Preschool-Age Children (STH Coalition – PSAC) Work Stream
Teleconference
Tuesday, March 10, 3pm ET

Participants

David Addiss, Children Without Worms	Lauren Labovitz, Children Without Worms
Clayton Ajello, Vitamin Angels	Ada Lauren, Vitamin Angels
Akudo Anyanwu, Children Without Worms	Steven Silber, Johnson & Johnson
Katie Eves, Mentor Initiative	Amy Steets, Vitamin Angels
Alison Greig, Micronutrient Initiative	Eric Strunz, Children Without Worms
Alex Jones, Children Without Worms	Susan Talbot, World Concern
Jodi Keyserling, Children Without Worms	Katherine Williams, Evidence Action
Richard Kumapley, UNICEF	Carol Wylie, World Vision
Roland Kupka, UNICEF	

Other Work Stream Members not able to Participate

Azadeh Baghaki, World Vision	Franca Olamiju, MITOSATH
Peter Colenso, CIFF	Linda Pfeiffer, INMED
David Doledec, Hellen Keller International	Victoria Quinn, Helen Keller International
Alan Fenwick, Schistosomiasis Control Initiative	Chandrakant Revankar
Kama Garrison, USAID	Faith Rose, CIFF
Grace Hollister, Evidence Action	Ken Surridge, Porridge and Rice
Dan Irvine, World Vision	Emily Toubali, Helen Keller International
Julie Jacobson, Bill and Melinda Gates Foundation	Yaobi Zhang, Helen Keller International
Mary-Lynne Lasco, INMED	Sasha Zoueva, CIFF
Aryc Mosher, Bill and Melinda Gates Foundation	

1. **Background and objectives**

- Several useful background materials were provided in advance of this call:
  - Meeting agenda containing a box recapping the Work Stream objective, areas of focus, and key numerical targets (see box below),
  - A *Drugs Market Assessment* prepared by the Bill and Melinda Gates Foundation (attached),
  - The report of the *NGO Deworming Inventory* (attached), and
  - A document with more information on the Partners Map (attached)

- Objectives for today's call:
  - Agree on challenges constraining efforts undertaken to achieve PSAC Work Stream key targets
  - Agree on mechanisms for reporting on commitments
  - Set priorities for Work Stream attention and follow-up
  - Add further information about how we might want to collaborate with other work streams
  - Discuss the way forward for this Work Stream

Background

Objective: Support national governments and NGOs to double the drug coverage in preschool-age children (PSAC) by 2016 by leveraging existing platforms

Areas of focus:
- Identify partners to contribute to increasing preschool-age children drug coverage and detail their

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commitments.

- Improve supply chain: Quality drug supply, coordination, and delivery
- Clarify mechanisms for, and ensure accurate reporting and monitoring of, deworming programs.

Key Target(s):

- Reach 200 million (75%) of 266 at-risk preschool-age children with deworming drugs, annually, by 2020
- Reach 128 million at-risk preschool-age children with deworming drugs, annually, by 2016 - double the 64 million children treated (24% coverage) reported in 2013

2. Challenges for the preschool-age children work stream

2.1. Drug availability and quality

- Drug availability and quality are important and inter-related challenges. The challenge for the PSAC beneficiary group is different from the school age (SAC) beneficiary group. Preventive chemotherapy (PCT) drugs for SAC beneficiaries and PSAC involve entirely different mechanisms. PCT drugs for SAC beneficiaries are donated directly by two manufacturers (i.e., GSK and Johnson & Johnson) that have made massive multi-year commitments to donate drugs directly to the WHO which in turn allocates these, based upon national governmental requests, to national health services throughout the world. These donations, by agreement, can't be used for the PSAC beneficiary group. PCT drugs for PSAC must be procured. Procurement for the PSAC target group is done primarily by UNICEF and the NGO community. Apart from GSK, there are more than 100 manufacturers of albendazole globally, with manufacturing capacity that exceeds demand. However, due to inconsistent quality definitions, the availability of PCT drug that is acceptable to both UNICEF and the NGO community does not appear to meet demand. Additionally, it appears that GSK does not have any spare manufacturing capacity for albendazole sufficient to fulfill procurement requests from UNICEF and/or the NGO community.

