Global Partnership for Zero Leprosy

Preliminary Report
Research Agenda Working Group Meeting
Global Partnership for Zero Leprosy

23-24 August, 2018
Basel, Switzerland

The Global Partnership for Zero Leprosy was established in 2018 to catalyze and coordinate action toward the goal of zero leprosy, also known as Hansen's disease. The Research Agenda Working Group is the first of two major working groups to be convened in 2018 in pursuit of the Global Partnership's strategic objectives. The second, on Operational Excellence, will identify and promote best practices to achieve zero leprosy and help facilitate the uptake of best practices and new interventions into national leprosy programmes. Beginning in late 2018 a third working group, on Resource Mobilization and Advocacy, will take these initiatives forward to potential donors and partners.

The Research Agenda Working Group is chaired by Dr. Fareed Mirza, of the Novartis Foundation. Leading scientists serve as facilitators of seven sub-groups, which will focus on specific areas of research related to zero leprosy. Membership and participation in these sub-groups, which will meet virtually during September-October 2018, is open to all interested persons. Several scientific advisors have been appointed to provide overall guidance and support to the Research Agenda Working Group. On 23-24 August, 2018, these facilitators and advisors, in addition to observers from the Working Group on Operational Excellence, met in Basel, Switzerland with the following objectives:

1. Review current scientific knowledge related to leprosy, identify gaps in knowledge required to achieve zero leprosy, and propose key research questions and initiatives to close those gaps.

2. Initiate an inclusive process that will lead to a comprehensive research agenda that can align ongoing and new research leading to zero leprosy and be used to advocate for additional funding.

3. Equip sub-group facilitators with the information and support they need to conduct virtual sub-group meetings during the months of September and October, 2018 and to prepare a final sub-group report for inclusion in a comprehensive research agenda.

4. Elaborate a plan for bringing the sub-group reports into a comprehensive research agenda.

5. Engage with leaders of the Operational Excellence Working Group to ensure synergy between the two working groups.

This report summarizes the meeting. A list of attendees, as well as Working Group facilitators and advisors who were unable to attend, is shown in Appendix 1.

On the first day of the meeting, sub-group facilitators reviewed the current state of knowledge in seven areas related to zero leprosy; identified gaps in knowledge; and proposed research to close these gaps. Discussion followed each presentation. Areas of potential overlap among the seven areas were noted, and topics that

were not addressed, but were considered potentially important for a comprehensive research agenda, were assigned to specific sub-groups. An eighth sub-group on research related to digital health and technology has been added. Table 1 shows the eight research areas, the facilitator for each area, and proposed topics, questions, and approaches for further deliberation.

Table 1. Sub-group, facilitator, and possible research topics and questions

Sub-group	Facilitator	Possible topics, questions, and approaches
Vaccines	Steven Reed	• Phase 1, 2, 3, trials of candidate vaccines • Vaccine optimization • Vaccines in combination with other interventions (e.g., PEP) • Strategies for vaccination (target populations, settings) • Influence of stigma on vaccination coverage
M. leprae transmission and post-exposure prophylaxis (PEP)	Christa Kasang	• *M. leprae* transmission • PEP – which drug(s)? What frequency? How extensive (e.g., household, neighborhood, "blanket' coverage)? Cost. Impact. Informed consent and messaging. Integration with preventive chemotherapy for other NTDs
Diagnostic and screening tests	Milton Moraes	• Improvements on current microscopic methods • Test sensitivity, specificity, predictive value, validity, and performance under different conditions • Optimal tests for different settings • Screening tests • Biomarkers
Operational research	Paul Saunderson	• Mapping; use of GIS to identify "hot spots" and guide PEP • Surveillance; monitoring and evaluation • Integrated NTD operational research opportunities • Safety and efficacy of drugs and drug combinations • Drug resistance • Adherence to multi-drug treatment (MDT) for leprosy • Digital technology
Stigma	Wim van Brakel	• Effectiveness of stigma reduction interventions • Effect of the participation of leprosy-affected persons on research • Stigma as a barrier to PEP and other interventions to reduce leprosy transmission • Stigma in health care settings • Mental wellbeing of leprosy affected persons • Validation of tools/questionnaires to determine stigma
Disability	Liesbeth Mieras	• Efficacy trials of novel drug treatment of nerve function impairment (NFI) and reactions • Mechanisms of increased risk of reactions and nerve function impairment • Feasibility, effectiveness and impact of disability prevention • Impact of case finding/contact tracing on the prevalence of disabilities

		• Mapping of disabilities and disability services • Inclusion of persons with disabilities
Epidemiologic modeling and economics	David Blok	• Modeling to evaluate current and proposed strategies; assess impact of novel interventions (e.g., vaccines; "blanket" coverage with PEP); and explore mechanisms of disease and transmission • Cost studies, cost-effectiveness, cost-benefit • Investment case for elimination • End-game scenarios
Digital health and technology	David Heard	• Diagnosis (e.g., visual images, telemedicine) • Surveillance, programme monitoring, information exchange, communication with persons under MDT treatment

On the second day of the meeting, these discussions were extended and the respective work of the Research Agenda and Operational Excellence working groups was clarified. The Research Agenda Working Group is concerned with developing a comprehensive agenda for *research* needed to achieve zero leprosy, while the Operational Excellence Working Group will address best practices, capacity-building, and processes needed to build, support, and sustain *programmes* that can achieve zero leprosy.

