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Regional consultation on childhood TB in the WHO European Region

Copenhagen, Denmark, 12–13 November 2015

ABSTRACT

Against the backdrop of widespread tuberculosis (TB) among vulnerable and marginalized populations, which include children and adolescents, and in the context of increasing complexities resulting from HIV co-infection and multidrug-resistant (MDR) TB, the WHO Regional Office for Europe convened key actors working in the field of childhood TB in the WHO European Region for a regional consultation. This report summarizes outputs from the presentations and group work of the event.

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Acronyms and abbreviations

ACSM	advocacy, communication and social mobilization
AE	adverse event
BCG	Bacillus Calmette–Guérin
Bdq	bedaquiline
CAR	central Asian republic
CEE	central and eastern Europe
Cfz	clofazimine
CIS	Commonwealth of Independent States
CN	concept note
CT	computerized tomography
CUP	compassionate use programme
Dlm	delamanid
DOT	directly observed treatment
DR-TB	drug-resistant tuberculosis
DST	drug-sensitivity testing
DS-TB	drug-susceptible TB
ECDC	European Centre for Disease Prevention and Control
EMA	European Medicines Agency
EML	essential medicines list
ERS	European Respiratory Society
FLD	first-line drug
GDF	Global Drug Facility
GF	Global Fund (to Fight AIDS, Tuberculosis and Malaria)
GTB	(WHO) Global TB Programme
HCW	health care worker
HPC	high-priority country
HR	human resources
IGRA	interferon-gamma release assays
IMCI	integrated management of childhood illness
IPT	isoniazid preventive therapy
JTH	(WHO) Joint TB, HIV/AIDS and Hepatitis (Programme)
LTBI	latent TB infection
Lzd	linezolid
M&E	monitoring and evaluation
MDG	Millennium Development Goal
MDR/XDR-TB	multidrug- and extensively drug-resistant tuberculosis
MoU	memorandum of understanding
MSF	Médecins Sans Frontiers
NFM	(Global Fund) new funding model
NGO	nongovernmental organization
NRL	National Reference Laboratory
NTP	national tuberculosis (control) programme
PHC	primary health care
PV	pharmacovigilance
RCC(-TB)	Regional Collaborating Committee (on TB Control)
RIF	rifampicin
RMNCH	reproductive, maternal, newborn and child health
RR-TB	rifampicin-resistant TB

SAR	serious adverse reaction
SLD	second-line drug
SMART	specific, measurable, achievable, realistic and time-bound
TB	tuberculosis
TBAP	TB action plan
ToR	terms of reference
TST	tuberculin skin test
UNFPA	United Nations Population Fund
UNICEF	United Nations Children's Fund
USAID	United States Agency for International Development

Summary

Against the backdrop of widespread tuberculosis (TB) among vulnerable and marginalized populations, which include children and adolescents, and in the context of increasing complexities resulting from HIV co-infection and multidrug-resistant (MDR) TB, the WHO Regional Office for Europe convened key actors working in the field of childhood TB in the WHO European Region for a regional consultation. Collaboration across health sectors and communities is required to understand the full scope of the problem of childhood TB and to ensure that this complex health problem is prioritized in national health strategies, plans and budgets. The goal of zero TB deaths among children, endorsed by the international TB community, can only be achieved if various factors are addressed, including increasing diagnostic capacities, combatting the tendency towards excessive hospitalization of children with TB, and addressing the lack of guidance in specific areas of TB policy.

The objectives of the consultation were to:

- review the status of common childhood TB practices at country level;
- share experiences, lessons learnt and good practices;
- discuss reasons for, and potential solutions to, excessive hospitalization and other relevant childhood TB-related problems;
- establish priorities and design activities for strengthening childhood TB initiatives across the Region;
- highlight challenges in including childhood TB in national strategic plans in the era of the post-2015 global End TB Strategy and the regional TB action plan for 2016–2020; and
- formulate next steps to effectively update childhood TB in national strategic plans, in line with WHO recommended policies and strategies.

The consultation took place in Copenhagen across two days, bringing together country representatives and experts from 29 countries of the Region and international partners involved in TB at many health system levels,¹ with the expected outcomes that participants would be:

- updated on key changes and aspects of childhood TB treatment and management;
- involved in drafting a set of priorities for childhood TB at country level; and
- engaged in defining the next steps for updating childhood TB-relevant elements of current national strategic plans, in line with the End TB Strategy and the regional TB action plan.

¹ The provisional programme for the consultation can be found in Annex 1 and the list of participants in Annex 2.

Background

The full scope of the global problem of paediatric TB is not known. WHO estimates that over half a million children fall ill and up to 80 000 die each year because of TB, which is a preventable and curable disease. After decades of relative neglect, the childhood TB epidemic is now in the spotlight.

During the final year of implementation of the *Consolidated action plan to prevent and combat multidrug and extensively drug-resistant tuberculosis in the WHO European Region, 2011–2015*² and following (and in line with) the endorsement of the post-2015 global End TB Strategy by the Sixty-seventh World Health Assembly in May 2014,³ a new regional TB action plan (TBAP) covering the period 2016–2020 was developed and endorsed at the 65th session of the WHO Regional Committee for Europe in September 2015. The plan builds on the progress made through the implementation of the previous regional TB consolidated action plan (2011–2015) and is in line with the European Health 2020 policy framework. The role of patient-centred models of care and civil society involvement in the prevention of TB have also been highlighted in the TBAP.

As a result, Member States of the WHO European Region will need to revisit, update and adapt their TB national strategic plans. Childhood TB should be carefully considered for inclusion in country-specific plans, or development/updating as necessary, as it falls into several areas of intervention of the outgoing consolidated action plan and links to the three pillars of the post-2015 global End TB Strategy. This context requires concerted efforts to more effectively combat TB in one of the most vulnerable patient groups – children.

Thursday 12 November 2015

Opening remarks

Dr Nedret Emiroğlu, Director, Division of Communicable Diseases, Health Security & Environment

Dr Emiroğlu welcomed all participants to the meeting, speaking of the many challenges associated with childhood TB, particularly in the WHO European Region. She highlighted the strong political commitment in the Region to tackling childhood TB through various documents and strategies, including the recently signed *Global strategy and targets for TB prevention, care and control after 2015* (the End TB Strategy),⁴ the regional-level strategic policy framework Health 2020,⁵ with its particular focus on a life-course approach and on special requirements for children, and the European child and adolescent health strategy 2015–2020,⁶ which prioritized communicable diseases (including TB). Dr Emiroğlu reminded participants that the consultation was a ground-breaking event as the first childhood TB workshop of this scope to take place, and remarked on its innovative design, sharing her appreciation for the variety of interactive devices that were to be used, including posters, plenary sessions and group discussions alongside presentations. She outlined the expectations for the consultation, which included active sharing

² The action plan is available at the WHO Regional Office for Europe website:

http://www.euro.who.int/__data/assets/pdf_file/0007/147832/wd15E_TB_ActionPlan_111388.pdf.

³ More information can be found at the WHO Regional Office for Europe website:

http://www.who.int/tb/post2015_strategy/en/.

⁴ The strategy is available at the WHO Regional Office for Europe website: http://www.who.int/tb/post2015_TBstrategy.pdf.

⁵ Available at the WHO Regional Office for Europe website:

http://www.euro.who.int/__data/assets/pdf_file/0009/169803/RC62wd09-Eng.pdf.

⁶ Available at the WHO Regional Office for Europe website:

http://www.euro.who.int/__data/assets/pdf_file/0010/253729/64wd12e_InvestCAHstrategy_140440.pdf?ua=1.

of experiences, challenges and examples of good practice, taking into consideration national-level country contexts and how to manage interaction – between programmes, as well as within health and beyond health sectors – to address challenges in providing adequate services to children with TB.

Dr Malgorzata Grzemska, Coordinator, WHO Global TB Programme (GTB), Technical Support Coordination

Dr Grzemska introduced herself and reminded attendees of the role of the GTB, which was also hosting the Childhood TB Subgroup (established in 2003). She explained the renewed focus on vulnerable groups and on tackling childhood TB in particular, since children have no voice of their own. She described the work of the TB Task Force within the Stop TB Partnership and highlighted its active work with the WHO Regional Office for Europe in developing guidance documents. Dr Grzemska reiterated that the consultation was designed specifically to ensure learning was taken forward for and by all participants (whatever their TB-related standpoint), aiming to lead to concrete recommendations in the future.

Dr Masoud Dara, Senior Adviser, WHO Office at the European Union (EU) and Acting TB Programme Manager, WHO Joint TB, HIV/AIDS and Hepatitis (JTH) Programme

Dr Dara added his thanks and welcome to those of the previous speakers, and introduced the Regional Office's advocacy video on TB in the Region, outlining key achievements, challenges and the way forward.⁷

Presentation of objectives and appointment of chairs

Dr Martin van den Boom, Technical Officer, JTH Programme

Dr van den Boom presented the objectives of the consultation (Annex 3), appointing chairs for sessions across both days and reiterating that the purpose of the meeting was to combine forces, aiming for joint learning and working together to achieve the meeting objectives. He explained that participants could expect to be updated on key changes and directions in both policy and programmatic terms, and reminded attendees that – based on country experiences – priorities were to be developed in line with the post-2015 global End TB Strategy and the regional TB action plan for 2016–2020, as well as the Health 2020 framework.

Epidemiological highlights and update on the WHO European Region, focusing on childhood TB

Dr Andrei Dadu, Technical Officer, JTH Programme

Dr Dadu acknowledged the contribution of data from Member States, which had made extensive epidemiological analysis possible, as well as the key organizations involved in data analysis and related activities. He outlined the key achievements in reducing TB incidence, prevalence and mortality since the 2000 Berlin Millennium summit, at which the Millennium Development Goals (MDGs) had been established. Specifically, Goal 6 was to decrease overall incidence, which was being achieved since 2005. By 2014, however, only a 28% reduction in prevalence had been achieved since 1990 (compared to the MDG specification of 50%) and a 20% mortality reduction since 2005. Case detection rates had shown a significant increase since 1995 and were sustainable, with the Region having one of the highest TB detection rates in the world.

⁷ Available at the WHO Regional Office for Europe website: <http://www.euro.who.int/en/health-topics/communicable-diseases/tuberculosis/multimedia/video-tuberculosis-in-the-who-european-region-2015>.

Dr Dadu discussed the unequal distribution of the TB burden among countries, with 85% of the world's TB burden currently being found in 18 high-priority countries (HPCs) of the Region, (predominantly to the east). He also described the current significant prevalence of MDR-TB among new and retreated cases, describing an increase in the trend since 2007 that indicated continuous infection with MDR-TB among the susceptible population. These figures continued to remain high, but were at least stabilizing. As a core indicator for the performance of the TB programme, a cohort analysis tool had been used to monitor five main cohorts each year. Dr Dadu presented the results, highlighting outcomes of new and re-treatment TB cases, HIV and TB co-infection, rifampicin-resistant (RR)-TB/MDR-TB or extensively drug-resistant (XDR)-TB, showing in particular that the chances of a patient with XDR-TB being cured were currently as low as 30% and those with HIV co-infection only 50%.

Dr Dadu highlighted that children represent 10% of all TB patients globally, with a significant discrepancy in the Region between adult (79%) and child (32%) detection rates. He explained that prevention, diagnosis and treatment of TB in children had been relatively neglected over the years, while infectious cases in adults had been prioritized: this approach needed to be changed, as childhood TB was directly linked to the TB burden in adults. He also mentioned that the uneven distribution of TB between male and female adults and between girls and boys required further investigation: adult males were more affected, but the distribution across genders in children was even.

Dr Dadu emphasized the viewpoint that paediatric TB represented a failure to control transmission. The most common age to present with TB was 1–4 years and, according to TB surveillance standards and benchmarks, surveillance data for children reported with TB were considered to be reliable and accurate if the ratio of age groups 0–4 to 5–14 years was in the range 1.5–3. A question-mark remained over whether countries were able to properly detect childhood TB cases, and the aim of 1.5 or three times higher diagnosis figures in younger than in older children was not currently being achieved across the board, which required performance measures to be reassessed.

