

Global Consultation on Paediatric Tuberculosis: Disease Burden Estimation and Quantification of Its Drug Market

MEETING SUMMARY

25-26 September, 2013 | New York, NY

Hosted by the Speeding Treatments to End Paediatric Tuberculosis (STEP-TB) Project

Sponsored by



Objectives

1. To review available and relevant surveillance, research and drug market data highlighting the extent of work done, the gaps in data, and the extent of these gaps.
2. To present an overview of analytical methods used, and the respective epidemiological indicators of morbidity and mortality, and discuss their utility for estimating and quantifying the disease burden and drug market of paediatric TB.
3. To define and prioritise specific actions that can be taken by TB Alliance, WHO, and other participating organizations to improve market transparency and to stimulate engagement in the market including quantification of the size and identification of the location of the paediatric TB drug market.
4. To catalyse efforts to strengthen routine surveillance and promote consensus among relevant constituencies of the paediatric TB community on the direction forward in disease burden estimation for drug susceptible and drug resistant disease.

Expected outcomes

1. Recommendations on which analytical methods and indicators would be most effective for disease burden estimation and quantification of the drug market for both drug susceptible and drug resistant TB.
2. Proposed list of market studies and further analyses to be conducted by the TB Alliance, WHO, and/or participating organizations with clear delegation of the organization(s) responsible for undertaking the action proposed and the funding source.
3. Development of a priority list of research questions and epidemiological studies to address the identified data gaps for both drug susceptible and drug resistant paediatric TB.
4. Recommendations on strategies to strengthen routine surveillance data.
5. Document that provides a summary of available evidence presented, the recommendations generated, and the action plans developed during the meeting.

DAY 1

Welcome/Introductions

Dr. Mel Spigelman and Ms. Lisa Hedman opened the meeting with thanks to funders and participants. They highlighted the objective of the meeting: to ensure availability of TB medicines for children by looking at the available data and information but also addressing data gaps to guide change.

Co-Chairs Dr. Steve Graham and Mr. Andrew Jones welcomed the group and participants introduced themselves.

Meeting Framework and Guiding Principles

Ms. Elizabeth Gardiner and Dr. Babis Sismanidis presented the meeting framework and guiding principles, highlighting the focus on data and data gaps. Additionally, the link between the market size and TB disease burden was explained, underscoring that both are seeking to know the number of children needing TB treatment, whether arrived at by counting TB cases or by counting treatments/tablets.

Global response to paediatric TB

Dr. Steve Graham presented a comprehensive review of the global response to paediatric TB. Momentum is building, noted by the launch of the Childhood TB Roadmap in October 2013. He noted that as child mortality falls, TB's influence will become more important and better NTP engagement with child health sector is essential. The roadmap underscores the importance of 'know your epidemic' as a starting point to address paediatric TB, while recognizing that different countries have different epidemics. Examples of such variations included 1) a high proportion of young children with TB, lots of smear negative and extra pulmonary TB, 2) high incidence of TB, but low numbers of treatments due to surveillance systems not finding cases that remain in the community (under-diagnosis), 3) under-reporting of children that are diagnosed for example in the private sector not known to the national TB programmes, and 4) risk of over-diagnosing in the absence of bacteriological evidence based on clinical algorithms (e.g. x-ray). Dr. Graham highlighted the need to focus on children under 5, who have greatest diagnostic challenges and greatest burden. Additionally, he noted the importance of contact screening in households of TB cases to identify children with TB.

A literature review on epidemiological estimates of paediatric TB

Ms. Tharsiya Nagulesapillai presented a literature review on the availability of data to inform epidemiological estimates of paediatric TB. She found over 85 studies, most about the numbers of cases (incidence and prevalence), but the data are extremely heterogeneous making meta-analysis impossible. Ms. Nagulesapillai suggested that the next steps should include an evaluation of quality of studies for methodological rigor and future research should use existing vital registration systems and surveys to attain mortality data.

