Strategic and Technical Advisory Group for neglected tropical diseases

Report of a meeting of the sub-working group on monitoring and evaluation of disease-specific indicators – lymphatic filariasis

Task Force for Global Health, Atlanta, GA
1 October 2012
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1. **Background**

The Global Programme to Eliminate Lymphatic Filariasis (GPELF) targets the global elimination of lymphatic filariasis as a public-health problem by 2020. The programme recommends a comprehensive strategy for achieving the elimination goal through a two-pillar approach: (i) interruption of transmission of filarial infection in all endemic countries through mass drug administration (MDA); and (ii) prevention and alleviation of disability and suffering in individuals already affected by LF.

GPELF is one of the most rapidly expanding public-health programmes in the world. Of the 73 countries where LF is endemic, 53 countries have started implementation of MDA, of which 12 countries have implemented more than 5 rounds of MDA and transitioned to post-MDA surveillance.¹ When GPELF reached its half-way point in 2010, the World Health Organization (WHO) reviewed the progress made during 2000–2009 and developed a strategic plan to address the challenges in the next 10 years.² Since then, GPELF has progressed towards the targets and milestones set in the Strategic Plan, and supported endemic countries to start and scale up MDA, phase into post-MDA surveillance and achieve verification of elimination.

2. **Objectives of the meeting**

A meeting of the sub-working group on monitoring and evaluation of disease-specific indicators of the Strategic and Technical Advisory Group for neglected tropical diseases (STAG-NTD) was held at the offices of the Task Force for Global Health in Atlanta, GA, USA on 1 October 2012, in order to address the current challenges of GPELF. The list of participants is attached as Annex 1 and the Programme of work as Annex 2. The four objectives of the meeting were:

1. To review the status of transmission assessment surveys (TAS) and make recommendations on how to scale up these surveys;
2. To discuss morbidity indicators for GPELF, including those that reflect treatment outcomes;
3. To review the provisional strategy for MDA in areas where LF and loiasis are co-endemic and make recommendations on next steps to the STAG-NTD; and
4. To re-visit the global burden of LF and consider how to revise the global estimates after 12 years of GPELF.

The objectives of the meeting focused on the circled areas in the GPELF diagram shown below:

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3. Transmission assessment surveys

Ms Won presented the results of an informal meeting on transmission assessment surveys (TAS) held in Geneva, Switzerland on 12–13 September 2012. TAS is to be used as a decision-making tool for programmes to determine whether MDA has been successful in reducing transmission to a threshold below which it is likely no longer sustainable even in the absence of MDA. The meeting was to review the outcomes of the training workshops and the existing training materials, discuss the framework and content of WHO’s official TAS training material and timeline for finalization, and prepare a plan for future collaboration on TAS training and country support.

To accompany the publication in 2011 of the WHO manual on monitoring and evaluation of LF, regional trainings were held in 2012 in WHO’s Western Pacific Region (Manila: 9 countries, and Fiji: 11 countries), South-East Asia Region (9 countries), and the Eastern Mediterranean Region (2 countries). Each training lasted 3 days, and combined lectures, practical exercises and country presentations on a TAS plan. The objectives were to (i) strengthen the knowledge and skills on monitoring and evaluation (M&E) of national LF programmes, (ii) develop a TAS workplan, and (iii) strengthen knowledge on dossier development. Training outcomes were positive, with good group participation and a significant increase in M&E knowledge as measured by pre- and post-test scores. Practical exercises involving the Survey Sample Builder Excel tool and diagnostic tests were appreciated. Country preparation before the training was critical in order for countries to develop specific plans. Resulting critical needs included standardized data collection form templates, clear TAS planning and reporting mechanisms, improvement in the process for procuring diagnostic tests, and more robust post-MDA surveillance guidelines.

Materials from these training workshops will be transformed into a learner’s guide, a facilitator’s guide and a WHO position statement, which will be published and translated by WHO. National programmes
are encouraged to use these materials to organize and train survey teams in country with help from partners, while WHO regions can provide regional refresher trainings every 2 years.

The group recommended that Regional Programme Review Groups (RPRGs) review and endorse TAS plans to ensure that high-quality surveys are conducted at the appropriate time and to facilitate communication among national programmes, RPRGs, WHO regional offices, WHO headquarters and other partners. Standard forms will be developed as an ongoing virtual review mechanism. In addition, it was recommended that a TAS coordination group be established to capture TAS results, and forecast needs for immunochromatographic tests (ICT) and resources.