In terms of anti-TB drug use for paediatric TB, some countries in the Region were still using adult doses: this needed to be tackled. Further matters to be addressed included the distribution by gender and age of childhood MDR-TB cases. Younger adults (aged 24–34 years) were most affected, but MDR-TB levels were higher among children in some countries. Improvements were also required in treatment outcome monitoring to increase the current level (5%) of children being treated with their results not being evaluated.

Dr Dadu summarized the key issues to be addressed for children with TB in Europe, focusing on variations or inconsistencies between countries in several arenas, including incidence and prevalence, clinical practices for prevention, chemoprophylaxis protocols and monitoring. In addition, data on childhood TB were not recorded systematically, little information or data were available on MDR-TB prevalence in children or prevalence of HIV in children with active TB, and (despite new WHO recommendations for childhood TB treatment regimens) child-friendly formulations were not yet available to match the recommendations.

Overview of finalized regional TB action plan 2016–2020, including childhood TB-relevant content

Dr Masoud Dara

Dr Dara outlined the achievements of the consolidated MDR-TB action plan (2011–2015), including improvements in treatment coverage, MDR-TB case detection, drug-sensitivity testing (DST) coverage for first-line drugs (FLDs), electronic case-based data management, and advocacy and partnership to address the needs of special populations. In addition, loss to follow-up rates had declined somewhat, along with stock-outs of second-line drugs (SLDs). In line with the Health 2020 policy framework and the global End TB Strategy, the new regional TBAP endorsed at the Sixty-fifth session of the WHO Regional Committee for Europe was the result of a Region-wide consultation and development process, the key stages of which Dr Dara reviewed.

He explained the novelties of the new TBAP, including: scale-up of rapid diagnosis (increased DST coverage as culture testing takes too long); expansion of patient-centred care to include many models and a comprehensive care plan; shorter and more effective treatment regimens and increased use of new anti-TB medicines; scale-up of preventive therapy (discussion of how to do this was a key component of the current consultation); research for new tools to aid in the fight against TB; and the use of an intersectoral approach to addressing inequities, with ministries working together across and beyond the health sector (including in the private sphere).

In relation to the End TB Strategy, Dr Dara described the ideal vision as being a world free from TB, including zero deaths, disease or suffering, highlighting the subtle move from the goal of aiming to stop TB to ending TB. He also outlined the key targets (in terms of percentage reductions required in various indicators) and the temporal milestones involved in the plan (2020 and 2025). A key focus in the adaptation of the TBAP was putting an end to the catastrophic costs involved for families affected by TB and Dr Dara reminded participants that although the targets were high, particularly for treatment outcomes relating to MDR-TB patients (75% success rate), efforts needed to be increased to introduce new medicines and rapid diagnosis, if the MDR-TB epidemic was to be controlled. Strategic directions for the new TBAP included strengthening health systems' responses to TB, including inter- and intrasectoral collaboration to address the social determinants and their underlying links to TB. New diagnostic tools, medicines and vaccines were also required, along with national and international multistakeholder partnerships, crucially involving civil societies and communities and with a focus on a preventive approach. In addition, the rational use of existing resources would be needed, not only to identify gaps and stretch the available funds further, but also to ensure better outcomes and sustainability.

Dr Dara described the TBAP's areas of intervention, which encompass the three pillars of the End TB Strategy (integrated, patient-centred care and prevention; bold policies and supportive systems; and intensified research and innovation), and highlighted TBAP activities in the Region that are directly linked to childhood TB. These included:

- early diagnosis and rapid testing with DST, using diagnostic algorithms (section 1.B.1);
- management of latent TB infection (LTBI) and preventive treatment of high-risk individuals, with changes to vaccination practices – stopping Bacillus Calmette–Guérin (BCG) revaccination owing to lack of evidence (section 1.E.2);
- several parts of section C:
 - increasing equitable access to treatment and care (all TB forms) and supporting patients to facilitate treatment adherence by updating treatment guidelines in line with WHO recommendations;
 - developing a plan to ensure universal access and uninterrupted drug supply;
 - introducing rationally and safely new anti-TB drugs, including first-line fixed-dose combination drugs and paediatric formulations for drug-resistant TB (DR-TB) (section 1.C1. to 1.C.4); and

- using regulatory frameworks for case-based surveillance, strengthening vital registration, quality assurance and rational use of medicines, along with pharmacovigilance (PV) (section 2.C.10).

Dr Dara concluded that the cross-cutting nature of childhood TB meant that it was touched upon by the highest number of interventions within TB prevention and care activities. Key determinants for successful development of the TBAP were transparency, inclusiveness and the involvement of many partners and stages across and beyond the health sector, based on lessons learnt and good practices. Alignment and synergy with other plans and policies (Health 2020 and the End TB Strategy among others, and at various levels and implementation stages) were also vital to success, along with support provided to countries to encourage them to adapt and implement the required policies, strategic documents and action at national level.

Discussion

Epidemiological considerations

The detailed, impressive analysis of epidemiological data by the Regional Office was acknowledged, but the low case detection rate for paediatric TB remained a problem, despite high cure rates when cases were reported and treated. The fact that paediatric formulations were not available Region-wide was cited as a factor in this, and participants were reminded that early diagnosis and effective treatment were crucial.

The aforementioned high cure rate was also brought into question. It was explained that MDR-TB remained uncommon among children; TB cases in children were usually new cases with drug-susceptible strains, posing less risk of MDR-TB among children and allowing the cure rate to remain high. The notorious difficulty in obtaining clinical biological samples from children, however, could mean that the problem was underdetected. A significant discrepancy was evident in case detection and treatment success rates between adults and children, with lack of reporting as a principal culprit (and figures therefore not being included in national statistics or routine surveillance). It was also felt that the treatment success rate among children could be the result of a combination of other relevant factors, such as extra care by parents, relatively easier monitoring of treatment (and therefore also adherence), the paucobacillary nature of TB in children and the predominant lack of concomitant diseases among children compared to adults. WHO was working with national tuberculosis control programmes (NTPs) and health facilities in countries to understand and combat underreporting.

Household contact history was suggested as a surrogate for biological specimens in children, and it was agreed that the JTH Programme could look into this as an option when analysing data. In the context of low MDR-TB detection rates among children, however, such comparisons should be carried out country rather than programme level.

It was reiterated that country estimates of childhood TB were starting to be produced and would be available from 2016. Expert opinion was that in high-burden countries, childhood TB represented 15–20% of the overall burden. However, given the diversity of the Region, in which each surveillance and reporting system and NTP worked differently (with various strengths and weaknesses to take into account), relying on averages for averages' sake would be misleading and looking at countries' own data would be more useful. Strengthening surveillance was certainly vital and would ultimately bring about more and better data.

The question of whether the European benchmark ratio of 0–4 to 5–14 years (in the range 1.5–3) could be used as a global benchmark not just for Europe, and whether it could be revised, was

raised. It was agreed that this could be considered for future analysis, but it should be borne in mind that the European Region contact case-detection rate had been found to be higher, which could influence the figures and the metric applied.

It was confirmed that the JTH Programme was still in the testing phase in terms of establishing reliable assumptions, which would be followed by triangulating screening coverage (including by age group), resulting in a comparison of adult versus child data. This was in line with the operational research pillar of the new TBAP. It was suggested that Belarus could be a possible site for such a study (with technical assistance requested from WHO to do so). More data were required at country level and the JTH Programme would continue to monitor the indicators for detection rates, as well as asking countries for input on which assumptions should be taken forward for analysis and which factors required further consideration (such as whether underdetection in adult women could also be carried across to girls, or whether overdetection in boys could be a reason for the unusual discrepancy between girls and boys that had been shown in Dr Dadu's presentation).

TBAP considerations

The role of NTPs was discussed in terms of how to include children specifically in anti-TB activities. It was reiterated that a one-size-fits-all approach would not be effective, given the variety of country contexts, and that it was important to bring as many stakeholders together as possible to understand and distribute the tasks. The TB action plan should be in line with the regional TBAP in high-burden countries. Roles and responsibilities should be outlined, including going beyond the tasks of the NTP. National workshops should be convened between the national actors (even in low-incidence countries that were aiming for elimination of TB) to establish the appropriate strategic direction. WHO would support activities wherever possible.

It was also highlighted that a strategic plan was crucial from a human resources (HR) perspective to ensure a long-term sustainable approach reaching beyond simple implementation of training courses for health care workers (HCWs). A broad health-sector-wide HR development plan in each country would help to increase capacity and competences and countries were advised to establish needs before proactively submitting clear requests for help to ministries and WHO.

Poster session

Three countries with distinct epidemiological profiles presented their posters to the plenary: Belarus (high MDR-TB burden country), Tajikistan and Slovakia (low-TB incidence country).

Belarus

Dr Alena Skrahina, Scientific Director at the Republican Research and Practical Centre for Pulmonology and Tuberculosis in Minsk, presented the situation relating to childhood TB in Belarus (according to the poster template provided prior to the consultation), which included details of the country's childhood TB status in the following areas.

- Key epidemiological data were presented: notification figures were slightly decreasing; all contacts were investigated; and the paediatric MDR-TB rate was very high (17%) compared to adult TB (32%) (2014).
- Policy and practice was outlined (in terms of diagnosis and screening, treatment and prevention methods, activities, infrastructure and outcomes):
 - screening – tuberculin skin test (TST) was carried out in high-risk groups of children only (2015) (no longer used for all children), with follow-up for several years; interferon-gamma release assays (IGRA) were used in case of allergic reaction to tuberculin, certain skin disorders or failure of parents to provide

- consent; TB contacts with LTBI were also screened; and contact tracing was carried out for the second and third circle;
 - diagnosis – a special methodological instruction was introduced in 2014 (including diagnostic algorithms for timely, high-quality diagnosis); bacteriological methods were used, along with chest X-ray and other diagnostic tools if indicated; sputum samples (induced) and other tissue sampling methods were employed; and histological analysis was carried out, along with mandatory HIV testing;
 - treatment – national guidelines on TB and DR-TB treatment existed, including a childhood TB section since 2012, meeting the requirements of international standards; an MDR/XDR-TB consilium was in operation to review all cases; chemotherapy was available (all drugs); treatment was carried out either at the national TB centre or at various sanatoria, with some directly observed treatment (DOT) at home; intensive attention was given to children with TB, including school and social support (previously Global Fund (GF) support but currently locally funded, with special packages in place for ambulatory care);
 - results – all registered (drug-susceptible (DS)-TB) cases had been cured but DR-TB results were poor (“failure”);
 - prevention – BCG vaccination was conducted but mandatory revaccination would be cancelled from 2016 (pending decree); prophylactic treatment was based on contact tracing for all children aged 0–5 years, all HIV-positive and immunocompromised patients, and for those aged 5–17 years with positive TST or IGRA; preventive treatment protocol provided six months of isoniazid preventive therapy (IPT) in combination with rifampicin (RIF) where indicated; and no prophylactic treatment was given for close MDR-TB contacts (observation only).
- Monitoring and evaluation (M&E) was carried out by means of a national electronic TB register, dividing children into age groups; the register was connected to all TB cabinets and dispensaries, with widespread data input and controlled nationally; and disaggregated reporting forms were used for specific population groups.
 - HR development was discussed: one TB paediatrician was available to treat 20 000–22 000 children (46 paediatricians = 54.8%); and stringent training requirements existed, with refresher courses/additional training funded twice annually by the GF and once every five years by the state budget.
 - Existing stakeholders and roles were outlined. Belarus was coming to the end of its second grant from the GF, with a concept note (CN) approved for a further (~)US\$ 12 million for 2016–2018. The Ministry of Health and National TB Centre (country TB network and primary health care (PHC)) implemented the NTP, including administration, diagnostics, treatment and prevention. WHO dealt with policy development, provided technical assistance and advice on guidelines development, review and external expertise (the decision to end BCG revaccination was enabled by WHO), and nongovernmental organizations (NGOs) and patients’ societies were involved in conferences and developing competences. The International Committee of the Red Cross and Médecins Sans Frontières (MSF) provided social and psychological support to families, along with humanitarian aid, advocacy, communication and social mobilization (ACSM), active screening and assistance with introducing new drugs.
 - Childhood TB was included in national strategic documents through a comprehensive normative framework of guidance on: TB treatment, including DR-TB; organization of TB control in outpatient settings; laboratory diagnostics; diagnosis, prevention and treatment of BCG serious adverse reactions (SARs); TB infection outbreak and contact

tracing work; and immunodiagnostics and chemoprophylaxis for TB among children (the extent to which the guidance was followed in reality, however, was unknown).