- At the root of the "drug availability and quality" challenge is the lack of unified, standardized and accepted technical and finished product specifications (i.e., a product description for albendazole that also incorporates regulatory standards such as those contained in the USP or International Pharmacopoeia). The key to releasing the potential for increased manufacturing of a standardized quality albendazole drug is achieving: i) an accepted, standardized product description for albendazole, and ii) an accepted regulatory standard for a chewable albendazole drug in the International Pharmacopoeia. Resolving these issues is central to the Work Stream objective of doubling the PCT drug coverage in the PSAC target group by 2016 by leveraging existing platforms.

- Further complicating procurement by the NGO community is that WHO and UNICEF apparently adhere to different quality standards in conjunction with the WHO's "gift-in-kind" donations and procurement of albendazole. WHO depends upon adherence to manufacturing that complies with the International Pharmacopoeia, and UNICEF has its own quality guidelines that appear to be different from those of WHO. Without resolution of these differences, the NGO community will be unable to donate any albendazole drug to WHO for its conveyance to national health services due to WHO's own operating requirements. It is also not clear whether NGOs can donate PCT drugs to UNICEF because of these differences.

- WHO and Pre-qualification of Manufacturers

- No manufacturer of albendazole has yet been met the WHO requirements for pre-qualification. Lack of one or more pre-qualified manufacturers not only affects WHO, but may affect NGOs that seek to import product into the countries where NGOs support programs.
- Presuming one or more manufacturers volunteers to become pre-qualified, it may take 2-4 years to complete the process.
- In the interim period, there is no guidance for the NGO community on purchasing product from any particular manufacturer for itself or for onward donation to WHO or UNICEF.

- Upcoming WHO meeting, March 12 and 13, in Geneva
  - WHO is convening a meeting of PSAC-STH Partners in Geneva to address a number of issues. Dr. David Addiss and Roland Kupka plan to participate.

- Action items:

  In conjunction with the PSAC-STH Partners Meeting in Geneva OR subsequent to this meeting:
  - Roland Kupka of UNICEF is encouraged to: i) clarify with UNICEF colleagues how UNICEF's quality assurance guidelines align with those of WHO, ii) ascertain if NGOs can purchase albendazole directly from UNICEF, and if so, using what product description and what regulatory standards, and iii) whether such product can be donated back to WHO or UNICEF.
  - Dave Addiss and Roland are encouraged to identify what are the barriers for WHO to pre-qualify the manufacturers that UNICEF is already using.
  - Dave Addiss is encouraged by the PSAC Work Stream members to present as feasible to the WHO PSAC Partners Meeting: i) a summary of the drug quantity/quality challenges identified by the PSAC Work Stream, ii) a recommendation that WHO consider convening a meeting at which there is representation of technical expertise from WHO, UNICEF, and the NGO community to help the NGO community gain clarification on their concerns pertaining to drug quality standards, and iii) a recommendation – given the length of time likely required for WHO to achieve pre-qualification of a manufacturer – that WHO provide an interim solution pertaining to quality standards (product description and regulatory standards) that can allow NGOs to procure albendazole without delay for their own global programs and for onward donation to WHO or UNICEF.
  - The STH Coalition – PSAC Work Stream is encouraged to convene a meeting among its own, interested members (and potential manufacturers with interest) to develop a "product description" for albendazole that can be utilize by the NGO community as the common basis for procurement/tendering actions by all Work Stream members.
  - ***Action item for all work stream members:*** If you have other suggestions, email them to Clayton (cajello@inlexo.com) and Carol (cwylie@worldvision.org) with a copy to STHCoalition@taskforce.org.

2.2. Targeting Support and Reporting Drug Coverage

- Targeting & Reporting Background and Issues:
  - On average, globally, national health services reach about 70% of the population. For the remaining 30% of the population, a key reason underlying the need for individuals and families to find alternative health care services is that they don't have geographical or physical access to national health services. Among the remaining options for accessing credible health services, the largest source for health services for this 30% of the population is NGO health service systems.
  - The fact that such a large portion of the population cannot access health services from a national health services system suggests a need for robust coordination between governments (i.e., national health services) and NGOs partners. In this regard, targeting of services (i.e., both to find beneficiaries

that reside in zones of high STH burden and to identify persons that don't receive services from national health services) becomes an important issue.

