
Research for Implementation

Report of the Scientific Working Group

18-19 September 2018, Geneva

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Executive Summary

The Scientific Working Group (SWG) was impressed by the productivity of this small group of TDR Research for Implementation staff over 2018, and their alignment with global priorities including the UN Sustainable Development Goals and WHO Global Programme of Work (including *Universal health coverage*, *Addressing health emergencies* and *Promoting healthier populations*).

Selected projects were reviewed in depth and recommendations were made, primarily on priorities for the 2020 – 2021 biennium. The SWG recommended that most projects reviewed in detail be continued as planned, namely:

- The Early Warning and Response System (EWARS) work programme should be continued, including expanding the evidence base with prospective studies, implementation research, support for capacity building, and ensuring sustainability by linking with networks.
- The active and financial support of TDR in CariVecNet and WIN networks can be phased out.
This is not the case for the arboviral network in West Africa, which is still developing and should be continued while developing a pre-defined transition plan to self-sustaining model. TDR should seek new opportunities for research through such networks.
- TDR's considerable long-term investment in the science of elimination should be continued until brought to conclusion by:
 - Completing the case study on Visceral Leishmaniasis elimination in Nepal as proposed (Phase 1 and Phase 2), and ideally in a comparator country (e.g. Bangladesh). TDR's role would be focused on adapting methods and tools for their sustainable, integrated use in the "last mile" i.e. in (very) low-incidence areas. This should be complemented by facilitating policy research by a third party (e.g. consultancy by social scientist/health policy and systems researcher/s), as achieving and sustaining elimination will require intense engagement at political and economic fronts.
 - With the successful uptake of some TDR initiated onchocerciasis elimination research projects by other research groups / funders, TDR could now focus on the tools and capacity strengthening needed for the deployment of moxidectin (and advocacy for moxidectin funding strategies), and for implementation research on its deployment.
- Drug safety (and the safety of interventions more broadly) is a cross cutting issue that should be integrated within each health system. TDR should continue to conduct pilot studies on how best to overcome challenges to embedding drug safety within WHO programmes and national health systems.

The SWG recommended that two (or three) projects be expanded:

- The WARN-TB and CARN-TB projects should be expanded (deepened) within the same region, with linkage to the arboviral network, and define pathways to policy impact that can bring learning to other networks.
- The programme of work on gender-responsive health interventions towards ensuring that an intersectional lens is embedded across the TDR / Research for Implementation gender-responsive thinking and work. The planned November meeting would be invaluable in informing this strategy.
- In addition, SORT IT will be expanded but increasingly franchised; TDR activities will remain focused in their niche areas and will not necessarily expand.

Two work programmes in important fields were considered that could be phased out or transitioned into clearly defined new work programmes:

- The current project on residual malaria will be phased out after completing the full evaluation of the work to date; these results will be used to define a new ‘big ticket’ project that can be integrated within TDR’s project on multi-sectoral approaches for the prevention and control of malaria and other vector-borne diseases.
- Although the inter-relationship between climate and health will remain highly topical, the team needs to specify priorities for future work programmes before an SWG recommendation can be made.

A number of cross-cutting recommendations were made:

- The implementation research value of the vast data generated through TDR needs to be maximised; evaluations, done well, are implementation research and an output in themselves. Thus, recommended interventions (from policy briefs and other outputs) need to be implemented and tracked as a form implementation research.
- Data sharing is central to a number of TDR activities and TDR can play a central role in the evolving data sharing landscape. TDR is particularly well placed to inform governance of the sharing of routine surveillance data of national ministries of health, to facilitate the timely sharing and impactful re-use of these data.
- TDR needs to define a strategic direction and approach for its response to requests for participation in networks. It would be good to use TDR’s experience with networks to set these criteria (as with other partnerships) and to define its exit strategy at a relatively early stage in the development / planning of these networks.
- To foreground Research & Communication / Global Engagement activities so that learning from one project can be applied across relevant projects within TDR, WHO and more broadly.

Background

The Scientific Working Group (SWG) on Research for Implementation has an important role in advising the TDR secretariat on the implementation and planning of TDR research activities, in the context of overall guidance by the Scientific and Technical Advisory Committee (STAC) and the Joint Coordinating Board (JCB). STAC recommendations provide the framework for TDR’s approach toward research and the work programme for 2018-2019 and 2020-2021.

To ensure independence, SWG members cannot be current recipients of TDR funding. Members were asked to declare any possible conflict of interest by completing, and if relevant updating, the WHO Declaration of Interests form. Members may be requested to recuse themselves from any discussion(s) related to the area(s) in question.

Expected output from the meeting

By the end of the meeting, it is expected that the SWGs will have made recommendations for consideration by TDR staff and the director based on: 1) review of progress made against the 2018 workplan; 2) prospects for implementation of the 2018-2019 research workplan, and 3) prospects for the 2020-2021 portfolio and relevant budget.

