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6.1 Global strategy and targets for tuberculosis prevention, care and control after 2015

Background

Secretariat note: "Following extensive consultation, the Director-General presents a comprehensive review of the global tuberculosis situation to-date, as well as new multisectoral strategic approaches and international targets for the post-2015 period. The Board is invited to consider the draft strategy and targets and to provide further guidance."

In 1993 WHO declared tuberculosis (TB) as a global public health emergency. Many actions were implemented (the DOTS strategy; inclusion of tuberculosis-related indicators in the Millennium Development Goals; development and implementation of the Stop TB Strategy that underpins the Global Plan to Stop TB 2006–2015; and adoption in 2009 of resolution WHA62.15 on the prevention and control of multidrug-resistant tuberculosis and extensively drug-resistant tuberculosis) in order to accelerate the global expansion of tuberculosis care and control.

In May 2012, WHA requested the DG to submit a comprehensive review of the global tuberculosis situation and to present a new strategy for the post-2015 period to the Sixty-seventh World Health Assembly in May 2014, through the Executive Board. The process to prepare this has involved consultation across a wide range of partners.

Document EB134/12 provides an outline of the achievements, challenges and approaches needed in controlling the TB epidemic and a comprehensive description of the draft post-2015 Global TB strategy. Such a strategy, with its vision (a world free of TB), goal and targets (divided into milestones for 2025 and targets for 2035), is articulated around three pillars and their relative components, and four principles. Finally the document gives suggestions on how adapting and implementing the strategy as well as measuring progress and impact through a list of key global indicators, and envisages the role of the WHO Secretariat. The EB is invited to consider the draft strategy and targets.

PHM comment

Milestones and targets

Considering that TB is a highly infectious disease and every active TB case can infect up to 20 people in its surroundings per year, the incidence rate per 100.000 population is a good indicator of the burden of TB in a population. Whereas, understandably, the WHO's focus has

been on the 22 high-burden countries (22 countries that account for 80% of TB cases in the world), it is now time to pay more attention to countries that might not have a high total number of cases but have a high incidence rate. Of the top-ten countries with highest incidence rates, only three are counted among the 22 high-burden countries: South Africa, Zimbabwe and Mozambique. The danger of not placing more emphasis on these countries and monitoring them more closely is that they become reservoirs of TB that will spill over into other countries. To successfully reach the 2035 target of 90% reduction in TB incidence rate, we need a strong focus on high-incidence rate countries and not only high-burden countries.

Pillar One. Integrated patient-centred care and prevention

Under the first pillar, a lot of emphasis is given to diagnosis and treatment while scarce attention is devoted to the effective cure. Among the illustrative indicators, only one focuses on the treatment success rate but there isn't a target to be reached; at the same time the document does not mention interventions that get patients cured.

Pillar Two. Bold policies and supportive systems

The draft Global strategy clearly recognises the role of social determinants in shaping the epidemic and also states, in its principles, that policies and strategies for addressing the TB response have to explicitly address human rights, ethics and equity. However, the draft strategy fails to identify strong drivers which would promote real change and tackle the root causes of the disease spreading and maintenance such as urbanisation and marginalisation, migration and detention in refugee camps, unhealthy working and living conditions and the health care access barriers that in turn depend on the unequal distribution of resources and the structure of power.

One potential driver to really embed a human rights approach into the strategy would be to provide support for appropriate litigation, seeking to use the authority of the law to advocate for social change on behalf of individuals whose voices are otherwise not heard, including the right to care for TB infected people. It is not enough to call for political will to give TB prevention and care the priorities in financing and management that they need. New accountability structures are needed to investigate and prevent barriers to access and treatment, drug shortages, treatment interruptions, waiting lists and inappropriate marketing of drugs and diagnostic tests. One option for WHO would be to work with the UN Human Rights Council to sponsor public hearings and strengthen the accountability of funders, managers and service providers.

