 Sustainable Development Goals (SDGs) for the period 2016–2030, and the last year of the Stop TB Strategy 2006–2015 before its replacement with the End TB Strategy 2016–2035.

This document discusses the use of HBC lists by WHO up to 2015, describes options for their use post-2015 that were considered, and presents the three updated lists that have been defined for the five years 2016–2020. It has five main sections:

- 1. A brief history of the development of HBC lists. This draws on interviews with people who played a central role in the establishment of the lists in use in 2015.
- 2. The HBC lists in use in 2015 and their use in global reporting. A tabular summary of the purpose, definition, included countries and any updates since the original establishment of each list is provided. The way in which HBCs have been featured in annual WHO global TB reports is explained, alongside a short discussion of how HBC lists are used in the context of other (non-TB) global reporting efforts.
- 3. The HBC lists in use in 2015: advantages and disadvantages. The main potential benefits of the HBC lists in use in 2015 as well as possible disadvantages are described. The content of this section was initially drafted by staff in the Global TB Programme (GTB), and then updated following input from across the WHO TB network and review by external partners.
- 4. **Results from an online survey about HBC lists**. A survey designed to elicit opinion from a wide range of stakeholders was widely advertised and run for two weeks in May 2015. This section highlights the main findings.
- 5. The three HBC lists of 30 countries each ("20+10") that will be used by WHO, 2016–2020. Following discussions at the June 2015 meeting of WHO's Strategic and Technical Advisory Group for TB (STAG-TB), which was informed by an earlier version of this background paper, GTB produced a final set of three updated HBC lists to be used during the period 2016–2020. The three updated lists are defined and explained.

### 1. A brief history of the development of HBC lists

The concept of the 22 HBCs was devised in 1998 in preparation for the "Ad-hoc Committee meeting on the Global TB Epidemic".<sup>1</sup> This committee met in London, UK at a time when TB was barely on the global health agenda. The rationale for creating the list was to highlight the scale of the epidemic, with a focus on a small set of countries with the largest number of TB cases, as a basis for interventions and advocacy by WHO and its partners for policies, funding and action to improve TB control for both a national and global impact. Concentrating on a relatively small number of countries responsible for 80% of the total number of TB cases worldwide also meant that scarce resources could be focused on "the big countries with big problems", and provided a framework within which Ministers of Health and Ministers of Finance of the 22 countries could be invited to a high-level ministerial conference on TB and sustainable development that was held in 2000 in Amsterdam, the Netherlands (20/22 of the countries were represented at the conference).<sup>2</sup> The 22 HBCs were defined as those with the highest absolute burden of TB (in terms of estimated number of incident cases). Subsequently, there has been one change to this list: following a rapid reduction in TB incidence, Peru "graduated" from the list in 2002 and was replaced by Mozambique.

In 2004, WHO issued its first guidance on the implementation of 12 collaborative TB/HIV activities to jointly address the co-epidemics of TB and HIV. As part of global efforts to promote and expand these activities, the DOTS Expansion and TB/HIV Working Groups of the Stop TB Partnership decided to follow the approach of defining a priority list of HBCs. In 2005, after much debate, a list of 41 TB/HIV HBCs was agreed. It consisted of countries that collectively accounted for 97% of the estimated global burden of TB among people living with HIV.<sup>3</sup> This list was then used to promote scaling up of TB/HIV activities and to help advocate for Global Fund support for these activities. The list was updated each year until 2009, after which it was left fixed to simplify advocacy and communication vis à vis the Global Fund. The Global Fund used the list to prioritise funding, and in 2014 to define which countries would be required to submit a combined (one single) concept note for TB and HIV.<sup>4</sup>

In 2008, the MDR-TB Working Group of the Stop TB Partnership decided that a list of high MDR-TB burden countries would be important to help accelerate progress in detection and treatment in line with targets set in the Global Plan to Stop TB for 2006–2015. After some debate, the criteria were agreed: countries that collectively accounted for 85% of the estimated global burden (in terms of the estimated number of MDR-TB cases) and that had either >4000 estimated cases each year and/or  $\geq 10\%$  of new TB cases with MDR-TB. The list was used in advocating for Global Fund support for MDR-TB activities, especially for middle-income countries with a high MDR-TB burden in central Asia and Eastern Europe that would not otherwise be eligible for Global Fund support. The 27 countries were also those invited to a high-level conference on MDR-TB held in Beijing, China in April 2009.

<sup>&</sup>lt;sup>1</sup> <u>http://whqlibdoc.who.int/hq/1998/WHO\_TB\_98.245.pdf?ua=1</u> See also WHA resolution 51.13 (May 1998) <u>http://apps.who.int/iris/bitstream/10665/79811/1/ear13.pdf?ua=1</u> which was passed in the same year. <sup>2</sup> <u>http://www.stoptb.org/assets/documents/events/meetings/amsterdam\_conference/decla.pdf</u> See also p10 of <u>http://whqlibdoc.who.int/hq/2001/WHO\_CDS\_STB\_2001.11.pdf.</u> Out of the 22 countries invited, only 2 were not represented: Afghanistan and Myanmar.

<sup>&</sup>lt;sup>3</sup> Besides the list of 41 priority countries, a list of 63 countries has also been used (this list was featured in global TB reporting 2007–2009, but not other years), primarily to expand advocacy efforts related to implementation of collaborative TB/HIV activities. In addition to the 41 countries (shown in Table 1), this included any other countries classified by UNAIDS as having a generalised HIV epidemic in 2004: Bahamas, Barbados, Belize, Benin, Dominican Republic, Equatorial Guinea, Eritrea, Estonia, Gabon, Guatemala, Guinea, Guinea-Bissau, Guyana, Honduras, Jamaica, Liberia, Madagascar, Niger, Panama, Somalia, Suriname, Trinidad and Tobago.