Review of progress during 2018

The Scientific Working Group (SWG) was impressed by the productivity of TDR Research for Implementation staff over 2018, and their alignment with global priorities including the UN Sustainable Development Goals and WHO Global Programme of Work (including *Universal health coverage*, *Addressing health emergencies* and *Promoting healthier populations*). Some efforts have been made to seek out and build on synergies between the IIR and VES groups, but this process has been interrupted by restructuring within WHO.

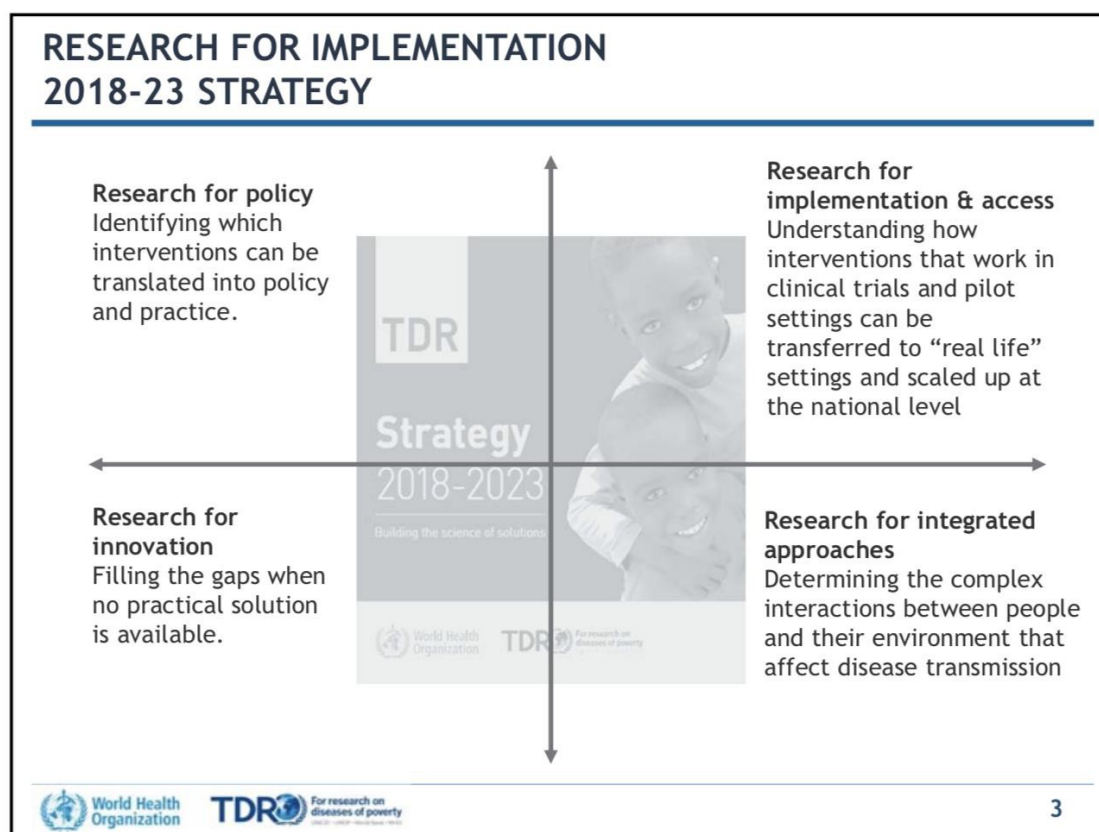
Key achievements presented included:

- **Moxidectin** approved by US FDA and granted priority review voucher (PRV). This is the first drug approved for onchocerciasis in 30 years and provides a new tool for onchocerciasis elimination end-game. It illustrates a model for ensuring that the use of the PRV benefits the poor.
- **Rectal artesunate** for pre-referral treatment of severe malaria was WHO-prequalified, which is a key step towards broader availability of this product of decades long TDR leadership.
- A tool to improve response to **dengue outbreaks** has been optimised, with more countries supported, uptake increasing, and disease scope expanding.
- Innovative tools and sustainable combined approaches developed for the “last-mile” of **visceral leishmaniasis elimination** in the Indian Subcontinent, with impact demonstrated in Nepal and Bangladesh.
- Africa sub-regional **networks for TB control** have expanded geographically, addressing health-system issues, generating a sustainable regional dynamic, and mobilising ~ US\$2.4 M to enhance country programme research capacity
- **SORT IT** continues to evolve: growing national leadership, developing new study designs, methods and themes, with concrete moves towards strengthening country capacity to deal with **antimicrobial resistance** (AMR) soon to start. AMR has been included as a major TDR project.
- The 5 research projects on the *Impact of **Climate Change** on Vector-borne Diseases (VBD)* and *Resilience of the most vulnerable populations in dryland Africa* have been completed, and the evidence generated is now being used to mitigate the impacts of climate change on VBD transmission. TDR has been recognized as a strong partner and is engaged in the development of the next Libreville declaration.
- Research projects on **residual malaria and impact of insecticide resistance** on LLINs efficacy have been completed and demonstrate that malaria transmission is persisting in many settings. This should not be classified as residual malaria as ongoing transmission is actually due to inadequate coverage and use of available tools (e.g. LLINs and IRS).
- **Networks on preventing emerging vector-borne diseases** have been established and are now becoming self-sustainable (e.g. Caribbean Network on vector-borne disease (CariVecNet), and a global network on insecticide resistance monitoring (WIN).
- A Special Issue on **prevention and control of VBDs in urban health** recently published in the *Journal of Infectious Diseases of Poverty*
- The **Global Vector Control Response (GVCR)** to which TDR made a substantial contribution was supported by a resolution at the World Health Assembly (WHA70).