Under the call for action on the determinants of TB, the document fails to mention the ongoing battle to ensure access to diagnostics and medicines which are patented and priced out of reach of the populations that need them most. The bold policies promised in the second pillar should also work towards counterbalancing market tendencies that lead to inequalities by:

- opposing unjustified and excessive profits on critically needed tools and medicines,
- patent law reforms in high burden countries to prevent unfair practices,

- opposing corporate practices that trap governments - and public budgets- into expensive long-term contracts (e.g. exorbitant prices for warranty on GeneXpert modules).

While governments are being called upon and held accountable for their part in ending the TB epidemic, the same should be expected from industry actors.

Universal health coverage is presented as a fundamental tool for effective TB care and prevention, but few words are spent on the paramount importance of health system strengthening and the need for a better integration of TB services into the health system as well as a better connection with other health sectors, such as paediatrics. Likewise NCDs will increase in importance and relevance over the time period of the strategy.

Pillar Three. Intensified research and innovation

While it is valuable that there is a specific pillar on research and innovation, not enough attention is there paid to innovative mechanisms to ensure new and adequate sources of funding and the affordability of products. It could be done through scaling up new and public investment models able to delink innovation from pricing (if not through the WHO, then through some kind of BRICS pooling mechanism).

In terms of drug development and availability, further pressure on drug companies may be needed in order to ensure that appropriate trials are undertaken, including the phase III bedaquiline trials.

At the same time, it would be crucial to focus on the time it takes to implement a new tool or innovation and the barriers are to that. Considering the bedaquiline is still not being used outside the Compassionate Use programmes a year after its registration; it would be important to investigate ways of national programmes working together in regions to facilitate or speed up the implementation of such new tools. In order to track this process, a specific indicator could be added to those listed in Table 2, namely the time to new innovation/tool becoming widely available in the national TB programmes.

In terms of diagnostics, the WHO should set up prequalification systems for TB diagnostics to ensure a more strict control over the chaotic TB diagnostic market which is allowing some poor quality tests to be used in some countries. At the same time, more research is needed before recommending a new diagnostic tool ensuring that its applicability and feasibility, both in financial and practical terms, are considered.

Adapting and implementing

The document states that “A prerequisite for adoption of the strategy and preparation for its adaptation will be a detailed assessment of the national epidemiological and health system situation”. To this regard, it is important to recognise that available data are rather poor and, while waiting for countries to set up their surveillance systems, a few massive surveillance

studies should be funded in order to get information on the magnitude of the epidemics including information on the real cure rate the programmes are able to achieve.

It is also crucial for countries to set specific national level targets to achieve global goals to reduce TB mortality; this is a priority, in particular for high burden countries.

Moreover, in order to paint a clearer picture of reservoirs and breeding grounds of TB within countries, much light should be thrown on high-risk population groups such as correctional centres, mines, schools and transport systems, centres for detention of illegal migrants. Even though this is a responsibility for governments and health departments, an increased focus from the WHO on these key populations would certainly assist. For example, the WHO European Region is the only region that systematically collects and analyses data from member states on the burden of TB in correctional centres. This needs to happen in all regions and to be expanded to other hotspots like mines, schools, etc.

Notes from Debate

In brief

The majority of the Member States endorsed the new strategy and its multisectoral approach although they recognised that the proposed targets are quite ambitious and need to be more flexible and tailored to the different country's situations.

Echoing the document, MSs also recalled the importance of the social determinants in shaping the epidemics. South Africa stressed the role of the labour market, while others mentioned the role of poverty, environment, lack of education as well as access to basic services. On the same issue, Colombia called for a strong political commitment and the importance of social protection. Also the Universal Health Coverage was envisaged as a tool to improve the disease prevention and control.

The EU, along with others MSs, raised the problem of the vulnerable at-risk groups including migrants, homeless and people with HIV/AIDS. The issue of the HIV coinfection and the challenge of the multidrug resistance were common concerns across the interventions.

