Report of a Technical Meeting on the Use of Lot Quality Assurance Sampling (LQAS) in Polio Eradication Programs

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Introduction

On June 25, 1998, the United States Agency for International Development (USAID) with the MEASURE *Evaluation* Project hosted a Technical Meeting to discuss the use of Lot Quality Assurance Sampling (LQAS) in polio eradication programs. The meeting was called in response to USAID's and other donors' interest in:

- strengthening monitoring and evaluation of polio eradication activities, and
- applying rapid assessment tools in the health sector (Appendix 1).

LQAS was chosen as the focus of the meeting due to its potential for use in rapid assessment and the relative lack of widespread experience with the method. The aim of the meeting was three-fold:

- discuss the strengths and limitations of using LQAS as a rapid assessment tool to monitor polio eradications activities (e.g., National Immunization Days or NIDs);
- define a strategy for assessing the validity and feasibility of LQAS for routine monitoring of polio eradication activities (e.g., NIDs); and
- discuss the validity and feasibility of using LQAS as a rapid assessment tool to monitor performance of other immunization activities.

Participants included representatives from the World Health Organization, the Centers for Disease Control and Prevention, USAID, BASICS, Johns Hopkins and Harvard Universities, Plan International and the MEASURE *Evaluation* Project (Appendix 2). The main discussion points and conclusions of the meeting are reported below.

I. The Status of Monitoring and Evaluation in Polio Eradication Efforts

The need for accurate and timely data to assess polio eradication activities throughout the world is universal. Key questions to be addressed in the context of polio eradication range from the effectiveness of national immunization days to the impact of program activities on the incidence of polio. The choice of appropriate assessment tools and the amount and frequency of data collected depends mainly on program needs and priorities. While every program is different, at a minimum reliable information is needed for three general purposes: monitoring immunization coverage; improving the management and effectiveness of National Immunization Days (NID); and surveillance of acute flaccid paralysis.

Program managers and their partners currently employ a number of methods to monitor and evaluate polio eradication activities.

<u>Coverage</u>

Many countries rely on administrative data from NIDs to assess coverage of polio immunization. However, there are problems inherent in the use of administrative data to assess impact. Administrative data can distort coverage estimates when there is confusion about eligible age groups or inaccurate population estimates. In countries where routine data systems are poor and estimates of administrative coverage following NIDs are less robust than expected, supplemental verification activities may be needed for monitoring coverage or certifying the absence of polio.

For example, in countries with low routine coverage, program strategies emphasize repeated National Immunization Days (NID). If surveillance is also weak, data may be needed following each NID to identify groups or areas of low coverage and focus "mop-up" activities between NIDs. Another critical decision in the process of polio eradication in each country is determining when to shift program strategies from repeated NIDs to "mop-up." In the absence of a strong surveillance system, specific coverage data may be needed to make that decision. The 30 cluster coverage survey is sometimes used to validate administrative coverage and identify missed opportunities. However, this technique has limited ability to identify pockets of low coverage when overall coverage is high. It is therefore not the optimal choice for directing future NID or "mop-up" efforts.

Monitoring NIDs

When a country conducts a series of National Immunization Days, basic monitoring is helpful for identifying problems in planning and reporting, noting specific areas of inadequate coverage, and predicting the likelihood of polio transmission (BASICS, 1998). In addition, the introduction of systems to monitor the quality and effectiveness of NIDs may be useful in strengthening routine immunization once eradication activities cease. Nevertheless, the use of monitoring and evaluation information before, during and after NIDs is often limited. In practice, establishing and employing reliable methods to gather such data can be overlooked in the build up and execution of these large national events. It often appears that the quality of information at the lower level decreases as eradication fervor increases.

Surveillance

In most countries surveillance of acute flaccid paralysis is underway, but the scope and reliability of surveillance systems vary greatly. Surveillance systems are mainly facility-based and polio cases are not always presented at the health center. In countries with poor access to health services or low utilization, it may be necessary to gather information on cases of acute flaccid paralysis directly from communities.

II. Lot Quality Assurance Method

Description of the lot quality method

Lot Quality Assurance Sampling (LQAS) was developed in the 1920s as a quality control technique for goods produced on a factory assembly line. It was used to examine a small number of units randomly selected from each lot. If the number of defective items in that small sample exceeded a predetermined number, the lot was examined more closely and either repaired or discarded. Otherwise the lot was accepted. The number of units tested and the maximum

allowable number of defects were determined to ensure that there was a high probability that the lots accepted contained no more than a specified proportion of defective goods, and that the lots rejected contained a relatively high proportion of defective goods. Since the 1980s, use of LQAS in health assessment has increased. In 1991, WHO identified LQAS as one of the more practical rapid assessment methods and encouraged further study. For examples of LQAS application in the health field, see Robertson, S, M. Anker et. al, 1997. A list of references relating to LQAS is found in Appendix 3.