Review of Research for Implementation Strategy (2018 – 2023)

The new Research for Implementation Strategy (2018-23) was reviewed, as illustrated in Figure 1 below, and the positioning of each current project within this framework discussed. This strategy was supported by the SWG. It was suggested that TDR consider including a cross-cutting themes or umbrella functions within this graphic.

Figure 1: TDR Research for Implementation Strategy for 2018 - 2023



In-depth Review of Selected Projects

Based on the 2017 SWG recommendations specific projects were identified by TDR for critical review, for example ones that are long-haul, resource-intensive, require strategic direction. Two reviewers were assigned by the SWG chair to review each of these projects. The relevant documents

were provided to all members in advance (<https://workspace.who.int/sites/swgs>). Each project was examined against the following pre-defined criteria:

1. Relevance – why are we doing it? (addressing a significant public health need, which could be current or anticipating a forthcoming issue).
2. Uniqueness – why TDR?
 - Recognised TDR role
 - Project stands out in the global arena

3. Output – what will be delivered:

- Demonstrable impact – how measured?
- What has the project already delivered?
- What will the project deliver?
- Timeliness – still relevant when results will be delivered?

4. Appetite:

- For partnering (other organisation's interest)?
- For funding?
- For uptake of research output?

5. Required human and financial resources: covered vs. required – can we do it?

6. Risks vs benefits if: continuing; expanding; downsizing; phasing-out?

Each project was presented by TDR staff in charge of that project, and an overview of the review of the project by designated SWG members was given, highlighting the specific output. These presentations introduced the group discussion where the SWG was asked three general questions for each area of work:

- Is the project strategically delivering?
- How should the project be evolving?
- What's the opportunity costs of working on this project?

Topic 1: Tropical (vector-borne) diseases and environmental health

Increasing resilience under climate change conditions in Africa (ER 1.3.3)

Than Tun Sein & Sassy Molyneux

The initiative had demonstrated the importance of multi-disciplinary research in generating new knowledge and interventions that could reduce populations' vulnerability to vector borne diseases. Although the number of professionals trained (59 post-graduate students) and manuscripts published (152 manuscripts, 9 policy briefs in 7 countries) is very impressive, evidence for the uptake of the research results is limited. A knowledge gap remains in terms of showing how the recommended new knowledge and interventions could be further integrated into the existing national health systems of African countries, after translating them into policies and practices, tailoring them into local community contexts and scaling them up. The effects of climate (e.g. seasonality, climate variability) were shown, but those of climate *change* specifically were not clearly isolated from other factors.

SWG Recommendations: Any future phase of this project should consider including Implementation Research / Participatory Action Research approaches to document the process and extract key new learning. Crystallising knowledge generated to date is needed to identify key new questions that TDR is uniquely well placed to address. This would define research for implementation priorities that will attract substantial TDR funding (in the region of \$10 million from a new funding source e.g. African Development Bank, Africa Climate Change Fund, IDRC). In addition, recommended interventions (from policy briefs and other outputs) need to be implemented and tracked as a form of implementation research. Where implementation success is seen, scale up should be facilitated. Networks could help facilitate the advancing of this initiative and test the generalisability of findings across different geographic areas.

SWG Conclusion: Although the inter-relationship between climate and health will remain highly topical, the team needs to specify priorities for future work programmes before an SWG recommendation can be made.

Topic 2: Challenges in malaria control

Residual Malaria (ER 1.3.6)

Mario-Henry Rodriguez-Lopez & Than Tun Sein

Initially the project, with six research projects, aimed at understanding the determinants of residual malaria transmission and included the effect of insecticide resistance on the efficacy of Impregnated Nets (LLINs), and Indoor Residual Spraying (IRS), as well as entomological, parasitological, and socio-anthropological factors associated to LLINs/IRS efficacy. Two of the projects also investigated mosquito and human behaviours that may explain failure of LLINs/IRS treatments in controlling malaria. The results generated limited information on insecticide resistance and no mosquito resistance mechanisms were investigated. Human behaviour, such as staying outdoors at times of high mosquito biting and sleeping in huts in the forest / farm, stands out as a determinant of LLINs limited efficacy in the control of malaria transmission. The presence of outdoor biting mosquito species was shown to limit the effectiveness of LLINs and importantly the perception of lack of protection was one of the reasons why people do not sleep under LLINs. In all study sites, except in Viet Nam, coverage with control interventions was incomplete. Thus, ongoing transmission occurred primarily as a result of gaps in malaria control, and this should not be classified as residual malaria transmission (RMT, previously termed “Refractory Malaria”).

