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Measuring Treatment Coverage for Neglected Tropical Disease Control Programs: Analysis of a Survey Design

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Monitoring of treatment coverage following mass drug administration is essential to ensure program success. Coverage results reported by drug administrators are often validated by using population surveys. This study evaluates the design of a multistage cluster sample survey conducted in 2007–2008 and implemented at the district level to assess drug coverage in the 4 African countries of Burkina Faso, Ghana, Niger, and Uganda. Estimates of precision of coverage were calculated, and factors contributing to the observed variance were analyzed. Precision of ±5 percentage points was obtained in 39% ($n = 12$) of cases, and precision of ±10 percentage points was obtained in 77% ($n = 24$) of cases. The factor having the largest impact on the actual precision obtained in these surveys was the high level of clustering, the impact of which is incorporated in the design effect. Key recommendations are made for the design and analysis of future surveys; guidelines are presented for thinking through the number of clusters that should be selected and how a cluster should be designed.

coverage survey; design effect; monitoring and evaluation; neglected tropical diseases

Neglected tropical diseases affect more than 1 billion individuals worldwide (1). The control of 7 of the most prominent neglected tropical diseases is addressed by provision of safe and effective treatments, known as preventive chemotherapy, to eligible populations through annual or semiannual mass drug administration campaigns (2, 3). These diseases are lymphatic filariasis, onchocerciasis, schistosomiasis, trachoma, and 3 soil-transmitted helminth infections (ascariasis, hookworm, and trichuriasis). As a group, these diseases are estimated to account for more disability-adjusted life-years than malaria, causing substantial disability from blindness, eye pain, skin lesions and itching, swollen limbs, hydrocele, organ damage, anemia, and growth and cognitive deficits and resulting in large-scale lost productivity and discrimination (4).

Current preventive chemotherapy strategies targeted at neglected tropical diseases require that appropriate preventive chemotherapy doses reach an adequate proportion of the at-risk population annually to achieve disease control objectives (Appendix Table 1). Monitoring and evaluation of treatment coverage following campaigns is therefore essential to identify areas with low coverage so that appropriate changes to program implementation can be made (5). In addition, for programs that have disease elimination as a goal, as is the case with the program for lymphatic filariasis, results of monitoring coverage provide important data for determining when to stop treatment (6). Drug coverage has traditionally been measured in 2 ways: by using data routinely reported by field workers administering the treatments (administrative coverage) and by conducting household surveys. This study reports on the design of a survey used effectively in 4 African countries to validate the results of national administrative coverage reports for neglected tropical disease control programs.

Administrative coverage (also known as reported coverage) is calculated by using data on the number of persons treated as recorded on registers or tally sheets by drug distributors, divided by the target or at-risk population. There are 2 main sources used for calculating denominators—census data and program data—each with its own strengths and weaknesses (5). Routine monitoring of administrative coverage is invaluable because it rapidly provides program managers with information on the success of their activities and allows for prompt follow-up action. However, this

method has been reported by various disease control programs to be prone to certain bias and measurement errors, including inaccuracies in estimation of the denominator, weak health information systems, and at times, intentional inflation in response to target setting and a desire to show high performance (7–12).

Coverage surveys have therefore been used as an alternative measure, particularly by immunization, malaria, and some of the disease-specific neglected tropical disease control programs (7–10, 13–17). Survey coverage rates are calculated from sampled population data. A sample is selected from the targeted population, and trained interviewers ask people whether or not they swallowed the drugs being offered. Although surveys are prone to their own—though different—biases, they can effectively validate administrative coverage. In addition, coverage surveys can be used to monitor gender and ethnic inequities, differential access to treatment of those in certain age groups and geographic localities, the effectiveness of social mobilization efforts, and drug distributors' adherence to program guidelines.

High-quality monitoring and evaluation contribute to high-quality programs that make the most of available resources. However, for every programmatic activity there is an opportunity cost; thus, it is important to have a survey design that is cost effective. The cost of a survey is typically determined by the size of the sample and the complexity of the design and analysis; more complex surveys require external technical support and the use of more costly statistical analysis software.