Overview of routine surveillance data and prevalence surveys

Dr. Babis Sismanidis presented a comprehensive overview of available data sources generated from routine surveillance systems, as well as a historical overview of national pulmonary TB prevalence studies in the 1990's and 2000's that included children. He explained the WHO methodology for the annual collection of TB case notification data from almost all countries in the world (about 99% of global TB case notifications), requested to be reported in total, as well as disaggregated by: (i) new/retreated, (ii) case type of TB, (iii) age and gender (only for new cases). Most countries (about 99% of total smear positive notification) report age and gender disaggregated data for smear-positive TB (which is not the bulk of childhood TB), and some also report age and gender disaggregated data for smear-negative and extra-pulmonary TB (about 85% of total smear negative and extra-pulmonary notifications). In 2011, only 15 of 22 HBCs reported disaggregated data by all case type and smear positive/smear negative/ extra-pulmonary TB. However, this had improved significantly in the 2013 report (based on 2012 numbers). For better incidence estimates, countries need to: 1) Improve reporting, 2) Address under reporting (e.g. private sector, paediatricians, etc.), and 3) Address under diagnosis (cases not found/diagnosed). Additionally, Dr. Sismanidis called for more work on HIV-associated TB mortality information and on vital registration systems.

Discussion Points:

Discussion on the inclusion of children in prevalence surveys followed. Screening was highlighted as a challenge (essentially having chest X-rays of healthy children taken with no benefit to them), and the discussion was deferred to a meeting on the topic planned in Paris as part of the Union meeting. MDR-TB case notifications are also requested to be disaggregated by age (<15, 15+) but few countries report these data.

Distribution of first line paediatric drugs in 22 HBCs--How close are we to treating all children with TB?

Dr. Cherise Scott presented data on the distribution of first line pediatric TB drugs in the 22 HBCs. She noted that analysis of supply data can provide an indication of estimates of coverage rates in terms of treatments. The Global Drug Facility's (GDF) comprehensive data indicates GDF provided sufficient medication to cover around 17% of new notified pediatric cases in 2011. Some countries have considerable mismatch between case notification and treatments supplied by GDF including both over- and under-estimation of treatment needs. Several countries have not procured from GDF, despite the availability of free treatments for children via the UNITAID grant. Next steps for this work are to fill in gaps in understanding of procurement in countries that are not supplied by the GDF.

Discussion points:

Discussion ensued about the differing country needs for supply (i.e. not all want to buy via one channel like the GDF) and the potential advantages of a large single purchaser like the GDF providing a guarantee to manufacturers and preventing market fragmentation.

Overview of case finding approaches and results from TB REACH

Mr. Jacob Creswell presented TB REACH's experience on improving case detection among children. Relevant childhood specific interventions include contact investigation and active case finding activities (mobile lab, community engagement, school-based screening). The number of childhood cases found varied across different countries depending on case detection activity and TB epidemiology and many children were lost to follow up. He concluded that anecdotal evidence suggests that children may be ill /dying before contact and diagnosis. During the discussion, it was noted that the value of contact tracing diminishes as the disease burden becomes more generalized.

Overview of data collected from TB vaccine trial sites

Dr. Vicky Cardenas and Dr. Ellen Mitchell provided an overview of the data collected from TB vaccine trial sites (selected based on convenient sampling from "hot spots" of TB) where infant and adolescent cohort studies took place. The effort to diagnose TB in the youngest children (<3 years) and compare results to notification data was very expensive, lengthy, and quite frustrating. The studies may be useful for global projections through determining a case detection rate for the areas they represent, which could be different from that of adults. They also concluded that verbal autopsy was not a robust means of to identify TB in children <3 years.

Getting to incidence: understanding the gaps in recording and reporting, and measuring of the market from a country perspective: Findings from programme reviews and rapid assessments in 4 high burden countries.

Dr. Ejaz Qadeer presented Pakistan's work to understand the pediatric market. Although just 6.3% of TB caseload is children according to reported cases, the country has a large private sector, where most initial case detection happens. From the pediatric rapid assessment and inventory study (all ages), considerable but variable (7-76% in Karachi and Islamabad) under-reporting of childhood TB is estimated. Recommended next steps were to raise the profile of new guidelines, engage other stakeholders like pediatric associations, make reporting of TB mandatory in Pakistan, and consider an inventory study for childhood TB.