Speaking about new drugs and diagnostic tools, many MSs agreed on the need for more investment on R&D while Germany criticised that the document specifically cites the GeneXpert technology without being more generic or citing other tests.

Among the civil society speakers, the International Pharmaceutical Federation, renewing its commitment, highlighted the role of the pharmacists as front providers and the need to systematically engage them in the fight against TB.

Both MSF and the PHM recalled the importance of developing new medicines and making them available to the poorest in-need populations by decreasing the price and delinking it from the innovation.

After the discussion, the EB took note of the report.

The discussion based on the Report by the Secretariat was accompanied by a draft resolution (EB134_CONF4Rev1) proposed by Brazil and cosponsored by many MSs. See text of final resolution EB134.R4

More detail

Monday 20 Jan (D1)

Chair: summarises Secretariat note (EB134/12); reference to draft resolution (EB134_CONF4Rev1).

Belgium: European region thanks for the detailed report, endorses the goal of the strategy to strengthen TB fight, strengthen research and innovation to realise the vision of a TB free world. TB affects the poorest. It depends on all persons with TB getting all the treatment without financial burdens and need for success in prevention, treatment of multidrug resistance cases. Need for screening of high risk groups, organising and sustaining services for TB prevention, overall strengthening of health systems and social services. Important to reach out migrants, homeless and persons with HIV/AIDS. A comprehensive response to TB is needed, as well as a multisectoral and integrated approach. It is a challenge to transform to reality. Goals and measures should be adjusted to different situations, the full commitment of all stakeholders is paramount. EU region commits to invest, cooperate to end TB epidemic.

Brazil: TB has an impact on social determination and shows direct relations with poverty; it needs special measures for diagnosis and treatment. In 2012 began with WHO kicking off process. We have made some progress; we have reached number of goals in reducing the number of cases of TB, but have to continue making further progresses. There is a stagnation in number of cases and a question of resistance as well. Funding is limited, there is a need to invest more in R&D. We want to be able to meet commitment for 2015 and beyond.

Cameroon: on behalf of Afro; disproportionately higher number of cases from Africa; region not on track for MDG TB; incidence on decline since 2010; low detection rates; low uptake of diagnostic technologies; HIV comorbidity; drug resistance and problem of over reliance on donors. Five out of nine high burden countries have seen falling prevalence and other achievements. Concerns of countries of the region have been taken into account. We welcome and support the proposed resolution.

PNG: commends the secretariat; TB burden is enormous in WPR; PNG has a high burden; 286/100,000 notification rates. Treatment success of new smear positive people now up to 69%.

We have 58 MDR diagnosed with 6 XDR cases. PNG thanks the secretariat for good work and supports global strategy.

Malaysia: agrees that success of the post 2015 TB strategy will depend on execution of government responsibilities. The inter country collaboration must be strengthened. Supports addition by China in OP3 and OP5 as proposed by Canada. OP5: at “regular intervals” was used, how will this be integrated by secretariat and how does this fit within WHO reform? Wishes to join as co-sponsor of the draft resolution.

Australia: welcomes progress in TB control; supports draft post 2015 global TB strategy and likes the targets; in particular the focus on MDR and XDR; HIV linkage; at risk groups; access to quality medicines; need to address globally and locally.

Mexico: supports the report that has been submitted and happy to see strategy; need to look into question of migrants and other vulnerable groups; urge WHO to provide surveillance especially to drug resistant TB.

Saudi Arabia: supports the global strategy. Stagnation in the reduction of cases of TB; many TB cases detected after long delay. More involvement of stakeholders needed; multi drug resistant TB poses a threat; health systems scale up necessary. In GCC region TB rates low, working closely with WHO to address elimination in the region.