- Currently, complicating both targeting and reporting, is the fact that when NGOs deliver PCT services, it is difficult to know that the selected population receiving services actually needs PCT; and once PCT is delivered, there is no guarantee that numbers of persons reached are reported and integrated into national health statistics (or the statistics that get rolled up to WHO).

- Children Without Worms (CWW) recently completed an NGO Deworming Inventory in 2008 and 2009 to address the challenge of reporting of NGO PCT to ensure integration of NGO PCT services into national and WHO statistics. CWW is interested in assuming this role until such time as an alternate mechanism at a national level can take hold. WHO colleagues seem to be very excited about this idea. The process is not intended to be a separate reporting process but a way to try to capture the treatments that are being given by NGOs and identify areas where they're not being overlapped. WHO can flag countries where there's a great divergence. CWW was unable to take that second step effectively after the last inventory, but the landscape has changed quite a bit since then.

- Mapping Background and Issues:
    - The NTD Partners Map is ready for data entry. It was designed to answer the question "Who is doing what, where?"
    - CWW is trying to meet the needs specifically of the STH Coalition and particularly that of the PSAC Work Stream members.
    - The NTD Partners Map can still be modified based on the needs and feedback of partners.
    - The map was originally designed to record by location numbers of people treated but not a denominator of number of targeted people. New variables can be introduced relatively easily. If there is an interest in pursuing a more robust capacity, CWW can pursue it in a relatively timely fashion.
    - This Wormy World has probability maps for STH prevalence by geographical areas within an individual country. You can see prevalence on This Wormy World and then go to the partners map to see who is working in those districts. Further refinement for the NTD Partners Map would be to overlay prevalence with activities.
    - Johnson & Johnson is actively supporting PATH for a more robust, inexpensive STH diagnostic test that has relevance for mapping.

- Action Items:
    - The Work Stream encourages CWW to follow-up with WHO to ascertain the utility of CWW continuing the responsibility to aggregate NGO PCT data as needed and as feasible.
    - The Word Stream encourages CWW to continue to explore the opportunities to combine (overlay) prevalence data with PCT activities by NGOs (an possibly governments).
    - *Action item for all work stream members:* Familiarize yourselves with both types of maps, use those tools, and submit data. **Email Eric Strunz (estrunz@taskforce.org) to get a password and enter data.** For those of you who are large NGOs, CWW is also happy to work with you to import data from excel spreadsheets and do heavy lifting with and for you.

3. **Work Stream Priorities**

- Broad agreement was expressed by participants of the PSAC Work Stream that the issues identified with respect to quality of the drug supply and improving targeting and reporting of PCT by NGOs should remain as the initial key priorities of the Work Stream.

4. **Reporting Work Stream members on their Commitments and Progress**

This topic was not dealt with in great detail in this meeting except to say that all members of the Work Stream are encouraged to enter their accomplishments in delivering PCT into the Partners Map. Additionally, the co-chairs noted that there may be room for further follow-up survey of each partner.

5. **Inter-Work Stream collaboration**

- Work Stream chairs will meet in person 1-2 times per year to come together.
- The STH Coalition is working on finalizing a governance structure; we'll make sure there's collaboration and synergy across work streams.
- If Work Stream members have suggestions for how best to ensure inter-work stream collaboration, we welcome comments at STHCoalition@taskforce.org.

6. **Way forward for the PSAC Workstream**

This topic was not addressed in any detail during this meeting, and will be added to the agenda of the next Work Stream meeting. In the meantime, there is a need for (and it is the function of CWW) continued communication and facilitation of information sharing among the PSAC Work Stream members. As action items identified above are undertaken, CWW will share that information with the membership. Additionally, the co-chairs will work to propose a next meeting during which ideas can be shared on how often this group should meet and to define an equitable way to set agenda topics of broad interest to the Work Stream members. If you are responsible for or contributing to an action item, please forward these updates to the STH Coalition.

Action Item: Please send your updates on progress to: STHCoalition@taskforce.org.