In an attempt to find the optimal balance between required scientific rigor and resource constraints, various coverage survey sampling methods have been used for assessing indicators for mass drug administration and other global health interventions. Probability sampling designs are used in demographic and health surveys and in multiple-indicator cluster surveys (18–20). Nonprobability designs are used in "expanded program on immunization" surveys (21–26). Some surveys are conducted in schools (15–17), and others use the lot quality assurance approach (a methodology that requires relatively small sample sizes to determine with adequate precision whether the sample supports acceptance or rejection of a process based on a simple dichotomous "pass/fail" criterion) (27, 28). Although these designs vary in several respects, the primary consideration is whether they lead to a probability sample, that is, a sample in which each person has a known probability of selection of >0. It is generally recommended that when accuracy is of particular importance, as it is when validating reported coverage rates, the selected designs be limited to those that use probability-based samples (26).

When drugs targeting multiple diseases are administered concurrently (or within a short time interval) in the same geographical area, as is the case with neglected tropical disease control programs, costs can potentially be reduced by conducting an integrated coverage survey. The challenge is to develop an integrated survey that is both easy to use and affordable (29). The Neglected Tropical Disease Control Program, funded by the US Agency for International Development (Washington, DC), was one of the first to support large-scale treatment programs for neglected tropical diseases. To monitor these efforts, the Neglected Tropical Disease Control Program developed an integrated post–mass drug administration coverage survey to validate treatment coverage rates and to ascertain coverage rates by age and gender. The first version of this survey was implemented in Burkina Faso, Ghana, Niger, and Uganda in 2007–2008 within 4 months of completing the mass drug administration campaigns. The aim of this report is to provide a review of the survey design in order to inform further development of an integrated coverage survey for neglected tropical disease control programs. Estimates of precision of coverage were calculated, and factors contributing to the observed variance were analyzed. We sought a balance between cost and scientific rigor to develop a survey design that is "precise enough" for programmatic purposes.

MATERIALS AND METHODS

Survey design

We used the survey process to measure the coverage achieved during drug distribution. The survey design was a multistage cluster sample implemented at the district level in 3–5 purposively selected districts per country. The rationale for district selection included very high or very low reported coverage rates, reported coverage rates about which the program manager had doubts, and representation of the different combinations of drugs administered.

The primary sampling unit was the village, also referred to as a cluster. Taking advantage of the fact that the survey was being implemented in 4 countries, we varied the number of clusters selected by country to assess the effect of the number of clusters on the precision of coverage estimates. Six, 12, or 30 clusters were selected per district (Table 1) with probability proportional to the estimated population size. For the selection of households, community members were asked to list all households in a village. Households were then selected from this list by using systematic sampling without replacement.

The following formula was used to estimate sample size (30):

$$n = \frac{\text{design effect}\,(Z^2 p \times (1-p))}{(\text{precision})^2},$$

where n is the required sample size, Z is the desired level of the confidence limits (chosen as 95%, which corresponds to the z value of 1.96), and p is the proportion of persons who received the treatment during mass drug administration, which is assumed to be 0.5 on the grounds that this was the most conservative estimate for sample size calculations. The value "precision" refers to the desired precision of the survey estimate, here chosen to be ±5 percentage points from the population mean for coverage estimates.

Because cluster sampling results in higher sampling variance (and therefore less precision) than does simple random sampling (30), sample sizes for cluster surveys need to be increased by a factor called the design effect. Studies reporting the design effects for surveys of preventive chemotherapy

Table 1. Precision of Surveyed Coverage Rates by District and Drugs Administered, Burkina Faso, Niger, Uganda, and Ghana, 2007–2008

