LOT QUALITY ASSURANCE SAMPLING TECHNIQUES IN HEALTH SURVEYS IN DEVELOPING COUNTRIES: ADVANTAGES AND CURRENT CONSTRAINTS

Claudio F. Lanata a & Robert E. Black a, b

Health surveys have been widely utilized in developing countries to provide information to health planners for programme evaluation or monitoring. Traditional survey methods are costly in terms of personnel and time. The results are usually available a considerable time after the survey is completed, making it difficult for health planners to use when making decisions. Moreover, most health surveys only provide information at the regional or national level, not at the level of small health units or population groups, where information is needed in order to direct supervisory activities to those small areas with the poorest health-programme performance. Individual districts do not usually have the resources to carry out health surveys in large and even small areas. Hence, the growing interest in developing methods that are particularly suited to small areas.

The utilization of survey methodology developed in industry for quality control provides tools that could potentially overcome these limitations of traditional health survey methods (1). Among these, lot quality assurance sampling (LQAS) has been proposed as a useful methodology for monitoring health programme performance at both health centre or community level (2, 3). In this article the practical applications of LQAS techniques in health surveys in developing countries will be reviewed, describing their advantages and the current constraints that still limit their use in health monitoring. A detailed description of the methodology and its statistical principles can be obtained elsewhere (3, 4, 5).

After a brief description of the method, each aspect of the LQAS methodology in its application to health surveys will be discussed, addressing current difficulties. The following areas will be reviewed:

- the different ways of defining a lot and a sample unit for its use in LQAS;
- the need to have a precise sampling frame and how this can be created;
- the available methods for calculating the sample size for different sampling schemes;
- a detailed description of how to conduct the sampling, in particular in community surveys, and the key role of the survey team.

Finally, the interpretation of survey results and their use when monitoring health programmes will be discussed. A concluding section will consider the current limitation and potential uses of LQAS in health surveys.

The method

LQAS methodology was developed to help manufacturers determine (at a minimum cost) whether their products met a set of quality standards. This was achieved by utilizing small sample sizes. Since industrial production is usually done in batches or lots, the sampling strategy was developed to classify sampling units (lots) into acceptable or unacceptable according to preset quality levels, minimizing the risk of misjudgement—considering the production lot as acceptable when it is not (consumer’s risk) or unacceptable when it is (producer’s risk). The method selects a sample size and the maximum number of permissible defects to be found in a sample to consider the lot acceptable. To satisfy the statistical assumptions of the method, the selection of each individual unit to be sampled in each lot has to be done following a random sampling process. It is important to mention that the method does not provide an estimate for the lot sampled; it only classifies it as acceptable or unacceptable.

LQAS methodology utilizes small sample sizes and can be used as frequently as needed to provide information on each lot sampled. It is also possible to combine lots in order to obtain relatively precise estimates of the quality level for the entire area sampled. Because of these advantages, the use of LQAS methodology has been advocated for health monitoring.

In this issue of the World health statistics quarterly, Lemeshow & Taber give a complete description of the LQAS methodology and its application in industry and health areas in general. This article will concentrate on the use of LQAS in health surveys to monitor health programmes. Because of the need for a detailed sampling frame, as described later, the application of LQAS to monitor a health programme at the community level would only be justified if repeat surveys are expected to be done in the same area to monitor the programme. This will only occur with a health programme under active implementation, and when multiple surveys can be considered to monitor the progress of the programme, concentrating supervisory skills in the areas (lots) most at need. LQAS should not be considered as the methodology of choice to be used when a single survey is planned at the community level, unless a detailed sampling frame can be easily obtained; in this case, traditional survey methods would be more convenient and efficient.

Defining the lot

For its application in health surveys, a lot has been defined as a population area assigned to a health unit (2, 5), a health centre, or even health records within a health centre (6). An ideal lot is the smallest unit that could provide meaningful information to the health planner when evaluating a health pro-

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*Research Division, Institute of Nutrition Research, Lima, Peru.

bDepartment of International Health, School of Hygiene and Public Health, Johns Hopkins University, Baltimore, Maryland, United States of America.

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gramme. For a given lot, it is assumed that the sampling units within the lot have had similar exposure to the health programme under study. If an area assigned to a health unit has had different exposures to a health programme, because of distance to the health centre for example, it would have to be divided into subareas, each called a lot, for sampling purposes. For example, a health unit in charge of an immunization programme in a large population area, involving both urban and peri-urban or rural areas, could be divided into two or more areas or lots, some for urban and others for peri-urban or rural areas.