Dr. Dyah Mustikawati reported similar trends in Indonesia where an estimated one-third of cases are not reached by NTP. An estimated 9-11% of notified cases are children, and she assumed a similar proportion of children among the missed cases. The rapid assessment showed that the degree of under-reporting was even bigger than expected. An inventory study is planned to develop a more precise estimate.

Dr. Joshua Obansanya noted that the very small numbers of additional pediatric TB cases confirmed the suspicions of the NTBLP, which were documented in the programme review. He noted that the 3% of cases identified may represent a problem of children either not coming forward for treatment, or their not being identified as possible TB cases. This is a significant challenge for pediatric TB control in Nigeria. The NTBLP has concluded that they need to engage other providers to improve treatment of childhood TB, including pediatricians. In addition, there is an effort to improve coordination within major facilities, to ensure that children with suspected TB are picked up, whatever the first point of contact within the facility. Each of 72 tertiary centres in Nigeria will engage a TB facilitator looking to diagnose correctly and link patients to treatment.

Dr. Lindiwe Mvusi spoke of South Africa's experiences with childhood TB. She acknowledged that they have little idea of what is happening in the private sector, and that insurance does not cover TB. She noted that challenges in detection and defaulting are a huge gap. Public laboratory data suggests that more children under 5 are diagnosed than 5-14.

Ms. Renia Coghlan summarized the session noting that there is an awareness of the reported numbers being non-representative, that better reporting and engaging of stakeholders in reporting is key, and that there is a recognized need for engagement and discussion with the private sector and other partners.

How do we use the available data to inform efforts to achieve the best estimates of the paediatric market? What data gap do you want to see addressed to improve the accuracy of disease burden?

A discussion followed about the importance of looking at countries on a country-by-country basis. Additionally, the potential conflict that over-diagnosis is a lesser concern among those trying to estimate market size than among those trying to determine TB burden was noted, as the two have different objectives: a market perspective requires an assurance to produce the volume of medicines demanded (even if incorrectly used), while a public health focus puts the emphasis on ensuring that a disease is correctly diagnosed and treated. The long term goal is to ensure that these two approaches are aligned.

Disease burden estimation of paediatric TB: current analytical approaches and epidemiological indicators used

Dr. Sismanidis kicked off a session on indicators used and estimation of pediatric TB disease burden by explaining the rationale, estimates for 2012, strengths and limitations. For 2011 WHO's estimated approximately 500,000 incident childhood TB cases and 64,000 deaths from TB (among children who are HIV-negative). Some of the limitations noted, including case detection rate assumptions, under- and over-diagnosis, lack of disaggregation by HIV status, and unavailability of vital registration data in areas of the world where TB is highly prevalent. A vibrant discussion followed including the need to disaggregate data by region, develop estimates for TB/HIV mortality, and the benefit of including children in prevalence surveys.

Mathematical modelling exercise to estimate the potential market size for paediatric TB

Dr. Pete Dodd followed with a presentation on a mathematical model to estimate the number of new cases of children with TB in 2010 among the 22 TB high burden countries (that make up 80% of TB burden). His is a transmission model both in the community and at the household, starts from the premise of prevalent adult TB, moves to infection in children and calculates expected incidence allowing for differentials according to HIV levels and BCG protection. It differs from and is a complementary to WHO's approach which is based on numbers of reported cases of pediatric TB and contributes to a better understanding of estimates and appreciation of key data gaps. The inputs (including TB cases, HIV and BCG) contribute to the uncertainty of the estimates. A discussion followed concerning the design of the model, which will be discussed further in the context of the WHO Global Task Force on TB Impact Measurement subgroup of methods meeting which will take place in 2014.

Estimating the global incidence of paediatric MDR-TB

Dr. Ted Cohen presented on estimates of the MDR-TB burden in children. His approach was to develop, based on the shape of the relationship between TB incidence in adults, inference for how this information might be used to estimate prevalence in children. The estimates derived were 900,000 pediatric TB cases (2010) including 27,000 MDR-TB cases among children. A discussion focused on questions on the approach, though the gap between case estimates and number of children treated is enormous, especially in MDR TB.