Country and Districts	Drugs Administered	Survey Coverage Rate		Design Effect[a]
		Total No. of Survey Respondents	95% CI[b]	
Burkina Faso[c]				
Bogande	Azithromycin and tetracycline	1,351	84.9, 89.9	1.0
	Albendazole	471[d]	84.7, 94.1	4.1
	Praziquantel	1,104	79.2, 90.1	3.9
Koupela	Azithromycin and tetracycline	1,295	79.7, 92.8	5.9
	Albendazole	552[d]	93.4, 97.5	0.8
	Praziquantel	1,003	85.3, 95.5	4.2
Tenkodogo	Azithromycin and tetracycline	1,539	81.9, 95.5	12.0
	Albendazole	389[d]	87.3, 97.7	6.6
	Praziquantel	1,194	84.9, 96.2	8.8
Niger[c]				
Illela	Azithromycin and tetracycline	1,145	70.9, 87.3	7.0
	Ivermectin and albendazole	1,170	60.8, 77.1	3.29
Madaoua	Azithromycin and tetracycline	1,487	45.5, 88.8	56
Kollo	Azithromycin and tetracycline	1,115	35.5, 91.8	92.3
	Ivermectin and albendazole	1,102	33.0, 86.9	70.6
	Praziquantel	1,112	33.4, 84.2	55.9
Loga	Praziquantel and albendazole	1,592	55.0, 82.3	26.6
Tillabery	Praziquantel and albendazole	1,058	52.0, 90.1	18.2
	Azithromycin and tetracycline	1,226	65.3, 90.8	18.19
Uganda[c]				
Dokolo	Praziquantel	1,115	64.8, 84.9	12.4
	Albendazole	1,765	69.7, 84.2	11.4
	Ivermectin	1,813	69.6, 82.0	7.6
Iganga	Azithromycin and tetracycline	1,939	85.0, 89.8	3.5
	Albendazole	2,002	74.5, 82.3	3.1
	Ivermectin	2,009	71.4, 78.5	3.1
Kamuli	Azithromycin and tetracycline	1,403	80.2, 87.7	3.8
	Albendazole	1,767	84.0, 90.0	3.7
	Ivermectin	1,797	74.2, 81.5	4.0
Ghana[c]				
Agona	Ivermectin and albendazole	2,502	51.0, 66.0	14.0
Bawku West	Ivermectin and albendazole	3,203	80.1, 87.5	3.7
Central Gonja	Ivermectin and albendazole	3,591	76.8, 88.36	14.6
	Azithromycin and tetracycline	3,591	76.1, 87.5	14.0

Abbreviation: CI, confidence interval.

[a] Design effect is a measure of the ratio of true sampling variance under a specific design over the variance that would have resulted if the sample had been drawn as a simple unclustered random sample.

[b] 95% confidence interval range (low, high).

[c] Numbers of clusters sampled per district are as follows: for Burkina Faso, 6–7; for Niger, 5–6; for Uganda, 30; and for Ghana, 12.

[d] Number eligible for albendazole in Burkina Faso includes children aged 5–15 years only because only school-age children were targeted for this program.

are few, and coverage rates reported from post–mass drug administration surveys often do not take into account cluster methods in the analysis, resulting in artificially narrow confidence intervals. A high degree of homogeneity is expected in any cluster because the drugs were distributed in each area by the same team; therefore, we assumed a relatively high design effect of 3.

Without any prior experience with integrated post–mass drug administration coverage surveys, it was difficult to establish a realistic level of nonresponse; however, extrapolating from similar surveys, we assumed a nonresponse rate of 10%.

Finally, the target sample size n was divided by the national average household size (obtained from national census data) to determine the number of households to be visited in each district; dividing this target of total households by the number of clusters resulted in the target number of households in each cluster. Within any given country, the same number of households was selected per cluster.

All household members living in the selected households who were present during the survey were to be interviewed. Information for children aged 1–10 years was collected from their primary caretakers. If no one was at home, interviewers revisited the household later in the day. Where several families were living in the same household or compound, this was counted as 1 household. Interviewers registered all persons in the household who were present at the time of the mass drug administration, regardless of whether they were present at the time of the interview. Interviewed subjects were asked whether the administered drugs were actually swallowed as opposed to just received.