Korea: continue the momentum of decreasing rate leading to eradication; continuing efforts needed; full support the resolution; communicable disease including TB in post 2015 agenda; need reporting mechanism of health policy discussed in EB134/7; TB management crucial; important universal health system of TB checkups for vulnerable classes and access to treatment

Lithuania: aligns with Belgium, in the 2nd decade of 21st century TB still public health problem. Adoption of MDGs has mobilised community to act. Ambitious targets set for TB. In Lithuania visible progress in diagnostics and outstanding results in fight of TB in prisons. Steady decline in MDR TB. Social support in more vulnerable group of patients has room for improvements. Still a lot remains to be done: guided by MDG based targets. The level of TB remains too high, decline of TB does not meet expectations. New TB global strategy: ambition targets, the vision, goal of the strategy although ambitious achievable; willing to co sponsor

South Africa: lends its support to Cameroon statement; commends Secretariat for global strategy; hope that it will lead to world free of TB; concerned about migrant labour situation a key driver; importance of attending to vulnerable groups including mine workers, ex mine workers and health workers; support strengthening of occupational health systems to manage silica especially TB in the mines; welcome support and collaboration of affected countries especially in SADC region.

Myanmar: important that we give undivided attention to containment of drug resistant TB. Need for more info as early as possible. Request regional offices to share information and stories. In the post 2015 strategy: would like to fine tune the three pillars so they are robust and practical.

Cuba: the report that has been put forward gives overarching view of international goals. Now we have goals for TB for 2015: will allow to strengthen attention to TB. Important to continue R&D to better focus attention on TB. In Cuba there is a positive situation. Problems is also HIV/AIDS and also look in light of MDR. In agreement with strategic plan and resolution.

Nigeria: aligns with Cameroon on behalf of Afro; commends Secretariat; note persistent burden and stagnation of notification; led to surveys; TB complicated by AIDS /HIV; DOTS helped to develop programs around HIV linked TB; institutions and systems for enabling environment and shared responsibility; aggressively pursue R&D. Call on WHO to note how these can be strengthened. Poverty reduction and economic growth. Support draft resolution

Panama: happy to see implementation of global strategy and targets after 2015. Main problem : diseases in deterioration in environment; lack of education ,access to basic services; main causes of diseases in children and elderly. STDs and HIV have also brought in reemergence of TB. Co sponsor.

Japan: join other members. Improvements in detection rate, is important to strengthen coverage, problem with multidrug resistance. New drugs for TB have been developed by Japanese pharma, hope will contribute. Working document, no reference to word DOTS, need to insert

Maldives: TB common in SEAR; long global neglect; WHO 1993 declared TB a great problem; second only to AIDS; lots of new cases; SEAR. Maldives only a few MDRs. Big problem in Maldives is stockouts. Remarkable results; disease burden declined in all regions since 2001. Yet challenges like MDR, and association with HIV still a problem. Strict controls over drugs necessary.

Azerbaijan: the task of enhancing the fight against TB. One of the main challenges in Azerbaijan. Joint partnerships with donors and intergovernmental organisations. We have achieved number of results. Legislation on TB control provides a sound legal basis to take forward efforts for further works. We intend to work on further standards, diagnosis and prevention including MDR TB. Fully equipped for MDR TB detection. Have also worked with health personnel ensuring that they are trained and have right equipment. Have been able to stabilize TB incidence in recent years. Important to have international policy with clear definition of priorities.

Colombia: thanks WHO for new approaches to eradicate TB which affects poorest populations. Research must be intensified and focused on the patient. No new products developed, need for more innovations and new treatments. Strong political commitment in prevention, social protection and attention on SDH.

China: Thanks chair; China in principle agrees with report in terms of principles, pillars and components; innovative measures timely for member states; notes that the targets and milestones are ambitious and challenging; the analysis in the report shows outstanding challenges for high burden and developing countries; need to allow some flexibilities for high burden countries; at UN level promote international collaboration; develop appropriate targets and indicators. China following prevalence, incidence and mortality; targets have been achieved ahead of schedule; cure rates of smear positive at 85%; sustained international support has assisted; in the next period we will look at MDR, migration, and HIV co-infection. Will conduct necessary data collection and analysis based on strategic framework.

