

Leadership Team Meeting**3 December 2020****Participants****Leadership team members and guests**

- Bill Simmons (Chair), President & CEO, American Leprosy Missions
- Geoff Warne, CEO, International Federation of Anti-Leprosy Associations (ILEP)
- Erwin Cooreman, Team Leader, WHO Global Leprosy Programme (observer)
- Rao Pemmaraju, Technical Officer, WHO Global Leprosy Programme (observer)
- Benedict Quao, Program Manager, National Leprosy Elimination Program of Ghana
- Mauricio Lisboa Nobre, Consultant to Brazilian Leprosy Program
- Arielle Cavaliero, Global Franchise Lead, Leprosy, Novartis
- Takahiro Nanri, Executive Director, Sasakawa Health Foundation
- Jan van Berkel, Chair, Executive Group, Leprosy Research Initiative (LRI)
- Linda Hummel, CEO, Leprosy Research Initiative (LRI)
- Amar Timalisina, President, International Association for Integration, Dignity and Economic Advancement (IDEA) Nepal
- Maarten van Cleeff, Former Director of Challenge TB project, KNCV (guest)
- Mathias Duck, Chair of ILEP Panel of Persons Affected by Leprosy
- Wim van Brakel, Medical Director, Netherlands Leprosy Relief (NLR)

Secretariat

- Bill Gallo, Secretariat Director, Global Partnership for Zero Leprosy
- Andie Tucker, Project Manager, Global Partnership for Zero Leprosy
- Mondie Tharp, Project Manager, Global Partnership for Zero Leprosy
- Caroline Cassard, Communications Specialist, Global Partnership for Zero Leprosy

Invited but unable to attend

- Alice Cruz, UN Special Rapporteur (observer)
- W. Cairns Smith, Emeritus Professor of Public Health, University of Aberdeen
- Mark Alexander Rogers, Senior Global Program Head Neglected Tropical Diseases, Novartis
- Rekha Shukla, Joint Secretary, Ministry of Health and Family Welfare, India
- Gangadhar Sunkara, Senior Global Program Clinical Head, Novartis

I. Welcome: Bill Simmons

- **Bill Simmons:** Jan will introduce Linda.
- **Jan:** Linda is my successor as CEO of NLR and CEO of the LRI. Linda will be in my position from 1 January. This is my last meeting with the Global Partnership Leadership Team (LT).
- **Linda:** I'm looking forward to working with you all on this important mission.

II. Rifampicin discussion and next steps: Arielle Cavaliero

- **Arielle:** Everything we do in terms of supply and production is always in partnership with WHO. Earlier this year there was a communication by health authorities requesting testing of rifampicin to all manufacturers, not only Novartis. The release of all the finished products were temporarily placed on hold. We are working closely with WHO on the analysis. We have clarity on which batches have been affected and will be blocked. Production is now ongoing and we are working with WHO to ensure that country needs are met. This is a weekly conversation between our value chain team and WHO procurement.

We are working to have this regularly communicated by WHO. The latest communication was on 23 November from the director of the MDT department. The MDT issue is more or less under control. There will be country-specific questions. The challenge is that for Novartis, the current indication that we have for rifampicin is for the treatment of leprosy (MDT) and not the prevention of transmission (SDR).

- **Erwin:** We met last week and two weeks ago with headquarters and also with Brazil because this country was most severely affected by the interruption of MDT supply. The batches that have less than 5 parts per million as contamination are considered safe and will be released. Batches with a higher amount will be discarded and cannot be used.

Brazil will receive a two-month supply to allow other countries to be supplied. At the moment, production is not at its maximum. As a short-term measure, we have staggered supply to countries to prevent stock-outs. Ministries have been made aware of the situation so they can mitigate as much as possible.

