Summary of Prioritized Research Needs

1) Initiate multi-center, longitudinal studies to define the relationship and comparative effectiveness of the available diagnostic monitoring tools (antigen, antibody, PCR) used in human or vector populations, to determine
a) when to stop MDA,
b) how to perform surveillance to ensure absence of resurgence,
c) how to verify absence of transmission,
2) Use data from such multi-center studies to refine predictive models,
3) Study the role of mobility and migration both in populations and by modeling to define their effects on LF transmission dynamics,
4) Investigate both the effects of non-compliance on the LF Elimination Program and the sociologic reasons underlying it,
5) Refine and validate tools for monitoring morbidity management programs,
6) Develop guidelines for monitoring multi-program effectiveness and outcome in situations where LF elimination is coordinated (integrated) with other public health interventions (e.g., onchocerciasis, intestinal parasite, trachoma, or malaria control; and/or with vector control activities).

2.5.1 Overview

Monitoring is a systematic, repeated assessment of the progress of a piece of work over time; it is also a basic management tool for identifying a program's strengths and weaknesses. While such monitoring may involve a wide variety of issues (including finance, personnel, vehicles, etc.), the LF Elimination Program focuses particularly on monitoring program outcomes and on pursuing research needed to ensure that the monitoring approach has a sound scientific basis. For the GPELF both process and impact monitoring are essential for achieving the Program's two principal goals: interruption of transmission and diminishing disease morbidity.¹

Process monitoring provides information on the progress of the activities being carried out. For LF programs, the main process indicator relating to transmission interruption is MDA coverage, which can be operationally defined as reported coverage, surveyed coverage, or geographic coverage, each determined differently and each with a specific program implication.² For diminishing disease morbidity the potential process indicators have yet to be evaluated.

Impact monitoring provides information on progress towards achieving the objectives of a program and on the impact the program is having in relation to these objectives. For LF programs the principal impact indicator relating to transmission interruption is the prevalence of infection in humans as defined by microfilaremia; serum antigen (ICT) positivity and incidence of infection (antibody positivity) are also assessed.²,³ Sentinel-site populations are followed serially from baseline observations to monitor program impact on transmission. For diminishing disease morbidity the principal impact indicators remain to be defined.

2.5.2 Research Needs

Tools for monitoring.

Impact.

With respect to GPELF's goal of interrupting transmission, it is generally agreed that the diagnostic tools now available to assess the presence of infection or the exposure of humans to infection are very good. High sensitivities and specificities have been recorded for most of the available assays, and their successful use for mapping the geographic distribution of LF and monitoring the early stages of program progress have proven them to be of practical value.⁴ However, what has not yet been done is to define the comparative sensitivities and specificities of the various available diagnostics when they are challenged to identify extreme endpoints such as the absence of transmission. Since findings might be expected to differ for the different LF parasite-vector complexes, such assessments need to be performed in multiple regions of LF endemicity. Therefore,

* a multi-site assessment of the comparative effectiveness (including other parameters such as ease-of-use, cost, reliability, etc.) of all monitoring tools available (MF detection, ICT, DNA [in human blood and in mosquitoes], antibodies [especially those detecting exposure to infection]) is essential and should be undertaken immediately through
1) laboratory-based testing of existing serum collections, 2) field-monitoring of sentinel sites in countries with active LF elimination programs.

Tools (and indicators) for assessing progress towards morbidity control goals have been proposed but not yet agreed. Therefore,

* the proposed, still untested, indicators (and tools for defining them) to assess the impact of morbidity control efforts should be evaluated at multiple sites and in multiple programs

Process.

For efforts to interrupt transmission, reported coverage from MDAs is confirmed by independent coverage surveys that depend for their accuracy on rigorous sampling methods. Currently recommended is the Expanded Program on Immunization–cluster survey technique, which is both time-consuming and expensive.⁵ If acceptable alternative sampling techniques were available, programs could effect savings and increase the extensiveness of their coverage estimates. Therefore,
alternative sampling techniques to determine surveyed coverage values for MDA activities should be tested for cost-effectiveness in comparison to the standard cluster-survey techniques now being used.

Tools (and indicators) for monitoring morbidity control activities have been proposed but not yet tested. Therefore,

- the proposed process indicators for monitoring the morbidity component of LF elimination programs should be evaluated at multiple sites, so that selection of the most effective indicators can be finalized.

Setting thresholds—testing strategies.

Impact.

Strategies have been defined for GPELF that use the existing diagnostic tools to reach decisions about when to stop the MDAs, how to define the absence of transmission, and how to conduct surveillance for possible recrudescence of transmission.1,2 However, these strategies have not yet been tested, so it is not clear which indicator or combination of indicators will best address these issues or even whether different indicators could be more efficient in determining the status of endemicity in new areas being considered for targeting with MDA. Therefore, it is essential

- to test as soon as possible the protocols now recommended to determine whether or not it is safe or appropriate to stop the MDAs (then modify the protocols as/if necessary),
- to evaluate both the current guidelines for verifying absence of transmission and the different diagnostic tools that could be used,
- to develop background (or other) surveillance strategies and test them for use in early detection of recurrent transmission in areas where MDA activity has stopped.

Concern has been raised about the threat of introduction of LF into previously non-endemic areas or re-introduction into areas where elimination has been achieved, principally because of inter-country or intra-country migration of workers or other populations or because of a region’s proximity to an LF-endemic area. Research is needed, therefore,

- to define the prevalence of infection in migrating expatriate or other populations and evaluate the threat posed by them in settings that were previously either endemic or non-endemic.

Process.

To eliminate LF by the end of the predicted 4–6 rounds of yearly MDA, it has been estimated that a minimum MDA coverage of 70–80% of the total population is required. However, it is not clear what happens if a certain proportion of the population never participates in taking the drugs during the repeated MDAs (i.e., there is systematic non-compliance), even if a targeted 80% coverage is achieved.3 Therefore, it is very important to study populations in ongoing LF elimination programs

- to determine if such systematic non-compliance exists,
- to identify particular characteristics of these non-compliers, the reasons for their non-compliance and whether community mobilization efforts can overcome it,
- to gauge the effects of systematic non-compliance on the effectiveness of the LF elimination program.

Monitoring integrated or linked programs.

There is no question but that linking or integrating public health programs is of high priority today.7 The GPELF has already built a strong infrastructure for health care delivery based on once-yearly contact with communities that targets MDA to everyone in the enormously large at-risk populations (often whole countries). Because of this infrastructure, along with the popularity of the program’s beneficial free drugs and a good monitoring framework to assess program effectiveness and impact, the GPELF is a good match for other programs with similar needs to develop partnerships. Programs already actively engaged in trying to develop integrated or coordinated activities with LF programs include those focused on malaria, trachoma, onchocerciasis, intestinal parasites, and schistosomiasis.

Such program linkages can and will operate at many functional levels, including capacity-building, social mobilization, program implementation, monitoring, evaluation and others. While the principles underlying each of these activities are the same for each of the different programs, the individual details are unique. However, as the pay-off for successfully exploiting the complementarity of these programs and activities is so great, it is very important

- to conduct the operational research necessary to identify those elements of program monitoring and evaluation that can be effectively coordinated or linked with those of other similar or complementary public health programs,
- to develop appropriate protocols and initiate collaborative studies between LF and other large-scale national or global programs to assess the cost-effectiveness of sharing or integrating their activities.

2.5.3 References