<sup>&</sup>lt;sup>4</sup>A "concept note" is the term used for a funding application to the Global Fund as part of a new funding model introduced in 2013.

# 2. The HBC lists in use in 2015 and their use in global TB reporting

### 2.1 The HBC lists in use in 2015

A tabular summary of the three HBC lists in use in 2015, along with their purpose when first established, the criteria used to define them and included countries is provided in Table 1.

### 2.2 How HBCs are featured in WHO global TB reports

WHO has published an annual global TB report since 1997. Each report has included global and regional analyses of the TB epidemic and progress in implementing recommended global TB strategies (DOTS and the Stop TB Strategy) in the context of global targets (first set for 2000 and then postponed to 2005; from 2006 to 2015, the focus was on targets set for 2015 in the context of the MDGs).

The countries in HBC lists have been given particular attention in each global TB report. For example, in the 2015 global TB report:

- the chapter on TB disease burden had two tables that included country-specific data for the 22 HBCs (alongside global and regional aggregates) and there were three figures with 22 panel plots that showed trends in TB incidence, prevalence and mortality in each of those countries;
- the chapter on drug-resistant TB included two tables and one figure with country-specific data for the 27 MDR-TB HBCs;
- the chapter on the co-epidemics of TB and HIV included one table with country-specific data for the 41 TB/HIV HBCs;
- Reports published since 2002 have included an annex with country profiles for each of the 22 HBCs.

At the same time, all countries are featured in global TB reports (in printed or accompanying online material). This reflects the fact that data are compiled from all countries without any restrictions to HBC lists.<sup>5</sup> Country profiles, annexes with key indicators and downloadable data files that cover all countries have been provided online since 2010.

### 2.3 Other global reports published by WHO and UNAIDS

A review of global reports produced by other WHO departments and by UNAIDS shows that the concept of priority or focus countries is used for other diseases. For example:

- The global malaria report includes presentation of the "top-ten" countries for several indicators. The Roll Back Malaria Partnership has also focused its efforts on the top 10 highest burden countries.
- The GAP report for HIV/AIDS has highlighted data for a specific set of countries over a period of several years. The HIV department in WHO has recently identified a set of 26 top priority countries.
- The *Countdown to 2015* report for Maternal and Child Health reports data for a specific cohort of countries and has done so for several years.

<sup>&</sup>lt;sup>5</sup> In the late 1990s, certain data were collected only for the 22 HBCs, and initially in the mid-2000s some TB/HIV data were collected only for TB/HIV HBCs.

List	Purpose	Definition	Countries in the list in use in 2015	Updates
The 22 high-TB- burden countries	To provide a focus for global action on TB. It was used to promote and establish high-level political engagement with the countries in the list and allowed WHO and others to target limited resources to the countries with the largest number of TB cases.	Countries that ranked first to twenty second in terms of their estimated number of incident cases in 2000, which accounted for approximately 80% of the global total of estimated new cases of TB.	Afghanistan, Bangladesh, Brazil, Cambodia, China, DR Congo, Ethiopia, India, Indonesia, Kenya, Mozambique, Myanmar, Nigeria, Pakistan, the Philippines, Russian Federation, South Africa, Thailand, Uganda, UR Tanzania, Viet Nam, Zimbabwe.	Peru "graduated" in 2002 and was replaced by Mozambique.
The 41 high- TB/HIV-burden countries	To galvanise global action on HIV-associated TB, with particular emphasis on nationwide scale-up of collaborative TB/HIV activities and engagement of HIV stakeholders in priority countries.	Countries that account for 97% of the estimated global number of HIV-positive TB cases.	Angola, Botswana, Brazil, Burkina Faso, Burundi, Cambodia, Cameroon, Central African Republic, Chad, China, Congo, Côte D'Ivoire, Djibouti, DR Congo, Ethiopia, Ghana, Haiti, India, Indonesia, Kenya, Lesotho, Malawi, Mali, Mozambique, Myanmar, Namibia, Nigeria, Russian Federation, Rwanda, Sierra Leone, South Africa, Sudan, Swaziland, Thailand, Togo, Uganda, Ukraine, UR Tanzania, Viet Nam, Zambia, Zimbabwe.	Updated annually since its establishment in 2005 until 2009; no changes since 2009 to simplify advocacy and communication messages.
The 27 high-MDR- TB-burden countries	Originally requested by the MDR-TB Working Group to feed into the Global Plan to Stop TB 2006–2015. The aim was to identify countries where improvements to the diagnosis and management of MDR-TB should be prioritized, covering both countries with a high burden in terms of absolute numbers and those with a high burden in relative terms (proportion of cases with MDR- TB). It was then used by WHO to advocate for Global Fund support for MDR-TB activities in many central Asian countries that are middle- income countries and which would not otherwise have been eligible for Global Fund support.	Countries estimated by WHO in 2008 to have had at least 4,000 MDR-TB cases occurring annually and/or at least 10% of newly registered TB cases with MDR-TB (accounting for approximately 85% of the estimated incident cases of MDR-TB).	Armenia, Azerbaijan, Bangladesh, Belarus, Bulgaria, China, DR Congo, Estonia, Ethiopia, Georgia, India, Indonesia, Kazakhstan, Kyrgyzstan, Latvia, Lithuania, Myanmar, Nigeria, Pakistan, the Philippines, Republic of Moldova, Russian Federation, South Africa, Tajikistan, Ukraine, Uzbekistan, Viet Nam.	Defined in 2008 and no changes 2009–2015.

