Multiple Category-Lot Quality Assurance Sampling: A New Classification System with Application to Schistosomiasis Control

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Multiple Category-Lot Quality Assurance Sampling: A New Classification System with Application to Schistosomiasis Control

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Abstract

Background: Originally a binary classifier, Lot Quality Assurance Sampling (LQAS) has proven to be a useful tool for classification of the prevalence of Schistosoma mansoni into multiple categories (≥10%, >10 and <50%, ≥50%), and semi-curtailed sampling has been shown to effectively reduce the number of observations needed to reach a decision. To date the statistical underpinnings for Multiple Category-LQAS (MC-LQAS) have not received full treatment. We explore the analytical properties of MC-LQAS, and validate its use for the classification of S. mansoni prevalence in multiple settings in East Africa.

Methodology: We outline MC-LQAS design principles and formulae for operating characteristic curves. In addition, we derive the average sample number for MC-LQAS when utilizing semi-curtailed sampling and introduce curtailed sampling in this setting. We also assess the performance of MC-LQAS designs with maximum sample sizes of n = 15 and n = 25 via a weighted kappa-statistic using S. mansoni data collected in 388 schools from four studies in East Africa.

Principle Findings: Overall performance of MC-LQAS classification was high (kappa-statistic of 0.87). In three of the studies, the kappa-statistic for a design with n = 15 was greater than 0.75. In the fourth study, where these designs performed poorly (kappa-statistic less than 0.50), the majority of observations fell in regions where potential error is known to be high. Employment of semi-curtailed and curtailed sampling further reduced the sample size by as many as 0.5 and 3.5 observations per school, respectively, without increasing classification error.

Conclusion/Significance: This work provides the needed analytics to understand the properties of MC-LQAS for assessing the prevalence of S. mansoni and shows that in most settings a sample size of 15 children provides a reliable classification of schools.

Introduction

Schistosomiasis is a tropical disease caused by infection with Schistosoma parasitic worms. The disease burden of schistosomiasis is greatest in sub-Saharan Africa (SSA) which shoulders 85% of the global burden [1,2], with school-age children as well as adolescent girls and women of childbearing age suffering the greatest consequences of infection [3,4]. The two main species responsible for schistosomiasis in SSA are Schistosoma haematobium, which causes urinary schistosomiasis, and S. mansoni, responsible for intestinal schistosomiasis.

The World Health Organization (WHO) recommends a three-way classification (≥10%, >10 and <50%, ≥50%) of the prevalence of schistosome infection to determine appropriate interventions for school-age children [4,5]. These classifications are generally made using classical statistical approaches with data collected in parasitological surveys of between 250 and 500 children in five to ten schools per ecological zone (about 50 children per school) [6,7]. However, this recommendation is based on logistical concerns more so than statistical ones. Sampling 50 children in multiple schools may be financially prohibitive and there is a need for rapid assessment methods for defining the distribution of infection in order to target control [8]. For identifying communities/schools with high prevalences of S. haematobium the WHO recommends the use of questionnaires of self-reported blood in urine or parasitological tests [9]. Concerns about the lack of a reliable questionnaire approach for S. mansoni has prompted researchers to explore alternative ways, including...
Specifically, we outline the theoretical underpinnings of MC-LQAS tool (MC-LQAS) and the lines for designing such surveys in other settings or for other to be used in other settings, it is important to understand the Moreover, the simulation approach to validation gives little method will perform when applied to different regions with even database and therefore provide little insight into how the same validation system against the standard approach to classification and show that the use of an LQAS based system can substantially reduce the necessary sample size, while providing valid information for selecting the appropriate intervention strategy.

Methods

LQAS

Traditional LQAS calls for a random sample of n binary observations from a “lot”. If the number of successes in the sample, X, is less than or equal to a predefined decision rule, d, the locale is classified as unacceptable. Otherwise, the locale is classified as acceptable. The word “success” is a statistical convention but typically denotes a failure to meet an established criterion or receive an intervention. In the case of sampling for S. mansoni, the number of successes are cases of S. mansoni infection. If the number of infected cases exceeded a pre-determined level, then the lot is rejected and the school/ community is identified as in need of mass treatment. A succinct summary of any LQAS design is the Operating Characteristic (OC) curve [22]. The OC curve depicts the probability of an acceptable classification against the true underlying prevalence, p. We assume that p represents the proportion in a given population with infection, such as S. mansoni infection. An example of an OC curve is given in Figure 1A with n = 15 and d = 7.