LQAS is a method that combines two standard statistical techniques: stratified random sampling for data collection, and one-sided hypothesis testing for data analysis. The technique provides minimal amount of information from each lot to determine whether the level of "defectives" is likely to be above a given threshold. The sample selected from each lot is quite small.

The first step in employing LQAS is to divide the study population into useful lots such as villages or facility catchment areas. After defining the lots, an upper threshold is set for the proportion of allowable defects in accepted lots and a lower threshold is set for the proportion of "defects" in rejected lots. Once upper and lower thresholds are determined, LQ tables or Operating Characteristic Curves (OC Curves) are used to define the sample size and the maximum allowable defects that correspond to the chosen thresholds. A random sample is then taken from each lot, and the lot is rejected if the number of defects exceeds the maximum specified limit. To reduce cost, it is possible to stop the survey as soon as the number of defects exceeds the specified limit. However, if a survey also seeks to obtain an overall estimate of performance among all the lots, sampling should be completed.

Experience with LQAS in the health sector

LQAS has been employed for a range of purposes, some of which are listed below:

- assessing immunization coverage;
- monitoring immunization program performance in Southeast Asia, Peru and the United States. In this case, supervisors sampled records to assess compliance with immunization protocols. The number "defective" or incorrect procedures allowed per lot was set to determine whether a facility (or lot) was accepted or rejected;
- assessing compliance with policy such as patient screening practices or immunization administration;
- identifying areas of high incidence of specific diseases (e.g., to assess program impact);
- Private Voluntary Organizations (PVO/NGO) have used LQAS in remote areas in Latin America and Africa for health service and system development. LQAS was employed to determine if local health worker coverage was adequate and assess the technical quality of

a range of basic services. Results were used to help make decisions at the local level about directing additional support to specific health workers.

- In Guatemala, NGO supervisors were trained in the use of LQAS to assess immunization coverage and CDD/ORT interventions. Used routinely, this approach enabled supervisors to identify problems with health worker training and populations at risk for vaccine preventable diseases. The method also identified health workers with good practices who were then used to upgrade skills of fellow workers.

- BASICS employed LQAS in 1998 in Bangladesh to identify specific areas of low polio immunization coverage in urban areas. A 30 cluster survey was unable to provide sufficient information to locate potentially high areas of polio transmission. LQAS was chosen because of its reliance on small sample sizes, ease of administration and the ability to analyze data quickly and act on it. Results were used to strengthen supervision in low coverage areas. The LQAS survey in Bangladesh was also used to build capacity for conducting similar surveys in other areas. Field staff commented that the greatest difficulty associated with the application of LQAS is the determination of sample size.

Characteristics of LQAS

- LQAS is a statistically valid form of stratified random sampling that enables conclusions to be drawn from small samples. Hence, LQAS is cost effective when the cost per subject is high. LQAS is not cost effective or practical for use in remote rural areas where populations are widely scattered.

- LQAS is an approach used to screen for specified attributes such as coverage. It is employed with the intention of classifying "good" lots and "bad" lots, or in the case of immunization activities, areas of acceptable levels of coverage from areas with low coverage. It is useful when there are specific targets to be achieved because it enables managers to assess the program performance.

- LQAS is unable to detect "poor" quality unless it is defined to be much inferior to "good" quality. Specifically, LQAS can distinguish between 70 percent coverage and 40 percent, but not between 70 percent and 60 percent coverage.

- In employing LQAS, it is important to be clear about the primary purpose of the application.

- LQAS is most efficient if the distribution of attributes being measured are homogenous within lots.

Sampling

- Sampling is one of the most complex aspects of using LQAS. Technical guidance in setting the thresholds and determining the sample size is often required. Specially prepared tables or operating characteristic curves are used to identify the appropriate sample size and the number of allowable defects in the sample. These tables and operating curves are available in a number of published documents.

- If there is no reliable population registry to use as a sampling frame, it is possible to use a modification of the 30 cluster sampling method to identify units.

- If thresholds are not set carefully, there is a possibility of misclassifying acceptable services and wasting funds trying to address problems that do not exist. Since both sensitivity and specificity should be emphasized, it is necessary to have some knowledge of the expected overall outcome in order to set appropriate thresholds.

- The way in which lots are defined can affect the outcome of the study. In the health field, for example, the more homogeneous the population within each lot with respect to exposure to disease or access to health care, the more likely it is that a small sample will be indicative of the entire lot. If lots are too broadly defined for the characteristic under study, subgroups within a lot with different characteristics may be overlooked.