Finally, there remains an urgent need for ICTs, with a preliminary forecast of 3 million ICTs needed between 2013 and 2018.

Discussion

In order to resolve issues with ICT procurement and reliability, the group concluded that more interaction with Alere would be helpful. GlaxoSmithKline is willing to make this approach at a high-level (including discussions of a donation), once the issues relating to rolling out the new platform, projections (including mapping) and appropriate focal points are delineated.

- WHO to coordinate a group to determine actual needs for ICTs and Brugia Rapid™ once or twice each year, including focal points for programmes supported by DFID (the UK Department for International Development) and USAID (the United States Agency for International Development).

- The approach to Alere should be coordinated with the Gates Foundation’s project focal points.

There is a need to field test the new ICT version in low prevalence areas. In field tests conducted in an area with 10% microfilaraemia prevalence, more positives were found with the new test than the current version. The new version appears to have higher analytical sensitivity (up to 30% greater) than the current test. It may be necessary to adjust the Survey Sample Builder to account for increased sensitivity of the new version of the test and to train national programme staff on its use.

There is a need for technical capacity to review TAS eligibility and reports. While the aspiration is to carry out this technical support at regional level, in the interim, there are resources of expertise through the M&E sub-working group on disease-specific indicators. Each RPRG could develop a subcommittee or focal point for technical review of TAS to help coordinate the expertise.

Countries may need assistance to develop plans of action if they fail the TAS, and should be made aware that they can consult with the RPRG and the M&E sub-working group for review of TAS data and recommendations on next steps.

It is also important to build capacity among professional public-health communities in key countries, including the capacity to manage their own data. Countries should be empowered to make TAS decisions, with guidance from technical groups if necessary.
4. Morbidity indicators

Dr Kumaraswami presented the status of WHO’s booklet on how to build a morbidity management and disability prevention (MMDP) component into national LF elimination programmes and on potential indicators to measure disease burden and progress of MMDP activities. The booklet follows the 2011 publication of a WHO position statement on managing morbidity, outlining a minimum package of care. There are a few outstanding issues that need to be discussed related to the booklet, including:

- What is the preferred dosage for individual treatment for individuals identified during campaigns or surveys in non-onchocerciasis endemic areas? The 2000 WHO programme managers’ guidelines recommend 6 mg/kg DEC (diethlycarbamazine) per day for 12 days. The goals of the MMDP component of GPELF are to alleviate suffering, improve the quality of life and reduce acute attacks. What should the impact indicators be, particularly for quality of life?
- The current form national programmes use to report to GPELF includes number of hydrocele cases, number of lymphoedema cases, number of patients trained and number of trained staff. Is this still appropriate?

For treatment of individuals, single-dose treatment has not been widely recommended (including in the USA), despite several publications advocating its use. Although no formal clinical trials have focused on optimizing treatment in individual patients, research shows that a single dose of DEC is as effective at killing microfilariae as 12 days of DEC, while a combination of single-dose DEC and albendazole is more effective than 12 doses of DEC alone. In addition, El-Setouhy et al. found no statistical difference in the ability to kill adult worms between single versus multi-dose DEC and albendazole. There is not yet adequate data comparing the effect of the two regimens on antigen status. No difference in frequency of adverse events was observed in these studies.

Discussion: morbidity management and disability prevention

The group agreed that the process indicators contained in WHO’s annual report were adequate but difficult to collect due to cost of surveys, low prevalence of conditions, and etiologies of lymphoedema and hydrocele. The aspirational need is for countries to report the number of lymphoedema patients, number of lymphoedema patients trained or under treatment, the number of hydrocele patients and the number of hydrocele surgeries. Given that the GPELF goal is to provide access to basic MMDP care for everyone, geographical and programme coverage indicators were the most appropriate at this time. A surgical backlog indicator, similar to trachoma’s surgical indicator, was recommended as a potential impact indicator. However, it might be difficult to estimate this denominator, both because of under-reporting and because of the observation that when programmes have offered hydrocele surgery in the past, many people with other conditions (e.g. hernias) have been included. ‘Return to normal activity’ was suggested as a potential quality-of-life indicator. Impact indicators should be revisited at a later date.

