Updating the Research and Development component of the Stop TB Partnership's Global Plan to Stop TB, 2006-2015

Second Workshop - Geneva 28-29 January 2010

Workshop Report

This workshop is a follow-up to the workshop held in Geneva in September 2009, in which draft versions of logical frameworks for new diagnostics, drugs, and vaccines were developed for the period 2011-2015. This second workshop was designed to produce close-to-final versions of the logical frameworks for the new diagnostics, drugs and vaccines components of the Global Plan to Stop TB for the period 2011–2015, including clear definition of the goal, objectives, major activities, indicators, targets, funding required and funding gaps, ensuring that research aspects related to MDR-TB, HIV/TB and childhood TB were fully addressed.

Day One:

Marcos Espinal, Executive Secretary of the STP, opened the workshop. After reminding the main objectives of the revision of the GP and the expected outcome of the workshop, ME emphasized that this revision ought to be credible, relying as much as possible on the present status of the situation and on present evidence on development of new drugs diagnostics and vaccines. He commended that discussions were enriched through the active contribution from the MDR-TB, TB/HIV and Childhood TB working groups/subgroup representatives. He also reinstated that all preparatory work be ready by April 2010, with a presentation to the CB meeting in Hanoi for endorsement.

Christian reminded on the full process to updating the R&D component of the Global Plan. He emphasized that the endpoint is to ensure that ambitious but realistic targets are set, with ambitious but realistic resource needs. A process of on-going evaluation of progress and funding available will ensue, through regular comparison with the TAG/STP R&D Global Funding Assessment Survey.

Christopher went through the details of the process so far and the updated logframes, focusing on the pending issues:

- targets, quantities, unit costs and total resource needs;
- available funding;
- annualization of costs;
- basic research and advocacy.

He insisted on the importance to consider Consistency, Cooperation, Cost-sharing and Credibility when revising and finalising the logframes.

Then, representatives from the WGs presented their respective logframes, detailing updated goal(s), objectives, major activities, indicators, targets, and cost estimates.

- NDWG (G. Roscigno): The total expected expenses for the remaining period of the GP are estimated at 1,207 millions. Case was made about the importance to invest on the development of a Point of Care test for DS and DRTB, as well as on the importance to invest on demonstration studies and studies on impact of new diagnostics in order to submit files for registration of validated tools and endorsement of new diagnostics tools by the WHO.
- WGND (B. Bishai & L. Parker): two different scenarios were presented depending on the expected "attrition rate" in drug development: a "realistic" prevision (10 new drugs in clinical trial by 2015), and an "optimist" prevision (35 drugs in clinical trial). The realistic scenario would cost USD 3.5 billion, while the optimistic scenario would cost USD 13.5 billion. It was restated that previsions must be based on progress achieved in 2010, and be as much as possible realistic and credible. It was also stated that we should not be bound by development of drugs solely but by development of *regimens*.
- WGNV (U. Fruth). The overall estimate for the remaining period is USD 1.5 billion. The case was made to have a wide discovery portfolio for a robust vaccine pipeline. Manufacture development was considered an important post to plan for, although it was not clear whether this should be reserved to production for conducting clinical trials only or whether it would be for wider production. Costs for capacity building for large scale vaccine trials are also included. It was considered essential to plan for regulatory related expenses, since situations are likely to vary widely from countries to countries. Lastly, specific and vaccine focused advocacy activities are taken into account.

Presentations were made by the TB/HIV (H. Getahun), MDR-TB (C. Mitnick), and Childhood TB (A. Hesseling) WGs/subgroup, in order to ensure that the particular aspects of each of them were taken into account in the larger frame of research for new diagnostics, drugs, and vaccines. All these comments are to be considered and taken into account by the respective WGs when revising their specific logframes.

In the afternoon, the assembly broke into groups for further work on the logical frameworks with the view to deliver close-to-final documents. It was requested that groups assess the logframes components ensuring together *realism and credibility*. It was further requested that groups work on available funding and annualisation of the cost estimates over the last 5 years of the GP, and that they ensure integration of Childhood TB, MDR and TB/HIV aspects and associated costs into the frameworks. Group discussions were facilitated by KF, IGB and CF for the WGs on new drugs, diagnostics and vaccines respectively.