In summary, the key childhood TB issues and challenges are:

- low levels of (ineffective) contact tracing;
- weak collaboration with HIV services and other paediatric services (HIV infection was rife and information was difficult to obtain and/or share);
- lack of recording and reporting and M&E experience, coupled with lack of specialists in these areas (HR);
- lack of options for treating children in various facilities across a range of age groups (for instance, what to do with young children who are currently healthy but are in direct household contact with a TB patient?);
- lack of paediatric formulations of TB drugs;
- low rating of the specialty among HCWs (not enough specialists, not held in high regard) and undermotivation of the workforce; and
- problems with continuing education and social life for children with TB.

Requirements for a future plan or way forward include:

- improving early TB and DR-TB diagnostics with proper contact-tracing and rapid testing;
- implementing new drugs and regimens (for example, only two children are receiving bedaquiline (Bdq), but most doctors are hesitant to prescribe it owing to the potential complications);
- introducing paediatric formulations of anti-TB drugs;
- establishing proper M&E and recording and reporting systems;
- strengthening collaboration with other medical and paediatric services (including HIV);
- motivating TB HCWs;
- providing social and other support to TB patients' families, including education about contact with people with TB;
- strengthening outpatient care (decreasing the number of sanatoria);
- providing continuing education for children with TB (attending school while sputum-smear/culture negative); and
- strengthening cooperation with NGOs and all partners to provide adequate prevention and care for children with, or at risk of, TB.

Discussion

It was clarified that GP training courses with a TB focus took place in Belarus. Most training is supported by written materials, but it was agreed that help was needed to implement it as there was a gap between the knowledge and what was carried out in reality. Clarification was also sought on the reasons for the treatment failures shown in the poster presentation. One case had been a patient with severe concomitant diseases which resulted in failure, and the other had been lost to follow-up as an adult, making it impossible to engage the patient or his parents any further.

In terms of the two children being treated with Bdq, it was established that no fluoroquinolones had been added to the regimen, which had consisted of five drugs, adjusted depending on the resistance pattern emerging.

Tajikistan

Dr Kurbonkhon Zakirova, child TB specialist of the Ministry of Health and Social Protection in Dushanbe, presented an overview of the childhood TB situation in Tajikistan (based on the poster template), which included details of the country's childhood TB status in the following areas.

- Problems with TB services in Tajikistan included: 93% mountainous terrain, which hindered access to medical services; large influxes of migrants, aggravating the TB problem; and a high level of poverty, which was the main social determinant of TB.
- Government has committed to implementing the NTP through three main mechanisms (since 2005): the National Coordination Committee under the Government, the Coordinating Council under the Ministry of Health, and the Monitoring Council under the Regional Centre for TB Control. Regulatory/strategic documents included a law passed in 2006 to protect the population from TB, a decree implementing the NTP for 2003–2010, the updated NTP for 2010–2015 and a national action plan for 2015–2020.
- TB detection took place through an extensive network of 66 national TB centres, four regional centres and 34 TB hospitals (2535 beds in total), with PHC facilities responsible for implementing the programme. Extensive laboratory services were in use, including some specifically for DR-TB, along with a national reference laboratory (NRL) at the national TB hospital, a national microscopy centre and a regional laboratory structure carrying out cultural examinations at regional level.
- National health indicators set out by executive order of the Ministry of Health defined four specific PHC performance indicators and diagnosis figures, and specified PHC-level responsibility for providing preventive care to children.
- Public funding for health care was provided by the Government (increasing each year); 2.5% of the total health care budget was allocated for TB services in 2013. The National Programme for Protection of the Population from TB was predominantly (80%) funded by donor agencies.
- Diagnostic algorithms were used for TB detection: microscopy, GeneXpert, culture, DST.
- Incidence and mortality rates had been decreasing since 2007 after climbing from 2002 to 2007; treatment success rates among new cases were almost at 90% (2014/2015).
- TB incidence in children and adolescents (aged 0–17 years) was analysed: 11.2% of the total number of TB cases in Tajikistan in 2014 were paediatric TB cases (down from the 2007 level but up from that of 2012); incidence in adolescents (aged 15–17 years) was 4–5 times higher (46.0%) than in children of other age groups (0–4 years 9.2%; 5–14 years 12.7%). The majority of paediatric TB cases were pulmonary TB, with all forms of TB cases declining since 2011.
- After (induced) sputum examination began (with thanks to MSF for help with collection and testing in a special facility), the paediatric TB detection rate improved. This approach was planned to be expanded throughout the country, with bronchoscopy examination and computerized tomography (CT) scans also forming part of the country's diagnostic portfolio.
- Key items or activities that had helped to improve the quality of TB services within the NTP, as well as ideas and plans for the future, included:
 - support from WHO for developing paediatric formulations (resulting in treatment now being more effective);
 - improved integration and collaboration between TB services and PHC (the latter being closer to patients and high-risk communities);

- use of GeneXpert units for molecular detection in sputum samples and RIF-susceptibility testing;
- adoption of an order by the Ministry of Health and Social Development to organize DOT rooms in certain facilities;
- workshops for PHC doctors and nurses (for continuous information dissemination and training);
- introduction of nationwide M&E (analysis of approaches and drawbacks after each mission in the field – where issues could not be solved at local/regional levels, they were raised to Ministry of Health level in coordinated efforts to solve problems);
- implementation of a special survey across 11 regions and almost 600 investigations to evaluate HIV and TB co-infection, specifically in HCWs and specialists to confirm (or refute) TB suspect cases, with the desire to carry this out nationwide to reach isolated areas and improve the timely detection and treatment of children with or at risk of TB; and
- the importance of focusing not only on DR-TB, but also on HIV co-infection.

Slovakia

Dr Ivan Solovic, NTP Manager and Head of TB Department at the National Institute for TB, Lung Diseases and Thoracic Surgery in Vyšné Hágy, presented details of Slovakia's childhood TB situation, focusing on the following points.

- Slovakia had a low (stable) TB incidence rate of 6.2 per 100 000 population (population 5 million, of which 700 000 officially (but realistically probably nearer 1.1 million) were Roma) and it was not a refugee transit country. In 2014 there were 42 relapses, 277 cases of pulmonary TB (59 extrapulmonary), 48.8% bacteriologically confirmed (68.1% total confirmed), with eight cases among foreign-born individuals.
- The End TB Strategy was being considered for implementation into the national strategic plan, but this would be impossible to achieve without help from surrounding countries.
- Large regional differences in incidence and significant gender differences existed, owing to problem areas with high homeless populations and large Roma communities (over 1000 settlements). TB notification for Roma individuals represented over 50% of all notifications in certain areas.
- TB could be described as almost exclusively a Roma problem, especially among children: 80–100% of paediatric TB cases were among Roma children, and only one non-Roma, non-foreign child had been infected with TB in 2015.
- BCG vaccination was stopped in 2012 (after considerable debate). Significant cause for concern remained regarding the Roma population and TB. Roma communities were vulnerable groups, with children moving around a lot, so contacts were particularly hard to define (especially in extended families and close communities, with some groups living in groups housing up to 120 people).
- Extraordinary activities were employed in Slovakia to resolve regional TB problems: the Regional Public Health Authority in Poprad ordered compulsory vaccination of neonates (aged 4 days to 6 weeks) from the three key Roma municipalities, but this was costly and difficult to coordinate. Prevention activities aimed to focus on timely finding of the source of infection and anti-epidemic measures against outbreaks.
- The national TB strategy involved regulation, strategic documents and guidelines on TB treatment, care and management (differentiated by type of HCW). Material was translated into Roma language. Good collaboration existed between stakeholders and across sectors and levels of the health system. Patient referral practices in various

facilities were well organized (between public and private services) and patient transfers were notified.

- Medical education targeting GPs, nurses and specialists was continuous and up to date, involving the TB centre, Slovak Society of Respiratory Diseases and other academic institutions.
- Treatment success rates were very high (91.3%) in the European context (76.5%); Slovakia was a small country in which TB was relatively easy to control (with the exception of among Roma communities), with very few cases of TB each year (of which 100% had been notified in 2013 and only one patient had died from TB).

Key issues and challenges were identified as follows.

- Treatment adherence was hard to control among TB patients, with DOT being particularly difficult in hard-to-reach subpopulations. Females from Roma communities were being trained as Roma assistants, working with GPs to try to increase adherence to treatment and follow-up. With limited funding, these models of patient-centred care were only implemented in a few communities, but cooperation was good between regional specialist pulmonologists, TB nurses and Roma assistants, overcoming ethnic problems to convey information and supervise treatment.
- Funding for TB control was provided through health insurance companies, with only limited funding from the Ministry of Health and no specific funding for the NRL.
- No paediatric formulations or fixed-dose TB drug combinations were available.
- TB care was fully reimbursed from public funds. Increased financial demands (technology and inflation) needed to be met by the national health insurance companies to reinforce the achievements in TB control to date.
- Child TB contacts were currently the only group of children targeted for diagnosis and treatment of both active TB and LBTI.
- Hospitalization of children was still standard for prophylactic treatment (this was regarded as better than remaining in Roma communities, where TB care was too problematic).

Dr Solovic explained that the 7th Conference of The Union (International Union against Tuberculosis and Lung Disease) European Region was to take place in Bratislava, 22–24 June 2016: childhood TB would be on the agenda and participants were invited to attend. He extended his thanks to WHO for the impetus and guidance to stop BCG vaccination in Slovakia.

Discussion

It was explained that WHO did not advise simply stopping BCG vaccination – especially among Roma populations – in fact, the recommendation had been to continue vaccinating certain children born in high-incidence risk situations or those moving around regularly.

To clarify the treatment success data shown in the presentation from Slovakia, Dr Solovic explained that patients were divided into groups and presence of disease and, as required by the European Centre for Disease Prevention and Control (ECDC), Slovakia differentiated but did not separate patients by sputum-smear results. He reiterated that monitoring the condition of patients in such a relatively small setting was not problematic; all families were monitored by public health agencies (330 cases nationwide, and some regions had no TB incidence at all).

The point was made that countries in which TB was rare must guard against complacency and that training did not automatically bring about behavioural change. It was therefore necessary to look beyond training for other resources. WHO advice could at times be understood to be a

contradiction of previous actions (a so-called telling-off of sorts), but transitioning to new ways of working was difficult and knowledge alone was often not enough: human beings needed time to accept change fully. As such, the first step was to understand the reality and the problem, and the second was then to decide how to improve.

The ethnic situation in countries like Slovakia (with large Roma populations) was discussed. It was often difficult to implement recommendations or advice for dealing with high TB incidence (and risk) among certain populations without aggravating ethnic problems (claims of discrimination in BCG vaccination policy among Roma populations, for example). Slovakia had managed this by identifying geographically (not along ethnic lines) the areas that were problematic and those children now were able to be vaccinated, containing the problem. It was discussed that policy direction was certainly needed but that the issue was sensitive, with adverse events (AEs) being reported in an inflammatory manner by the media. Nevertheless, stopping BCG vaccination in Slovakia was understood to be the right course of action, in part owing to the risk of adverse side-effects if vaccines of uncertain quality were to be used in the future.

The conclusion had been drawn that 80% of complications with vaccines were the direct result of vaccination techniques, not the drugs themselves. This knowledge had allowed a change in vaccination and revaccination policy, as well as increased education and training to improve HCWs' vaccination techniques, resulting in a five-fold reduction in complications. It was concluded that country input and experience-sharing were vital, along with seeking and accepting guidance from WHO during the ongoing BCG vaccine shortage, which would take 1–2 years to solve. Reducing wastage and improving usage techniques would also help.