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The group discussed establishing a threshold of disease burden as a way to prioritize where services for lymphoedema and hydrocele should be established, but no conclusion was made about what this threshold might be or how to gauge it accurately.

The group recommended changing the language on page 23 of the draft MMDP document so that a specific technique for hydrocele surgery is not recommended. Likely in early 2014, an expert group will be convened to review the comparative effectiveness of different techniques.

The group agreed on encouraging national programmes to name morbidity focal points to help with reporting, as LF programme managers concentrate on activities to interrupt transmission. Potentially, a programme could have one focal point for lymphoedema (a medical officer) and one for hydrocele (a surgeon).

Discussion: individual treatment

The group decided that it was best to offer alternative treatment regimens, with references, for treatment of microfilaraemic or antigen-positive individuals found in surveys (antibody-positive persons in Brugia areas) (see Annex 3).

The group also decided that before treating hydrocele or lymphedema patients, they should be checked for microfilaraemia or antigenaemia and treated if positive.

For adults, doxycycline (6 weeks) could be included as an alternative, per the results of Tamarozzi’s 2012 paper.

There is a need to replicate Mand’s Ghana study on doxycycline treatment to better understand its effects on lymphoedema patients.

5. Strategy for areas where loiasis is co-endemic

Dr Yao Sodahlon presented the summary recommendations of a March 2012 meeting held in Accra, Ghana to develop a provisional strategy for LF MDA in areas where loiasis is co-endemic.

In situations where loiasis and onchocerciasis are co-endemic, the use of ivermectin must be based on risk–benefit analysis. In areas where onchocerciasis is meso-endemic or hyper-endemic (REMO ≥20%) and the risk of ocular and cutaneous morbidity is high, treatment benefits are to be weighted towards relative benefit. However, in areas where LF alone is present or where LF is co-endemic with low-prevalence onchocerciasis, treatment is considered to be of less benefit because MDA is mostly preventing prospective morbidity, so ivermectin should not be used in these areas.

Research is ongoing into the optimal treatment strategy in areas of LF and loiasis co-endemicity, including a test-and-(not) treat strategy in Cameroon, high-dose albendazole in the Congo and the Democratic Republic of the Congo, the impact of insecticide-treated nets in Nigeria, and the development of macrofilaricides.

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While the operational research is being conducted, the provisional recommendations for areas without onchocerciasis but co-endemic for LF and loiasis are to start MDA with albendazole 400 mg every 6 months. In areas of LF and loiasis co-endemicity where malaria is also co-endemic, the albendazole monotherapy strategy should be combined with malaria vector control for added impact. Although the current evidence is limited, published data show that single-dose albendazole leads to a slow reduction in *Wuchereria bancrofti* microfilaraemia. The duration of this strategy would be 5 years; monitoring of microfilaraemia or antigenaemia in sentinel and spot-check sites at baseline would be after the third and fifth years of MDA.

**Discussion**

The group agreed that MDA twice a year was preferable, but that for logistic and financial reasons, implementation might be difficult for countries. The consensus was that implementing one round a year with albendazole only was better than not implementing MDA at all.

The group agreed to endorse the language in Annex 3 of the provisional strategy, with two changes:

- The first bullet should read (italics added to reflect proposed changes): “Where *Loa loa* infection is present based on RAPLOA and onchocerciasis is non-endemic or hypo-endemic (that is, less than 20% of nodule prevalence), mass drug administration could be implemented with albendazole alone (400 mg) *once or twice a year, with twice a year being preferable.*

No conclusion was reached on whether there is a better threshold for loiasis prevalence (rather than none) to decide that ivermectin can be added to albendazole during MDA. Collection and analysis of additional data to correlate the percentage of the population with high microfilaraemia counts with RAPLOA results and with occurrence of severe adverse events are needed to refine this strategy. It also would be helpful to update the risk prediction maps with new data from APOC (the WHO African Programme for Onchocerciasis Control) in order to better determine areas of co-endemicity.

WHO is preparing a manual of LF entomology, with the goals to reduce the annual transmission potential to zero during MDA and to maintain zero transmission potential during the post-MDA surveillance phase.

