

Translating Research Findings into Program Practice**Session Date:** Saturday, November 4**Session Time:** 9:00am – 12:00pm**Session Location:** Potomac

Session Description: The goal of this session is to discuss the pathways, the requirements and the challenges, faced in taking new research discoveries to full field implementation for the filarial disease elimination programs. There are many formal and practical steps that need to be addressed in adding a new methodology to, or changing a strategic approach for, the already long active and successful nationally implemented elimination programs across endemic zones. In this session, we will hear from researchers, regulators, donors and country program managers as to their requirements, perspectives and needs, for this translation. The session will discuss this issue with for new chemotherapies, new screening methodologies and for other potential enhancements to the global filarial disease eliminations efforts.

Session Chair: Charles Mackenzie, The Task Force for Global Health**Session Rapporteur:** Drew Deathe**KEY DISCUSSION POINTS**WHO Requirements for Program Approval

The World Health Organization (WHO) has created a thorough document detailing the criteria required for research results to turn into guidelines and recommended strategies. Discussion focused on how researchers can ensure the results produced from their studies meet WHO standards and turn into approved guidelines. Any guidelines produced by WHO are based on the best evidence from rigorously designed and representative studies. WHO uses a systematic process for making guidelines and they highly recommend that researchers develop solid study designs and use the PICO (problem/patient/population, intervention/indicator, comparison, and outcome) criteria when doing so. Additionally, WHO establishes recommendations and guidelines based on consensus results.

Funding Agency Perspectives

Donors have stringent rules for how and what they can provide funding for. Every dollar has a specific purpose and intention behind it. Funding agencies have priorities and it is vital that researchers learn to harmonize their research efforts with these priorities. While it is acknowledged that this model is somewhat restrictive to innovation, it is important that donors and researchers share ideas and together learn how to incorporate innovation with the priorities. Discussion on this idea was focused on bridging the gap between silos, for example, creating joint efforts between NTDs and maternal and child health.

Triple Drug Therapy Development

This scenario is an excellent example of research results going from a major discovery to policy change. From a temporal perspective, this study began with an idea in 2009 and ultimately led to policy change in 2017. The idea was to use Ivermectin, Diethylcarbamazine, and Albendazole (IDA) to clear *Wuchereria bancrofti* microfilariae from the blood of patients with lymphatic filariasis. At the time, the current therapy was either Diethylcarbamazine + Albendazole or Ivermectin + Albendazole. Results from the clinical trial conducted showed that after one year 97% of individuals treated with IDA were amicrofilaremic compared to about 34% of those treated with DEC + ALB. After these significant results were obtained, meetings with stakeholders were held in 2015 to plan an accelerated path toward policy change. This policy change was necessary for IDA to become an option for LF elimination programs. Safety was a primary concern and WHO required “cohort event monitoring” and they needed data from at least 10,000 patients treated with IDA. There was no difference found in the safety profile of IDA compared to DEC+ALB; similar proportions of treated persons reported adverse events. The results from these efforts are extremely positive and IDA has the potential to reduce the time and cost of elimination efforts. District level pilot roll out is now being planned in key countries. The pharmaceutical industry is waiting for the full WHO guideline document to be published before they move forward and make major decisions related to this new IDA therapy option. (note: Merck announced their support of IDA through an expanded ivermectin donation shortly after the COR-NTD meeting)

KNOWLEDGE GAPS IDENTIFIED

- How can researchers produce evidence that meets WHO standards and are eligible to turn in to guidelines and policy? What is necessary and sufficient?
- What happens when a guideline is changed or updated? How is this information communicated to programs?
- If there isn't sufficient evidence available to establish guidelines, how do you circumvent the rules and procedures for creating guidelines to put something in place?
- How can researchers strengthen their evidence and make it more apparent that certain interventions are effective and something that should turn into a guideline?
- How can modelling be used for making guidelines?
- Now that IDA has been deemed safe and very effective, how can we translate this into millions of people receiving the therapy?
- How can we increase compliance with IDA in the future roll out?

RECOMMENDED NEXT STEPS

- Roll out of IDA therapy is being planned in select countries. This roll out needs to be coupled with enhanced MDA to increase compliance.
- Researchers need to more diligently employ PICO questions and guidance to plan research. If this is the type of evidence needed to turn findings into guidelines, higher quality evidence must be obtained.
- Researchers must share ideas and be transparent with donors and WHO.
- Researchers should understand that evidence from multiple countries provides stronger evidence for policy change than data from a single country.