In this way, programme performance in these different areas could be evaluated independently, allowing the health planner to take specific remedial measures. Lots can be redefined when evaluating a different health programme or when an area has achieved a uniform performance level for the programme being evaluated.

This ideal lot definition, however, needs to be contrasted with practical and financial constraints of the health programme to be evaluated. In the case of a nationwide health programme, it is not practical to create lots based on small population groups of health units that would need to be independently evaluated. It is possible to utilize traditional survey methods, like stratified cluster surveys, for sampling large geographical or population-based areas to first identify which region or population-sectors (each requiring the conduct of a complete traditional survey) should require further sampling utilizing LOAS, thus concentrating supervisory activities on those areas only. This combined survey strategy has not yet been tested and will need to be evaluated before it can be recommended.

Experience in the use of LOAS in health surveys is still limited. Small population bases in both urban (2) and rural (5) areas have been used as lots in experimental evaluations of LOAS in monitoring immunization programmes in Peru. In a large evaluation of LOAS in Costa Rica, an initial random sample of 60 health units at the national level was taken and the population assigned to those health units was treated as one lot and sampled using LOAS methodology (7). Since only one round of surveys was conducted, a complete evaluation of the LOAS methodology was not properly carried out.

Sampling frame

When sampling, one needs to make sure that each sampling unit has been drawn randomly, ensuring that the probability of selecting the sampling unit has been equal for all similar units within the lot. In order to satisfy that requirement, a sampling frame with a complete listing of all sampling units or an acceptable equivalent is needed. Such an equivalent could be households. In the case of community surveys for example, it is important that the sampling frame be as complete as possible, in order not to select a biased sample.

When sampling from a population, a complete census of all households or city blocks (with a similar number of households per block) could be used as a sampling frame to select each sampling unit. In many countries, detailed maps are available for small population areas used as census sectors when conducting national censuses. Although they often require some updating (2, 8), these census maps are very useful as a sampling frame. They may not be available for many areas of developing countries, however. When a census can be conducted in a particular area, it will provide the ideal sampling frame. Alternatively, a listing of communities with their estimated population size could be used to select those communities from which one or more sampling units will be required.

Independently of the sampling frame used, it is important to have an estimate of the number of sampling units available in each lot to be sampled, in order to select an appropriate sample size and to obtain weighted estimates of performance level for several lots combined.

When sampling health records, a sampling frame could be selected within the health centre at the time of sampling, eliminating the need for a pre-existing sampling frame.

Systematic random sampling

LOAS requires that each individual sampling unit be selected following a random procedure. When conducting community surveys, it is very useful to have the sampling frame constructed with some geographical order. Then, when sampling, a systematic random sampling could be used to assure that the random selection of sampling units will cover all areas within the lot. If the sampling frame is a list of urban blocks, a number of blocks is then selected. In the field, once the selected block has been identified, the survey team needs to select, following a random procedure, an initial household to look for the sampling unit used in the survey. A complete enumeration of households in the block can be done and one household selected using a table of random numbers. Once the initial household has been identified, the surveyor contacts the family members to determine whether the sampling unit used in the survey is available in the selected household. If not, the next household to its right (or left, following a consistent pattern) is selected, until a sampling unit is identified and classified.

This procedure is not applicable when the only sampling frame available is a list of small communities, which is often the case in poor rural areas. Once the communities have been selected by simple random sampling proportional to the total population, the survey team needs again to select the initial household in which to look for the sampling unit. When conducting cluster surveys in rural communities of Peru (C. Lana et al., unpublished), it was found practical either to do a rapid enumeration of households in the community with the help of a local leader, or to divide the community into two equal parts, and then to select one randomly. That selected sector was then divided into two similar sectors and one selected randomly. This procedure was repeated until the initial household was identified and the search for a sampling unit initiated. Much simpler approaches could be used when a complete census exists. In this case, the exact unit to be sampled is identified from the sampling frame.

Sampling units

Depending on the purpose of the survey, a sampling unit could be a child 12-23 months for immunization coverage, a child <5 for oral rehydration usage in
cases of diarrhoea, a pregnant woman for use of prenatal services, a woman aged 12-49 for use of family planning methods. The sampling unit used to be the one which will provide the most useful information to evaluate a particular health programme.

The sampling unit can be changed once an initial quality level has been achieved by the programme, so that the programme can focus on another quality level. For instance, if the initial target of an immunization programme was to achieve at least 90% coverage of children aged 12-23 months, a subsequent target could be selected once the initial one has been achieved, for example to provide timely immunization to children <1. This age group could then be sampled to evaluate the percentage of children who have received the appropriate vaccines at the correct age, a target more difficult to achieve.