**6. GPELF progress: what have we accomplished?**

As Dr Ramaiah was not able to attend, Dr Pat Lammie presented on his behalf. The original estimates of the burden of LF disease were 1.39 billion at risk (1995), 120 million infected (1996) and 40 million clinical cases (2000). Updated numbers of infection and clinical cases were estimated, based on data reported to WHO by endemic countries using LF annual reports, and literature searched for burden estimates, epidemiology, clinical trial results, MDA impact and treatment coverage. Dr Ramaiah ran models of anticipated benefits in areas of known treatment coverage, using country data from the WHO Preventive Chemotherapy databank, to find populations at risk protected by MDA and those not yet protected by MDAs. He generated a curve based on pretreatment microfilaraemia rates and percentage reduction in microfilaraemia by rounds of treatment. For the population protected, the prevalence of those infected for 2010 was estimated by taking into account the duration of MDA and the treatment coverage. The 2010 estimated burden was calculated at 43 million infected, 14 million with lymphoedema and 20 million with hydrocele.
In addition, there is also a need to forecast MDA at country level (using published data from the Preventive Chemotherapy databank) and at implementation unit (IU) level (using unpublished information from annual reports). This should include forecasting the number of evaluation units (EUs) that will move to TAS and will require including EU data in the new joint reporting form. The joint drug request and reporting platform should be flexible enough to include information on TAS and morbidity. Once in the database, that information could be made accessible to RPRG members and other partners.

Discussion

Dr Bradley shared his spreadsheet, which used baseline WHO data to determine reduction in at-risk populations using an entomological index. Although data entry was stopped in 2008, it could be updated and compared with Ramaiah’s data, if necessary.

The data used in Ottesen et al. (2008) showed the number protected from being infected and on the progression of disease. These could be recalculated after 15 years of GPELF.

The group reflected that this analysis showed little change in overt numbers of clinical cases, as MDA will have little impact on these estimates. Instead, countries would have to collect data on numbers of new cases to see a trend.

It was mentioned that the Institute for Health Metrics Evaluation is estimating disease burden figures. Likely, these figures will differ from Dr Ramaiah’s estimates, but a comparison should be done when the study is released.

The group confirmed that this is an important study to publish. A small group, including WHO, the Lymphatic Filariasis Support Center, GSK and Michigan State University, will set up a conference call with Ramaiah to discuss next steps.

The group suggested that generic national M&E database software that could generate reports for WHO and others would be very helpful for countries to manage their data.

7. Other issues

The group discussed the presentation of GPELF status at the upcoming global meetings in November, particularly how to balance success versus challenges. It was recommended that trajectory towards 2020 goals and challenges should be presented by WHO Region in order to better capture the current issues. It would be helpful to include progress towards the milestones in the LF Strategic Plan in the WHO presentation. The NTD meeting will use the scorecard approach to appraise where programmes are and what is needed to meet London Declaration goals.

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8. **Conclusions and recommendations**

1. **Transmission assessment surveys**
   Recommendation on development of official WHO training materials and WHO Position Statement on TAS
   Endorse moving forward with this process.
   Encouragement of reporting and monitoring mechanism of TAS (role of RPRG)
   National programmes will provide standardized TAS eligibility and reporting forms as part of annual plans and/or master plans.
   Conduct technical reviews of the eligibility for performing a TAS and of the survey results. While the aspiration is to have technical support available at regional level through RPRGs, that capacity is currently being built. In the interim, there are resources of expertise through the M&E sub-working group on disease-specific indicators.
   Continue WHO’s role in monitoring country progress and maintaining updated forecasting of MDA and drug/ICT needs in close coordination with the TAS coordination group.
   **Recommendations on ICT procurement**
   A small group, including WHO, GlaxoSmithKline and the Bill & Melinda Gates Foundation, will develop a case to present to high-level officials at Alere to help coordinate forecasting, ordering and launching the new version of the ICT.