A consensus statement was requested by Dr Masoud Dara to ensure the correct instructions and information on how to proceed with BCG vaccination were reaching the correct people. In Finland, TB meningitis cases had been greatly reduced by scaling back BCG vaccine coverage (from 98%) to only risk groups; in United Kingdom (England), only neonates from high-risk groups and children moving to the country from high-TB burden countries had been vaccinated since 2005; and in Norway, adolescents aged 14–15 years had been vaccinated until 2009, then switched to neonatal vaccination only, plus additional risk groups. Some occupational risk groups also continued to be vaccinated, but this was turning out to be highly dependent on country of birth, rather than occupation per se, with more investigation required. In the Netherlands, vaccination of risk groups among children had been ongoing for over 15 years but with poor coverage. The most serious cases of paediatric TB were found to be among non-vaccinated risk groups. HCW vaccination had been stopped since 1985, with the very low number of cases indicating that the workforce were not a risk group in such a low-prevalence country. In the Russian Federation, on the other hand, paediatric TB deaths were most common among non-vaccinated children, so further consideration was needed before cancelling BCG vaccination in high-incidence countries.

Regarding occupational vaccination with BCG, a question was raised about vaccinating entire prison populations (which had been a previous protocol but would become difficult in light of the BCG vaccine shortage). It was explained that vaccinating adults was not necessarily effective, with mixed messages emanating from different countries and studies based on a variety of factors (including climate). Comparisons across countries were not guaranteed to be useful, given the wide range of country contexts.

Participants were reminded that the most recent official statement from WHO on BCG vaccination was from 2004, with an update due in 2016 on the basis of ongoing work with vaccine departments that were currently reviewing the literature for evidence to support or stop the recommendation to vaccinate. In the meantime, for prison populations, if no TB infection was detected, vaccination did not make sense; if a case arose in such a crowded setting, however, outbreak protocols should be set in motion and timely treatment administered as indicated. More generally, evidence must be built on a case-by-case basis and policy decisions should be country-specific and evidence-based.

To provide concrete feedback on the poster session, countries were requested to list three major challenges and associated actions to be pursued going forward. These were collected for analysis by the Regional Office and the three example countries presented theirs to participants.

Belarus noted that:

- contact case investigation needed to be strengthened;
- timely diagnosis of MDR- and XDR-TB was required;
- diagnostic testing (methods and coverage) needed to be expanded; and
- the focus should be switched to ambulatory care rather than always hospitalizing children with TB (to reduce the effect on children's education and social development).

For **Tajikistan**, the major challenges were:

- contact case investigation needed to be expanded to include orphan children, co-infection cases and others; and
- careful evaluation of cases was needed, not only during the intensive phase of treatment but in the continuation phase and even during follow-up.

Slovakia highlighted:

- active case-finding needed to be strengthened, working with families and finding the source of infection;
- prophylactic treatment was not always possible;
- training was based on outdated, basic TB knowledge (TB was expected to have been eliminated by the year 2000!); re-training was therefore now needed for GPs and paediatricians, focusing on differential diagnosis and bringing TB to the forefront of HCWs' minds; and
- a change in thinking was required regarding hospitalization – whether it was necessary, for whom (active TB patients or LTBI cases as well?) and for how long.

Dr Masoud Dara emphasized the need for more advocacy and called for input to work towards a more effective vaccine, for which regional collaboration would be needed. Resources would also need to be injected into R&D (as per a three-year grant approved for a regional proposal for health system strengthening for 11 countries). Disincentivization of ambulatory care needed to be tackled in particular to move away from inpatient care models, as did social support to paediatric TB patients.

Regarding prophylactic treatment regimens, Dr Dara requested specific feedback from countries on existing paediatric treatment schedules. In Finland, weekly prophylactic (isoniazid/rifapentine) combination regimens were working well in paediatric cases, but delays to continuation often occurred once treatment had started. In the Netherlands, prophylactic treatment drugs were not yet registered in many places and manufacturers were hesitant to

pursue wider registration without proof of economic or commercial value. This represented a significant issue to be taken up, as there was much to gain if these new possibilities for prophylactic paediatric TB treatment could be made more widely accessible.

Dr Dara suggested that smaller countries (with less demand) could work together, taking advantage of the option of pooled procurement (by means of a European Commission bilateral agreement) to reduce costs and encourage drug manufacturers to provide treatment regimens for low numbers of patients. WHO was only permitted to support such activities to a limited extent but could certainly help with how to present a reasoned argument to the pharmaceutical industry, **to try to facilitate procurement and supply.**

Summary of status (with focus on challenges) of childhood TB at country level

Dr Martin van den Boom

Dr van den Boom's presentation focused on good news (key achievements), challenges and ways forward. Achievements included increases in:

- the number of up-to-date paediatric TB national clinical and programmatic guidelines;
- the number of Member States with paediatric TB reflected in their national strategic plans; and
- the number of countries with childhood TB included in their GF CNs (formerly grant applications).

Challenges included:

- several aspects of diagnosis;
- lack of paediatric formulations (not featured on essential medicines lists (EMLs)) and fixed-dose combinations of drugs;
- lack of timely and adequate diagnosis and treatment, particularly in terms of active case-finding (quantity and methods), contact investigation and case management;
- lack of country-adapted prophylactic therapy guidelines and TB contact investigation (especially DR-TB patients);
- unnecessary hospitalization (especially for prophylactic treatment for LTBI) and lack of ambulatory care practices;
- revaccination practices (BCG) in adolescents and vaccine availability;
- lack of operational research capacity for new/more efficient vaccine (BCG replacement);
- lack of (or outdated) HCW knowledge and/or sustainable capacity (training alone was not enough);
- insufficient collaboration and communication between all sectoral elements and disciplines (lack of well defined strategies);
- lack of community involvement and paediatric TB-relevant advocacy, as well as lack of advocacy for finance reform for paediatric TB cases; and
- limited capitalization of external support (such as from GF) and activities often limited to contact investigation or pilot projects.

Going forward, participants were invited to consider translating the status quo into priorities for action and improvement, following the partners' presentations and the forthcoming update on WHO global childhood TB policy.

Discussion

There was some debate over whether child and adult TB services were integrated or separate in various countries, with the conclusion that a variety of approaches existed, including regional variations within individual countries, depending on the figures and the scope of the problem. This differentiation should be reflected in official guidelines to encourage countries to do what works, according to the country-specific context.

Update on new developments in diagnosis and treatment of childhood TB and global childhood TB perspective

Dr Malgorzata Grzemska

Dr Grzemska presented a global update on WHO recommendations. Rather than repeating the detailed epidemiological data already conveyed, she referred participants to the global TB report.⁸ She outlined the global TB burden (as at 2014) and highlighted the need to understand whether the estimated HIV co-infection deaths were also reported as part of global HIV programmes (double reporting). Other points included the fact that from a global public health perspective, MDR-TB was a massive burden in five key countries and no WHO estimates were available for the burden of MDR-TB in children (although prevalence was likely to reflect that of the adult community). The crucial paediatric TB figure to consider was that 10.5% of all TB cases were among children (although this was realistically only the European Region figure, not global), amounting to 140 000 deaths. Child TB regional estimates had emerged in 2014 for the first time, and country estimates were expected during 2016.

Good news included increased reporting of paediatric TB (although some countries, including Turkmenistan, were still not reporting at all), with estimates now in line with surveillance. Dr Grzemska reminded participants that the clinical challenges were diagnostic in nature (especially with young children) and that WHO guidance existed to help countries analyse all available factors using rapid diagnostic testing (recent meta-analysis supported its use). She emphasized that a negative GeneXpert test does not exclude TB (with sensitivity only around 60% and high specificity, albeit 40% more sensitive than smear microscopy) and that clinical assumptions were more reliable with more parameters. WHO recommendations in this area were usually conditional given the low quality of evidence, which was understandable as children rarely took part in clinical trials. GeneXpert MTB/RIF was strongly recommended (albeit with low quality of evidence) for suspected HIV-associated or MDR-TB paediatric cases and as the initial diagnostic test for TB (including extrapulmonary) (this was a conditional recommendation, acknowledging the resource implications of doing so).

WHO had issued interim guidance on paediatric dosing of FLDs in 2010 (updated/reiterated in 2014). Four specified drugs were recommended for treatment and adult dosages and preparations could be used to treat paediatric TB in patients with bodyweight of 25 kg and over.

Dr Grzemska reiterated the treatment situation today, with the following key factors to be considered:

- there was a lack of appropriately dosed, quality-assured, child-friendly TB medicines;
- many providers were required to crush or cut drugs, or create syrups, to achieve the desired dosages;
- many challenges existed in administering drugs to children (not least the above factors, among others), with much scope for error, leading to decreased treatment adherence;
- there was no unified response to the problem of administering TB treatment to children; and

⁸ Available at the WHO website: http://www.who.int/tb/publications/global_report/en/.

- dispersible tablets with simplified administration routes were to be made available on the market during 2016 (improved formulations for first-line treatment, not new drugs), offering the opportunity to improve paediatric treatment (including prophylactic therapy).

Dr Grzemska provided details of the new WHO-approved formulations (dissolvable, palatable, correct doses), including the numbers of tablets needed according to the patient's weight and treatment phase, highlighting that the new formulations would involve fewer weight bands and fewer pills. The pathway to availability of these new formulations would be difficult, however, as countries would need to adopt updated WHO guidance on paediatric TB management. WHO prequalification and registration on the WHO EML alone would not be enough: advice would be available from WHO to help countries with local registration where necessary and to guide inclusion on national EMLs. Application through the Global Drug Facility (GDF) would be possible for some countries, but not all; provision for legal use of the drugs would need to be included in national budgets and procurement plans.

Various tools, guidelines and platforms were available to assist countries and individuals working in the field of paediatric TB (namely, the *Roadmap for childhood TB: toward zero deaths*, the *Guidance for national tuberculosis programmes on the management of tuberculosis in children*; the *Childhood TB training kit* and the KNCV Tuberculosis Foundation tool for self-assessment *Benchmarking childhood TB*).⁹ Ongoing WHO activities included programme reviews (with participation of childhood TB experts), regional workshops, consultations and training events (with a high level of commitment from all regions), and work towards regional action plans and frameworks.

In conclusion, awareness of and commitment to paediatric TB had been increased in the Region and paediatric TB was high on the Regional Office agenda. The standardized tools needed to be used (adapted and translated), including national guidelines and training materials, to modernize the approach to childhood TB; specifically, to improve the link between HCWs working in paediatric TB settings and to base practice on evidence, not tradition. Areas for improvement had been identified and acknowledged, and now it would be necessary to act on recommendations and consensus reached at regional workshops and meetings (such as the present consultation). Additional technical assistance to countries and NTPs was also available from WHO.

Discussion

The need for European legislation if paediatric drug formulations were to enter the market was raised. Manufacturers would not be easily convinced, given the low numbers of patients in certain settings (in cases of underdetection, for example, or low-incidence countries). Direct procurement (not grant-funded) through the GDF was one option, but was not available to all countries. WHO could help with the pathway to registration, discussing the steps required after WHO prequalification. For small countries, European approval would be enough (non-registered procurement for small quantities), but it was agreed that the standard regulatory process would probably not be of interest to most manufacturers, who wanted large-scale orders of drugs.

Discussion ensued regarding the point at which dosing should be switched from paediatric to adult (age or weight?). It was explained that expert opinion and consensus showed that dosing by weight is considered the norm, so switching to age would add confusion. However, deciding the weight brackets was difficult, given various country-specific trends and settings (such as

⁹ Tools available at WHO, The Union and KNCV websites: <http://www.who.int/tb/publications/en/>;
https://childhoodtb.theunion.org/info/additional_resources?locale=en;
https://www.kncvbc.org/uploaded/2015/09/session_7_pres_4_gebhard_benchmarking_childhood_tb_eng1.pdf.

malnourishment in Africa and India), so an age–weight crossover had been used to define the 25 kg point at which to switch to adult dosing, based on toxicity risk calculations (such that they were possible in children). As studies emerged, the recommendation could change.