- LQAS is not only used to identify high risk populations, *per se*. It should be used to identify where a health intervention is not being implemented appropriately. If a lot is heterogenous, it may be practical to stratify the lot.

Data collection

- Like many survey techniques, LQAS requires motivated and well-trained data collections staff.

- It is possible to end data gathering when the number of "defects" found in a lot have surpassed the allowable number. In effect, one can use even smaller sample sizes than specified in the plan to draw conclusions.

Analysis

- Interpretation of the data collected using LQAS is relatively easy and quick.

- Once classification of lots is completed, it is possible to aggregate the results to get an overall estimate of the attribute under study. For example, when measuring immunization coverage, lots can be aggregated to provide an overall measurement of coverage for the combined lots. This level of analysis is likely to be performed by program managers and can be accomplished easily with a calculator or a computer spreadsheet program.

Limitations

- Technical support is usually required to develop a sampling plan and determine the sample size.

- Current literature on the use LQAS is not as accessible to potential users as it could be. Interpretation of available LQAS tables is often difficult.

Routine use

- LQAS has been used mainly as a survey tool. There is little experience to date of its use in routine data systems. However, participants felt that it has potential for use in routine monitoring and evaluation. For example, LQAS could be used by supervisors over time to assess performance or compliance with policies through observation, exit interviews, or record review. As noted above, LQAS has been used in routine immunization programs to review records and events and detect problems with dose intervals.

- Whether for routine or research application, it is necessary to develop and test some generic guidelines to make the method more accessible to field-based workers.

- There are other sampling methods, such as Control Charts, that may be superior to lot sampling methods for use in routine monitoring.

III. Using LQAS in Polio Eradication Efforts

Participants discussed a range of potential applications of LQAS for meeting the monitoring and evaluation needs in polio eradication programs.

- Data needs in polio eradication are increasing

  In the early stages of eradication programs, there is a danger of introducing too many measurement activities. Often it is more practical to act rather than measure progress. However, as polio eradication programs advance, the demand for precise information increases. Starting early and establishing some local systems to assess progress and provide data is advisable.

- Identify pockets of low coverage between National Immunization Days

  Information is needed to assess the effectiveness of NIDs. Problems found in the use of administrative data might indicate a need for more precise tools to assess the impact of NIDs and improve the coverage of subsequent NIDs. LQAS could be used after the first in a series of NIDs to identify areas of low coverage or specific populations that are being

missed by NID activities. While it may be difficult to gain acceptance of the need for post-NID evaluation, LQAS may provide a simple and rapid tool that will not distract program managers from preparing for the next NID. In the same light, LQAS may be useful for confirming suspected areas of low coverage such as border areas and slums, and quantifying the level of risk.

- Identify areas of high risk of polio transmission to focus mop-up

  For the purpose of polio eradication, WHO currently defines high risk areas (or those where polio virus is likely to be circulating) as:

  1. Areas of low coverage
  2. Areas with transient populations
  3. Densely populated urban and peri urban areas
  4. Areas with poor sanitation
  5. Areas with poor access to health care.

  As polio moves from an endemic to an epidemic state, it becomes increasingly necessary to be able to identify these high risk areas to determine appropriate interventions. LQAS might be useful for identifying areas of low coverage and assist in focusing future NID activities.

- Identify areas of high risk of polio transmission, marking a change in strategy

  National Immunization Days are usually sequential, occurring 4-6 weeks apart. Once a country has achieved sufficient coverage with NIDs, it is recommended that the eradication strategy focus on intensive, door-to-door immunization in areas of expected low coverage (or mop-up). In South America where polio eradication is well advanced, surveillance data was used to identify areas of high risk and determine when to stop NIDs and begin mop-up. This evaluation approach is not feasible in many parts of the world, particularly in subSaharan Africa, where surveillance systems are still underdeveloped. In these countries, LQAS could be used to assess coverage levels and determine when to shift from a NID to a mop-up strategy.

  If thresholds were set for coverage levels indicative of "high risk," LQAS could be used to identify those areas during program strategy reviews. Guidelines could then be developed to guide program activities.

- Application to measles control and eradication

  The use of LQAS may increase in importance should a global measles eradication program begin. Measles vaccine is not as easy to administer as polio vaccine and may require more focused program activities. In addition, measles is more infectious than polio, and its eradication will require high and consistent coverage to interrupt transmission. Precise

"mop-up" activities will become increasingly important as will timely access to reliable data on areas of high risk for measles transmission.

- LQAS would not be useful for validating national coverage estimates.

- The potential for using LQAS for surveillance of acute flaccid paralysis is limited. Occurrence of paralytic polio is too rare to be usefully detected with LQAS.