- **Mauricio:** Today I talked with the national programme. We have external and internal problems in MDT delivery. Our national drug department takes around two months to authorize. When we have the communication that the batch is ready to be sent, they have to ask for authorization, which takes more time. If they start the process earlier, we can avoid this internal problem as well.
- **Benedict:** For countries, what actions should we take with the batches that are already in the country? It's not clear.
- **Arielle:** I suggest reaching out to the procurement officer based in Geneva. He is charged with the mandate to give guidance. There's an opportunity to include that in the next communication to the extent that it can be answered with accurate information.
- **Erwin:** We do not know if those batches have a similar contamination problem or not. Because many countries have little or no stock, I haven't seen any guidance on whether or not those batches are safe or not safe. We should flag this issue. Headquarters will have to answer that.
- **Wim:** I want to clarify that we are talking about impurities, not contamination. This is part of the production of rifampicin, so it affects all manufacturers. There is a statement on the FDA and EMA website: As long as the levels are below a certain amount of impurity per day, that treatment should continue. The risk of not giving treatment to TB outweighs the risk of this relatively small impurity.

In the view of the ILEP Technical Commission (ITC), if batches are below that level, they can continue to be supplied. We will issue further guidance. Geoff already disseminated a letter from ILEP on the MDT issue to ILEP country offices. If there is an in-country facility to test rifampicin, then that is our recommendation.

Secondly, we drafted our recommendation on PEP. That has not been finalized, but because of ethical reasons, we should not be giving SDR-PEP that could be contaminated to healthy people.

- **Mathias:** I want to give a perspective on how this affects people affected. We don't know about the causes of this, but we have been hearing for months from our sisters and brothers in Brazil and Sierra Leone. I want to make sure that we understand the urgency of this. With the delay of treatment, we are talking about more transmission, more disability, and more children with leprosy and disability. And we're potentially talking about more stigma. I don't know about the causes, but I think we need more information. People affected have the right to know if their

medication is not available or will not be available. This situation makes us need to consider what we can do in the future as the Global Partnership to make sure that this does not happen again.

- **Erwin:** This year has been one problem after another, all of them interlinked. At the country level, particularly in India, we have seen a dip in case detection due to COVID-19. We are pushing Novartis to have a larger buffer stock in the plant while also considering the tradeoff that too large a stock could allow for drugs to expire.

III. Ghana country model implementation: Mondie Tharp, Benedict Quao

- **Mondie:** The Ghana country review just finished so we will share some early findings:
 - TOR between the Ministry of Health and GPZL outlined work and identified deliverables.
 - International experts were identified through Ghana MoH and GPZL.
 - Fieldwork covered 4 regions to represent high, medium, and low endemicity. National level and district level data were collected
 - 60 Stakeholders met to review the data and identify strengths and weaknesses (as outlined in the presentation)
- **Bill Simmons:** Was there an initial stakeholder meeting with a wider group of NGOs?
 - **Benedict:** Yes, we had people from the public sector, regional directors, and coordinators. We had divisional directors, health service, and various NGOs and partners. We invited stakeholders not just limited to leprosy, but all NTDs.
- **Maarten:** How do we know that the case detection for leprosy is low? What are your proxy indicators?
 - **Benedict:** This would be best answered by the reviewers. I am presenting on behalf of them and they noted that the problem was low: 280 plus or minus cases per year. It may be more than that. The surveillance is still predominantly through passive cases.

IV. 2021 Work plan and budget: Geoff Warne, Arielle Cavaliero, Taka Nanri, Bill Gallo

- **Bill Gallo:** Thank you to Arielle, Geoff and Taka for helping to draft our work plan for the coming year. Our first meetings have focused on the activities for the coming year and how to balance our efforts within our 3 main pillars: research, country work, and resource mobilization. We are still revising it. I'll walk you through the draft with Andie.
- **Andie:** This is the timeline that we developed:
 - 20 October: Budgeting discussion during LT bi-annual meeting
 - Oct - Nov: Draft budget and work plan
 - Dec: Validate budget and work plan with LT, edit, and submit for approval
 - Mid-Dec: Final budget approved

We're moving into December with the finalization of milestones and flushing out the numbers assigned to those milestones for the overall budget. In this presentation, we'll get into the work plan and milestones. The discussion about the budget is still to come.