### Table 1. The HBC lists in use in 2015: purpose, definition, included countries and updates since their establishment

### 3. The HBC lists in use in 2015: advantages and disadvantages

The HBC lists in use in 2015 have been considered to have various advantages. Some potential disadvantages have also been suggested. A list of the main advantages and disadvantages (the list is not intended to be exhaustive) is provided below. These two lists were initially drafted by GTB, informed by discussions with those involved in the development of the HBC lists in use in 2015, and then updated based on feedback from across the WHO TB network and external partners (including major global funding and technical agencies, and staff from national TB programmes). Feedback on the extent to which people agreed or disagreed with these advantages and disadvantages was then sought through an online survey (Section 4).

### 3.1 Potential advantages

- 1. Can be important to prioritise international donor funding and technical assistance for countries where improving TB prevention, diagnosis and treatment is most needed to have a global impact.
- 2. Can help national TB programmes in HBCs to advocate for political commitment and support (including funding) from their own governments as well as international agencies.
- 3. Can help to ensure that countries with a serious TB, TB/HIV and/or MDR-TB problem are included in the priority lists of international funding and technical agencies when this might not otherwise be the case.
  - The priority lists of international donor and technical agencies are influenced by several factors. Some countries may have been included as priorities mainly or only because they were on an HBC list. Possible examples in recent years include several European countries on the list of MDR-TB HBCs.
- 4. Can influence the policies of international funding agencies.
  - For example, in 2014 the list of countries from which the Global Fund decided to request "concept notes" (funding proposals) that integrate both TB and HIV activities was defined as the list of 41 TB/HIV HBCs.
- 5. Encourages global and regional monitoring of progress in a particular set of high priority countries.
- 6. Countries in an HBC list have more opportunities to attend, and for their voice to be heard in, international meetings and events.

### 3.2 Potential disadvantages

- 1. The list of 22 HBCs in use in 2015 is based on absolute burden, so countries with very high rates per capita but with relatively small populations are not included.
  - At various times, several countries in the African Region expressed strong concern that they did not have the same access to international financial and technical support as HBCs, even when their disease burden estimates or notification data suggested that their burden was more severe than neighbouring countries that were in an HBC list.
- 2. Funding for TB in countries that are not in an HBC list may be relatively neglected by national governments, even when their TB burden is high relative to their population.<sup>6</sup>
  - For example, governments may not perceive that TB, TB/HIV and or MDR-TB as important issues for investment when a country is not defined as "high burden".

<sup>&</sup>lt;sup>6</sup> This is not the case for international donor funding. The top international donor for TB, the Global Fund, allocates country funding envelopes using an allocation formula based on disease burden (using WHO estimates and with no link to lists of HBCs) and income per capita (a proxy for ability to pay). The largest bilateral donor, the US government, has 54 priority countries, including countries that are not in an HBC list.

- 3. A few countries, especially those that do not rely on donor funds, may not welcome being part of an HBC list. Examples that have been provided are:
  - Brazil and the Russian Federation have expressed reservations about being in the list of 22 HBCs, on the basis that there are countries with higher per capita incidence rates that should be highlighted instead.
  - When the list of 41 TB/HIV burden countries was used to determine the countries that would be required to submit a joint TB and HIV concept note to the Global Fund to access funding, India and Indonesia had concerns on the basis that their TB/HIV burden is low (in terms of the proportion of TB cases living with HIV).
- 4. The current lists use inconsistent cut-offs (80% of total burden for TB, 97% of total burden for TB/HIV and 85% of total burden for MDR-TB), and inconsistent criteria absolute numbers for TB and TB/HIV, and a mix of absolute numbers and proportions for MDR-TB.
- 5. The lists do not account for the strength or weakness of TB disease burden estimates (they do not consider uncertainty intervals). Especially towards the lower end of each HBC list, there may not be a clear difference between countries that are included in a list and those that just miss being included. If existing estimates are weak, a new survey or improved surveillance data may result in a country moving from not meeting the criteria to be included in a list to meeting the criteria, or vice versa.<sup>7</sup>
- 6. Countries not in HBC lists do not receive the same level of attention as HBCs in the global TB report.

### 3.3 Other points related to advantages and disadvantages

Section 3.1 and Section 3.2 highlight the main advantages and disadvantages of the current HBC lists on which there appeared to be strong agreement during the development and review of this document. Additional miscellaneous points that were raised were:

- HBC lists have been used for prioritisation. At the same time, priority lists are influenced by political, economic (e.g. income level) and other factors.
- India and China have been the top-two HBCs in terms of absolute numbers of TB cases and MDR-TB cases, but do not necessarily require the same level of support from the international community as some other countries, including those not in an HBC list.
- HBC lists may not be useful for prioritisation at regional level if there are no or only a few countries from that region. For example, there is only one country from the Americas and one country from the European Region in the list of 22 HBCs.
- HBC lists can help manufacturers identify markets for new TB tools.
- There are countries that either a) no longer qualify to be in an HBC list according to the original criteria, but which are currently still referred to as an HBC; or that b) meet the criteria to be defined as an HBC according to the latest estimates of TB disease burden, but which have not yet been defined as an HBC.
  - Angola and DPR Korea are in the top 22 countries in terms of total estimated TB incidence, but are not called HBCs.
  - Afghanistan and Cambodia are in the list of 22 HBCs but are no longer in the top 22 in terms of total estimated TB incidence.
  - Bulgaria does not meet the criteria for being an MDR-TB HBC.