Given the emerging importance of digital technology and the number of sub-groups in which research on digital technology might be relevant (e.g., in diagnosis, communication, mapping), an additional sub-group on digital technology will be convened.

Several recurrent themes surfaced during the meeting, including the following.

- Research studies can be designed to advance several lines of knowledge at the same time. For example, studies of PEP provide opportunities to better understand the epidemiology and transmission of *M. leprae*, evaluate the utility and performance of novel diagnostic assays, and assess approaches to reduce leprosy-related stigma and convey information related to risk of leprosy at the community level.
- Increasingly, programmes to control and eliminate individual NTDs are integrated, or at least highly coordinated. Operational and implementation research on leprosy will often occur in the context of research on other NTDs, particularly related to self-care, mental health, stigma, and programmatic issues such as mapping, monitoring, and reporting.
- The perspective and input of national leprosy programme managers and of persons affected by leprosy will be crucial to developing and refining the research questions.
- Conceptually, much of the research and programmatic innovation necessary to achieve zero leprosy may fall into five categories:
  - *Identifying* persons at increased risk of leprosy through (e.g., through intensified case-finding, mapping, and novel screening tests);
  - *Preventing* leprosy in persons at increased risk (e.g., through PEP, vaccines, and prompt and effective treatment of persons with *M. leprae*);
  - *Identifying* persons with *M. leprae* infection in a timely fashion and bringing them to treatment (e.g., through reducing stigma and operational research to support capacity-building and improve early detection and treatment);
  - *Preventing* disability before, during and after antimicrobial treatment*;* and

- *Eliminating* stigma and discrimination.

Facilitators will convene the sub-groups by teleconference (most likely using Zoom or similar technology) during September and October 2018, with the objective of having preliminary sub-group reports completed by the end of October. These reports will review current knowledge; describe research currently in progress; and propose key research questions, indicating their relevance for achieving zero leprosy. Sub-group deliberations will also address the relative priority and importance of proposed research for zero leprosy; suggest the design of proposed studies; and identity opportunities for leprosy-related research with other ongoing NTD research.

A draft comprehensive research agenda is anticipated by mid-December 2018. Persons desiring to participate in the deliberations of a sub-group can indicate their interest on-line at https://zeroleprosy.org/join-research/ by 7 September 2018.

Appendix 1. Zero Leprosy Research Working Group

Zero Leprosy Research Agenda Working Group Meeting

23-24 August 2018, Basel, Switzerland

	Invitee	Sub-Group	Country	Gender	Comments
Chair	Fareed Mirza	Research Agenda working group Chair	Switzerland	M	
Facilitators	Milton Moraes	Diagnostics tests	Brazil	M	
	Steve Reed	Vaccines	USA	M	
	Paul Saunderson	Operational Research	Norway	M	
	Christa Kasang	PEP	Germany	F	
	David Blok	Epidemiologic modeling, cross-cutting	Netherlands	M	
	Liesbeth Mieras	Stigma & Disability	Netherlands	F	Not able to attend in Basel
	Wim van Brakel	Stigma & Disability	Netherlands	M	
Advisors	Cita Rosita Prakoeswa	Advisor	Indonesia	F	Not able to attend in Basel
	Diana Lockwood	Advisor	U.K.	F	Not able to attend in Basel
	Anil Kumar	Advisor	India	M	Not able to attend in Basel
	Erwin Cooreman	Advisor	India (WHO)	M	Not able to attend in Basel
	Christian Johnson	Advisor	Benin	M	
	Paula Soares Brandao	Advisor	Brazil	F	Not able to attend in Basel
	Kofi Nyarko	Advisor	Ghana	M	Not able to attend in Basel
	Annamma John	Advisor	India	F	
	Marivic Balagon	Advisor	Philippines	F	
	W. Cairns Smith	Advisor	U.K.	M	
	Jan Hendrik Richardus	Advisor	Netherlands	M	Not able to attend in Basel
	Bart Vander Plaetse	Chair, Operational Excellence working group	Switzerland	M	
	David Addiss	Advisor	United States	M	
Observers	Christine Fenenga	Coordinator, Operational Excellence working group	Netherlands	F	
	Geoff Warne	ILEP representative (WG2 convener)	Switzerland	M	
	Arielle Cavaliero	Novartis Foundation representative	Switzerland	F	
	Courtenay Dusenbury	Secretariat, Global Partnership for Zero Leprosy	United States	F	