Child Health Epidemiology Group's (CHERG) vision for TB

Dr. Robert Black explored estimates of levels and causes for global child mortality to examine how TB relates to childhood mortality and how child mortality estimates might better incorporate TB mortality. He outlined the role of the Interagency Group on Child Mortality (IGME) and explained how vital registration records are used to produce mortality estimates for children across all diseases. He underscored the need to know how much TB is mistakenly captured under pneumonia, malnutrition, HIV, meningitis, etc. As new interventions are being rolled out for pneumonia, malnutrition and meningitis, there will be a residual effect on TB. A discussion followed that focused on the etiology of diseases, autopsy data that reveals that kids have TB concurrent with another disease, the complexity of co-morbidity and the challenges of identifying which is the underlying cause. The issue of misdiagnosis and misclassification of disease resonated strongly for Nigeria, as this might help to explain the low levels of childhood TB officially recorded in that country. He maintained his commitment to continue the collaboration with the childhood TB community to improve mortality estimates and ensure TB is recognized fully under the CHERG activities.

What other epidemiological indicators or approaches to surveillance of disease burden could we use?

Several people provided short presentations on other epidemiological indicators or approaches to surveillance of disease burden.

- Dr. Phil Hill presented his Burden and Management of Public Health for TB (BUMP) idea, together with Dr. Graham, to use sentinel sites to collect surveillance data and extrapolate to global estimates of disease burden. At

a limited number of facilities, intensified investigations could take place and provide both incidence (denominator) and case identification (numerator) numbers.

- Dr. Anne Detjen presented on the role of GeneXpert in pediatric surveillance. She recapped the recent systematic review of the use of Xpert for the diagnosis of pediatric TB based on 13 studies. While the pooled sensitivity of Xpert was 66% and the pooled specificity was 98%, Xpert does not detect many culture negative children and 40-80% of childhood TB cases will be Xpert negative. Nonetheless, Xpert is better than smear microscopy. Access to Xpert can be used as a motivation for healthcare workers to obtain pediatric specimens. Discussion followed on the use of other types of specimens with Xpert.
- Dr. Soumya Swaminathan discussed inclusion of children in prevalence surveys. She has developed a protocol to include children in a population based prevalence survey in Chennai, India using probability proportion to size and stratified clusters. The aim would be to determine the prevalence of TB (all forms) in children aged < 15yrs in rural and urban settings in the Chennai area. The survey would also serve as a test of the NIH consensus clinical trial case definition for diagnosing pulmonary TB in children aged <10yrs and would evaluate the performance of the Xpert in the diagnosis of pulmonary and extra-pulmonary TB in children. Discussion ensued on the reliability of symptom screening for TB as many symptoms are common with other diseases. Also, Mozambique is planning to include children of contacts of adults in their prevalence survey using Xpert and provide exposed but not ill children with IPT.
- Dr. Sismanidis presented Ben Marais' comments on inclusion of children in prevalence surveys. He proposed using digital chest X-ray for first line screening. If there were suggestive symptoms, sputum would be induced. Children over 10 would be screened as adults. The group expressed some concern about x-ray among children.

Strengths and weaknesses of current approaches. What else could/should we be doing?

The day ended with a discussion on measures of actual burden. Additionally the importance of clarity on the size of the market, and on the assumptions made to arrive at estimates was noted, along with additional drivers to bring manufacturers into the production of pediatric medicines for TB.

Several NTP Managers spoke of their challenges with regard to pediatric TB and reporting of pediatric TB. Dr. Mustikawati noted the importance of sitting in an NTP Manager's shoes. She made a strong plea for partners to work with and support countries to build a strong foundation to address underlying problems. She called on partners to support comprehensive health systems approaches rather than individual project work. She asked that partners consider the challenges faced by program managers who receive many fragmented, one-off suggestions for improvements which then must be translated into a comprehensive plan.

DAY 2

An overview of TB Alliance market measurement initiatives and learning to date

To start off day two, Ms. Coghlan reminded the group that the long term goal is to achieve the ideal state where all childhood TB cases are being diagnosed and receiving treatment. To understand the current market and where and how it could be expanded into a larger 'potential total market,' Ms. Coghlan summarized the work the TB Alliance is doing to understand demand/incidence and supply, the private market, and current policy and practice. These include: 1) a literature review that confirmed the availability of very little published data on childhood TB, 2) the survey of policy in HBCs; 3) incidence modelling (detailed above); and 4) rapid assessments on the role of the non NTP sector.