Slovakia: fully support EU region statement, continues to participate actively, co sponsor of resolution. Slovakia has low incidence of TB, recognise need of increased collaboration with all low incidence countries in order to prevent transmission in context of trend of global mobility, poverty reduction crucial in elimination of TB.

Russia: supports the adoption of post 2015 global strategy. Need to attain through common efforts; combatting MDR TB and HIV TB. Meeting in Paris last year; reduction for TB in BRICS countries. Need to pay attention to vulnerable groups. Improve way people are given treatment. How to reduce cost of antiretroviral drugs. Need to develop internatoinal instruments to questions treating and diagnosing TB in migrants. Target: 90 per cent reduction rate target, need to look carefully. It might be appropriate to keep goal of less than 10 cases for 1000 without having the percentage component. Need to also look at scientific aspect, research, collaboration. Scientific school in Russia,

France: aligns with Belgium for EU; support draft strategic plan; high quality; dynamic; necessary in this time; underscore that we co-sponsor draft resolution; partnerships very good; if everyone is mobilised we can throttle this epidemic; call upon rapid action towards UHC; towards prevention and health care; ambitious but possible with political will; France a great contributor and continues its commitment; fight against stigma as well; increase research at local level especially in high burden countries; focus on co-infection with TB and HIV; further strengthen health care systems; greater extend access to drugs, quality diagnostics; tools crucial and possible within the framework of the strategy.

Indonesia: the national TB programme has made progresses. Mortality reduced 20% . This progress needs to be strengthened in the post 2015 agenda. Sustain the decline. New approaches are inevitable and need the support of global community. Fully support the agenda post 2015.

Canada: supports the new global strategy; also support draft resolution; want to co sponsor; want to stress importance of working in close collaboration.

Germany: aligns with Belgium on behalf of EU; welcomes strategy and targets; especially co-infection of TB and HIV; encourage MSs to invest more into prevention; could be highlighted more prominently in the strategy; more work to resist the spread of MDR and XDR; should be reflected in the surveillance as well; heterogeneity globally should be made clearer in the

strategy; TB in childrens often neglected; report mentions Genex expert; should be more generic or mention all tests; welcome inclusion of UHC and social protection; but needs more complete operationalisation of these for TB milestones; budget planning is important; difficult for federal states. Targets very ambitious; Germany with a low incidence has had a slower rate of reduction.

Bangladesh: globally Bangladesh is amongst 27 high TB resistant countries, 70,000 people died due to TB. Estimated burden is still high, in pulmonary, child TB. Another challenge in sustaining partnerships with NGOs, research institutes etc. Strengthening laboratory services. Slow progress in drug resistant TB. Need to ensure uninterrupted flow of TB drugs. Insufficient resource mobilization and funding gaps. Need for actions in poverty reductions and better living and working conditions. Supports the draft resolution.

Ecuador: TB document is a good basis but don't take into account economic situation and other country specific issues. Also the political aspects and the resources. Different characteristics of countries need to be considered. Otherwise the targets won't be feasible. In order to reduce mortality scientific news available on time; different therapies need to be avalable in different formats, technical support and integrated approach. Ecuador is committed to strengthen financial support and a new program strategy addressing most vulnerable people.

India: compliments to Secretariat for comprehensive report; broadly endorse new multisectoral strategy; better platform for TB control; will need country specific innovation and strategies to universalise and reach every person because mainly come from a class suffering from poverty; India is a high prevalence country; significant rise in MDR TB; new strategy to put in place services across country for MDR TB; one of the solutions lies in better implementation of DOTS program; implement this program across country with help of several NGOs but the burden of political and fiscal commitment lies with government to introduce new initiatives to streamline and increase budgetary commitment; there is a will.