Several reviewers of earlier drafts of this document also commented that it would be very helpful to categorize countries in terms of their TB burden (e.g. high, medium, low, using for example the TB incidence rate per capita), and to present lists of the countries that fall within each category in annual global TB reports. Such a categorization would be all-inclusive and also allow progress to be illustrated as countries graduate from one category to another.

<sup>&</sup>lt;sup>7</sup> To date, this has happened only infrequently. A survey of drug resistance in Bulgaria showed that it should not be part of the MDR-TB HBC list. New data from prevalence surveys implemented since 2009 have only resulted in countries moving up or down the list of 22 HBCs, and no new countries qualifying to be included.

### 4. Results from an online survey about HBC lists

Following development and refinement of the list of advantages and disadvantages of current HBC lists, an online survey designed to elicit opinion about HBC lists from a wide range of stakeholders was run for two weeks in May 2015. This used a structured questionnaire (Appendix 1) that allowed respondents to comment on the extent to which they agreed or disagreed (five options from strongly agree to strongly disagree were provided) with a list of statements about HBC lists based on the advantages and disadvantages listed in section 3 (these statements were programmed to appear in random order), to comment on other characteristics of HBC lists (their useful lifetime, the number of countries that should be in a list), and to state which of four "high-level" options for the future use (or not) of HBC lists was preferred. Respondents were also asked about the constituency that they represented (manager or staff member of a national TB programme; Ministry of Health or national public health agency, but not a staff member of the national TB programme; national nongovernmental organization (NGO) and/or civil society representative working on TB; international donor or technical agency working on TB; other). At the end of the questionnaire, a comments box was provided for respondents to provide any additional remarks.

The survey was widely advertised via a GTB Newsflash that was sent to all those on the email distribution list for GTB newsflashes; this was further circulated via other email distribution lists (e.g. working groups of the Stop TB Partnership), and as a mass email to all those involved in annual reporting of TB data to WHO in annual rounds of data collection (i.e. all those registered to use the online global TB data collection system). Specific efforts were also made by WHO Regional Offices to alert people to the survey. The survey was available in English, French, Russian and Spanish.

A total of 323 people completed the survey, of which 50% were national respondents (national TB programmes, national NGOs and/or civil society representatives, national Ministries of Health or public health agencies) and 34% were respondents from international or technical agencies. The remaining 16% were in the "other" category.

The main findings about whether to continue using HBC lists, and their associated advantages and disadvantages, were:

- 1. There was strong support for continuing the use of HBC lists, overall and from each of the four major constituencies. Only 5% of respondents preferred the option of stopping using HBC lists, and none of these respondents was from a national constituency.
- 2. There was strong agreement that HBC lists are important to help national TB programmes in HBCs to advocate for political commitment (including funding) from their own governments as well as international funding agencies. This was true overall and for all constituencies.
- 3. There was strong agreement that HBC lists are important to prioritize international donor funding and technical assistance for countries where improving TB prevention, diagnosis and treatment is most needed to have a global impact. This was true overall and for all constituencies.
- 4. There was strong agreement that HBC lists are important to ensure that countries with a serious TB, TB/HIV or MDR-TB problem are included in the priority lists of international and technical agencies. This was true overall and for all constituencies.
- 5. There was agreement (most respondents agreed or strongly agreed, with more in the former category) that HBC lists encourage global and regional monitoring in a consistent set of countries.
- 6. There was either strong agreement or agreement that it is a problem that the current list of 22 HBCs is based only on the number of TB cases, so that countries with many cases per capita but smaller populations were not included.
- 7. There was either strong agreement or agreement that countries not in HBC lists may be relatively neglected by international funding and technical agencies, even when they have a high burden relative to population.

The main findings related to the future design of HBC lists were:

- 1. The preferred option for HBC lists in future was to develop 3 new lists based on new criteria (about 50% of respondents). About 40% favoured updating the lists using the original criteria, and about 15% favoured the development of one list only.
- 2. The vast majority (about 80%) of respondents favoured lists that have between 11 and 30 countries. The remaining 20% were approximately split between a list of 10 or fewer countries, and a list of more than 30 countries.
- 3. The vast majority (about 85%) of respondents favoured lists defined based on criteria that have a lifetime of 3–5 years, and supported the prompt entry or removal of a country from a list if new data show that this is justified.
- 4. The lists should have consistent cut-offs.

In the box provided for any miscellaneous comments, one topic dominated. This was that it is a major problem that countries with a severe TB burden in per capita terms but not absolute numbers were not featured in the list of 22 HBCs in use in 2015. There was strong feedback that if HBC lists continue to be used by WHO, this problem should be addressed.

## 5. The three HBC lists of 30 countries each ("20+10") that will be used by WHO 2016–2020

In earlier drafts of this document, four "high-level" options for the use of HBC lists post-2015 were identified. These were:

- 1. Discontinue the use of HBC lists.
- 2. Continue to use three HBC lists (TB, MDR-TB, TB/HIV) but update them using the original criteria.
- 3. Continue to use three HBC lists (TB, MDR-TB, TB/HIV) but define them using new criteria.
- 4. Define one HBC list only.

Following feedback received directly on earlier drafts of this document and through the online survey, Option 1 was not considered viable. There was strong support for the continued use of HBC lists by WHO after 2015, and experience with the current lists as well as feedback provided on earlier drafts of this document and via the online survey showed that there was clear scope to improve upon the current lists and address most of the stated disadvantages.

Given that there was clear scope to improve upon the current lists and address their disadvantages, Option 2 of updating the current HBC lists using the original criteria was also ruled out as a viable option.<sup>8</sup>

In preparation for the STAG-TB meeting, there was no obvious way to define one HBC list (as also illustrated by the diagram on page 9).