The choice of the sample size and decision rule are critical, as they determine the expected classification error in the procedure. Generally, n and d are chosen so that the probability of incorrectly classifying a locale as having low prevalence is less than or equal to \( \alpha \) and the probability of incorrectly classifying a locale as having high prevalence is less than or equal to \( \beta \). In many cases, practitioners associate the labels “low” and “high” with values of prevalence below and above some value, \( p^* \), respectively. In practice, classification probabilities are evaluated at upper and lower thresholds \( p_U \) and \( p_L \), and the value of \( p^* \) serves little purpose aside from informing the choice of these two parameters. For an appropriately chosen design, the values of the OC curve at \( p = p_U \) and \( p = p_L \) will be approximately equal to some predefined values \( 1 - \alpha \) and \( \beta \), respectively. For example, the design depicted in Figure 1A is chosen so that at \( p_U = 0.40 \) and \( p_L = 0.60 \), the probability of an acceptable classification is less than or equal to \( \alpha = 0.20 \) to the left of \( p_U \) and greater than or equal to \( 1 - \alpha = 0.80 \), to the right of \( p_L \).

Due to the monotonicity of the OC curve, it follows that for any \( p \) beyond the upper or lower thresholds, the probability of committing an error is no greater than \( \alpha \) or \( \beta \).

\[
\Pr(X < d | p_U) = \sum_{x=d}^{n} \binom{n}{x} p_U^x (1-p_U)^{n-x} \leq \alpha \\
\Pr(X \geq d | p_L) = \sum_{x=d}^{n} \binom{n}{x} p_L^x (1-p_L)^{n-x} \leq \beta
\]
An additional property of the OC curve is that it makes explicit the values of $p$ for which LQAS runs a risk that is higher than the maximum of $a$ and $b$; the value of the OC curve increases from $b$ to $1/2a$ as $p$ increases from $p_L$ to $p_U$. The area between $p_L$ and $p_U$ is commonly referred to as the “grey region”. Thus a locale which truly has prevalence $p$ such that $p_L < p < p_U$ will be classified as acceptable with probability somewhere in the range $(b, 1/2a)$ (assuming $b < 1/2a$).

**MC-LQAS**

The MC-LQAS procedure extends basic LQAS by classifying a sample against multiple decision rules. In the following we develop MC-LQAS for three-way classification although the method is generalizable to more than three categories. For three-way classification, we must choose a total of two decision rules, $d_1$ and $d_2$. If the number of successes, $X$, out of a total of $n$ observations is less than or equal to $d_1$, classify the prevalence as low. If $X$ is greater than $d_2$, classify the prevalence as high. Otherwise, classify the prevalence as medium, the middle category.

Analogous to the OC curve, for a specific design we can plot the probability of classification into each of the three categories against $p$ to succinctly summarize the MC-LQAS design. Figure 1B shows the OC curve for a three-way classification procedure with $n = 15$, $d_1 = 1$, $d_2 = 7$. Note that this is a simple extension of the two-way design discussed previously where we now allow for the

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**Figure 1. Operating Characteristic curves and Average Sample Number for LQAS and MC-LQAS.**

A) Operating Characteristic curve for LQAS design with $n = 15, d = 7,$ and $a = b = 0.20$; B) Operating Characteristic curves for low (dashed-dotted), medium (dashed), and high (solid) categories for MC-LQAS design with $n = 15, d_1 = 1, d_2 = 7,$ and $d_1 = d_2 = b = 0.20$; C) Average Sample Number for semi-curtailed (solid) and curtailed (dashed) LQAS with $n = 15$ and $d = 7$; D) Average Sample Number for semi-curtailed (solid) and curtailed (dashed) MC-LQAS with $n = 15, d_1 = 1,$ and $d_2 = 7$.