Day Two:
The group discussions continued in the morning and feedback to the group took place in the afternoon:

- NDWG (A. Ramsay): the total revised budget for the next 5 years was estimated at USD 1,584 million. This takes into account the need for consistency across and between logframes, including manufacturing of diagnostics for scale-up,

advocacy, and regulatory aspects. Focus is on the need for a POC diagnostic test for MDR-TB and childhood TB.

- WGND (L. Parker): the logframe for new drugs has been largely revised and estimated costs subsequently reduced to 4,000 million approximately. Figures still need to be checked and updated in a number of activities (notes have been taken in the revised logframe). Further work is needed to finalise the logframe, with careful attention to the pending questions and remaining issues. It was also reminded that information should be sought from Pharma companies on key costs (phase I, II, III trials, etc…).

- WGNV (M. Brenan):The overall funding for the years 2011-2015 is estimated at USD 1,552 millions, which includes vaccine-specific basic research and product manufacturing. Costs also include capacity building, regulatory aspects and advocacy. The WG annualised costs through all objectives and activities throughout the 5 year period.

A series of cross-cutting issues have been identified that need to be addressed by each WG:

1- "Transversal" basic research pertaining to the discovery aspects for the three tools will be singled out as a stand alone component of research in the GP update, so shall not be included in the activities and budget estimates. However, downstream tool-specific basic research should be included;

2 - Tool-related advocacy issues are to be included in each WG activities;

3 - Consistency over the three logframes is essential, e.g. patients costs in trials (drugs and vaccines), capacity building, regulatory aspects, etc…

4 - Available funding for each tool have to be identified in order to estimate gaps and needs for the updated GP. TAG is proposing to hire a consultant who will identify the funds committed over the next years for each WG.

5 - Lastly, collaborative synergies between WGs should be identified

Timeline and Future steps:
The fully finalised logframes will form the basis of the Research component of the updated GP. For this, it has been agreed that the logical frameworks be finalised by 31st March 2010, through a series of iterations involving the WG chairs/co-chairs, secretaries, members and the WHO/STP staff in Geneva. A wide circulation is recommended amongst WG members to get their comments and input and be sure of wide approval and endorsement.

The finalised logframes must include the following:
- annual breakdown of costs over the next 5 years

- indication of available funding and funding commitments
- inclusion of advocacy activities
- inclusion of "tool-oriented" basic research only
- inclusion of TB/HIV, MDR-TB and childhood TB specific research aspects

In addition, for the narrative of the GP, each WG will prepare a **two-page document** listing the key aspects to consider for the GP update document (bullet points), including:

- Major achievements in the GP by 2015
- highlight of main targets and activities 2015
- full justification of the importance to achieving each objective (shortened TB treatment, POC diagnostic, harmonized regulatory process, etc…)

Lastly, on the basis of the logframes, each WG will list the **research priorities** to reach the revised targets that will serve for the Global TB Research Agenda that the TB Research Movement is putting together for the end of the year.

Task	Timeline	Responsible person(s)
Circulate close-to-final logical frameworks within WGs (New Vaccines, Diagnostics & Drugs). – address any outstanding query – finalise pending issues (annualization and available funding) – get final input from Core Group and WG members – identify research priorities to reach revised GP targets for new drugs, diagnostics and vaccines	February 2010	WG chairs/co-chairs and secretaries
Send revised logical frameworks to Geneva	7 March 2010	WG secretaries
Revision of last version of logical frameworks in Geneva: – recapitulation of activities and costs – consistency checks – costs checks	15 March 2010	CF, IGB, KF, CL
Final circulation of logical frameworks to WGs chairs/co-chairs and secretaries for approval	22 March 2010	WG chairs/co-chairs and secretaries
Send logical frameworks back to Geneva for inclusion in the Global Plan update	31 March 2010	WG secretaries

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2 February 2010