One proposal was presented for consideration by STAG-TB, which was characterized as three "20+10" HBC lists: one for each of TB, MDR-TB and TB/HIV. Each list included 30 countries, consistently defined as the top 20 in terms of absolute numbers of cases, plus the 10 countries with the most severe burden in relative terms that do not already appear in the top 20 ("20+10").<sup>9</sup> STAG-TB supported this "20+10" proposal, while also recommending the use of rates to define the additional 10 countries for all three lists and application of a threshold for a minimum number of cases within this group (to avoid global lists including countries with very small numbers of cases that would fit better within regional HBC lists).

 $<sup>^{8}</sup>$  A table showing the countries that would be in each of the lists if they were updated using the original criteria is provided in Appendix 2.

<sup>&</sup>lt;sup>9</sup> STAG-TB members were also asked for their suggestions, if any, regarding one consolidated list. Their comments were that the diagram on page 9 illustrated why it would be better to have three separate lists, rather than attempting to develop one consolidated list.

The three updated HBC lists of 30 countries each, to be used by WHO post-2015, are shown in Figure 1 and Table 2.

The lists were defined based on the following principles/design characteristics:

- 1. The purpose of each list should be stated.
- 2. The lists (TB, MDR-TB, TB/HIV) should be defined using consistent criteria.
- 3. The lists should result in similar cut-offs in terms of their share of the global burden.
- 4. The criteria used to define lists should be easy to explain, use and reproduce.
- 5. The time period (useful life) of the list should be defined.
- 6. The list should be relatively short (no more than 30 countries).
- 7. If possible there should be a clear distinction between countries in and outside the list.

The new lists can be characterized as follows:

- 1. The purpose of each of the three lists is stated.
- 2. The lists of 30 countries are all defined as the top 20 countries in terms of absolute numbers of incident cases, plus the additional 10 countries with the most severe burden in terms of case rates per capita that do not already appear in the "top 20" and that meet a minimum threshold in terms of absolute numbers of cases (10 000 per year for TB, and 1000 per year for TB/HIV and MDR-TB).
- 3. The three lists result in similar cut-offs (85–89% of the estimated global burden).
- 4. The criteria used to define lists are easy to explain and use, and can be reproduced.
- 5. The useful life of each list is defined as five years.
- 6. The lists are relatively short and all have the same number of countries (30 countries each).

The new lists address the major concern with the lists in use in 2015 i.e. that those lists did not feature countries with small populations but high TB rates per capita.

A diagrammatic illustration of the three lists, including their areas of overlap, is shown in Figure 1. In total, the three lists include 48 countries and clearly illustrate where action on TB and the subepidemics of TB/HIV and MDR-TB need to be prioritized in different parts of the world.

### Figure 1: The three HBC lists of 30 countries each that will be used by WHO in the period 2016–2020, and their areas of overlap



Further background, including figures and a table that illustrate the estimates that were used to define the lists, is provided in Appendix 3.

### Table 2: The three HBC lists for TB, TB/HIV and MDR-TB, of 30 countries ("20+10") each, that will be used by WHO for the five years 2016–2020

List	The 30 high TB burden coun	tries	The 30 high TB/HIV burde	en countries	The 30 high MDR-TB burden countries			
Purpose and	To provide a focus for global a	ction on TB in the countries	To provide a focus for globa	l action on HIV-associated TB in	To provide a focus for global action on the MDR-TB crisis in			
target	where progress is most needed	to achieve End TB Strategy and	the countries where progress	is most needed to achieve End	the countries where progress is most needed to achieve End			
audience	SDG targets and milestones, to	help build and sustain national	TB Strategy, UNAIDS and S	DG targets and milestones, to	TB Strategy targets and milestones, to help build and sustain			
	political commitment and fund	ing in the countries with the	help build and sustain nation	al political commitment and	national political commitment and funding in the countries			
		olute numbers or severity, and to		the highest burden in terms of	with the highest burden in terms of absolute numbers or			
	promote global monitoring of p	progress in a well-defined set of	absolute numbers or severity		severity, and to promote global monitoring of progress in a			
	countries.		monitoring of progress in a v		well-defined set of countries.			
Definition	The 20 countries with the high	est estimated numbers of	The 20 countries with the hig	ghest estimated numbers of	The 20 countries with the high	ghest estimated numbers of		
	incident TB cases, plus the top		incident TB cases among peo	pple living with HIV, plus the		s the top 10 countries with the		
	estimated TB incidence rate that		top 10 countries with the hig			incidence rate that are not in the		
	absolute number (threshold, >1	0 000 estimated incident TB		the top 20 by absolute number	top 20 by absolute number (t			
	cases per year).		(threshold, >1000 estimated	incident TB/HIV cases per year).	incident MDR-TB cases per			
Countries in	The top 20 by estimated	The additional 10 by	The top 20 by estimated	The additional 10 by	The top 20 by estimated	The additional 10 by estimated		
the list based	absolute number (in	estimated incidence rate per	absolute number (in	estimated incidence rate per	absolute number (in	rate per 100 000 population		
on 2014	alphabetical order):	100 000 population and with	alphabetical order):	100 000 population and with	alphabetical order):	and with a minimum number		
estimates		a minimum number of 10 000		a minimum number of 1000		of 1000 cases per year (in		
published in	Angola*	cases per year (in	Angola	cases per year (in	Bangladesh	alphabetical order):		
the 2015 WHO	Bangladesh	alphabetical order):	Brazil	alphabetical order):	China			
global TB	Brazil		Cameroon		DPR Korea*			
report	China	Cambodia	China	Botswana	DR Congo	Angola*		
	DPR Korea*	Central African Republic*	DR Congo	Central African Republic	Ethiopia	Azerbaijan		
The 14	DR Congo	Congo*	Ethiopia	Chad	India	Belarus		
countries that	Ethiopia	Lesotho*	India	Congo	Kazakhstan	Kyrgyzstan		
appear in all 3	India	Liberia*	Indonesia	Ghana	Kenya*	Papua New Guinea*		
lists are shown	Indonesia	Namibia*	Kenya	Guinea-Bissau*	Indonesia	Peru*		
<u>in bold</u>	Kenya	Papua New Guinea*	Lesotho	Liberia*	Mozambique*	Republic of Moldova		
	Mozambique	Sierra Leone*	Malawi	Namibia	Myanmar	Somalia*		
<u>An asterisk</u>	Myanmar	Zambia*	Mozambique	Papua New Guinea*	Nigeria	Tajikistan		
indicates	Nigeria	Zimbabwe	Myanmar	Swaziland	Pakistan	Zimbabwe*		
countries that	Pakistan		Nigeria		Philippines			
were not on the	Philippines		South Africa		Russian Federation			
equivalent (i.e.	Russian Federation		Thailand		South Africa			
TB, TB/HIV or	South Africa		Uganda		Thailand*			
MDR-TB)	Thailand		UR Tanzania		Ukraine			
HBC list in use	UR Tanzania		Zambia		Uzbekistan			
in 2015	Viet Nam	201	Zimbabwe	50/	Viet Nam	50/		
% global total	83%	3%	84%	5%	80%	5%		
Lifetime of list	5 years (review criteria and inc	luded countries in June 2020).	5 years (review criteria and i	ncluded countries in June 2020).	5 years (review criteria and included countries in June 2020).			

