COR-NTD 2015
Philadelphia, PA, October 22-23

Breakout Group Summary Report

This document is intended to capture the key outputs of your breakout discussion, and to be representative of the group as a whole. Please denote your group's topic, presentations and research priorities before the start of the session, and dedicate the latter portion of your session to determining the key discussion points, knowledge gaps and recommended steps. Also, please indicate whether your group's recommendations align with the specified initial priority target. Your report will be shared on the NTD-SC website, and will inform future advisory panel discussions and donor priorities.

Section I

To be filled out before the session begins.

Breakout Topic:

3A: Looking Beyond School-Age Children for Schistosomiasis and STH Control and Elimination

Presentations:

Why is expanded treatment needed? (W. Evan Secor)

Why hasn't it been before? (Amadou Garba)

What is the future benefit of benefit/significance of expanded access to treatment?
- Moving beyond school-based deworming in Kenya: TUMIKIA and TakeUP (Grace Hollister and Rachel Pullen)
- Treating other parts of the population – transmission (Deirdre Hollingsworth)
- Deworming beyond SAC for SCH and STH: cost-effectiveness considerations (Hugo Turner)
- Upon future morbidity alongside other co-infections (Dan Colley)
- Future studies within CouNTDown (Sam Wanji)

Research priorities to be discussed:

Three groups were formed and discussed the following issues in turn:

1. Cost and benefit aspects of expansion beyond SAC
2. Delivery and indicator systems
3. Bottlenecks and regulations

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Section II

To be filled out as the session concludes.

What were your group's key discussion points?

Why is expanded treatment needed? (W. Evan Secor)

Treatment is currently primarily targeted at school-aged children (SAC) for a number of reasons (epidemiological, cost, etc.). However, other age groups can have similar exposure risks (pre-SAC, pregnant women, occupationally at-risk adults). A review of infection levels in pre-SAC across Mali, Niger, Sudan, Uganda and Zimbabwe revealed schistosomiasis (SCH) is a significant problem with infection levels approaching those of SAC. Treatment of pre-SAC is acceptable and safe, however the current dosing of praziquantel (PZQ) may not be appropriate.

Why hasn't it been before? (Amadou Garba)

Dr Garba raised the question of what research is needed to expand treatment coverage in at risk groups (SAC/pre-SAC/at risk adults/entire communities in high endemic areas). If elimination as a public health problem is the aim, there is a need to expand treatment beyond current levels. Presently, there is a focus on SAC because of the lack of PZQ globally (both tablets donated by Merck Serono and those available on the open market) to currently reach all targeted populations. The estimated need is 700 million tablets annually however current availability is less than 300 million.

There is no current recommendation by WHO on how to treat pre-SAC in MDA situations. There are still several outstanding issues, including:

- the development of a safety database on the use of crushed PZQ in pre-SAC
- the need to conduct different PZQ dose trials in pre-SAC for appropriate dosing
- expanding the development and validation of POC diagnostics for pre-SAC
- the need to conduct a multicenter study on the morbidity of SCH in pre-SAC using ultrasound and impact of PZQ in the reversal of lesions at different follow-up times.

In addition, further investigation is warranted to include:
- social science studies on the reasons of non-integration of pregnant and lactating women in PC for SCH and STH
- identifying strategies to reach pre-SAC, pregnant and lactating women through maternal and child health services
- studies on the efficacy of PZQ on female genital schistosomiasis
- identifying strategies for treatment of SAC within secondary schools
- identifying strategies to reach occupational groups such as fisherman, farmers, irrigation workers, car washers.

What is the future benefit of benefit/significance of expanded access to treatment?

-Moving beyond school-based deworming in Kenya: TUMIKIA and TakeUP (Grace Hollister and Rachel Pullen)

There are 2 studies within Kenya to determine if it is epidemiologically possible to break transmission of STH (TUMIKIA project) and if it is operationally feasible and cost-effective to establish a deworming programme that goes beyond school-based treatment (TakeUP).

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Initial results from TUMIKIA, a cluster randomized trial in 2 settings assessing the difference in annual school-based deworming vs annual school and community (house-to-house) deworming vs bi-annual school and community deworming, indicate that treatment coverage was 80% validated in school-based only compared to 89% validated in the school and community distribution.

-Treating other parts of the population – transmission (Deirdre Hollingsworth)

Ongoing work within the modelling consortium indicate that hookworm has a large burden within adult age groups who will not be reached through school-based treatments and will therefore have an ongoing impact on transmission. Trichuris also has a high burden within the pre-SAC age group. It is not clear how these children contribute to transmission.

Recent publications from ERASMUS and the Imperial College modeling group indicated that for STH, 75% coverage in SAC will break transmission in some settings by 2025. However, treatment is all age groups will be essential to break transmission of hookworm. Achieving high coverage in women and children will help to reduce morbidity but more will be needed to actually break transmission.

For SCH, results from Case Western (Schistosoma haematobium) and Imperial (S. mansoni) indicate that in some settings, treatment of adults will be necessary but that treatment will also need to be supplemented with WASH and snail control. Treatment of Pre-SAC will have a limited impact on transmission. Some remaining questions include:
- how do the age profiles of infection within the population change in changing transmission settings
- quantifying the contribution to transmission (from age-distribution)
- can we break transmission using MDA?