International Pharmaceutical Federation: thanks; welcome global strategy; will continue and further improve; in 2013 we signed statement with WHO, a statement about pharmacists and TB control; often front line providers; need systematic engagement of pharmacists; action oriented collaboration with national pharmacists in fight against TB and MDR TB. in India local orgs of pharmacists signed aagrement wIth central Indian government. In several regions specially trained pharmacists are referring and also serving as DOTS providers. Illustrate Pillars 1 and 2 and engagement of all public and private. Renew our commitment for implementation of global strategy.

MSF: welcomes the global strategy, concerned re increased rates of DRTB. Encouraged to see R&D innovations pillar. The R&D pillar has a number of elements: need for greater focus on earlier studies with new drugs. Ensure that no area or population is neglected. All MSs should increase investments towards this. Prize funds: delink cost from final price. High price of current tools negatively impacts countries' response. New TB medicines priced out of reach for middle

and low income countries. Use of public use safeguards to decrease price. Strengthen R&D pillar so new tools given more emphasis

MMI/PHM

We welcome the Global strategy and targets after 2015 and we would like to comment on a few key issues.

The strategy clearly recognises the role of social determinants in shaping the epidemic and asserts that policies for addressing the TB response have to explicitly address human rights, ethics and equity. However, it will need strong drivers to effectively tackle root causes, including marginalization, exclusion and detention in refugee camps.

To address social determinants, both a strong human right approach and a health system structured on PHC principles are essential.

We urge WHO to work with the UN Human Rights Council to provide support for public hearings and litigation as appropriate, to use the authority of the law to advocate for the right to care for TB infected people and the right to high quality effective treatment and action around social determinants. TB care needs to be nested in comprehensive PHC so that health care practitioners are supported as advocates as well as carers.

In target setting, a stronger emphasis is needed on cure rates and access to treatment. Better data are needed about the kinds of service delivery systems which are curing people and preventing disease effectively, not just on how many cases are under treatment.

Moreover, an important set of actions missing from the strategy are those necessary to overcome barriers to access to diagnostics and medicines associated with extreme IP restrictions and associated high pricing. Such actions should foster the full use of TRIPS flexibilities and complete avoidance of the TRIPS-plus provisions being advanced through bilateral trade agreements.

Finally, we urge closer links between the implementation of this Strategy and parallel actions also on the agenda of this EB directed at scaling up public investment and delink innovation from pricing.

Secretariat : thanks for the positive feedback; overwhelming strong support; raised couple of challenges: co-infection, low detection, funding partnership, and high risk population.

Responding to questions

1) high risk groups (Mexico, South Africa, Korea): important component of new strategy; the number one pillar is patient centred approach;

2) social determinants (Panama): this is the 2nd pillar of the new strategy;

3) DOTs: DOTS strategy serving as basis for pillar number 1, some criticisms of DOTS gives impression that it is not patient centred enough;

4) monitoring and periodic reporting: at this moment the Secretariat is following a 3 years cycle of periodic monitoring of progress. The cluster has some diseases on eradication which need to be reported yearly others we can report every 3 years. Waiting for further guidance.

5) ambitious target: the targets are challenging but coming from evidence, after WW2 there was a dramatic decline in TB in Europe, linked to the start of expansion of health care coverage, that kind of situation is observed in emerging economies. The assumption of this model is that the incidence will decrease by 10% that will bring the goals which appear in Table 1. Case fatality rate to decrease from 10% to 6.5%.

Chair: note the report? Yes. Now to the resolution

Brazil: thanks to sect and countries for contributions to the draft; we are proposing informal consultation meeting starting now and include recent contributions from countries.

Romania: support for the Brazilian resolution and ask to be included in the list.

Ethiopia: support the Brazilian resolution. To be included in the list of cosponsors.

TB is left open and we will move on to the next item

The discussion was resumed on Day 2 (Tuesday 21 Jan) and the resolution, as amended was adopted (EB134.R4).