Countries in the TB HBC list in use in 2015 but not in the 2016–2020 list: Afghanistan, Uganda.

Countries in the TB/HIV HBC list in use in 2015 but not in the 2016–2020 list: Burkina Faso, Burundi, Cambodia, Côte d'Ivoire, Djibouti, Haiti, Mali, Russian Federation, Rwanda, Sierra Leone, Sudan, Togo, Ukraine, Viet Nam.

Countries in the MDR-TB list in use in 2015 but not in the 2016–2020 list: Armenia, Bulgaria, Estonia, Georgia, Latvia, Lithuania.

### Appendix 1: Questionnaire used in online survey about HBC lists



### Use of high TB burden country lists by WHO after 2015

This short questionnaire asks for your opinion on the current lists of high TB burden countries used by the World Health Organization (WHO). It should take you 5 – 10 minutes to complete.

- <u>The 22 high TB burden countries list</u>: Countries that accounted for approximately 80% of the global total of estimated new cases of TB in 2000.
- The 41 high TB/HIV burden countries list: Countries that account for 97% of the estimated global number of TB cases each year among people living with HIV.
- <u>The 27 high MDR-TB burden countries list</u>: Countries that accounted for approximately 85% of the estimated incident cases of MDR-TB in 2008, composed of countries with at least 4 000 estimated MDR-TB cases occurring annually and/or at least 10% of newly registered TB cases with MDR-TB.

The 22 high TB burden country list has remained unchanged since 2002, and the lists for TB/HIV and MDR-TB have not been updated since 2009 and 2008, respectively.

The role of high burden country lists after 2015 will be discussed at the June 2015 meeting of WHO's Strategic and Technical Advisory Group for TB (STAG-TB). We will use feedback from this survey to help prepare a background document for the meeting.

### About you

#### \* What constituency do you represent in answering this survey?

Choose one of the following answers

•	0	National TB programme (you are a manager or a staff member of the programme) Ministry of Health or national public health agency (but not a staff member of the National TB programme) National non-governmental organization and/or civil society representative working on TB
•	0	International donor and/or technical agency working on TB Other

### \* Which country?

(Drop-down list of countries appeared if one of the first three options above were chosen)

\* Please state whether you agree or disagree with the following statements

	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree
It is a problem that the high burden country lists use inconsistent cut-offs in their inclusion criteria (80% for TB, 97% for TB/HIV, and 85% MDR-TB)	C	C	C	C	<u>C</u>
A country should be promptly moved in or out of a high burden country list when strong new evidence emerges to justify this (e.g. results from a drug resistance survey, or a national TB prevalence survey)	C	C	C	C	C
It is a problem that the list of 22 high TB burden countries is based on the number of cases, so countries with many cases per capita but with smaller populations are not included	0	0	С	C	C
High burden country lists are important to help the national TB programmes in those countries to advocate for political commitment and support (including funding) from their own governments as well as international agencies	C	C	C	С	Ç
High burden country lists encourage global and regional monitoring in a consistent set of countries	0	0	C	C	С
High burden country lists are important to ensure that countries with a serious TB, TB/HIV and/or MDR-TB problem are included in the priority lists of international and technical agencies	0	0	C	C	C
High burden country lists are important to prioritise international donor funding and technical assistance for countries where improving TB prevention, diagnosis and treatment is most needed to have a global impact	C	C	С	C	<u>C</u>
High burden country lists have a positive influence on the policies of international funding agencies	0	0	С	C	C
Countries not in high burden country lists may be relatively neglected by international funding and technical agencies, even when their TB burden is high relative to their population	C	C	C	C	C

### \* How long do you think the "useful life" of a high burden country list should be? (i.e. the number of years for which the list is used before the criteria used to define high burden countries are reviewed and updated)

Choose one of the following answers



#### \* How many countries do you think should be in a high burden country list for it to be useful?

Choose one of the following answers

•	C	10 countries or less
•	0	Between 11 and 20 countries
•	0	Between 21 and 30 countries
•	0	31 countries or more

Which of the following options for the future use of high burden country lists and associated global reporting by WHO do you prefer?