-Deworming beyond SAC for SCH and STH: cost-effectiveness considerations (Hugo Turner)

Is it cost effective to expand to community-wide treatment for SCH and STH? Both impact and cost-effectiveness will be dependent on the epidemiological setting where the treatment is taking place. Modelling results show that MDA has notable economies of scale but many models assume that cost per treatment remains constant over time. There is currently a lack of high quality costing studies and poor understanding of costs involved (school vs community based treatment). There is no simple answer – the absence of cost data and the way costs and morbidity data are collected can be flawed although improvements are being made. Cost-effective community-wide treatment will depend on the epidemiological setting and whether the goal is morbidity control or breaking transmission.

-Upon future morbidity alongside other coinfections? (Dan Colley)

Adequate annual MDA with PZQ in most endemic areas lowers the proportion of individuals who develop severe disease and correlates with decreasing intensities of infection. Expanded treatment into communities will therefore bring this benefit to more people (IF it continues for 'x' years). Egg counts are still an insensitive measure and more information is needed on how subtle morbidly translates into life-long impact. Currently, it is not known how early we need to treat children to prevent subtle morbidity from occurring. Questions which require investigation include:
- When does subtle morbidity begin to be detected and how do we measure this in very young (pre-SAC) children?
- When should we start including pre-SAC children in expanded MDA programmes?
- What are the factors which prevent including young children in expanded MDA programmes?
- Do we get an added benefit of treating young (pre-SAC) children?

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-Future studies within CouNTDown (Sam Wanji)

Cameroon's SCH and STH programme is aligned behind an NTD Master Plan (2012-2016 and recently updated to 2020). It focuses on school-based delivery of PZQ as the main route for systematic deworming. Bottlenecks occur around: limited impact studies, appropriate financial forecasting, treatment too close to the end of school year, delays in timely reporting back to central level, high reinfection rates. The programme is aiming for:
- equitable access to treatment for pre-SAC, out of school SAC and adults towards universal health coverage
- use of community led total sanitation
- treatment twice per year to review impact on rapid reinfection rates
- the application of social science to address barriers to scale-up
- assessing the impact on female genital schistosomiasis and capacity development for surveillance.

High-level takeaways:

• Any child who is infected has the right to be treated and drugs should be made available for this purpose.

• For certain infections, it is advantageous to treat pre-SAC with the goal of stopping treatment. Can an ethical case be made for the inclusion of pre-SAC in MDA?

• The cost of control of morbidity versus the cost associated with breaking transmission. If everyone is treated, it enhances both goals but what is the cost-benefit?

• Countries should have the flexibility to adapt their programmes as required. It would be useful to have a tool which country programme managers could use (e.g. epidemiological models, integration with other health interventions) to review the impact on coverage which would allow them to adjust their programmes accordingly to maximize programme benefits.

• General policy review is required to clarify what is meant by the targeted population and implications for platform of delivery. Denominator issues should be clarified; the age range for school-based distributions should be clearly defined; administrative questions on drug use to improve uptake.

• Monitoring and evaluation information is collected but not systematically. Sentinel site information is usually available but only at school level and not within communities.

• There is currently a limited strategy for STH control in terms of a one size fits all approach.

• A number of barriers to scale-up of treatment beyond SAC still exists, including;
    o The amount of PZQ available globally
    o Non-optimal formulations and dosing of PZQ for pre-SAC
    o Engagement with other groups, including the Ministry of Education.
    o Food requirement when MDA is occurring.

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What knowledge gaps (if any) did your group identify?

• The assessment of cost data needs to be clarified, particularly in terms of measuring financial versus economic costs in a consistent way to allow comparisons to be made.

• There is currently a limited understanding of the cost/benefit of treating pre-SAC. Elucidating this might require an expensive clinical trial, particularly for the new pediatric formulation of PZQ for pre-SAC [given that it will not be donated]. WHO clarification is needed on the issue of including pre-SAC into MDA programmes.

• There is currently not enough evidence on country level cost per treatment, and particularly the costs associated with those who wish to self-treat when excluded from MDA.

• Monitoring and evaluation efforts should be extended to capture assessments across all age groups

• Guidelines for preventive chemotherapy using a school-based platform are not sufficient. It is not clear how effective schools are as a distribution point for treatment beyond SAC. It is necessary to address issues surrounding access to treatment for the inclusion of pregnant women and women of child-bearing age in programmes.

• There is limited information on what is holding back the scale-up of treatment for SCH and STH. There is a need to understand the education at community level on the different infections to inform what works in terms of treatment provision at community level.

What next steps does your group recommend?

Further information is needed on the cost-benefit of treating other groups beyond SAC, particularly pre-SAC. Additional cost data being made available could help to inform this.

Programme managers need a tool to assist them in guiding the direction of their programmes in terms of maximizing coverage of treatment.

Definitions of at risk populations are required when expanding treatment beyond SAC.

Do your recommended steps align with the research priorities identified on page 1? ◉ **Yes** ○ **No**