SWG Recommendations: These findings indicate a clear need for more locally adapted and strategically designed integrated approaches, and for new tools to control outdoor transmission and prevent biting before / after people are inside their bed nets; community involvement will be important. New tools are also needed to eliminate transmission in refractory malaria areas. Residual malaria determinants remain a key question that should still be addressed in settings where coverage of control interventions is complete. As all these projects have been completed, the SWG recommended that evaluation of the final reports should be finalised, and implementation research value of the data generated maximised during 2018 / 19 biennium. All available results should be used to define how best for TDR to re-focus its malaria related ERs. However, no continuation should be considered without substantial external funding. With such funding, TDR should focus on its niche areas such as implementation research for understanding outdoor transmission of vector borne diseases in general, not only malaria. It was not recommended for TDR to get involved in further research on residual malaria, unless explicitly requested by the Global Malaria Programme. Nor should TDR focus on developing new tools for malaria control, although TDR could participate in assessing new tools and developing the multi-sectoral implementation strategies to optimise their deployment.

SWG conclusion: The current project on residual malaria will be phased out after completing the full evaluation of the work to date; these results will be used to define a new ‘big ticket’ project that can be integrated within TDR’s project on multi-sectoral approaches for the prevention and control of malaria and other vector-borne diseases.

Topic 3: Country preparedness for disease outbreaks: Prevention and control of Aedes-borne diseases

Olaf Horstick & Mario-Henry Rodriguez-Lopez

Early Warning and Response System (EWARS) (ER 1.1.1)

The activities to develop the Early Warning and Response System (EWARS) go back to 2011. The relevance of this system has been highlighted by recent outbreaks of *Aedes*-borne arboviral diseases and is unique in being the only available system that is not based on an increase in numbers of cases with a specific disease. It therefore has the potential to pre-empt and hopefully prevent such outbreaks. The evidence supporting EWARS is based on systematic literature reviews, country case studies, and studies developing and testing EWARS. All evidence supporting EWARS has been published in peer reviewed journals, and TDR published an Operational Guide: The Early Warning and Response System (EWARS) for Dengue Outbreaks in 2018. The EWARS is now being tested in several countries and several dissemination workshops have been held in PAHO and SEARO. EWARS was developed for dengue; however, EWARS is now being tested in the context of other arboviruses such as Chikungunya and Zika.

SWG Recommendations: Further prospective studies to test the broader applicability of the EWARS tool would be beneficial. For example, EWARS could be further tested in the network for arboviral diseases in West Africa. One challenge is that this tool requires reasonably good surveillance systems (and should ideally be compatible / articulated with the increasingly used DHIS2 system), as well as infrastructure for collecting meteorological data (e.g. temperature, rainfall monitoring). Thus, the tool may provide an incentive to collect and share such data where these data are lacking, but this is resource intensive. WHO TDR may be in a good position to advocate for access to satellite meteorological data. The SWG also supports strengthening EWARS implementation research as well as knowledge transfer / skills sharing / technical support for early warning of arboviral diseases.

SWG conclusion: This programme of work should be continued, including expanding the evidence base with prospective studies, implementation research, support for capacity building, and ensuring sustainability by linking with networks.

Networks on emerging arboviral diseases (ER 1.3.10)

Three different regional networks that advance urban health and outbreak control are currently supported:

- Network on surveillance, diagnostic and vector control of vector-borne emerging diseases in the Caribbean region (CariVecNet),
- Worldwide International Network on surveillance of insecticide resistance for vectors of emerging arboviruses (WIN), and
- Network for strengthening country capacity for improved arboviral diseases control in West Africa.

CariVecNet and WIN are now self-sustaining, having attracted funds from other funding agencies.

SWG Recommendations: The active and financial support of TDR in CariVecNet and WIN can be phased out. This is not the case for the arboviral network in West Africa, which is still developing and should be continued while developing a pre-defined transition plan to self-sustaining model. TDR should also seek new opportunities for research through networks.

SWG cross-cutting recommendations: As further opportunities may arise, with research topics developing in the networks that may be of interest for the research funding portfolio of TDR, TDR needs to define a strategic direction and approach for its response to requests for network participation. TDR's experience to date with these networks can be used to set criteria for future involvement in networks (as in other partnerships), which may include: engagement requests by partners; if the work is relevant for TDR activities; and a network considered the best solution for a given poverty-related infectious disease problem. It is recommended that TDR develops these criteria further and defines an exit strategy (or 'Role of TDR' transition strategy) that should be embedded at a relatively early stage in the development / planning of these networks.