2. **Morbidity indicators**
   Acknowledged the MMDP document as an important guide for programme managers to develop MMDP component in NPELF.
   Recommended as individual treatment any of the following regimens: (i) a single dose of a combination of albendazole (400 mg) and ivermectin (150–200µg/kg) in areas where onchocerciasis is co-endemic; (ii) a single dose of a combination of albendazole (400 mg) and DEC (6 mg/kg) in areas where onchocerciasis is not present; (iii) DEC (6 mg/kg) for 12 days in areas where onchocerciasis is not present. For adults, doxycycline (200 mg/day) for 6 weeks is under consideration as an alternative.
   **Recommendation on impact indicators**
   National programmes should concentrate at this time on collecting data on morbidity process indicators rather than on impact indicators, which can be developed in the future.
   **Encouragement for development of reporting mechanisms**
   Programme managers should continue to include the morbidity data currently asked for in WHO annual reports to be reviewed by RPRG. Appointment of National Programme focal points for lymphoedema and hydrocele should be encouraged.
MMDP technical meeting should be conducted in 2014 to discuss the new tools, evidence and approaches, such as specific surgical approaches for hydrocele.

3. **Strategy for areas where loiasis is co-endemic**
   
   **Recommendation on Loa provisional strategy**
   
   Agree with recommended language with two changes (in italics): "Where Loa loa infection is present based on RAPLOA and onchocerciasis is non-endemic or hypoendemic (that is, less than 20% of nodule prevalence), mass drug administration could be implemented with albendazole alone (400 mg) *once or twice a year, with twice a year being preferable.*"

   Present for endorsement by the M&E working group a practical handbook on LF entomology, currently being developed in response to one of the recommendations of the Ghana meeting (5–9 March 2012).

4. **GPELF progress**
   
   **Recommendation on GPELF progress monitoring, forecasting and feedback**
   
   Include TAS planning and results and morbidity information in WHO annual joint reporting form.
   
   Use the PCT databank and Weekly Epidemiological Record to enhance publication of country progress monitoring and forecasting, including that of MDA and drug/ICT needs.
Annex 1. List of participants

Dr David Addiss  
Director, Children Without Worms  
The Task Force for Global Health, 325 Swanton Way, Decatur, GA 30030, USA  
Tel: +1 404 592 1415; e-mail: daddiss@taskforce.org

Dr Mark Bradley  
Scientific Support, GSK House, Global Community, Partnerships  
Brentford, Middlesex TW8 9GS, UK  
Tel: +44 208 0475521; e-mail: mark.h.bradley@gsk.com

Ms Molly Brady (rapporteur)  
NTD Technical Advisor, ENVISION, RTI International  
701 13th St NW, Ste 750, Washington, DC 20005–2207, USA  
Tel: +1 202 728 1967; e-mail: mbrady@rti.org

Mr Brian Chu  
Research Project Manager, The Task Force for Global Health  
325 Swanton Way, Decatur, GA, USA  
Tel: +1 (404) 592 1427; e-mail: bchu@taskforce.org

Dr LeAnne Fox  
Division of Parasitic Diseases and Malaria, Centers for Disease Control and Prevention  
Mail Stop D-65, 1600 Clifton Rd., Atlanta, GA 30329, USA  
Tel: +1 404 718 4739; e-mail: lfox@cdc.gov

Dr Ralph Henderson  
Consultant, 1098 McConnell Drive  
Decatur, GA 30030–3402, USA  
Tel: +1 404 329 9235; e-mail: rafeh@bellsouth.net

Dr Adrian Hopkins  
Director, Task Force for Child Survival and Development  
Mectizan Donation Program, 325 Swanton Way, Decatur, GA 30030, USA  
Tel: +1 404 687 5616; e-mail: ahopkins@taskforce.org

Dr Julie Jacobson  
Senior Program Officer, Global Health Program  
Bill & Melinda Gates Foundation, P.O. Box 23350, Seattle, WA 98102, USA
Dr V. Kumaraswami
Lymphatic Filariasis Support Center, The Task Force for Global Health
325 Swanton Way, Decatur, GA 30030, USA
Tel: +1 404 416 4583; e-mail: VKumaraswami@taskforce.org

Dr Dominique Kyelem
Project Manager, Lymphatic Filariasis Support Center, The Task Force for Global Health
325 Swanton Way, Decatur, GA 30030, USA
Tel: +1 404-687-5601; e-mail: dkyelem@taskforce.org

Dr Patrick Lammie (chair)
Division of Parasitic Diseases and Malaria, Centers for Disease Control and Prevention
Mail Stop D-65, 1600 Clifton Rd., Atlanta, GA 30329, USA
Tel: +1 404 718 4135; e-mail: pjl1@cdc.gov

Professor Charles Mackenzie
Professor, Michigan State University, A57 VMC Veterinary School, East Lansing, MI 48824, USA
Tel: +1 517-432-3644; e-mail: mackenz8@msu.edu