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“unacceptable” category to be parsed into “moderate” and “low”,
thus making explicit the connection between this development and
that of Myatt et al and Brooker et al [8,16]. Of note is the bell-shape
of the curve for classification into the moderate category. The lack
of monotonicity for this curve is one characteristic of MC-LQAS
which sets it apart from LQAS and plays an important role with
respect to choosing a design.

As with LQAS, in practice we choose to control for potential
misclassification at predetermined thresholds, which we call \( p_{L1}, p_{U1}, p_{L2}, \) and \( p_{U2} \). These should be chosen so that \( p_{L1} < p_{L2} < p_{U1} \) and \( p_{L2} < p_{U2} \), and in practice it oftentimes makes sense to set \( p_{L1} = p_{L2} \) and \( p_{U2} = p_{U1} \). To control for the amount of misclassi-

ication, we choose \( d_1 \) and \( d_2 \) so that the probability of correct
classification remains high at these thresholds. That is, choose the
decision rules so that

\[
\begin{align*}
\Pr(X \leq d_1|p_{L1}) & \geq 1 - \delta_1 \\
\Pr(d_1 < X \leq d_2|p_{U1}) & \geq \delta_1 \quad \text{and} \quad \Pr(d_1 < X \leq d_2|p_{L2}) \geq 1 - \delta_3 \\
\Pr(X > d_2|p_{U2}) & \geq 1 - \delta_4
\end{align*}
\]

where \( \delta_1, \delta_2, \delta_3 \) and \( \delta_4 \) reflect the acceptable levels of potential
error determined by the investigator. This is directly analogous to
choosing upper and lower thresholds, \( p_{L1} \) and \( p_{U1} \), in classical two-
way LQAS with the notable exception of the moderate category,
where we see that it is important to control for the possible error at
two locations. This has to do with the aforementioned bell shape of
the moderate OC curve. The lack of monotonicity makes it so that
one must control for error at both \( p_{U1} \) and \( p_{L2} \).

We note that in the above formulation, we have ignored possible misclassification into the extreme categories. Depending
on the distance between thresholds, misclassification into a non-
contiguous category can be minimal for even small samples.
Hence, for moderate sample sizes, we only worry about four possible misclassifications, which are those misclassifications into contiguous classes.

**Curtailed and Semi-Curtailed Designs**

In certain situations, it is possible to reduce the sample size
needed to reach a decision by “sampling to the decision rule”. For example, suppose we define a traditional LQAS plan with a
sample size \( n = 15 \) and \( d = 7 \). Suppose further that during data
collection we find that the first eight observations are successes. At
this point, we need not sample further to know the resulting
classification will be acceptable. The analytical properties of this
type of sampling are neither well-documented nor well-understood
in the public health literature. However, this process is referred to as
semi-curtailed sampling in the statistics literature where it has been
in use for the past fifty years [23,24,25]. The main benefit of this
type of sampling is the potential to reduce the overall number of
observations, or the Average Sample Number (ASN), required
to reach a decision. The semi-curtailed ASN is plotted as a function
of the prevalence with \( n = 15 \) and \( d = 7 \) in Figure 1C and its
derivation provided in the Appendix S1. A feature of semi-
curtailed sampling is that it preserves the OC curve, which means
that the expected error rates are not affected [25]. Thus, there
seems to be little drawback to employing semi-curtailed sampling
when feasible to reduce the sample size.

Indeed, one can benefit even more by adopting a curtailed
sampling plan [23]. That is, one can terminate sampling either if
the number of successes is too great or too few at a given point. To
continue with our example, suppose instead that the first eight
observations are failures. In this case, it is not possible to observe
more than seven successes in the remaining observations, and
sampling can also cease. The curtailed ASN plotted as a function
of the prevalence with \( n = 15 \) and \( d = 7 \) is plotted in Figure 1C and
its derivation is included in the Appendix S1. Once again, the
employment of curtailed sampling does not affect the OC curve.

The notion of curtailed sampling is easily extended to MC-
LQAS. For example, MC-LQAS also allows for the potential of
early stopping by sampling to the decision rule, or semi-curtailed
sampling. For example, when utilizing an MC-LQAS design with
\( n = 15, d_1 = 1 \) and \( d_2 = 7 \), sampling can terminate with a high
classification as soon as the number of successes exceeds seven.
The ASN for MC-LQAS when employing semi-curtailed sampling is
equal to the ASN in traditional LQAS.