A known problem was that paediatric formulations of drugs were not consistent with the new dosing and the only incentive to use these new formulations of first-line drugs was therefore their dispersible nature (as their shelf-life was still likely to be very short). It was not yet known what the shelf-life would be, but it was hoped that by the end of 2016 it could reach three years (increased from the current two years). In addition, pooled regional procurement could be useful – a mechanism available in the United States of America but not yet in Europe (although possibilities existed through the European Commission, whereby Belgium, Luxembourg and the Netherlands were already in discussion with the pharmaceutical industry).

Participants were reminded that in Annex 5 of the 2014 WHO guidance, an interim approach was presented on how to achieve the desirable paediatric doses using the current formulations, and the new formulations should be available from 2016 (they are already available in the GDF catalogue, without prices, which were currently under negotiation). An expert panel was in the process of updating guidelines on the treatment of DR-TB, including in paediatric care (SLDs, including fluoroquinolones), which would become available in March 2016. It would then be the responsibility of each country’s national authorities to implement them (with technical assistance). WHO had no influence over national recommendations but their own recommendations were based on the most recent evidence, so it was hoped they would be adopted into the national context.

It was expressed that countries are grateful to WHO for recommendations on optimum doses and guidelines to follow, not least because it allowed changes to be brought about in the pharmaceutical industry, leading to improved paediatric TB care.

Dr Masoud Dara wrapped up the first day of the consultation, stating that the key message was that interaction was greatly needed and actions to be taken forward must be extracted from the lists of challenges established so far.

Summary of day 1

Many challenges were identified to be explored in greater depth in working groups on Day 2 of the consultation, including:

- diagnosis (difficulties in paediatric diagnosis, plus other hindering factors);
- active case-finding and contact tracing (to varying degrees);
- co-infection (HIV);
- MDR/XDR-TB diagnosis methods and amount/scope of testing;
- lack of paediatric formulations of drugs (and discrepancy with the current recommendations);
- BCG continuation/revaccination (issues vary by country context);
- transition from hospitalization to ambulatory care (difficult);
- training of HCWs (update/retrain to focus on current TB context);
- scarcity of prophylactic treatment in the Region (lack of guidelines and associated regulations, in particular for MDR-TB in children);
- communication and collaboration between disciplines and across sectors; and
- lack of advocacy (childhood TB and community involvement, and financial).

Key actions are also needed going forward:

- evidence was needed to form the basis of WHO recommendations and guidance;
- countries needed to dare to explore new ideas, to move forward and to make progress; and
- to this end, research would be supported by WHO wherever possible – strongly encouraging countries to work with all possible partners, to (a) build evidence to feed into policy and recommendations and (b) work towards an effective vaccine.

Specifics highlighted were as follows.

- MDR-TB in children – evidence was needed to enable prophylactic treatment of childhood TB. New guidelines were in the pipeline but a rigorous approval process was ongoing (an update is expected in March 2016).
- New drugs were soon to be available (GDF would be one channel but would not be suitable for all countries). Pooled procurement could be a possibility (the European Commission initiative/framework agreement to enable procurement for smaller countries/smaller demand, whereby pharmaceutical companies would otherwise not be interested). WHO would support this as far as possible, within its legal framework.
- Barriers to understanding the situation in high-burden countries (eastern-most countries of WHO/Europe) needed to be broken down to facilitate progress. Regional collaboration was also needed.
- Considerations for childhood TB diagnosis and treatment must always be country-specific, based on in-country experience and evidence (it is difficult to compare across the Region with so many different contexts to consider).

Friday 13 November 2015

Brief overview of contributions from the European working/task force group on childhood TB

Dr Martin van den Boom

Dr van den Boom presented a snapshot of the key elements of the working group, including its hosting by the WHO Regional Office for Europe Secretariat (JTH Programme) and partner organizations, explaining that the group's composition was synergistic (comprising core and some more flexible members) but had been very active and committed in recent years. Virtual conferences and meetings were convened (to reduce costs and facilitate logistics) – under Dr Masoud Dara's leadership for the TB-related element – to discuss events and possible novelties in the childhood TB arena. Dr van den Boom extended the invitation to all participants who might wish to become members of the group, in accordance with the requisite WHO mandates.

Key scientific contributions of the group included: peer-reviewed journal publications; global meta-analysis of paediatric MDR-TB treatment outcomes (ongoing in South Africa); and two surveys aiming to improve understanding of the regional childhood TB situation (2012/2013 and 2014/2015), specifically in terms of policy and practices in HPCs of the Region. Findings were positive, with most countries having well defined national strategic plans and specific paediatric TB targets with which to move forward. Hospitalization rates of paediatric TB patients needed further improvement, along with school attendance and social support levels. Key programmatic contributions of the group included technical assistance and advocacy support, helping to increase the number of updated national clinical and programmatic childhood TB guidelines in the Region, Member States with childhood TB included in their GF CNs (under the new funding model (NFM)), and Member States with childhood TB reflected in their national strategic plans.

The group was also helping to improve understanding, coordination and updating of policy and practice implementation at country level, driving paediatric TB-relevant advocacy and awareness-raising to continue to translate improved knowledge into better results.

Discussion

It was acknowledged that the group had been looking forward to the present consultation to direct its activities in appropriate directions. The surveys described in the presentation had given a good picture of country-specific contexts and a survey on adolescent TB in particular was under development. Participants were further encouraged not to hesitate to become members of the group and to participate; the report from the consultation would be used to identify areas for future work.

Use of tools for country assessments: benchmarking tool

Dr Connie Erkens, Senior TB Consultant, KNCV Tuberculosis Foundation

Dr Erkens described the purpose and functioning of the KNCV benchmarking self-assessment tool, explaining that the audience at the consultation were important stakeholders in childhood TB. Broadly, the aim was to strengthen technical assistance to countries with a tool that could be used to guide self-assessment of their situation. One key purpose of the tool was to visualize progress in the implementation of childhood TB policies towards alignment with all WHO TB-related guidelines, within the framework of an NTP.

WHO's *Framework for conducting reviews of tuberculosis programmes*¹⁰ was a compilation of documents, guidelines and standards representing a comprehensive overview compiled from world expert opinion on how to address paediatric TB properly. It was used as a basis for the KNCV benchmarking tool, which was in turn intended to serve as a basis for discussions, brainstorming and joint planning with stakeholders. Use of the tool provided insight into (among other issues): political commitment, management and partner coordination; technical approaches to childhood TB and its place in national policy; access to childhood TB care; and status of implementation of the NTP. It would help to define objectives and next steps, as well as the main actors for taking those steps, and the intended users were representatives of the ministry of health, NTPs, paediatricians, mother and child health services, NGOs working in childhood health settings and paediatric health experts working in the TB field.

Dr Erkens talked the participants through the process, describing the two versions of the tool (a static, Microsoft Word version and an Excel version that was more in-depth, but also a working tool under constant development) and the two-part structure of each version (a summary of routine surveillance data followed by standards and benchmarks aligned with WHO policies). She demonstrated the functioning of the tool with two example standards as indicators, explaining that the tool (albeit not the latest version) had been translated into Russian and that it would be made available to attendees after the meeting. Inclusion of, and discussion with, as many stakeholders as possible was essential to obtain the best results. With enough input and criteria, the tool would identify standards met, shortfalls and priorities, which could be useful in a broad variety of environments. Dr Erkens strongly encouraged participants to translate and use the tool – it was intended for dissemination and the KNCV was keen to receive feedback from users on experiences and ideas on how to improve the tool.

Discussion

¹⁰ Available at the WHO website: <http://www.who.int/tb/publications/framework-tb-programme-reviews/en/>.

It was clarified that the most beneficial individuals to lead such diagnostic efforts at country level would be likely to be actors within the NTPs, but other stakeholders involved in the childhood TB arena might also find it useful as a process (not just the results). KNCV believed the tool should be as useful as possible to as wide an audience as possible, and it was being adjusted and updated continuously on the basis of feedback from a questionnaire included with the tool (hence the existence of multiple versions and updates). Implementation in individual country settings would mean adjusting it to country-specific parameters (including, crucially, translation for use by all stakeholders), but the benchmarks included were based entirely on WHO standards, so countries should ideally find them to be relevant and therefore not stray too far from the template.

It was reported that Brazil was currently translating the tool into Portuguese for wider use, having found it to be very useful, particularly in terms of its link to Challenge TB and annual planning cycles for funding. This was an example of how the results from the tool could be translated into direct funding possibilities.

Ultimately, the most up-to-date version of the tool would become available on the KNCV website. In the meantime, it could be shared with colleagues after the consultation.

Overview of UNICEF projects in the WHO European Region with linkages to TB prevention and care

Dr Ruslan Malyuta, United Nations Children's Fund (UNICEF) Regional Office for countries of central and eastern Europe or the Commonwealth of Independent States (CEE/CIS)

Dr Malyuta described UNICEF's involvement in supplying anti-TB drugs to many countries, albeit not all 53 Member States of the Region (predominantly countries of the former Soviet republics and central Asian republics (CARs)). From a global viewpoint, TB among children was not the largest problem; many more children died each year from other diseases. That said, TB prevalence in children was high and the systems in place across the Region were not sufficient to tackle the problem. It was hoped that cooperation between WHO and country partners could lead to pilot projects to establish optimal care provision systems, including TB management at programme level (with a policy and system focus). Within the framework of a global agreement between WHO and UNICEF to widen the scope of work on TB in the field, new opportunities had opened up for the Region. Energies were focused on tackling the recent increase in MDR-TB in the former Soviet countries and CARs (including in children) and the UNICEF Regional Office in Geneva was also working with HIV co-infection cases and mother-child transmission.

Training was being carried out, including among paediatric specialists, and tertiary care provided for children with HIV/TB co-infection. Awareness also needed to be raised in PHC settings (as well as with specialists) to increase early detection and timely referral of children. WHO and UNICEF had produced the integrated management of childhood illness (IMCI) strategy¹¹ to improve TB detection and case management. However, increased focus on prevention was nevertheless required. An online course on paediatric TB for HCWs was now also available,¹² implemented and managed by The Union (with plans to translate into Russian for use by doctors in Russian-speaking countries).

¹¹ Available at the WHO website: http://www.who.int/maternal_child_adolescent/topics/child/imci/en/.

¹² Available at The Union website: <http://www.theunion.org/news-centre/news/child-tb-course>.

A further possibility could be to pilot test the online course on the ground, making it available to PHC workers, providing training and the relevant algorithms to allow paediatricians and GPs in remote areas to access it.

To further centralize activities, in conjunction with NTPs and WHO, UNICEF aimed to be more actively involved in country-specific TB management plans in the coming year. Issues for further attention included rights protection, education and health care provision. UNICEF representatives in individual countries were able to work autonomously in the field, but to benefit from this, it was essential for national partners to communicate directly, prioritize issues and guiding UNICEF on where help was most needed in each setting.

Discussion

Participants shared experiences of working with UNICEF, describing evaluations or projects that had been carried out and their direct results in terms of patient outcomes and improvements, as well as reduced mortality rates. Child-friendly clinics, rapid-testing scenarios, specific programmes and/or health protection strategies for children and adolescents, and involvement of multidisciplinary expert analysis (enabled by UNICEF) were cited as examples. It was highlighted that communication and collaboration were the key to success, with countries, national and international partners and NGOs working together to support the projects.

Overview of MSF childhood-related projects and key challenges and progress

Dr Jay Achar, MSF

Dr Achar described MSF's paediatric TB activities with countries in the Region, focusing on ongoing challenges, progress made and areas for attention going forward. He explained that MSF worked with TB programmes in eight countries throughout the eastern part of the Region, with a focus on DR-TB in particular, and on paediatric TB specifically in Armenia, the Russian Federation, Tajikistan and Uzbekistan. Support varied from operational research (in some countries as part of larger projects or programmes) to clinical case management, helping to implement comprehensive paediatric TB programmes, strengthening diagnostic capacities (introducing sputum induction for TB diagnosis in children in some countries) and introducing new and repurposed anti-TB drugs.