Dr Eric Ottesen
Director, Lymphatic Filariasis Support Center, The Task Force for Global Health
325 Swanton Way, Decatur, GA 30030, USA
Tel: +1 404 687 5602; Fax: +1 404 371 1138; e-mail: EOttesen@taskforce.org

Professor Dato C.P. Ramachandran
Chairman, Mekong-Plus RPRG, 8A-4-4 Belvedere Condo. 1/63, Off Jalan Tunku Bukit Tunku 50480, Kuala Lumpur, Malaysia
Tel: +603 2698 7275; e-mail: ramacp@hotmail.com

Dr Maria Rebollo
Centre for Neglected Tropical Diseases, Liverpool School of Tropical Medicine
Pembroke Place, Liverpool L3 5QA, UK
Tel: +44 7527520139; Mb: +44 7889720324; e-mail: maria.rebollo@liv.ac.uk

Dr Frank Richards
Director, River Blindness, Lymphatic Filariasis, Schistosomiasis & Malaria Programs
The Carter Center, 453 Freedom Parkway, Atlanta, GA 30307, USA
Tel: +1 404 420 3898; Fax: +1 404 420 3881; e-mail: frich01@emory.edu

Dr Yao Sodahlon
Associate Director of Programs, Mectizan® Donation Program
Dr Gary Weil
Professor, Washington University, Division of Infectious Diseases, Saint Louis, MO, USA
Tel: +1 314 454 7787; e-mail: GWEIL@DOM.wustl.edu

Ms Kim Won
Health Scientist, CDC/CGH/DPDM, Centers for Disease Control and Prevention
1600 Clifton Road, MS D-65, Atlanta, GA 30329, USA
Tel: +1 404 718 4137; e-mail kwon@cdc.gov

WHO SECRETARIAT

Dr Kazuyo Ichimori
Department of Control of Neglected Tropical Diseases
World Health Organization, 1211 Geneva 27, Switzerland
Tel: +41 22 791 2767; e-mail ichimorik@who.int

Dr Aya Yajima
Department of Control of Neglected Tropical Diseases
World Health Organization, 1211 Geneva 27, Switzerland
Tel: +41 22 791 3554; e-mail yajimaa@who.int
## Annex 2. Programme of work

Monday 1 October 2012

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<td>09:00–10:30</td>
<td>Opening</td>
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<td></td>
<td>- Welcome remarks</td>
<td>P. Lammie</td>
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<td></td>
<td>- Participants introduction</td>
<td>All participants</td>
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<td>- Administration matters</td>
<td>K. Ichimori</td>
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<td></td>
<td>- Objectives of the meeting</td>
<td>K. Ichimori</td>
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<td></td>
<td>- Review of the agenda</td>
<td>P. Lammie</td>
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<td>10:30–11:00</td>
<td>Coffee break</td>
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<td>11:00–12:30</td>
<td>Item 1 – Transmission assessment surveys</td>
<td>K. Won</td>
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<td>- Development of official WHO training material</td>
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<td>- Reporting and monitoring mechanism</td>
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<td>- ICT (availability and affordability)</td>
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<td>Item 2 – Morbidity indicators</td>
<td>V. Kumaraswami</td>
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<td>- Individual case treatment</td>
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<td>- Impact indicators</td>
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<td>- Reporting mechanisms of MMDP data</td>
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<td>12:30–13:15</td>
<td>Lunch break</td>
<td>Y. Sodahlon</td>
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<td>13:15–15:30</td>
<td>Item 3 – Strategy for areas where loiasis is co-endemic</td>
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<td>- Provisional strategy for loiasis co-endemic areas</td>
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<td>- Practical handbook of LF entomology</td>
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<td>15:30–16:00</td>
<td>Coffee break</td>
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<td>16:00–17:30</td>
<td>Item 4 – GPELF progress: what have we accomplished?</td>
<td>P. Lammie</td>
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<td>- Re-estimation of number of people infected and cases</td>
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<td>- Monitoring progress and forecast</td>
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<td>17:30</td>
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# Annex 3. Treatment of individuals

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<thead>
<tr>
<th>Regimen</th>
<th>References*</th>
<th>Comments</th>
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* Not an exhaustive reference list.