Can the Loascope be used successfully in the community?

Session Date: Saturday, October 27

Session Time: 1:00pm – 4:00pm

Session Location: St. Jerome, 3rd Floor

Session Description: The LoaScope has been used very successfully in a research setting to identify patients who should not take ivermectin in an onchocerciasis endemic are, due to a high level of *Loa loa* microfilaria circulating in their blood, potentially provoking a serious adverse event, including a possible fatal encephalopathy. However, using the LoaScope in a research situation, while demonstrating proof of principal, was a very costly procedure due to the intensive supervision and follow-up.

A further study has been performed using local health staff to carry out the tests, distributing ivermectin, and following up on any potential SAEs. This study involved more remote supervision and a study of the results, including the costings, by the research team. The main purpose was to ensure safety but also to study the feasibility of the process. The results of these studies will be presented, and recommendations made concerning the LoaScope's use in PHC.

Session Chairs: Adrian Hopkins, Independent Consultant
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Other speakers and affiliations:
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Session Rapporteur: Rand Carpenter, Mectizan Donation Program

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KEY DISCUSSION POINTS

1. Meso- and hyperendemic areas of onchocerciasis also co-endemic for Loiasis

In spite of the application of the guidelines set out by the Mectizan Expert Committee (MEC) and The Carter Center (TCC), fear of severe adverse events (SAEs) reduces treatment compliance in meso/hyperendemic areas that are co-endemic for loiasis. Due to the introduction of treatment for lymphatic filariasis (LF), ivermectin-naïve patients are now at risk of SAEs if they take treatment for LF. Two deaths have been reported from Cameroon recently. Is it not ethical, when we have access to rapid methods for testing for the intensity of Loa infection, to offer ivermectin treatment without testing ivermectin-naïve patients in these areas.

2. Mapping

Session participants recommend that LoaScope should be the gold standard. RAPLOA has been useful as a more rapid, less expensive tool to predict where there is Loa, but results require further validation. Mapping using the new serological testing may be a more useful indication of where the disease exists but not of intensity of infection. Decisions need to be made regarding acceptable risk so that not everyone in co-endemic communities needs to be tested with the Loascope.

3. Availability

The availability of LoaScopes is currently very limited, and the horizon for greater availability is unknown. This is of considerable concern as the population now has confidence in the process, which very much indicates the way forward to eliminate onchocerciasis in co-endemic communities. The group sees this as an urgent problem to resolve. It was announced that the Bill & Melinda Gates Foundation is in the process of producing 10,000 and an adequate supply of capillary tubes to support the work.

4. Costs

The cost of the current LoaScopes was $500/unit, and the necessary capillary tubes are $1 each. One possibility for reducing costs is to use phones other than iPhones, and likely the capillary costs will decrease with higher volume production. The life span of a unit is probably about 5 years.

KNOWLEDGE GAPS IDENTIFIED

- Are population movements important in the potential test-and-not-treat (TaNT) areas? What are the risks for patients newly arrived in the area and what are the risks for those who have lived in the area moving to a different onchocerciasis-endemic area where Loa is not co-endemic and no precautions would be taken?

- The LoaScope has become the new gold standard and the most effective tool for decision making in co-endemic areas. However, supply is extremely limited – just enough for use in field testing. When will more be available? Is it possible to conduct field operations in a meaningful way with the current stock?

- Predictive analysis points to only a short time commitment to a LoaScope TaNT strategy in each implementation unit (IU). Will this be consistent with application in the field, particularly if coverage is low?

- Estimated costs are now available. What factors would further reduce costs? Can we compare now more precisely the cost of using TaNT/LoaScope (testing all ivermectin-naïve patients) to the costs incurred in those mass drug administrations (MDAs) that are already engaged in enhanced surveillance for side effects?

- What are the factors other than fear of SAEs that influence compliance in these co-endemic settings? Can we reasonably expect a substantial increase in MDA participation if we test ivermectin-naïve individuals for Loa and prevent all/nearly all SAEs?

- How do we analyze the cost effectiveness of increased testing and management of occasional SAEs in order to reach elimination goals sooner?

- In newly identified meso- and hyperendemic foci of onchocerciasis co-endemic with loiasis (potentially in Democratic Republic of Congo and South Sudan), what is the acceptable cut-off point for prevalence at which we will continue MDA in onchocerciasis hyper-/meso-endemic communities using current MEC/TCC guidelines? Should we start with the LoaScope?

- Should the use of the LoaScope become the standard of care in newly identified onchocerciasis hypoendemic communities (prevalence of nodules <20%)?

- Assuming we have supplies, would we recommend TaNT in all Loa-endemic health districts? What would be the protocol for a "special" or "enhanced" approach to MDA with a new emphasis on community mobilization?

RECOMMENDED NEXT STEPS

1. Develop mapping protocols on how to use historical RAPLOA maps, where to use serological testing, and what is the best use of the LoaScope as a mapping tool. Can we use the predictability analyses (by Peter Diggle) to develop a convenient sampling strategy?

2. Develop protocols for testing in all Loa-endemic IUs after the first round of treatment. This could include TaNT in the community for the second round, or individual patient testing at a district hospital or health center, field testing by less rigorous methods, enhanced record keeping of individual patient status, and consideration of alternative treatment in ivermectin-naïve individuals, to allow MDAs to proceed.

Additional research questions include:

   a. How many years of TaNT are needed before commencing regular community-directed treatment with ivermectin (CDTI)?
   b. What are the effects on *Loa loa* microfilaremia in patients who had missed one or two rounds of Ivermectin treatment? Should they be systematically retested if they miss one round?
   c. What are the cultural and social factors affecting compliance (including fear of SAEs, but also other factors)?
   d. What are the best methods of social mobilization to maximize coverage in co-endemic areas?

e. What is the effect on onchocerciasis elimination of exclusion of Loa patients from ivermectin treatment? Should they be treated with doxycycline or simply excluded?
f. How does compliance change when using the LoaScope?
g. In view of the prolonged treatment period and the long history of Loa SAEs, should we consider new, creative mobilization methods such as a lottery or other prize giving in order to achieve the elimination goals?