Different sampling units can also be combined into a single multipurpose survey. In this case, the quality levels to be evaluated, the sample size and the sampling strategy need to be defined independently for each particular sampling unit. This multipurpose use of LOAS was evaluated in a pilot study conducted in Lima (Peru) (8). This evaluation related to the performance of the diarrhoeal disease control programme, the prenatal care programme and the immunization programme. A single sample size of 9 was selected with different numbers of permissible defects per sample (2 or 3), according to the indicator used. Within a week, a team of four surveyors evaluated 12 lots in a peri-urban community of Lima with a total population of about 86 000. 5 lots were rejected for their level of ORS use but none for ORS knowledge; 1 lot was rejected for its lack of use of prenatal care programmes; and 4 lots were rejected for their level of immunization coverage and the absence of immunization cards (8). This experience demonstrated the potential value of using LOAS for evaluating multiple health programmes in a single survey.

In the Costa Rica study, several primary health care programme activities were also evaluated at the same time (7). The Household Register Form, a form that stays in the household and is signed and dated by the health worker at every household visit, was used as a sampling unit to evaluate the health workers' programme. Children aged 1.5-35 months were used as a sampling unit to evaluate the immunization programme. Pregnant women were selected to evaluate the prenatal care programme, and infants <60 days were selected to evaluate the newborn referral programme to a physician. Children <6 years were selected as a sampling unit to evaluate the diarrhoeal disease control programme. All these survey experiences illustrate how sampling units are selected depending on the type of health programme to be evaluated.

For practical purposes, alternative sampling units which have a close relationship to the sampling unit to be evaluated are used. For example, when sampling at the community level to evaluate immunization of diarrhoeal disease control programmes, one could use the household as an alternative sampling unit, when at the time of the analysis children <5 will be used as sampling units. The use of households is needed to build the sampling frame and for the selection of the households to be included in the survey. Other equivalent sampling units could be selected depending on the health programme to be evaluated.

Selecting the sample size

To select a sample size the method requires that an upper and a lower level of performance be determined for each health programme to be evaluated. The sample size will then be selected to ensure that lots with a real performance level above the upper level of performance will have a good probability of being classified as acceptable, and lots with a real performance level below the lower level of performance will have good probability of being classified as unacceptable. The wider the gap between the upper and lower performance levels, the smaller the sample size.

An immediate concern when carrying out the first LOAS is to estimate the real performance level of the lots to be sampled. Available information can sometimes provide this estimate, making it possible to select the upper or lower performance levels based on that estimate. Frequently, however, these estimates are very different from the real performance level, and the first round of samples may not provide useful information. In our pilot trial in Lima (8), we used estimated performance levels for each programme indicator based on the information provided by the local health officers. For ORS knowledge, for example, the upper level of performance was set at 80% and the lower level at 10%. None of the 12 lots sampled were rejected and the weighted performance level of all lots combined for this indicator was 78% (95% confidence interval of 70-86%). To solve this problem, in our next evaluation of LOAS in a mountainous region of Peru (5), we conducted a baseline survey in the lots selected to identify the performance level, so that in the next rounds, samples using LOAS could be selected more appropriately.

LOAS should be used in health surveys in order to identify those lots that have the lower performance level. Therefore, the selection of the sample size should be done with the intention of separating lots into two groups: acceptable and nonacceptable. The selection of upper and lower performance levels determines the sample size required. There is an "art" to selecting those upper and lower performance levels: they should make sense to health planners, be reasonable from an epidemiological point of view, result in small sample sizes, and produce a reasonable number of lots accepted and rejected. This process is facilitated if there is great variation in the performance level of the health programme among the lots to be sampled. On the contrary, if all lots to be sampled have very similar performance levels for the parameter to be evaluated, LOAS will not be of much help because it will require a very large sample size to identify a narrow variation between the upper and lower performance levels, otherwise all lots will be either accepted or rejected, depending on their performance level, and the information will be of little value. In those cases where the performance level for the indicator selected to evaluate a health programme has little variation, another aspect of the health programme (indicator) with more variation in performance level could be investigated.

The process of selecting a sample size when monitoring a health programme is therefore an active one, in which careful consideration should be given to the indicator, the sampling units and the upper and lower thresholds, in order to make it possible to separate lots into two parts with acceptable misclassification risks, and to obtain small, thus practical and feasible, sample sizes. This active process represents the most
difficult part of the LQAS methodology, because of its complexity, limiting its application by health planners. The process should be simplified in order to encourage individuals in charge of health programmes to use this methodology.