<u>Note</u>: Whichever option is chosen, WHO will continue to feature specific countries or groups of countries in annual global TB reports. WHO will also continue to collect and publish detailed TB data from all countries through country profiles, annexes with key indicators and downloadable data files. These are published online alongside global TB reports.

Choose one of the following answers

Use three high burden country lists (TB, MDR-TB, TB/HIV) defined using new criteria.

Develop and use a new, single high burden country list.

Continue to use three high burden country lists (TB, MDR-TB, TB/HIV), but update them using the original criteria.

Stop using high burden country lists.

Do you have any other comments about whether or not WHO should continue to use high burden country lists?

List	Definition	Countries that would in an HBC list based on 2014 estimates published in the 2015 global TB report, if the original criteria used to define the lists are applied	Countries that are added to or removed from the list in use in 2015 when the original criteria are used with the 2014 estimates published in the 2015 global TB report	Countries in the list in use in 2015 that are not in the updated list to be used 2016–2020
The high-TB- burden countries	Countries with the highest estimated numbers of incident TB cases that account for 80% of the global total.	<b>17 countries</b> : Bangladesh, China, Democratic People's Republic of Korea, DR Congo, Ethiopia, India, Indonesia, Mozambique, Myanmar, Nigeria, Pakistan, South Africa, Philippines, Russian Federation, Thailand, United Republic of Tanzania, Viet Nam.	6 countries removed: Afghanistan, Brazil, Cambodia, Kenya, Uganda, Zimbabwe. 1 country added: DPR Korea	Afghanistan, Uganda.
The high-TB/HIV- burden countries	Countries with the highest estimated numbers of incident TB cases that account for 97% of the global total.	<b>47 countries</b> : Angola, Botswana, Brazil, Burundi, Cameroon, Central African Republic, Chad, China, Colombia, Congo, Côte d'Ivoire, DR Congo, Ethiopia, Ghana, Guinea, Guinea-Bissau, Haiti, India, Indonesia, Kenya, Lesotho, Liberia, Madagascar, Malaysia, Malawi, Mexico, Mozambique, Myanmar, Namibia, Nigeria, Pakistan, Papua New Guinea, Peru, Philippines, Russian Federation, Sierra Leone, Somalia, South Africa, South Sudan, Swaziland, Thailand, Uganda, Ukraine, United Republic of Tanzania, Viet Nam, Zambia, Zimbabwe.	<ul> <li>7 countries removed:</li> <li>Burkina Faso, Cambodia,</li> <li>Djibouti, Mali, Rwanda,</li> <li>Sudan, Togo</li> <li>13 countries added:</li> <li>Colombia, Guinea, Guinea-</li> <li>Bissau, Liberia, Madagascar,</li> <li>Malaysia, Mexico, Papua</li> <li>New Guinea, Pakistan, Peru,</li> <li>Philippines, Somalia, South</li> <li>Sudan.</li> </ul>	Burkina Faso, Burundi, Cambodia, Côte d'Ivoire, Djibouti, Haiti, Mali, Russian Federation, Rwanda, Sierra Leone, Sudan, Togo, Ukraine, Viet Nam.
The high-MDR- TB-burden countries	Countries estimated to have had at least 4000 MDR-TB cases among notified TB cases each year and/or at least 10% of newly registered TB cases with MDR-TB (excluding countries with less than 10 estimated MDR-TB cases among notified).	<b>21 countries</b> : Azerbaijan, Bangladesh, Belarus, China, Estonia, Georgia, India, Indonesia, Kazakhstan, Kyrgyzstan, Lithuania, Myanmar, Pakistan, Philippines, Republic of Moldova, Russian Federation, South Africa, Turkmenistan, Ukraine, Uzbekistan, Viet Nam.	<ul> <li>7 countries removed:</li> <li>Armenia, Bulgaria, DR</li> <li>Congo, Ethiopia, Latvia,</li> <li>Lithuania, Nigeria</li> <li>1 country added:</li> <li>Turkmenistan</li> </ul>	Armenia, Bulgaria, Estonia, Ethiopia, Georgia, Latvia, Lithuania.

### Appendix 2: What updated HBC lists would look like using original criteria

Advantage: The concepts used to define the lists are familiar.

**Disadvantages:** Do not address most of the stated disadvantages described in the document. For example: the number of countries is inconsistent across lists, as are the cut-offs used to define them; the TB and TB/HIV lists exclude small countries with severe burdens; the TB/HIV list is long; there is no clear gap between countries in a list and the rest.

# Appendix 3: Additional background to illustrate how the new HBC lists were defined

Figures 2–4 show the top 30 countries in terms of both absolute numbers and burden severity, based on the latest estimates of disease burden published in the 2015 global TB report. Burden severity is defined using estimates of cases per capita combined with a minimum threshold in terms of the absolute number of cases, as recommended by STAG-TB. The threshold is 10 000 new cases per year for TB, and 1000 new cases per year for MDR-TB and TB/HIV. Table 3 shows the top 20 for each indicator (without application of any threshold for a minimum number of cases per year), and their contribution to the estimated global total individually and collectively.