The goal of the rapid assessments was to understand where children are taken, what happens at these facilities, and what numbers are seen in these non-NTP facilities. The initial assessments in three countries (Indonesia, Pakistan, Nigeria), were discussed above. For manufacturers the implications could be that the market is considerably larger than current notifications, but probably equal to their total current sales, as many of those treated in the private sector are getting treatments which are not reported to NTP. In each country, certain types of facilities see and diagnose large numbers of pediatric TB cases. A better dialogue with the non-NTP sector is needed to identify these patients and close the gap with case reporting. In addition, more detailed country-level understanding is required in order to get a better sense of the current demand and supply dynamics in key countries.

Discussion Points:

Discussion followed on the value of rapid assessments, inventory studies, provider surveys, and other market studies that might help us arrive at numbers.

Getting to direct measurement of paediatric TB through strengthened surveillance

Dr. Sismanidis provided an overview of the WHO's Global Task Force on TB Impact Measurement, a group of key technical funding agencies, TB HBC NTPs, with the Secretariat at WHO Global TB Programme/TB Monitoring & Evaluation Unit that aims to improve surveillance with three strategic areas of work: 1) national TB prevalence surveys; 2) strengthening surveillance; 3) periodic updates of the methods used for translating surveillance data into disease burden estimates. He detailed the case study of Indonesia that resulted in funding from GFATM to improve surveillance. A discussion ensued on the possible methodologies to arrive at better numbers: mystery client surveys, contact tracing studies (may find kids earlier, but we don't know if whether kids would have been found anyway), drug consumption studies, inventory studies, and possibilities for extracting useful data and other information on childhood TB from TB programme reviews and other quantitative and qualitative assessments of surveillance.

Break-out Sessions

The remainder of the meeting was focused on group discussions to guide action steps. Mr. Jones noted that childhood TB's fit into the larger child survival and mortality framework was an important consideration, but no breakout group was focused on this issue given this meeting's objectives.

- 1) Strengthening surveillance: bringing the non-NTP sector into national and global reporting, etc.
- 2) Studies to address identified data gaps necessary for better quantification of numbers of children with TB
- 3) Further analyses to improve estimates: what works, what needs refinement, and what data can improve estimates

At the breakouts, and throughout the meeting, the group was asked to consider what gaps could be addressed and what priority studies could and should be done. These suggestions were made without regard to financial constraints and with an eye to ensuring that the studies actually led to improved quality of care for children. These ideas were then grouped and discussed, and are presented in the Annex to this report.

Next Steps

The TB Alliance committed to reviewing the list of recommended studies and strategies and review the best indicators for understanding the burden and market. It is expected that several of the proposed studies would be undertaken by the STEP-TB project. Continued consultation with the meeting participants would contribute greatly to the delivery of these concrete actions.

WHO to continue coordinating work on improving disease burden estimates, ensuring alternative complementary analytical approaches are appropriately reviewed and if appropriate fully integrated in new estimates to be released in the future.

Annex1—Notes from Break-out Sessions 1,2,3

Annex2—List of Participants

Note: Background documents and meeting materials can be obtained at <https://portal.tballiance.org/pediatrictb/>. The username and password was provided to participants by e-mail. Please e-mail cherise.scott@tballiance.org to request access credentials.