To select the exact sample size and the maximum number of permissible "defects" per lot, there are two options: (i) the use of a series of tables, where different upper and lower performance levels are shown for given type I and type II errors (4, 6, 9, 11); and (ii) the use of a series of curves (called operative characteristic (OC) curves), where the probability of acceptance of the lot is plotted according to the prevalence of defects in the lot (10). The tables are easier to use and understand, but the series of tables currently published have not taken into consideration the finite population correction for lots that have a relatively small number of sampling units. Moreover, the tables do not allow minor variations of type I and II errors, variations that can result in a mild but important reduction of the sample size per lot, a factor that is crucial when sampling a large number of lots in a community survey, some of which may be located in distant geographical areas. The published series of OC curves take this into consideration but are difficult to understand. A spreadsheet microcomputer program, like the one available from Lemeshow & Taber, will enable the user to produce tables for any levels of type I and type II errors. This may help overcome some limitations inherent in any set of published tables. However, using tables or OC curves for selecting sample sizes is awkward at best. What is needed is a friendly interactive microcomputer-based "expert" system which would request the desired upper and lower performance levels, the lot size, and then draw OC curves or prepare tables showing sample sizes and number of permissible defects for different sampling strategies, giving alternative suggestions to the health officer using the system, so that the best sample size could be selected. This potential use of microcomputers would facilitate the application of this powerful method by health personnel with a minimum of training.

Another aspect of the selection of a sample size is what to call a defect. If the immunization programme is used as an example, a typical defect would be a child not vaccinated. However, in the case of a lot where the overall coverage level is very low, the majority of children would be classified as "defects". This creates problems when selecting a sample size, because most OC curves and tables expect a prevalence of a defect to be below 50%. In those circumstances the classification system should be used backwards. In other words, in the case of an immunization programme, to call a "defect" a child who is vaccinated, and classify a lot as acceptable when more than the allowable number of "defects" are identified in the sample and to classify the lot as unacceptable when the number of "defects" identified is equal to or below the number of allowable defects for that particular sample size. When doing this, care must be taken to keep an acceptable type I error, because when the tables or OC curves are used in this way, type I and II errors are also reversed. Again, a computer expert system may solve these problems.

Sampling scheme

Different sample schemes could be used in LQAS, the simplest being the single-sample scheme, in which a sample size and a maximum allowable number of defects per sample is selected. The entire sample needs to be covered in the single-sampling scheme. An alternative scheme is the two-stage sampling scheme, in which two sample sizes are given with two critical values: \( d_1 \) and \( d_2 \). For the first sample, the lot is accepted if \( d_1 \) or fewer defects are found. The lot is classified as unacceptable if \( d_2 \) defects are found. If the number of defects found in the first stage is greater than \( d_2 \), but less than or equal to \( d_2 \), a second sample is chosen. If the second sample is completed without exceeding \( d_2 \) defects (from the first and second stages of sampling combined), the lot is classified as acceptable. This two-stage sampling scheme has the advantage that the second sample is only conducted in those lots that require an additional sample to classify them as acceptable or unacceptable, limiting the sample to those lots that could be classified as the first sample, therefore utilizing a minimum sample.

When evaluating a mass immunization campaign in urban and rural communities of a mountainous region in Peru (8), we decided to assess the usefulness of a two-stage sampling scheme. The sample for the first stage was 7, and required 0 defects to classify the lot as acceptable, and 3 or more defects to classify the lot as unacceptable. If either 1 or 2 defects were found in the first stage, a second sample of 8 was required. The surveyors found it very difficult to conduct this sampling scheme, especially in rural areas. The three investigators had to get together at the end of the first sample to determine whether a second sample was needed. Then in many cases, they had to return to hard-of-access areas where they were before for the second sampling. Finally, one surveyor did not know if the maximum number of defects was already passed since the other surveyors were in other areas, with the result that most second samples were not stopped when the lot was already classified as unacceptable. This experience has demonstrated that the two-stage sampling scheme may be impractical in community surveys when several surveyors are sampling distant areas.

Another sampling scheme used in industry is sequential sampling (11). It is based on the same principle of double sampling, but extending it to triple and multiple sampling, providing continuous assessment of the need for further information before making the final decision of accepting or rejecting the lot. The method provides two upward-sloping parallel lines in a graph having the number of defects on the y axis and the number of samples taken on the x axis. The results of each sample are plotted and the sample is stopped when either line is crossed or the total sample size is completed. This powerful sampling scheme has not yet been reported as having been used in health surveys, although a pilot trial yielded very positive results, when a team was sampling mosquitoes in a malaria-endemic area, looking for drug-resistant malaria strains (G. Stroh, personal communication). Since there was not much information on the prevalence of resistant strains in the area, and the cost of the laboratory procedures was high, a sequential sampling scheme was chosen to minimize the laboratory testing. Sampling was stopped in all lots tested because the upper line was crossed quite soon, classifying the areas as drug resistant without the need to exhaust the complete sample.