Topic 4: The science of diseases elimination – strategies to achieve and sustain elimination

Karen Barnes & Pascale Allotey

Visceral leishmaniasis elimination (ER 1.2.1)

Visceral Leishmaniasis elimination requires a health system wide approach that includes communities and integrates other febrile diseases and cutaneous conditions (e.g. TB, malaria, leprosy). Community involvement ranges from active post-treatment follow up by community volunteers to their participation in vector control and case and vector surveillance. Such implementation research, inclusive of programme managers, local researchers and community members can help drive success and without this many learning opportunities on the science of elimination will be lost.

SWG recommendations: TDR's considerable long-term investment in this important project should be continued until brought to conclusion by completing the case study in Nepal as proposed (Phase 1 and Phase 2), and ideally in a comparator country (e.g. Bangladesh). TDR's role would be focused on adapting methods and tools for their sustainable, integrated use in the "last mile" i.e. in (very) low-incidence areas. This should be complemented by facilitating policy research by a third party (e.g. consultancy by social scientist/health policy and systems researcher/s), as achieving and sustaining elimination will require intense engagement at political and economic fronts. Documenting, analysing and sharing the approach over time will be a valuable contribution and output in itself. This project is expected not only to advance visceral leishmaniasis elimination in Nepal where cases have been reduced to 250 (and ideally Bangladesh) but also contribute to public health more broadly in those countries and advance the science of elimination more generally.

The SWG acknowledges the critical human resource gaps with two experts who have driven TDR's efforts in VL elimination retiring imminently (Piero Olliaro is retiring in October 2018; consultant A Kroger retiring end 2019). These scarce skills will be hard to replace, and we would encourage TDR to work proactively and creatively with HR to minimize the loss of momentum on this important pioneering project. One suggestion was to identify and work with institutions in the region (e.g. tropical disease programs in Singapore, Malaysia, Thailand, China) as part of the succession planning, perhaps retaining Piero as a consultant to support the ongoing work. This may enable access to funding in the region which would otherwise not go to WHO (or other UN agencies) for a range of reasons.

SWG Conclusion: TDR's considerable long-term investment in this important project should be continued until brought to conclusion by completing the case study in Nepal as proposed (Phase 1 and Phase 2), and ideally in a comparator country (e.g. Bangladesh). TDR's role would be focused on adapting methods and tools for their sustainable, integrated use in the "last mile" i.e. in (very) low- incidence areas. This should be complemented by facilitating policy research, as achieving and sustaining elimination will require intense engagement at political and economic fronts.

Onchocerciasis elimination (ER 1.2.1 and ER 1.1.4)

The programme of work on onchocerciasis, as for VL, has been a long-term investment for TDR (since 1970s). The cornerstones of current onchocerciasis control approaches emerged from TDR research including safety of ivermectin during mass drug administration, ivermectin distribution strategy, and recently the major achievement of FDA licensing of moxidectin treatment (with the award of a Priority Review Voucher). Current focus is on addressing critical issues for sustained elimination (e.g. delineation of *O. volvulus* transmission zones, characterisation of the variability in response to ivermectin used in the control group of the moxidectin Phase 3 RCT, and transmission models to estimate the impact of migration and resistance). The programme has been successful in handing over components of this work, for example, research on the variability of pre-MDA parasite response to anthelmintic drugs will be continued independently with Wellcome Trust grant leveraged in part through TDR research. It is hoped that an NIH grant application for the parasite genome research is similarly successful.

SWG recommendations: The SWG recommended that this long-term programme of work be continued. TDR has a unique profile and the potential to catalyse success in the “last-mile”. A focus could be the tools and capacity strengthening needed for the deployment of moxidectin (and advocacy for moxidectin funding strategies), and implementation research on its deployment. We acknowledge that the speed (and extent of TDR recognition) will depend on the extent of additional funding raised. Should funding be limited the modelling work (patch model) was considered a lower priority for TDR.

SWG conclusion: With the successful uptake of some TDR initiated onchocerciasis elimination research projects by other groups / funders, TDR could now focus on the tools and capacity strengthening needed for the deployment of moxidectin (and advocacy for moxidectin funding strategies), and implementation research on its deployment.

Topic 5: Structured Operational Research and Training Initiative (SORT IT) (Evolution)

SORT IT evolution (evolution: ER 1.1.7, 1.1.4)

Pascale Allotey & Karen Barnes

Over the last decade, SORT IT has proven to be a sustainable and scalable approach to build capacity for generating and utilizing operational research data to support evidence informed decision-making to improve public health. To date 64 SORT IT courses have been held with 684 participants from 90 countries. The programme has evolved through franchising, expanded partnerships and alumni led courses. A recent independent evaluation led to the development of a supplementary toolkit, and recommended, inter alia, inbuilt SORT IT metrics on “impact of research” with interviews with facilitators, stake holders and individual participants unable to complete the course.