Challenges faced included lack of understanding of the extent of TB incidence, particularly paediatric TB, since it was known to be underdetected, with a potential large proportion of children remaining untreated as a result. Better estimates of the international disease burden were needed. Active case-finding was labour-intensive and required additional resources, and high levels of stigma in countries was also a significant barrier. Access to paediatric diagnostic services was a problem in some countries, coupled with treatment gaps. Countries relied heavily on positive diagnostic tests; TB was notoriously difficult to diagnose in young children but should be easier in those aged 5–14 years. Dr Achar nevertheless emphasized that children were simply not being diagnosed and that it was important to work to understand why.

Some countries were focusing on age-specific psychosocial and family support for children with TB, but resources were limited. Harm due to treatment also required attention, not only in terms of monitoring for toxicity, but also changing approaches to continuing children's education during treatment and a turning the focus away from hospitalization. Access to new DR-TB drugs was limited, with underfunding of drug development, and new fixed-dose combinations and paediatric formulations of anti-TB drugs were not yet available. In terms of research and development, the focus needed to change from adult to paediatric TB (children had been

excluded from research for a long time) and evidence-based dosing guidelines for SLDs needed to be implemented.

Going forward, it was important to continue to focus on finding and diagnosing paediatric TB cases by all possible means (sputum induction, gastric lavage, fine needle aspiration, GeneXpert, liquid-based culture, DST, etc.). Clinical guidelines needed to be improved and paediatric and TB doctors (re-)trained. MSF was advocating for access to new drugs (Bdq, linezolid (Lzd), clofazimine (Cfz)) and for child-friendly formulations and compounds of anti-TB drugs to be made safely available.

Discussion

It was confirmed that no specific MSF programmes were in place for paediatric TB in prisons in the Region; the penitentiary arena was usually the responsibility of individual NTPs.

Dr Achar provided further details on the composition of the ongoing MSF work in Armenia: an incidence and prevalence study of 160–170 children in close contact with DR-TB, including a two-year follow-up period but no prophylactic element, and with genotyping carried out for any positive cases found. He also clarified the MSF training of HCWs mentioned in his presentation, describing the combination of training types employed by MSF. One type was 2–3 day symposia, targeting doctors that treat children with TB, organized within a project to focus on a specific problem or issue at hand (such as how to improve diagnosis rates) and involving discussions, dissemination of information and updates. MSF also provided on-the-job training for nurses, laboratory specialists and other HCWs, which comprised more specific and targeted sessions.

Dr Achar clarified that each country had a different process to procure new drugs for paediatric TB treatment, depending on the specific importation regulations, guidelines, laws and other factors involved. For example, in the Russian Federation, the drugs were licensed and available on the market, while in other countries, compassionate use programmes (CUPs) were the only option at present. CUPs provided access to the drugs where otherwise it would not be possible; MSF sat on CUP committees to gain and share insight into the use of the new drugs and their induction in various countries.

Dr Masoud Dara requested a detailed overview of MSF's operational research activities in the WHO European Region to be communicated to the consultation participants.

Given the fact that Bdq and delamanid (Dlm) were not approved for use in children, when countries wished to act outside of the guidelines to treat paediatric DR-TB using these drugs, it was important to collaborate with the individual NTP to agree on the risks and benefits of doing so. Certainly lines were blurred from an ethical viewpoint between operational research and the need to treat sick children, and this caused problems for clinical trials (which rarely involved children), so the evidence base to refer to was very limited.

Similarly, the decision by some countries to focus on contact-tracing (or not to do so) – and whether this should be followed by prophylactic treatment (IPT) or not – depended entirely on the country context. Experience in the east of the Region showed that IPT coverage was in fact very good where the contact-tracing identified a need for treatment. The key area of focus at present (globally) was DR-TB in children and whether those (exposed) children should be provided with prophylactic treatment (studies were ongoing to this effect).

Childhood TB, GF perspective

Dr Anna Scardigli, TB advisor for the GF

Presenting virtually, Dr Scardigli explained that in the last year, many countries had undergone the process of developing CNs according to the NFM, based on their national strategic plans, engaging partners and various implementing agencies within their country contexts. A CN was an in-depth analysis of the current country situation, providing a description of the landscape and a detailed funding request based on the country's needs for TB care. There had been eight so-called windows for CN submission so far under the NFM (amounting to US\$ 12 billion in funding allocated) and another window was expected in early 2016.

Dr Scardigli demonstrated various TB-specific CN modules and their related paediatric interventions, including in areas such as case detection, active case-finding, diagnosis, treatment (paediatric formulations), preventive therapy (contact evaluation, IPT) and coordination with other services/programmes/sectors (reproductive, maternal, newborn and child health (RMNCH)). She explained that the GF was in the process of reviewing these modules and, while only limited changes would be made (to allow continuity in comparing the current funding cycle to the next one), paediatric TB needed to be positioned carefully within the process and the system needed to be improved. She therefore welcomed any suggestions by participants to review and improve the system or the specific modules.

In terms of technical lessons learned, Dr Scardigli explained that certain elements were often included (and others often lacking) from countries' submitted CNs:

- children and women were almost always reported as vulnerable population groups, but very few interventions expressly addressed them (limited data/no in-depth information provided);
- contact-tracing was often mentioned as a key intervention, but without a key strategy as to how to operationalize or strengthen related activities;
- diagnosis improvement was usually cited as a focus for activities, but diagnostic algorithms were needed to support specific interventions;
- very few CNs mentioned antenatal care services as an opportunity to expand TB screening for women and children;
- interventions for children were often proposed as pilot activities or operational research, but without a nationwide strategy to support them;
- most CNs contained targets that could be far more ambitious and should focus more on the paediatric setting, with greater health system strengthening or RMNCH stakeholder involvement; and
- budget requirements were rarely specific or detailed enough, and the division of paediatric versus adult activities in budgeting needed to be clearer.

Dr Scardigli discussed how to protect mothers and children, indicating that service integration was the key to enabling interventions for HIV/AIDS, TB and malaria and to improve outcomes, with better health leading to more wealth. Investing in children (and mothers) also meant investing in the country's economy and future, and antenatal care could be a gateway to improving TB care (and health care in other areas) as it was already an access point to the health system for many women who would otherwise not be in contact with health care providers. This made it an ideal point to introduce preventive care, ultimately influencing TB care outcomes.

The NFM aimed to help countries in their fight against TB by designing programmes to maximize the impact of interventions on mothers and children, with a multi-step process to achieve the aims: involving RMNCH stakeholders in the country dialogue, including RMNCH in situational and gap analyses, and prioritizing RMNCH in CNs (using the module template, but also through health system strengthening investment to improve effective delivery of health services). Good practices should be documented and operational research carried out, strengthening the evidence base and informing countries on how best to address maternal and child TB. Technical assistance from partners could also be required to identify needs and help with cost-effective interventions.

Dr Scardigli outlined some innovative partnerships under way for investing in RMNCH, including memoranda of understanding (MoU) with UNICEF and the United Nations Population Fund (UNFPA) in 2014 and collaboration with the World Bank. She emphasized that it was important to: maximize the impact of investment to improve mother and child health; accelerate efforts to achieve the MDGs; and end deaths from TB in children, as an integral part of the global TB control strategy.

Key messages for participants and all countries seeking GF support included advice to:

- plan ahead (not only in TB terms but for all communicable diseases);
- ensure CNs were directly related to the country's national strategic plan – it was important to develop the plan first, for a greater chance of the application being successful;
- ensure epidemiological data on the key affected populations (especially children and adolescents) were robust;
- analyse the situation, identify gaps and needs in reporting and documenting data, as well as lessons learnt (reflecting strategic plans);
- think creatively about opportunities to address paediatric TB within the country context as well as considering potential health system entry points for TB (and HIV) detection and care for children;
- be ambitious, aiming for additional funding (available above the indicative funding allocated per country);
- ensure targets specifically for children were defined;
- seek out strong implementers to contribute to better grant performance; and
- identify areas where technical assistance would be required.

Discussion

The role of fathers (compared to mothers) in the spread of TB was discussed. While mothers were seen as the key to care, TB prevalence was higher among men than women, and fathers appeared to be just as likely to infect young children as mothers. It was concluded that countries were encouraged to analyse differences in approaches to care between genders and that most countries considered the adult male population to be adequately addressed (albeit not specifically), while women continued to be considered a vulnerable group, without the same access across the board to prevention and care interventions. While many services were widely available (in theory women had equal access to men), not enough evidence was available to support this. It was noted, however, that it could be worth exploring the role of fathers, specifically, as a route of TB transmission to children. Gender was a politically interesting and important issue and gender-sensitive approaches were required, including for men, depending on the context. In Georgia, for example, female gender had been found to be an independent risk factor for new MDR-TB cases, as they were often palliative caregivers to TB patients (usually

men or children) and were therefore vulnerable to new DR-TB infection. A separate model of care was therefore needed – in terms of DOT – for female caregivers to babies and infants as many women were unable to manage breastfeeding and adhere to TB drug regimens. From the KNCV viewpoint, this kind of feedback was very useful to assess interventions and direct approaches to including paediatric TB in the NFM assessment system.

Thirteen of the 29 countries represented at the consultation were eligible for GF support. Almost all countries included childhood TB in their funding model proposals, but the GF would like to hear opinions on how to improve inclusion of paediatric TB in CNs. Some countries had attended a meeting about the process and the GF was in the process of reviewing the intervention models but feedback was required on how to better position paediatric TB in the models. It was noted that the KNCV self-assessment tool could help with this (to be made available after the consultation).

Introduction to group work: scaling-up childhood TB

Dr Martin van den Boom

Dr van den Boom outlined the format for the group work and the fact that it would take into account the presentations and discussions around the posters. The country representatives were divided into four groups (two English-speaking and two Russian-speaking) to work with a template for collating their discussion and feeding back to the wider group.¹³

Each country was independently to identify its own three key priorities to enable the country to move forward in the paediatric TB context in the coming year. These lists which would be collected at the end of the session and analysed by the GTB. For the group work element, each group was to feed back their three *collective* SMART (specific, measurable, achievable, realistic and time-bound) priorities and goals for paediatric TB, focusing on how they could be addressed, by whom, and when. They were also to assess what support they would need to address the priorities and any gaps that might exist.

Group work session 1 focused on current in-country policy and national strategic plans (focusing on key challenges and the extent to which childhood TB is covered). **Session 2** was based on session 1 and looked at how to move from current policy to better care for children (through, for example, country adaptation of global policy and regional plans, improving hospitalization practices, fixed-dose combination drugs, legislation and contributions of relevant partners).

Reporting back from group work: four groups

Group 1

Dr Stefansson Thors explained that most countries in the group had had very low or zero paediatric TB incidence in the current year and that TB was a notifiable disease in all the countries. Many common aspects had been identified across the group, among which the following areas required action:

- contact investigation (especially for MDR-TB) and LTBI to prevent future cases;
- introduction of new diagnostic tools (for bacteriological confirmation, specifically taking into account the complex logistics of diagnosing TB in young children);
- HR and capacity-building;

¹³ The group work template/instructions can be found in Annex 4.

- lack of BCG vaccine availability;
- lack of child-friendly (easy-to-administer/palatable) drug formulations;
- treatment follow-up and completion (including for pulmonary TB and LTBI); and
- lack of (access to) services for key populations, including migrants and itinerant populations.

Priority 1. HR and capacity-building

How?

An intersectoral approach was needed, for example by setting up a national TB committee, with actors coming together to ensure a unified response and approach to paediatric TB. Priority resource-mapping would also be important to clearly identify and define needs for managing TB and treating sick children. Governments would need to be approached for assistance (including financial help).

Who?

Government input would be needed, alongside a national body of professional societies, paediatricians and other HCWs, actors from other sectors (including education), professional development representatives, infectious diseases colleagues, and so on. In low-burden countries, TB was becoming a so-called forgotten disease, as active cases were rare. The approach to TB therefore needed updating, to become an integral part of health care education; clinicians needed to be encouraged/reminded to “think TB”, including community health workers.

When?

This needed to begin as soon as possible and continuous evaluation would be required, differentiated according to the respective institutions involved.

Support required and/or gaps identified?