Many other industrial sampling schemes that have a high potential for use in health surveys have not yet been tested, but it is conceivable that with more experience with LQAS, other industrial sampling schemes could be used in LQAS.
To test the feasibility of applying LQAS in rural and urban areas in Peru, we decided to evaluate the implementation of three nationwide mass-immunization campaigns organized by the Peruvian government (5, 8) in a particular region. The results of the LQAS surveys were reported to health officials in charge of the immunization campaign at the local level, who after an initial hesitation took the results of our surveys seriously and carried out a series of changes, like changing personnel, redirecting volunteer workers to rural areas, providing travel facilities to health teams to enable them to reach distant areas before the local population left their homes to go to work, etc. Because of the specific changes introduced, we felt that LQAS had contributed to an improvement of the immunization coverage from 72% on the baseline survey, to 88% after the third campaign, although it could not be proved in the absence of a control area. It was interesting to see that the results of the LQAS surveys not only helped to correct programme strategies, but also provided feedback to the immunization teams who felt rewarded when they saw that their efforts were given recognition.

Although we used Ministry of Health personnel in our study with the idea that at the end of our project the LQAS methodology could be maintained in the area, this did not happen. The health officials found the methodology too confusing, especially when planning the next round of surveys and selecting an appropriate sample size. The use of OC curves was not clear to them. The public health nurses who were trained in the LQAS methodology resumed their previous tasks.

Conclusions

LQAS has great potential for monitoring health programmes, although its use has not extended further than in experimental evaluations of the methodology. There are several reasons for this. On one hand, because the methodology was developed in industry, it has not been disseminated much outside industrial circles, maybe in an effort not to facilitate the work of competitors. This may explain in part the fact that although the methodology has been available for more than 60 years, the first preliminary evaluations of LQAS in health surveys have only been carried out over the last decade. Despite successful trials of LQAS in health surveys, its routine use has not been established yet. Health planners might be reluctant to use this method frequently because of the difficulties inherent in its application. There is a need to simplify the methodology, perhaps with the help of microcomputers, in order to make it more accessible to health planners. Other limitations include the need to continuously update the sampling frame, which may require frequent censuses. In passing it can be mentioned that it is not rare for local health personnel to take censuses when planning their health actions; this information however is not usually utilized by health planners, who are restricted by the formal health system to the use of official estimates based on census projections. Finally, the random selection of sampling units and the need to have dedicated and committed personnel conducting the LQAS surveys may represent a problem for some areas.

A final limitation, also encountered in any type of supervisory activities, is the shortage of vehicles in most health programmes in developing countries, where available transportation is used almost exclusively to convey health teams and supplies, not leaving any room to conduct supervisory activities. The suggestion has been made that supervisors who
are visiting an area in conjunction with other supervisory activities could take advantage of the visit to carry out an LQAS survey. This has not yet been field-tested.

Despite their limitations, LQAS and other industrial sampling schemes present several advantages for application in health surveys. The small sample sizes, the fact that they can provide information on small areas (lots) as well as precise estimates on large areas when several lots are combined, the feasibility of repeating surveys as frequently as needed in the population areas requiring close monitoring, the possibility of using impact indicators instead of process indicators to monitor a health programme—these are some of the advantages that make industrial sampling schemes very attractive for use in health surveys. LQAS is an ideal technique for surveying areas in which considerable variation exists among the lots to be surveyed. More experience is needed to apply LQAS in large geographical areas, applicable to health surveys, such as simple- and double-sampling schemes, are discussed. The interpretation of the survey results and the planning of subsequent rounds of LQAS surveys are also discussed.

When describing the applicability of LQAS in health surveys in developing countries, the article considers current limitations for its use by health planners in charge of health programmes, and suggests ways to overcome these limitations through future research. It is hoped that with increasing attention being given to industrial sampling plans in general, and LQAS in particular, their utilization to monitor health programmes will provide health planners in developing countries with powerful techniques to help them achieve their health programme targets.

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SUMMARY

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This article describes the practical use of LQAS for conducting health surveys to monitor health programmes in developing countries. Following a brief description of the methodology, the article explains how to build a sample frame and conduct the sampling to apply LQAS under field conditions. A detailed description of the procedure for selecting a sampling unit to monitor the health programme and a sample size is given. The sampling schemes utilizing LQAS are visited an area in conjunction with other supervisory activities could take advantage of the visit to carry out an LQAS survey. This has not yet been field-tested.

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