ANNEX 1

Breakout Group 1: Strengthening surveillance, particularly in the non NTP sector

Short-Term Action Plan:

With a focus primarily on key markets, notably the large markets in Asia, work to understand the private sector pediatric TB market, combined with a landscape of manufacturers who are making pediatric TB treatments. Survey providers to find out how many pediatric TB treatments are being given to patients or bought. Some key activities could include:

- Interview key facilities and conduct a market survey of the biggest points of care in the above-mentioned five countries to see if they can provide any more specific numbers of pediatric TB cases
- Mine existing data on pediatric TB (UNICEF, NTP data, private sector data)
- Survey manufacturers currently selling pediatric TB drugs in the market
- Survey pediatric associations
- Survey wholesalers and pharmacies
- Conduct a rapid situational analysis

Medium to Long-Term Action Plan:

- 1) Work with child health providers to build capacity to improve diagnosis of pediatric TB cases. Also link with adult providers, assuming TB patients children may also end up being seen first by the same provider, to improve contact tracing and follow-up, screening and case management. Some key activities include:
 - Get NTP to work with child health providers to expand service of adult TB patients to children
 - Improve contact tracing systems
- 2) Move towards electronic case reporting systems (expand and adapt), however be cautious about changing forms or currently used reporting systems too much. Too many changes could significantly delay this shift. AGE, DISEASE and OUTCOME is all that is needed to collect information about childhood TB.
 - a. Can the training/inclusion of child health workers in the NTP improve reporting of children?
 - b. With little additional effort MDR TB could also be included in new reporting systems

Possible Donors:

- Global Fund
- USAID
- Non-traditional sources of funding with interest in overall child health (Comic Relief, UK)
- Reallocation of NTP awarded Global Fund funds

Responsible Parties/Possible Implementers

- TB Alliance
- National TB Programs
- Research Organizations
- Non-Governmental Organizations (PIH, MSF, UNICEF*, PSI, IRC, Save the Children)

*Link with UNICEF contact to make sure that TB is included in future priorities, notably in relation to activities around IMCI

Breakout Group 2: Studies to address data gaps for better quantification of numbers of children with TB

Prioritization of studies' contributions to quantifying the market:

		Impact	
		Low	High
Feasibility	High	<ul style="list-style-type: none"> -Rapid assessments -Quantifying the market for IPT -Household survey -Mortality studies -Pace of contact tracing 	<ul style="list-style-type: none"> -Forecasting/quantification/reporting systems -Prevalence studies (sentinel sites) -Distribution/mapping channels -Prescription studies -Over-diagnosis -Implementation/service capacity studies (review of existing service capacity data) -Consumption/drug shortage studies -Under-treatment -Inventory studies
	Low		<ul style="list-style-type: none"> -Prevalence studies (nationally representative) -Under-diagnosis (longer term goal) -Incidence studies -Adherence and treatment support study

Action Plan

	Who can do	Who can pay
Forecasting studies	STEP-TB NTPs	STEP-TB
Inventory studies	WHO	TB REACH- if linked to improved notification Global Fund BMGF
Prevalence	Sentinel project BUMP (Philip) KNCV CDC	Global Fund
Distribution channels	PATH WHO STEP-TB	STEP-TB
Prescription studies	STEP-TB	STEP-TB
Under-treatment	KNCV NTPs PATH	Global Fund
Over-diagnosis	KNCV NTPs PATH	Global Fund, USAID
Implementation study	KNCV	TB Cares
Drug Shortages	WHO, Essential Medicines, EMP	UNITAID

Next Steps

Further analytical work and critical review of additional qualitative and quantitative data sources not fully utilised currently to improve the estimation of the TB drug market for paediatric TB:

1. Analytical work
 - a. Further triangulating the mathematical model of paediatric TB incidence (country level), using specific country settings with a better understanding of disease burden (Pete).
 - b. Expanding the scope of the mathematical model of paediatric TB incidence, from 22 TB High Burden Countries currently to cover all countries in the world (Pete).
 - c. Comparison of all three complementary analytical approaches estimating paediatric TB incidence at both country and global level, to further refine approaches and identify key data gaps that need to be addressed (IHME, Babis, Pete, Ted).
2. Critical review of additional qualitative and quantitative data sources not fully utilised currently
 - a. Expansion of compilation/cataloguing of relevant data (program reviews, implementation of TB surveillance checklist) not yet tapped into (Ted, Babis, Pete).
 - b. Literature review of level of DR-TB in children (Harvard).
 - c. Literature review of contact tracing studies to inform mathematical modelling country and global level estimates of under-diagnosis (TB Alliance).
3. Presentation/proposal made at Q2-3 2014 Taskforce Meeting of these activities to get endorsement

ANNEX 2

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