Technical guidance would be required in the form of a policy framework (documents from WHO) and in terms of logistics (should the required infrastructure not yet exist, it would need to be built). Infectious diseases societies in countries should also be involved and SMART requests for help should be submitted to governments and relevant bodies.

Priority 2. Access to BCG vaccination, child-friendly TB drug formulations, and diagnostic capacity

How?

Intercountry dialogue would be required, along with analysis of existing national procurement mechanisms, specifically to consider a pooling mechanism. Supply of the BCG vaccine in particular was decreasing while demand increased; policies and procedures therefore needed to be reviewed (in terms of revaccination), along with diagnosis and treatment guidelines to assess whether efficiency gains could be achieved.

New diagnostic procedures needed to be introduced but analysis of national and other countries' situations would also be required to inform the process. WHO prequalification could be useful to increase pressure for uptake of new approaches/measures.

Who?

These approaches would need to be government-funded but could be facilitated by international partners, and collaboration between various groups of countries could also be helpful.

When?

It was necessary to start immediately, with regular re-evaluation intervals to assess how to improve.

Support required and/or gaps identified?

International leverage was needed (from WHO or international infectious diseases societies, UNICEF, and so on) to help to support arguments for change and development.

Priority 3. Contact investigation and LTBI focus

How?

Better defined and ambitious policies were needed, especially in the MDR-TB context, with clear criteria regarding who to treat and how (increasing the focus on LTBI). Ensuring treatment adherence and completion would require: monitoring, consideration of HR capacity for home visits, increasing the focus on ambulatory care (linking back to Priority 1) and assessing treatment adherence failures to aid improvement.

Who?

HCWs actually treating patients were to be the focus, including paediatricians and pulmonologists. An increased workforce, including community nurses, would also be needed.

When?

This work should be started as soon as possible and assessed continuously.

Support required and/or gaps identified?

Technical and financial assistance would be needed from governments, financial bodies and, in some countries, from the GF.

Group 2

Dr Thomas presented the three most common priorities identified through a roundtable exercise, using one country as an example, but in each case she first listed other points that had been captured within the various countries' "top three" to ensure full disclosure of the range of priorities identified.

Priority 1. Increase and improve contact tracing (except for one country)

Other priorities mentioned were: case management care models, hospitalization, strengthening HR and LTBI screening (particularly of migrant children and especially in low-incidence countries).

How?

Specifically, the priority was to establish a formal system of comprehensive contact-tracing, with in-country protocols and legislation to mandate it. In Latvia (the country used as an example), HR capacity would also need to be improved to achieve this and to enable routine home visits to identify children who would otherwise be neglected. Linkages would need to be strengthened between clinical care and public health, and formal guidelines were required on how to deal with parents who failed to bring their children for screening. A comprehensive database should be developed to record and monitor/analyse results. This should be a formal public health responsibility, not just the job of pneumonologists.

Who?

Epidemiologists and public health specialists should work on establishing this new approach, in collaboration with pneumonologists working in paediatric TB.

When?

The system should be achievable within a year (by the end of 2016).

Support required and/or gaps identified?

Government support would be required from, for example, the Ministry of Health.

Priority 2. LTBI

Other priorities mentioned were: strengthening HR, BCG vaccination, rapid diagnosis and specialist consultation mechanisms/consiliums.

How?

Specifically, the priority was to define how to treat LTBI in paediatric DR-TB contact cases. Systematic screening of migrant children also needed to be established (especially in low-incidence countries). In Estonia (the example country), clear guidelines needed to be developed on the management of paediatric DR-TB contact cases. Expert consensus and evidence synthesis would be required to improve the evidence base.

Who?

The National Institute for Human Development was identified to take this forward.

When?

The aim was to achieve these priority actions by the end of 2016.

Support required and/or gaps identified?

Support would be required from the ECDC, the Regional Office and the KNCV TB Foundation.

Priority 3. Paediatric formulations of anti-TB drugs

Other priorities mentioned were: BCG (re-)vaccination, treatment issues, access to new diagnostic tools and contact-tracing.

How?

Specifically, approval mechanisms were needed for registering paediatric formulations of anti-TB drugs: the availability of such formulations was problematic and paediatric drugs for MDR/XDR-TB were also lacking. In Georgia (the example country), GF support was needed (and already underway) to obtain paediatric formulations, including of new SLDs for DR-TB (Bdq/Dlm). More emphasis should to be assigned to this in the international community, representing leverage (through creative ways to push the issue on the international agenda) and aiming to lead to recognition within the community that appropriate formulations were needed. Regulations on “orphan diseases” or “extremely dangerous pathogens” and age-discrimination legislation also required attention.

Who?

WHO regions and individual Member States needed to be involved in submitting country requests and working on CNs (where application to the GF was possible).

When?

Yesterday!

Support required and/or gaps identified?

WHO, including the Regional Office for Europe, Member States and the European Parliament should all be involved. This was a significant issue given the high paediatric MDR-TB incidence in several countries of the WHO European Region. A further cross-cutting priority identified throughout Group 2's work was the need to improve HR and build capacity to achieve any of the priorities mentioned. Health-system HR planning needed to be strengthened; training (both in terms of basic curricula and specific, targeted training for key HCWs) needed to be increased and sustained ("embedded"); competences needed to be included in job descriptions; and motivated staff needed to be recruited and trained.

Group 3

Priority 1. Revision of paediatric TB control programmes and development of implementation plans

A working group should be established by 1 June 2016 to bring together stakeholders to analyse/review paediatric TB control activities and begin an implementation plan, aiming to increase the timely detection of TB in children and improve treatment (and therefore outcomes). NTPs and as many stakeholders as possible from across various sectors should be involved in the process, which would require technical support from WHO (particularly in terms of the implementation plan), along with the necessary financial planning and allocation from various sources.

Priority 2. Organization of paediatric TB prevention, diagnosis and treatment, including hospitalization practices and recording and reporting activities

The following activities should be carried out.

- Risk groups should be reviewed to improve performance.
- Prevention efforts should be increased. Intersectoral collaboration should aim to improve PHC and social support in particular, with functional responsibilities developed and activities monitored.
- Access to timely health care should be improved by introducing rapid diagnostic methods (including for MDR/XDR-TB).
- Available evidence on length of hospitalization should be reviewed, and outpatient pilot tests carried out to assess comfort and conditions for the provision of proper medical care in ambulatory environments. Outpatient care should be expanded to allow for this change in approach.
- Access to new drugs for paediatric TB and approaches to vaccination should be improved (and revaccination cancelled), after assessment and review of norms regulations.
- Simplified processes should be implemented for the introduction of paediatric formulations of new drugs (which should in turn improve access), including monitoring of their administration.
- Current models of recording and reporting should be assessed for development/improvement.
- Advocacy activities should be carried out (including engaging former students) and children's rights should be taken into consideration.

Concerted effort would be required from all stakeholders involved, and most of these activities were planned to take place during 2016. Technical assistance would be required from WHO, MSF and UNICEF, with financing from governments and the United States Agency for International Development (USAID) where possible. For social support in particular, ministries of labour or social protection could help, along with involvement of other departments as

necessary. Gaps identified included lack of M&E mechanisms and know-how, as well as the need for financial help to achieve all priorities identified.

Priority 3. HR development

PHC (including social support workers) training programmes for HCWs should be reviewed and updated (using interactive approaches) to improve paediatric TB diagnosis and treatment. Parents should also be trained. HCW motivation needed to be increased, involving students in research.

Technical assistance would be required from WHO, along with financial planning and support to expand HR capacities and improve paediatric TB outcomes.

Group 4

Priority 1. Increase work with sensitive and resistant forms of paediatric TB (including DR-TB contact cases), build capacity and strengthen TB services (including in social support, PHC and HIV services, etc.) through increased intersectoral collaboration

Specifically, the following points should be considered.

- A working group should be created, involving wide participation by many institutions and NGOs across a variety of sectors (including social services), by 1 July 2016.
- Regulations and training approaches should be revised (with regular courses organized using interactive methods and incentives to attend), by the end of 2016.
- The distribution of functions between the different services provided should be analysed and adjusted as necessary, specifically to include performance monitoring (using IT systems and connectivity to full advantage).
- Ministries should be involved in establishing coordination mechanisms across systems and sectors.
- Most countries would need help from WHO and NGOs, particularly to tackle the lack of implementation plans and M&E activities that had been identified, as well as financial support for most activities.

Priority 2. Assess criteria for paediatric TB hospital admission and increase ambulatory treatment (strongly linked with HR capacity-building)

- A review should be conducted of existing models of funding paediatric TB treatment (planned for March 2016).
- Existing entry criteria should be reviewed at international level (March 2016).
- A pilot scheme should be prepared and conducted at regional level with 6–9-month and 12–24-month implementation periods (including prior training of nurses and parents).
- HCW motivation should be increased; one approach could be to involve the workforce in research.
- Good practices and experiences could be shared among countries to inspire approaches.
- Most countries would need help from WHO and NGOs, as well as financial support.

Priority 3. Increase access to fixed doses of (new formulations of) paediatric TB drugs

- Introduction of the new drugs should be advocated in countries (by NGOs, communities, former patients, NTPs, and so on) and legislation/regulation should be implemented accordingly.
- Efforts should be increased to identify high-priority population groups.
- Drug registration procedures should be clarified and simplified where possible (during 2016).

- Technical support from WHO partners (UNICEF, MSF, etc.) would be required by most countries, along with financial assistance (government funding, GF, World Bank, USAID, etc., as applicable) and psychosocial assistance could also be provided through ministries of labour and/or social protection.

Additional priorities identified by the Group 4 countries included BCG revaccination (with help needed to phase out as necessary) and review of regulatory documents (in some countries).

Identifying priorities for action based on group work reporting and additional feedback, adding to the key priorities

Dr Malgorzata Grzemska

Dr Grzemska highlighted that the priorities identified by the four groups were applicable to all countries and any differences were only in the scope or volume of the problems and in the method used to address them. She made the following key points, to summarize.

- The issue of MDR-TB contacts, whether on a massive scale or individually, needed to be addressed across the board. Dr Grzemska called on the Regional Office (and would communicate to the ECDC the necessity) to revisit existing evidence to help countries to issue interim recommendations before the final guidelines were to be released (within 2–3 years).
- A clinical trial of chemotherapy using SLDs was due to begin in 2016 but results would not be available for some time. In the meantime, countries should share existing knowledge and experiences.
- Capable HR capacity with the appropriate expertise was difficult to maintain in countries with low TB burden. Programmes were still functioning vertically but services were fragmented. HR seemed to be available (for instance, 46 HCWs for 52 cases in one country); it was a matter of ensuring the personnel were available in the right places, providing appropriate care. Certain issues also required increased focus and interaction, such as whole families with or at risk of TB, migrant children, and so on. WHO could facilitate action in this area by indicating what training and materials were widely available to countries seeking to improve their HR capacity.
- Paediatric formulations of drugs (especially SLDs) in fixed-dose combinations were soon to be made available. Countries, however, would need significant help where strict regulatory processes existed that would prevent the use of these drugs. Manufacturers of generics were unwilling to supply these drugs in some countries, so a route needed to be found so that they could be used to treat sick children.
 - Some high-burden countries had signed for pre-qualification, removing the need for additional scrutiny of manufacturers. When a dossier was to be submitted to WHO for approval, registration would take three months and this did not take into account EU countries that did not form part of the prequalification agreement. Pooled procurement could be a possible route, through the European Commission/European Medicines Agency (EMA) bilateral agreement mechanism. Dispersible, properly dosed and pre-qualified medicines existed, so now countries needed to find mechanisms to be able to use them.
- BCG (re-)vaccination had been discussed at length and it was clear that policies and guidance needed to be revised. WHO would help countries take this forward according to the country context.
- Criteria for hospitalization of paediatric TB patients needed to be revised, particularly in the eastern countries of the Region. Ambulatory care models should be strengthened, which was directly linked to financing models. Support would be provided from WHO

and regional TB programmes and funding was available through individual grant applications (CNs through the GF) and WHO. Technical assistance would also be provided. Requests to the Regional Office to help countries to move forward in the paediatric TB field had been heard and noted. Experience-sharing would continue (and be increased) and information on pilot schemes disseminated.