The curtailed version of MC-LQAS is slightly different than its
traditional counterpart in that it allows for early stopping for low,
moderate, or high classifications. Continuing with our example, if
the first thirteen observations are failures, then it follows that the
lot will be classified as low irrespective of the remaining observations.
Likewise, if in the first twelve observations are four successes and eight failures, then sampling can stop with a
moderate classification, as neither low nor high classifications are
possible at this point. The semi-curtailed and curtailed ASNs for
an MC-LQAS design with \( n = 15, d_1 = 1 \) and \( d_2 = 7 \) are plotted as
a function of the prevalence in Figure 1D. We note that the
functional form of the ASN under curtailed sampling will generally
be bi-modal, which reflects the two areas of uncertainty or grey
regions. It follows for the same reasons as in the traditional LQAS
setting that the OC curves for MC-LQAS are not affected by
sequential sampling of this nature. Proofs of these results are given in
the Appendix S1.

**Application to Prevalence of S. mansoni in East African Schools**

In the following, we consider S. mansoni data reported in four
different studies; two in Kenya [19,21], one in Uganda [26], and
one in Tanzania [20]. In each study, a sample of school children in
multiple schools were randomly selected to provide stool samples
which were examined microscopically for the ova of S. mansoni,
hookworm, Ascaris lumbricoides, and Trichuris trichura. The number
of schools sampled ranges from 21 [19] study to 199 [26] with
school sample sizes as low as 21 and as high as 202. In Figure 2,
the estimated prevalence of S. mansoni in each of the 388 schools,
along with 95% exact binomial confidence intervals, are plotted
for each of the four studies.

We use these data to assess the performance of the MC-LQAS
design with \( n = 15, d_1 = 1 \), and \( d_2 = 7 \) and compare with expected
performance. This design differs slightly from that which was
utilized in the 2005 Brooker study, where \( d_1 = 2 \) [8]. Our current
choice reflects a 2006 change in WHO guidelines which shifted
the lower programmatic threshold from 20% to 10% [5]. Note
that decision rules \( d_1 = 1 \) and \( d_2 = 7 \) corresponds to prevalence
decision thresholds of 6.7% and 46.7%, respectively. To choose
upper and lower thresholds, we assume that the desired probability
of correct classification should be greater than or equal to 0.80
uniformly (i.e. \( \delta_1 = \delta_2 = \delta_3 = \delta_4 = 0.20 \)). Under this assumption,
we can solve for the upper and lower thresholds, yielding \( p_{L1} = 0.035, p_{U1} = 0.188, p_{L2} = 0.392, \) and \( p_{U2} = 0.606 \). Additionally, to assess
the impact of increasing the sample size on classification
agreement, we consider an MC-LQAS design with \( n = 25, d_1 = 2 \)
and \( d_2 = 12 \). Using the same approach, we identified upper and
lower thresholds of \( p_{L1} = 0.662, p_{U1} = 0.164, p_{L2} = 0.417, \) and
\( p_{U2} = 0.583 \) for this design.

We generate 1000 MC-LQAS classifications of each school in
the sample by repeatedly “sampling down” the individual data to
15 or 25 students and classifying each school based on these
observations. To compare the classifications resulting from MC-LQAS with those that result from binning the full sample prevalence, we calculate for each simulation the weighted kappa statistic, which measures agreement between classification methods across locations [27]. We report the mean kappa statistic and interquartile range (IQR) across the 1000 simulations. In addition, we calculate the ASN in each simulation when employing both semi-curtailed and curtailed sampling plans and report the mean ASN and IQR across the 1000 simulations. Lastly, we calculate the proportion correctly classified as a function of the full sample prevalence. All simulations were conducted using R statistical software, version 2.11.1 [28].