SWG Recommendations: The SWG supported the findings of the independent evaluation and supports the continuation of SORT IT. Although it will be expanded overall, it will be increasingly franchised so TDR activities will remain focused in their niche areas and will not necessarily expand. This will allow TDR’s commitments to remain manageable and ensure a long-term strategy that could sustain SORT IT even without TDR’s support. TDR should focus on new areas with designated funding (such as AMR) and on tools to ensure quality and impact of its franchised courses. TDR should have an opportunistic approach to global engagement and can play a catalytic role in response to requests from country partners, but also better define its boundaries / limits (e.g. IDP, EQUITY, optimising use and feedback to improve collection of routine data rather than any empirical research). Consideration should be given to the role of SORT IT in advancing south-south collaboration, gender sensitive research (ideally taking an

intersectional approach) and fostering individual participant data sharing. The implementation research potential of the vast data generated through SORT IT was highlighted. As routine surveillance data currently underpins most outputs, SORT IT has the potential to facilitate the enhancement of the quality of this data. In future, alternative software to Epidata may be considered, and prospective data collection may be needed particularly for SORT IT+ AMR. Reviewing SORT IT outputs could be used to derive quality benchmarks for “Quality of Implementation Research” evidence. A preference was expressed to embed gender analysis within SORT IT (rather than “gender blind” demographics current reported), acknowledging the tension between feasible and meaningful metrics. Closer articulation between SORT IT and other research capacity strengthening activities could prove synergistic.

SWG conclusion: SORT IT will be expanded overall, but increasingly franchised. TDR activities will remain focused in niche areas and will not necessarily expand.

Topic 6: Improved delivery of interventions

WARN/CARN-TB, Diama, Rafa, Rafa-screen (ER 1.2.6)

Bertie Squire & Lely del Rosario Solari

Although operational and implementation research is recognised as a key driver for TB control (and is the third pillar of the End TB strategy), there has been a lack of international support for TB research in West and Central Africa where the TB burden remains high. WARN-TB has brought together 16 national TB programmes and established 16 national multi-disciplinary TB research taskforces facilitating country implementation of national TB research plans and strengthening National TB surveillance systems (using DHIS2) in West Africa. WARN-TB is now starting to generate outputs and a similar regional network (CARN-TB) was launched in Central Africa in March 2018.

SWG recommendations: Focus should be on consolidating and planning for the future in WARN-TB & CARN-TB, rather than expanding geographically; consider a “TDR-lite” approach if projects in other regions are considered in future. Outputs include explicit metrics on Process (Secretariat, Website, WhatsApp groups), qualitative case studies and attention to on how impact will be measured. The multi-disciplinary taskforces are currently only made up of members from the health discipline and could benefit from being expanded into other relevant disciplines (e.g. economics, politics, social science). Adding a more substantial regional research project, selected using a research prioritization approach, would be preferable to several smaller pilot projects.

SWG cross-cutting recommendations: As with the Networks on emerging arboviral diseases (see above), a longer term strategy will be needed to understand how these networks should look in 2, 5 and 10 years. The strategy should include plans for sustainability, criteria for when TDR will step back and exit, and for when TDR gets involved in other networks. As with other projects, potential synergies with other TDR activities (e.g. SORT IT) should be explored. TDR is also encouraged to use the opportunities of both TB and arboviral networks to investigate the key drivers of the networks, in order to sustain success, ensure research impacts on policy and practice, and identify aspects that are generalisable across diseases. Such evaluations, done well, are implementation research and an output in themselves.

SWG conclusion: WARN-TB and CARN-TB projects should be expanded (deepened) within the same region, with links to the arboviral network. Experience from these networks can be used to define pathways to policy impact that can bring learning to other networks.

Topic 7: Safety of interventions

Maximized utilisation of safety information for public health decision making (ER 1.1.8)

Lely del Rosario Solari & Fang Jing

Despite markedly increased access to medicines recently in resource poor settings, drug safety monitoring systems generally remain weak leading to under-reporting and limited local safety data. This is a public health concern as drug safety can be significantly altered by local factors (e.g. target population profile, co-morbidities, concomitant medicine use, and health system gaps), and is a particular problem when medicines are administered to those who may not benefit individually (e.g. mass drug administration (MDA), seasonal malaria chemoprevention (SMC)). TDR plays an important role by developing central data repositories when specifically needed (e.g. pregnancy registry, new regimens for drug-resistant TB, dolutegravir), developing innovative approaches to facilitate safety monitoring in resource poor settings (e.g. community level reporting on safety of MDA for NTDs and for seasonal malaria chemo-prevention), and supporting capacity development through national pharmacovigilance workshops.