It should be highlighted that at the time this background document was first prepared and again when it was updated, WHO had not published country-specific estimates of the incidence of MDR-TB. For this reason, Figure 4 shows estimates for a closely-related indicator for which estimates have been published: the estimated number of MDR-TB cases among notified cases with pulmonary TB. Lists using both indicators were generated and compared. Both indicators result in the same countries being included in a list of 30 MDR-TB HBCs, with four exceptions. A list based on estimated MDR-TB incidence results in the inclusion of Papua New Guinea, Somalia, Tajikistan and Zimbabwe instead of Afghanistan, Nepal, Republic of Korea and Uganda. WHO plans to review methods used to produce MDR-TB burden estimates in the first half of 2016, following which it is anticipated that country-specific estimates will be shared with countries for review and then published.

### Figure 2: Top 30 countries in terms of absolute numbers and rates: TB





### Figure 3: Top 30 countries in terms of absolute numbers and rates: TB/HIV



### Figure 4: Top 30 countries in terms of absolute numbers and rates\*: MDR-TB

\*These two panels show countries ordered according to *the estimated number of MDR-TB cases among notified TB patients with pulmonary TB*; these estimates have been published in the 2015 global TB report and in WHO's online global TB database, and represent *the estimated number of MDR-TB cases that could be detected if all notified cases were tested for drug resistance*. When countries are ranked using estimates of MDR-TB incidence (using country estimates that have not yet been published by WHO), four countries no longer qualify to be in the HBC list: these are Afghanistan, Nepal, Republic of Korea and Uganda. They are replaced by Papua New Guinea, Somalia, Tajikistan and Zimbabwe, as reflected in Figure 1 on page 9. WHO plans to review methods used to produce MDR-TB burden estimates in the first half of 2016, following which it is anticipated that country-specific estimates will be published.

### Table 3: Top 20 countries in absolute numbers and burden severity based on 2014 estimates published in the 2015 global TB report (with no threshold for a minimum number of cases per year applied): TB, TB/HIV, MDR-TB. Countries in bold are those in the top 20 in terms of both absolute numbers and rates.

ТВ				TB/HIV					MDR-TB			
Top 20, incidence absolute number	% global total	Top 20, TB incidence rate	% global total	Top 20, TB/HIV number	% global total	Top 20, HIV- positive TB rate per capita	% global total	Top 20, MDR-TB number	% global total	Top 20, MDR-TB rate per capita	% global total	
India	22.7	Lesotho	0.2	South Africa	22.5	Lesotho	1.0	India	23.7	Sao Tomé & Principe	0.1	
Indonesia	10.3	South Africa	4.6	India	9.2	South Africa	22.5	China	17.3	Rep. Moldova	0.5	
China	9.6	Swaziland	0.1	Nigeria	8.3	Swaziland	0.5	<b>Russian Fed.</b>	13.0	Swaziland	0.1	
Nigeria	5.9	Djibouti	0.1	Mozambique	7.1	Mozambique	7.1	Ukraine	4.3	Kyrgyzstan	0.7	
Pakistan	5.2	Namibia	0.1	Indonesia	5.3	Zambia	3.2	Pakistan	4.0	Ukraine	4.3	
South Africa	4.6	Mozambique	1.5	UR Tanzania	5.2	Namibia	0.5	Philippines	3.7	Kazakhstan	1.6	
Bangladesh	3.7	Timor-Leste	0.1	Kenya	3.3	Botswana	0.4	Myanmar	3.0	Russian Fed.	13.0	
Philippines	3.0	Kiribati	0.0	Zambia	3.2	Zimbabwe	2.1	Uzbekistan	2.3	Namibia	0.2	
DR Congo	2.5	Gabon	0.1	DR Congo	2.8	Guinea-Bissau	0.2	Indonesia	2.3	Uzbekistan	2.3	
Ethiopia	2.1	DPR Korea	1.1	Uganda	2.3	C. Afr. Rep.	0.6	South Africa	2.1	Kiribati	0.0	
Myanmar	2.1	PNG	0.3	Zimbabwe	2.1	Congo	0.5	Viet Nam	1.7	Belarus	0.6	
UR Tanzania	1.8	Zambia	0.7	Angola	1.9	UR Tanzania	5.2	Kazakhstan	1.6	Myanmar	3.0	
Mozambique	1.5	Indonesia	10.3	Cameroon	1.7	Malawi	1.6	Bangladesh	1.6	Lesotho	0.1	
Viet Nam	1.3	Cambodia	0.6	Ethiopia	1.6	Angola	1.9	DPR Korea	1.3	Georgia	0.2	
Russian Fed.	1.2	Botswana	0.1	Malawi	1.6	Kenya	3.3	Nigeria	1.1	DPR Korea	1.3	
Thailand	1.2	Congo	0.2	Myanmar	1.6	Cameroon	1.7	DR Congo	0.9	Azerbaijan	0.4	
DPR Korea	1.1	C. Afr. Rep.	0.2	Brazil	1.3	Equat. Guinea	0.1	Kenya	0.8	Gabon	0.1	
Kenya	1.1	Angola	0.9	Thailand	1.3	Uganda	2.3	Thailand	0.7	PNG	0.3	
Angola	0.9	Guinea-Bissau	0.1	China	1.1	Djibouti	0.0	Mozambique	0.7	South Africa	2.1	
Brazil	0.9	Myanmar	2.1	Lesotho	1.0	Nigeria	8.3	Peru	0.7	Philippines	3.7	
Total	83		23*		84		63**		87		35***	
Subtotal, top 10	69	201.4	8		69		38		76		23	

\*3% when those already in top 20 in terms of absolute numbers are excluded. \*\*3% when those already in top 20 in terms of absolute numbers are excluded. \*\*\*3% when those already in top 20 in terms of absolute numbers are excluded.