IV. Conclusions

Conclusions related to LQAS generally

- While there is heightened interest in LQAS and its potential application in the health field, the method needs to be put on a firmer footing. Potential users need to be aware of appropriate uses of LQAS, and its limitations. More attention is needed to defining the potential applications of LQAS in different contexts.

- The MEASURE Project might consider assessing the potential of LQAS in routine monitoring of basic health services. Field experience is needed to determine the extent to which LQAS can be used routinely and when it is most appropriate. For example, MEASURE could explore what role LQAS could play in results-based supervision.

  Other questions to be addressed related to routine use include:

  1. What are the main threats to securing valid results using LQAS?
  2. How much supervision is required to ensure the quality of the data?
  3. What is its potential for use in program management, feedback and problem solving?
  4. How would a district manager apply and use data generated from LQAS?

  There is a need for more awareness and consensus on these issues. The MEASURE Project could conduct case studies on routine use of LQAS for inclusion in a field guide and to raise awareness of the method. There are many opportunities for collaboration with other groups (e.g. PVOs) for applying LQAS in routine supervision or facility-based monitoring systems.

- There is very little information on the cost of conducting one-time or repeat surveys using LQAS. Cost is an important factor to be assessed in any implementation test or case study.

- There was a general consensus that user-friendly generic guidelines on LQAS are needed both for use of LQAS in surveys and routine monitoring. Given current trends in health system decentralization and results-oriented programming, the need for simple rapid assessment tools is increasing. District level staff are now expected to monitor changes in

quality and access of health services. Guidelines for using LQAS would facilitate its application at community level by supervisors and program managers.

LQAS guidelines should include information on defining lots, setting thresholds, choosing the sample size, interpreting the decisions rules and errors and analyzing, presenting and using data. A slide rule could be designed and included as part of a manual to make the sampling method accessible to field workers.

The MEASURE Project might consider composing these guidelines, and identify opportunities to test them. This type of manual might also summarize lessons from the field tests and other experiences with LQAS to clarify its purpose and potential range of uses. Guidelines should also highlight possible operational problems.

- Related to user guidelines, the MEASURE Project might also develop a Trainers Guide and spreadsheet to facilitate data entry and analysis at the level of aggregation.

Conclusion related to use of LQAS in polio eradication

- Guidance or guidelines that focus on monitoring and evaluation for polio eradication may be needed. Such a "cookbook" might help program manager define a minimum package of critical information needed for decision making, determine at what level information is needed and how to prioritize data gathering. These M & E guidelines should include a list of possible indicators, identify those of highest priority and suggest methods for gathering data to assess them.

- Guidance and advice is needed with respect to possible LQAS applications in polio eradication efforts. For example, only countries without a strong surveillance system may require rapid assessment techniques to identify areas of low coverage. M & E guidelines might also provide criteria for defining high risk populations and decision trees for program strategies based on the results of studies employing LQAS. The guidelines should include information on the different uses of LQAS and the standard 30 cluster survey, and when they can and should be combined.

- LQAS is potentially a very useful tool for defining high risk populations between NIDs.

- LQAS may also have potential in determining when to make the transition between NIDs and mop-up strategies, and focusing mop-up efforts.

- Using LQAS to identify areas of high risk of polio transmission may require different steps. Tracer indicators could be used to identify these areas. A subsequent step would entail an assessment of more specific indicators. Definitions of high risk must be specified before using LQAS for this purpose and should be part of the follow-up to this technical meeting.

- LQAS may have potential for use in routine monitoring of polio eradication and other immunization activities.

- LQAS could be used to assess whether publicity campaigns reached certain areas and whether people knew about the NID.

- LQAS could be used to assess the process of conducting NIDs if performance at vaccination sites cannot be evaluated. Areas to evaluate might include: vaccine availability, health worker knowledge, cold chain functions, use of expired vaccines, etc.

Appendix 1 WHO Statement on Rapid Assessment

In a 1990 meeting on Rapid Assessment sponsored by the World Health Organization, it was concluded that:

- Rapid assessment methods are useful and efforts should be made to improve their validity and field level applicability;
- Quantitative and qualitative tools are complementary and their dual use strengthens assessment activities;
- Identifying the appropriate use of rapid assessment techniques in special situations is partly dependent on the amount of time available for decision making.
- High standards and scientific objectivity is required for any assessment process.
- Rapid assessment is not an excuse for a quick and dirty approach.
- Logistics should not undermine quality and objectivity in rapid assessments.

Source: Anker, M., "Epidemiological and Statistical Methods for Rapid Health assessment Introduction", *World Health Statistics Quarterly*, 44(3): 94-97 (1991).

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