SWG recommendations: The SWG supported the continuation of this programme of work, expanding if funding permits, noting that it is mostly a neglected and under-researched field, and that many aspects of data sharing remain a challenge universally and particularly in resource poor settings. Qualitative and Quantitative metrics are needed to better demonstrate the achievement of “enhanced AE reporting system” and “the improvement of AE monitoring capacity” in involved LMICs. A priority for future research would be developing mobile technology as a tool for prompt notification of Serious Adverse Events. Drug quality is also a key issue that impacts on drug safety (as well as efficacy and antimicrobial resistance), so interaction with relevant WHO departments (such as Prequalification and Model List of Essential Medicines) would be beneficial. Synergy within TDR is already being exploited through e.g. links with WARN-TB, and could be expanded to link with other relevant TDR projects (e.g. embed safety module within SORT IT, consider safety of insecticides as well as drugs). TDR plans to hand over the data repositories to the relevant WHO programmes once development and pilot testing of the database and related tools is completed. This aligns with the shared SWG view that drug safety is a cross cutting issue that should be integrated within each health system, and designated funding should be sought to enable TDR to pilot research on how best to embed drug safety within national health systems. These data can be used to inform improvements in healthcare.

SWG cross-cutting recommendations: TDR is uniquely well placed to inform governance of the timeous sharing and impactful re-use of national ministry of health data routine surveillance data. TDR may also be in a strong position to leverage funding and IT support from digital innovators (e.g. Amazon, Google) given their “game-changing” potential in this field.

SWG conclusion: Drug safety (and the safety of interventions more broadly) is a cross cutting issue that should be integrated within each health system. TDR should continue to conduct pilot studies on how best to embed drug safety within WHO programmes and national health systems.

Topic 8: Gender

Gender-responsive health interventions (ER 1.3.12)

Sassy Molyneux & Fang Jing

This programme of work plans to generate new knowledge and evidence on the intersection of sex and gender with other social stratifiers to address power relations, social exclusion, marginalization and disadvantage in access to health services, prevention and control of Infectious Diseases of Poverty. These can be used to inform and design prevention and control interventions, research and decision making processes and optimize the implementation of available interventions and strategies. It was noted that there was limited research on men and boys, even though their gender norms and traditional beliefs can impact significantly health. During 2018 TDR will complete development of a toolkit to guide intersectional analysis in research on IDPs and convene an expert group meeting. A gender analysis course has been developed in partnership with the University of Ghana that includes qualitative and mixed methods gender analysis frameworks that are applied in practical exercises.

SWG recommendations: TDR has a long history of research on gender dynamics and inequalities, focused on gender equity with tracking of outputs by gender. The SWG recommended expanding on this programme of work based on a clear short- to medium- term strategy and noted that the planned November meeting would be invaluable in informing this strategy. No deep gender analysis has yet been performed within other TDR Research for Implementation activities and the SWG strongly supported the leveraging of internal funding to enable such linkages (e.g. with SORT IT, networks, climate change, male genital schistosomiasis). This would start with a few case studies, with additional qualitative work and expansion towards ensuring that an intersectional lens is embedded across the Research for Implementation programme's gender thinking and work, contributing to wider TDR discussions over time. This is seen as a priority across TDR activities given the increasing recognition globally that health systems, interventions and research are far from gender neutral. Gender unequal or blind research risks feeding into unequal power relations and outcomes, to the detriment of all. Intersectionality analysis supports equity analysis and allows us to deepen our understanding of inequality through better reflecting the complexity of the real world and does not make a priori assumptions regarding the importance of any one or multiple social categories (e.g. gender; race). It contributes to the 13th WHO's General Programme of Work, WHO's Global Vector Control Response (2017-2030) and the UN Sustainable Development Goals (2015- 2030) and to TDR's 2018-2020 Strategy. While there is a growing body of evidence on intersectionality, the applications to prevention and control of infectious diseases remain relatively limited. TDR has excellent convening power and value could be added to other TDR projects through embedding a more gender responsive approach. An appropriate budget should be sought internally to embed intersectional analysis within other TDR activities, with external funding to expand this programme to transition towards becoming gender transformative over time. The upcoming expert group meeting will pave the way to better define the scope of TDRs future research strands, including a call for relevant research proposals and their subsequent dissemination.

SWG conclusion: Expanding the programme of work on gender-responsive health interventions is recommended towards ensuring that an intersectional lens is embedded across the TDR / Research for Implementation gender-responsive thinking and work. The planned November meeting would be invaluable in informing this strategy.

Budget

The SWG reviewed the planned cost by ER for the current biennium (2018/2019), and the budget for the 2020-2021 biennium, for both the US\$ 40 million and \$ 50 million scenarios. In general, the SWG endorsed what was proposed by the Research for Implementation team. Suggestions included:

- Relocating ER 1.3.8 within ER 1.3.12
- Replace Residual Malaria ER with the new (to be defined) malaria-related research focus.
- As additional funds become available, increasing the 2020-21 budget allocation towards VL elimination, to include a policy science research call.
- As additional funds become available, increasing the budget towards embedding a gender responsive approach across TDR

Review of SWG structure, organization and function

The organization of future meetings was discussed. Most felt that it was productive to review selected projects in greater depth as this generated clear recommendations on each project reviewed. However, some commented that some review should be included for all projects that are continuing. Suggestions were made on the projects / topics that should be reviewed in greater depth in 2019, including:

- Allow time to review and discuss cross-cutting issues (data sharing, Research & Communication / Global Engagement, gender analysis), rather than just selected projects
- Data sharing governance & principles (including issues of ownership, equity and justice); shifting from collaborators sharing data from TDR projects to broader data access to make better use of vast data gathered through TDR supported projects. TDR should be actively involved in groups and collaborations driving the rapidly evolving field of data sharing. TDR is uniquely placed to inform governance of the timeous sharing and impactful re-use of national ministry of health data routine surveillance data.
- The opportunities for TDR creating a publishing platform with Faculty 1000 was also noted as a topic for discussion at the next SWG meeting given that others (such as Wellcome Open) are also moving into this space.
- Review strategies are being developed from prior experiences to guide the ways for TDR to engage and disengage from projects and networks.
- Research & Communication / Global Engagement activities be reviewed, so that learning from one project can be applied across relevant projects within TDR, WHO and more broadly.

While selecting SWG members to review projects that are not in their areas of interest / expertise encouraged more participation by all SWG members, some felt that the quality and efficiency of reviews would be enhanced by at least the primary reviewer having specific interest and expertise in that topic. Suggestions regarding topics for review were made as follows:

Bertie Squire	Disease elimination; optimized approaches; antimicrobial resistance
Pascale Adukwei Allotey	Disease elimination; optimized approaches
Karen I Barnes	Data sharing; drug safety; clinical malaria
Jing Fang	Gender / intersectionality; safety of interventions; antimicrobial resistance
Olaf R. Horstick	Arbovirus; vector control; summary evidence as systematic reviews and meta-analysis; research to practice
Lenore Manderson	Gender / intersectionality; qualitative studies; inequality
Sassy Molyneux	Health policy and systems research; empirical ethics; qualitative studies; gender / intersectionality
Mario H. Rodriguez-Lopez	Vector-borne diseases, entomology, epidemiology, control
Than Tun Sein	Climate change; multisectoral approaches in malaria
Lely del Rosario Solari Zerpa	Health policy and systems research and antimicrobial resistance

A suggestion was made to consider re-establishing the TDR “working group” approach previously used to define the research landscape in given fields and help identify priority new research topics that TDR is uniquely well placed to address, for example “the built environment, housing and health” (e.g. <https://www.who.int/tdr/publications/tdr-research-publications/swg-report-dengue/en/>).

TDR agreed to reflect on the skills experience and attributes of the current SWG membership and to take forward a discussion on how to fill relevant gaps in a future meeting.

Farewell

The SWG was concerned to hear that Piero Olliaro was to retire in October 2018 and expressed warm appreciation for the many contributions that he has made to TDR over the past 25 years. His breadth and depth of knowledge and skills and his dedicated commitment to his work, he and his team have made a substantial impact on reducing the burden of infectious diseases of poverty globally.

List of participants

Professor Stephen Bertel Squire, Director, Centre for Applied Health Research and Delivery, Liverpool School of Tropical Medicine, UK (Chair)

Professor Pascale Adukwei Allotey, United Nations University, KM Medical Centre, Malaysia (*joined selected sessions via Skype*)

Dr Jing Fang, Director, Institute for Health Sciences, Kunming Medical University, PR China

Professor Karen Barnes, Professor, Division of Clinical Pharmacology, University of Cape Town, South Africa

Dr Olaf R. Horstick, Director of the Teaching Unit, Institute of Public Health, University of Heidelberg, Germany

Dr Sassy Molyneux, Chair, Health Systems and Research Ethics Department, KEMRI- Wellcome Trust Research Programme, Kenya

Professor Mario H. Rodriguez-Lopez, Researcher, Center for Infectious Diseases Research, National Institute of Public Health, Mexico

Dr Than Tun Sein, Yangon, Myanmar

Dr Lely del Rosario Solari Zerpa, Senior Researcher, National Institute of Health of Peru, Peru (*joined selected sessions via Skype*)

Apologies:

Professor Lenore Manderson, University of the Witwatersrand, School of Public Health, South Africa

TDR Secretariat – Research for Implementation

Dr Florence Fouque, Team Leader, Research on Vectors, Environment and Society (VES)

Dr Piero Olliaro, Team Leader, Intervention and Implementation Research (IIR)

Dr Christine Halleux, Scientist, IIR

Dr Annette Kuesel, Scientist, IIR

Dr Corinne Merle, Scientist, IIR

Dr Mariam Otmani del Barrio, Social Scientist, VES

Dr Bernadette Ramirez, Scientist, VES

Dr Rony Zachariah, Scientist, IIR

Dr Axel Kroeger, Consultant, IIR

Mrs Madhavi Jaccard-Sahgal, Team Assistant

Mr Abdul Masoudi, Assistant, Project Management

Other TDR staff

Dr John Reeder, Director, TDR

Dr Garry Aslanyan, Manager, Partnerships and Governance, TDR

Dr Beatrice Halpaap, Portfolio and Programme Manager, TDR

Dr Dermot Maher, Coordinator, Research Capacity Strengthening & Knowledge Management, TDR

Dr Mihai Mihut, Administrative and Finance Officer