- Standards for TB care needed to be quickly revised and adapted by WHO, to allow country-specific adaptations to follow.

The following points were added, highlighting additional and more specific detail to the existing challenges and how to approach them.

- Screening and TB contacts were important.
- Consensus seemed to have been reached that revaccination practices should be stopped, wherever possible.
- Rapid diagnostics needed to be increased and expanded across the board.
- Hospitalization should be replaced by ambulatory/outpatient care where possible, to stop the chain of infection.
- HR capacity needed to be optimized or increased, collaborating with the PHC sector and all HCWs.
- Education and training were to be expanded, both for specialists and in PHC settings.

All priorities identified would be actively followed up by the Regional Office.

Participants were reminded of the 7th Conference of The Union European Region (Bratislava, 22–24 June 2016)¹⁴ and invited to attend. The paediatric TB network, TBnet, was also promoted and participants were encouraged to join.¹⁵ It was explained that TBnet was predominantly research-orientated but specific (often difficult) cases were also discussed and experiences shared. The next meeting of the NTP managers would take place during the summer of 2016, with details to be provided closer to the time.

Wrap-up, next steps, closure

Dr Masoud Dara

Dr Dara emphasized that good practices must be documented and eventually would be included in publications, such as the compendium of *Best practices in prevention, control and care for drug-resistant tuberculosis*.¹⁶ Another compendium on good practices in health system perspectives was also in production. He reminded participants of the Regional Collaborating Committee on TB Control (RCC-TB) meeting that would take place on 17 December 2015 and encouraged colleagues to become members of the RCC (the terms of reference (ToR) could be sent to anyone interested). The aim of the RCC was primarily to gather and disseminate good practices at the highest level, but a public website was also available for interested parties.¹⁷ The WHO/European Respiratory Society (ERS) consilium, comprising independent clinicians who assess complex cases and provide advice, was another source of support for countries dealing with paediatric TB.¹⁸ WHO was not mandated to advise on individual clinical cases, but this

¹⁴ Details available at The Union website: <http://www.theunion.org/what-we-do/conferences/region-conferences>.

¹⁵ Details available at the TBnet website: <http://www.tb-net.org/index.php/about-us>.

¹⁶ Available at the WHO Regional Office for Europe website: <http://www.euro.who.int/en/publications/abstracts/best-practices-in-prevention,-control-and-care-for-drug-resistant-tuberculosis>.

¹⁷ More information available at the WHO Regional Office for Europe website: <http://www.euro.who.int/en/health-topics/communicable-diseases/tuberculosis/activities/regional-collaborating-committee-on-tuberculosis-control-and-care-rcc-tb>.

¹⁸ Accessible through the TB Consilium website: <https://www.tbconsilium.org/>.

platform could be useful to countries dealing with complex TB cases (taking into consideration confidentiality concerns regarding patients' rights).

Dr Dara highlighted the importance of advocacy and awareness-raising (at all levels) for paediatric TB progress as vital background work to support the scientific, evidence-based approach. All ideas gathered would be passed to the Childhood TB Task Force for further action. The ECDC had carried out meta-analysis and the lack of concrete MDR-TB evidence meant that no official recommendations had been made (for ethical reasons). However, MDR-TB contacts meant that children were contracting the disease, falling ill and requiring treatment. Where MSF (for example) was working with countries in the field, more flexible arrangements could be made to support countries, but until the evidence base was available, WHO would remain cautious in what it advised regarding paediatric TB.

It was mentioned that a certain synergy between paediatric and adult TB could be useful; children contract TB from adults so any crossover in approaches could help in both arenas. It was important to focus not only on prophylactic treatment of children but also on combatting the source of the TB infection (as a multifaceted approach). The work of consultation groups such as this one was very important in defining next steps and the approaches to be taken in future.

Dr Nedret Emiroğlu

Dr Emiroğlu thanked attendees for contributing their ideas, as well as everyone involved in the design and organisation of the consultation; it had yielded rich proposals and useful insight into country needs. Requests for assistance in various forms would be taken forward, supporting implementation of various strategies and approaches in partnership. She reminded participants that it was important to look beyond the health sector to the bigger picture; success in improving the situation with paediatric TB in Europe (and beyond) would not be possible unless many sectors and civil society were engaged and a whole-of-government approach taken. All participants were advocates for this approach and above all they must advocate change – in terms of technical recommendations, to review and update, as well as at policy level – to combat paediatric TB.

Annex 1

PROGRAMME

**Regional consultation on childhood TB in the WHO European Region
Copenhagen, Denmark
12–13 November 2015**

Day 1. Thursday 12 November

Time	Topic	Speaker/lead
08:30–09:00	Registration	
09:00–09:05	Presentation of TB advocacy video	
09:05–09:20	Opening remarks	Dr Nedret Emiroğlu, Director, Division of Communicable Diseases, Health Security & Environment; Dr Masoud Dara, Senior Adviser, WHO Office at the European Union and Acting TB Programme Manager, Joint TB, HIV/AIDS and Hepatitis Programme; Dr Malgorzata Grzemska, Coordinator, Global TB Programme, Technical Support Coordination
09:20–09:35	Presentation of objectives and appointment of chairs for the event	Dr Martin van den Boom, Technical Officer, Joint TB, HIV/AIDS and Hepatitis Programme
09:35–09:55	Epidemiological highlights and update on the WHO European Region with a focus on childhood TB	Dr Andrei Dadu, Technical Officer, Joint TB, HIV/AIDS and Hepatitis Programme
09:55–10:15	Overview of finalized regional TB action plan 2016–2020, including childhood TB-relevant content	Dr Masoud Dara
10:15–10:30	Discussion	All, chair
11:00–12:30	Poster session as per pre-filled templates: 11:00–11:45: all participants to move freely from poster to poster viewing the country posters and discussing in small groups 11:45–12:30: three pre-selected countries present their posters to the plenary, either at the poster or in PowerPoint format (one high MDR-TB burden country, one low TB incidence country and one additional country)	All Belarus, Slovakia, Tajikistan
12:30–12:45	Discussion	All, chair

Time	Topic	Speaker/lead
14:00–15:15	Discussion on major issues/challenges raised in posters that need to be addressed in countries in preparation for group work	Panel consisting of chair and representatives of countries which presented before: one high MDR-TB burden country, one low TB incidence country and one additional country
15:15–15:30	Summary of status (with focus on challenges) of childhood TB at country level	Dr Martin van den Boom
16:00–16:30	Update on new developments in diagnosis and treatment of childhood TB and global childhood TB perspective	Dr Malgorzata Grzemska
16:30–17:00	Discussion	All, chair
17:00–17:15	Wrap-up of Day 1	Chair, Dr Masoud Dara, Dr Malgorzata Grzemska, Dr Martin van den Boom

Day 2. Friday 13 November

Time	Topic	Speaker/lead
09:00–09:15	Brief overview of contributions from the European working/task force group on childhood TB	Dr Martin van den Boom
09:15–09:30	Use of tools for country assessments: benchmarking tool	Dr Connie Erkens, Netherlands
09:30–09:45	Discussion	All, chair
09:45–10:00	Overview of UNICEF projects in the WHO European Region with linkages to TB prevention and care	Dr Ruslan Malyuta, UNICEF
10:00–10:15	Overview of Médecins Sans Frontières (MSF) childhood-related projects and key challenges and progress	Dr Jay Achar, MSF
10:15–10:30	Discussion	All, chair
10:50–11:05	Childhood TB, Global Fund perspective	Dr Anna Scardigli, Global Fund
11:05–11:15	Introduction to group work: scaling-up childhood TB	Dr Martin van den Boom
11:15–12:15	Group work session 1. Current in-country policy and national strategic plans (focus on key challenges and the extent to which childhood TB is covered)	All, facilitators (four groups as per introduction to group work)
13:30–14:30	Group work session 2. Based on session 1: how to move from current policy (taking into account key challenges from group work session 1) to better care for children (through, for example, country adaptation of global policy and regional plans, improving hospitalization practices, fixed-dose combination drugs, legislation and contributions of relevant partners)	All, facilitators (three groups continued)
14:30–15:30	Reporting back from group work: all four groups, each group has 15 minutes	All, chair, including discussion
16:00–16:30	Identifying priorities for action based on group work reporting	All, chair, Dr Nedret Emiroğlu, Dr Masoud Dara,

Time	Topic	Speaker/lead
16:30–16:45	Country individual feedback session: adding to the key priorities on how to move towards better paediatric TB care	Dr Malgorzata Grzemska, Dr Martin van den Boom Collection of three priority points per country, facilitators
16:45–17:00	Participant feedback on the regional consultation	All, chair
17:00–17:15	Wrap-up, next steps, closure	All, Dr Masoud Dara, Dr Malgorzata Grzemska, Dr Martin van den Boom

Annex 2

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Annex 3

SCOPE AND PURPOSE

Background

Tuberculosis (TB) remains a serious health problem in the WHO European Region. Significant challenges include widespread TB among vulnerable and marginalized populations, such as children and adolescents. Coinfection with HIV and increasing rates of multidrug-resistant TB (MDR-TB) are further hampering efforts to care for this vulnerable group.

The full scope of the problem of TB in children is not fully known. WHO estimates that globally, over half a million children fall ill and up to 80 000 die each year (about 200 children every day) because of TB, which is a preventable and curable disease. After decades of relative neglect, the childhood TB epidemic is now in the spotlight. The goal of zero TB deaths in children has been endorsed by the international TB community and has united key stakeholders in efforts to make this goal a reality. Childhood TB can only effectively be addressed with collaboration across health systems and communities. To meet the goal of zero TB deaths, it is critical that childhood TB is prioritized in national health strategies, plans and budgets.

The true extent of the childhood TB burden in the Region is highly uncertain. In common with the overall global TB picture, specific challenges, such as a tendency – albeit improving – of unnecessary hospitalization and high rates of drug-resistant TB (DR-TB), exist. While overall capacity for diagnosing TB (including in children) has improved in the Region, it still falls short of what would be achieved ideally. In addition, WHO policy guidance on measures for children who have been in contact with DR-TB patients is currently lacking.

During the final year of implementation of the *Consolidated action plan to prevent and combat multidrug and extensively drug-resistant tuberculosis in the WHO European Region, 2011–2015* and following the endorsement of the post-2015 global End TB Strategy by the Sixty-seventh World Health Assembly in May 2014, a new regional TB action plan covering the period 2016–2020 was developed and endorsed at the 65th session of the WHO Regional Committee for Europe in September 2015. Subsequently, Member States will need to update and adapt or at least revisit their TB national strategic plans. Childhood TB should be carefully considered for inclusion or redevelopment/updating as it falls into several areas of intervention of the outgoing consolidated action plan and links to the three pillars of the post-2015 global End TB Strategy. This context requires concerted efforts to more effectively combat TB in one of the most vulnerable patient groups – children.

Objectives

The objectives of the meeting are to:

- review the current status of common practices in relation to childhood TB at country level;
- share country experiences, lessons learnt and good practices in childhood TB;
- discuss possible reasons for excessive hospitalization of children and ways to reduce it;
- establish priorities and design activities for strengthening childhood TB initiatives in the Region;
- highlight challenges in including childhood TB in national strategic plans in the era of the post-2015 global End TB Strategy and the regional TB action plan for 2016–2020; and

- formulate next steps to effectively update childhood TB (in line with WHO recommended policies and strategies) in national strategic plans.

Expected outcomes

The expected outcomes are that:

- participants will be updated on key changes and aspects regarding management and treatment of childhood TB;
- a set of priorities for childhood TB at country level will be developed/drafted; and
- next steps in updating childhood TB-relevant elements of current national strategic plans in line with the post-2015 global End TB Strategy and the regional TB action plan 2016–2020 will be defined.

Annex 4

GROUP WORK TEMPLATE

Identify **three** priorities and goals (SMART – specific, measureable, achievable, realistic, time-bound) for paediatric TB in your country.

1. **How** should they be addressed?
2. By **whom**?
3. By **when**?
4. **What** support is needed, and from **which** organization?
5. **Where** are the gaps?