- **Bill Gallo:** Arielle gave us suggestions for identifying directions we could take with the Research Agenda.
- **Arielle:** A guiding principle for us was that the budget should be informed by the content. How do we build on this year with what we have achieved? What is the most logical next step? Our agenda was prioritised. With Nienke's help by the beginning of next year, we will better know what priorities are not being addressed. We discussed the need to see by the end of 2021 that all of those priorities have been anchored to a proper submission with resources mobilized to support them.

We look to leverage expertise from folks in leprosy and other research areas to work with them to landscape where we would like to see submissions made. We have a nice model: the FMDA model. We acknowledged last year that SDR was a priority and we gathered a group to identify an EDCTP submission. We're planning to have discussions with the people who made that submission to help those priorities find a home and be submitted by a dedicated team. By understanding this model we can understand the roles and responsibilities between the research group and the secretariat because that is something we'd like to further clarify.

- **Bill Gallo:** We are crafting internal plans for 11 countries for the country model implementation. We discussed the status of the model: template, tools, guidance documents, which are

well-developed but incomplete. The product gets us through the roadmapping process, but we need to supplement it with an M&E plan and an action planning component. As we're refining the original draft, we anticipate intensive work with a consultant that will work alongside Mondie. A lot of this discussion was prompted with concern for countries outside of our 10 country partners. We need a tool that is robust enough that countries can apply it on their own without GPZL.

- **Geoff:** We all want to see country programmes move forward. The new WHO GL strategy advocates for all countries with leprosy to put together national partnerships for zero leprosy and zero leprosy roadmaps. It is in our interest to get the consultant work done and complete a robust country model process. We learned a lot from implementation in Morocco and now in Ghana. Once that's done, we'll have something usable for other countries as well. That is a good goal for us.
- **Bill Gallo:** There was a good discussion about the fact that it's important to engage high-level leadership to engage the leadership within the country to get Ministry of Health support and NGO support to help meet gaps that exist. This is something that Taka has talked about.
- **Mauricio:** I would suggest a report from the Ghana meeting with leprosy indicators. I think that we could standardize a report for each country with key indicators and historical trend series for five years. For example, for each indicator like the number of cases, the percentage of visibility at the nose. I think that we could standardize something for every country that we are starting to support. It would be nice for us to have an epidemiological view of the country. I think that Ghana is a good country for us to have a pilot study.
- **Erwin:** I want to comment on Bill's point about the number of countries that the Partnership can support. I believe that comes from the idea that support requires the direct involvement of the Secretariat. The Partnership is bigger than the Secretariat. We have good partners. It doesn't all have to be done by the Secretariat.
- **Bill Simmons:** We won't have another meeting before work plan finalization
- **Bill Gallo:** We will invite input from the Leadership Team.
- **Andie:** We'll try to have something for you on Monday for your input. If we need to discuss this in this forum, we may designate some in our January meeting.

V. Letter to PLOS NTD: Bill Simmons

- **Bill Simmons:** I did not want to weigh in on this as the chair on behalf of the LT without running it by the LT first. Would we like to formally sign onto this as the GPZL? What questions or concerns does anyone have about the letter that has come out in response to the research from Bangladesh?
- **Mauricio:** I agree with the letter. Many times we identify the index case as the first case that arises in a community or family. This is not always the case in leprosy. Many times when we are doing the contact tracing, we find the real index case.
- **Geoff:** Two groups of scientists look at the same data and interpret it in different ways. But this happens all the time in the leprosy world. I don't think this is the role of the LT to comment on.
- **Erwin:** This guidance is on the WHO website. We clearly say that it should be done for all index cases. Index cases are not always the source case. All contacts should be investigated.
- **Benedict:** Some may have been invited to support this letter. What do individual members do? Because it will be reflected on the collective.
- **Bill Gallo:** Paul included some caveats. He understands why we may not want to be a signatory. It's not only if we agree with the letter. In technical terms, we have to decide if it is appropriate for the LT to sign onto.
- **Bill Simmons:** We decide that we will not sign the letter. This is a nuance because the Partnership is so broad and we include country programmes.

This is Jan's last meeting. Thank you, Jan. We are happy to have Linda, but we will miss you.

- **Jan:** Building the Partnership was one of the most exciting parts of my work in leprosy over the last 12 years, and I am confident leaving it behind in your hands. All the best.