Results

Figure 3A displays the average proportion of schools correctly classified as a function of the full sample prevalence. For expository purposes, we overlay the OC curve for this design, noting that the simulation results and expected curves coincide. Likewise, we display the average ASN under semi-curtailed (Figure 3B) and curtailed (Figure 3C) sampling as a function of the full sample prevalence and overlay the expected ASN curves. Once again, these quantities coincide, as expected.

The results of our simulation study are presented in Table 1. The overall agreement between the MC-LQAS with a sample size of 15 and full sample classifications was 0.87 (IQR: 0.86–0.89). Although not everyone agrees on the interpretation of the kappa statistic, values greater than 0.60 are commonly interpreted as implying “substantial” agreement, whereas values greater than 0.80 are thought to imply “almost perfect” agreement. For three of the four studies, the agreement between the MC-LQAS and the full sample classifications was high (κ > 0.75) [27]. On average the use of the MC-LQAS procedure resulted in either substantial or almost perfect agreement with these data.

The notable exception was the Clarke et al study from Kenya, where the kappa statistic was 0.46 (IQR: 0.34–0.58) when n = 15. Of the four studies, the Clarke et al study had the fewest observations and fewest schools. Furthermore, of the 21 schools sampled in this study, 13 schools had full sample prevalence lying within one of the two grey regions where potential error is known.
to be high (in comparison with 13 of 25, 20 of 143, and 49 of 199 in the Brooker, Clements, and Kabatereine studies, respectively). Thus, this MC-LQAS design is expected to be sub-optimal for this type of underlying distribution of prevalences. One might improve performance by increasing the sample size. The kappa statistics for all studies slightly increased when using a sample of size 25 (Table 1), although agreement in the Clarke study remained low with a kappa statistic of 0.52 (IQR: 0.39–0.62).

The ASN for a maximum sample size of \( n = 15 \) when utilizing curtailed and semi-curtailed sampling was 12.90 (IQR: 12.87–12.94) and 14.50 (IQR: 14.49–14.52), respectively. When the maximum sample size was increased to \( n = 25 \), the ASN for curtailed and semi-curtailed sampling increased to 21.54 (IQR: 21.50–21.59) and 24.2 (24.14–24.18), respectively.

Discussion

This work outlines a unified and systematic approach to designing Multiple Category-LQAS classification systems with application to the prevalence of \( S. mansoni \) in schoolchildren. Through simulation and using real data, we show it performs as well as existing methods in practice for classification of the prevalence of infection at a fraction of the sampling effort. Furthermore, for the first time in the public health literature, we have elucidated the theoretical properties of “sampling to the decision rule”, or semi-curtailed sampling, in LQAS, and extended these notions to multiple classification. Our validation study shows that an MC-LQAS design with \( n = 15, d_1 = 1, \) and \( d_2 = 7 \) provides classifications in near perfect agreement with the standard “binning” approach, yet using less than half as many observations. As expected, agreement between MC-LQAS and full sample classifications tends to be the worst for prevalences lying within the grey region (as found in the Clarke study), where the risks of classification error are high.

Our findings resonate with empirical results pointing to the reliability and potential cost-reduction associated with using LQAS for rapid assessment of \( S. mansoni \) [8]. Recent research suggests that an LQAS-based approach may also perform better

### Table 1. Kappa-statistic, Curtailed Average Sample Number, and Semi-curtailed Average Sample Number in four studies for two different MC-LQAS designs.

<table>
<thead>
<tr>
<th>SS (# Schools)</th>
<th>( n = 15, d_1 = 1, d_2 = 7 )</th>
<th>( n = 25, d_1 = 2, d_2 = 12 )</th>
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<td>( SS )</td>
<td>( k )-statistic</td>
<td>Curtailed ASN</td>
</tr>
<tr>
<td>All Studies</td>
<td>25246 (388)</td>
<td>0.875 (0.864–0.885)</td>
</tr>
<tr>
<td>Brooker et al</td>
<td>1739 (25)</td>
<td>0.774 (0.723–0.830)</td>
</tr>
<tr>
<td>Clarke et al</td>
<td>1093 (21)</td>
<td>0.459 (0.341–0.576)</td>
</tr>
<tr>
<td>Clements et al</td>
<td>8617 (143)</td>
<td>0.763 (0.722–0.808)</td>
</tr>
<tr>
<td>Kabatereine</td>
<td>13797 (199)</td>
<td>0.901 (0.889–0.912)</td>
</tr>
</tbody>
</table>

Point estimates are mean and quantities in parentheses represent the interquartile range over 1000 simulated datasets.

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than sophisticated geostatistical modeling strategies with respect to
correct classification, although at a higher cost per high
prevalence school correctly classified [11]. Thus, while we have
shown that MC-LQAS is a reliable tool for classification,
investigators should continue to take care to choose the evaluative
approach which best suits a given situation.

A limitation of this study is the lack of consideration for
diagnostic sensitivity and specificity. The standard method for
diagnosis of S. mansoni is the Kato-Katz method, which has been
criticized for having low sensitivity that varies depending on the
intensity of infection in an individual [29,30]. Some studies have
found sensitivities as low as 0.60, which is a serious violation of the
perfect diagnostic test assumption. Methods for estimating the
prevalence of S. mansoni in the presence of variable sensitivity and
infection intensity is an area of ongoing research [31].

A shortcoming of our study is that we ignore the underlying
distribution of prevalence. In the event that prior information on
the level or distribution of p is available, Olives and Pagano
provide Bayesian methods for choosing the sample size and
decision rule for traditional LQAS [32]. Olives discusses the same
approach in the context of multiple classification in [33], providing
the basis for incorporating complex disease dynamics into the
model. Although ignoring prior information does not impact the
viability of our results, it is expected that incorporating this extra
information would improve expected performance.

A strength of our study is the principled treatment of curtailed
and semi-curtailed sampling in LQAS. The ASN is a largely
ignored piece of information that program managers can utilize to
inform their choice of LQAS design. Note that curtailed sampling
plans allow for early stopping with a classification of moderate
prevalence, in addition to low and high. This is in contrast to other
sequential LQAS designs used for multiple category classification
in the literature, such as those used to classify transmitted HIV
drug resistance [34]. In the context of the classification of S.
mansoni prevalence, the use of curtailed designs will ultimately
require fewer stool samples to be analyzed via microscopy. The
reduction in sample size will be most pronounced in high
prevalence schools, where as few as eight slides may need to be
read before reaching a decision. Unfortunately in many cases, slides
will be prepared for all participants and sent to the
laboratory for microscopic inspection. Thus these savings are likely
to be less pronounced in the field than in the laboratory. For other
diseases, such as malaria and urinary schistosomiasis, where rapid
diagnostic tests and dipsticks (for haematuria) are the modes of
diagnosis, the use of curtailed sampling may be of more importance
in the field.

Further work is required to evaluate the use of MC-LQAS for
sampling for several infections; for example the collection of stool
samples to diagnose S. mansoni infection and urine samples to
diagnose S. haematobium, using either dipsticks for the detection
of haematuria or the urine filtration technique. How such an
integrated approach compares to the use of questionnaire surveys
for S. haematobium also needs to be investigated.

LQAS as a tool has come to be associated with simplicity and
versatility. MC-LQAS maintains these attributes so as to be useful
to a wider audience of practitioners. Here we consider the case of
S. mansoni, and show that as a tool for classification of the
prevalence of infection, MC-LQAS is both reliable and adaptable.
However, just as LQAS has had extensive use in multiple
areas in health, we anticipate that this work will have implications
reaching well beyond schistosomiasis for other infectious diseases,
such as malaria. The design we describe allows for easy adaptation
to other circumstances.

Supporting Information

Appendix S1 Derivations of ASN and preservation of OC
curves under curtailed and semi-curtailed sampling for
MC-LQAS.

(DOCX)

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providing access to their data.

Author Contributions

Conceived and designed the experiments: CO JJV MP. Performed the
experiments: CO MP. Analyzed the data: CO MP. Contributed reagents/
materials/analysis tools: CO SJBJ MP. Wrote the paper: CO SJBJ JJV MP.
Responsible for the primary statistical development of methods and
implementation: CO. Provided technical support and advisement of
statistical development: MP. Provided data and expert advisement for
application to schistosomiasis: SJBJ. Provided context and expert advise-
et for LQAS design and implementation: JJV.

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