Weighting

In the first stage, villages were selected with probabilities proportional to their population size: $p_1 = m \times C_i'/\Sigma C_i'$, where C_i' is the estimated population of village i, and m is the number of villages. Thus, a village with double the population of another village has twice the probability of being selected. In the second stage, a fixed number of households, b, was selected in each village selected in the first stage. Each household in the village was selected with probability $p_2 = b / B_i$, where B_i is the number of households in village i. Thus, there are unequal probabilities of selection at each of the 2 stages. The overall probability of selection is $p_{ij} = p_1 \times p_2 = m \times b \times (C\prime_i/B_i)/\Sigma C\prime_i$, where p_{ij} is the overall probability of selection of household j in village i. This application of 2-stage probability proportional to size results in unequal probabilities of selection because the term (C_i'/B_i) varies across villages i. Furthermore, the C_i measure is from a previous census or earlier data source, whereas B_i is based on current observation. It is expected that, in general, the factor (C_i'/B_i), a surrogate measure of the average household size in each village, will be somewhat constant; however, given the different sources of information for the 2, the variation in this factor could be nonnegligible. In certain cases where the ratio differed significantly from the national average, we adjusted the sample size for that village. The advantage of this sampling plan is that, at least theoretically, the number of households per village is fixed, which in turn simplifies the field process. Furthermore, this sample design leads to a self-weighted sample, again at least in theory, and insofar as the i-indexed factor in the above equation is constant across villages.

Data analysis

The data received as a result of implementing the survey described above were analyzed to determine the precision obtained. Precision was measured by calculating confidence intervals. Confidence intervals were calculated for each drug in each district. Confidence intervals for gender- and age-group–specific populations were also calculated. The confidence intervals were calculated as $p \pm 1.96 \times \sqrt{\text{design effect}} \times \text{SE}$ where SE is the standard error, square root of the sampling variance, calculated as $p \times (1 - p) / n$.

Factors affecting precision were analyzed, including sample sizes obtained, nonresponse rates, and design effects. Design effect is a measure of the ratio of true sampling variance under a specific design over the variance that would have resulted if the sample had been drawn as a simple unclustered random sample. Design effect was calculated as VarTrue/VarSRS (SRS (simple random sampling) refers to a sample design that does not involve complexities such as clustering and weighting, which tend to increase the sampling variance and the design effect), where VarSRS $= p \times (1 - p) / n$ and VarTrue incorporates the effect of clustering and stratification by using a formula that can be complex based on the number of stages in the design, the clustering details, and the stratification strategy.

Data received from the country level were processed, standardized, and analyzed by using SAS, version 9.2, software (SAS Institute, Inc., Cary, North Carolina) and SUDAAN, version 10.0, software (SUDAAN Statistical Software Center, Research Triangle Park, North Carolina).

Finally, several software packages for personal computers allowed calculations to be made that take into account the clustered nature of the data. Although SUDAAN or SAS would be the statistician's preferred tool for analysis of clustered data, Epi Info's C Sample program (US Centers for Disease Control and Prevention, Atlanta, Georgia) is a public-domain program and does not require the user to have as high a level of statistical training. Precision of results obtained by using data obtained in this study was compared among SUDAAN, SAS, and Epi Info's C Sample.

RESULTS

The results of the precision obtained in the surveys conducted in 4 African countries are presented in Table 1. The 95% confidence intervals calculated for treatment coverage rates for each drug ranged from ±2–7 percentage points in Burkina Faso; ±2–10 percentage points in Uganda; ±4–8 percentage points in Ghana; and ±8–29 percentage points in Niger. Precision of ±5 percentage points was obtained in 39% ($n = 12$) of cases, and precision of ±10 percentage points was obtained in 77% ($n = 24$) of cases (Table 1). When we omitted the data obtained from districts in Niger, which accounted for the highest levels of variance, precision of ±5 percentage points was obtained in 50% of cases and precision of ±10 percentage points was obtained in 100% of cases.

Sample size

Precision was affected by the sample size. The required sample size was estimated to be 1,268 persons. In the results obtained in this survey, when the number of respondents is broken down by district and drug, the sample size obtained was <1,268 in 14 of 31 cases (Table 1). Of these 14 cases, 3 had fewer than 1,000 respondents; these were in Burkina Faso, where the drug albendazole was targeted at school-age children only, and the survey sampled between 389 and 552 school-age children. In each of these 3 cases, confidence intervals were no higher than ±6 (i.e., total width less than 12), with high coverage rates of between 84.7% and 97.7% and design effects no higher than 6.6.

The target sample size was determined on the basis of assumed response rate, level of clustering, and desired

precision. The fact that we were unable to obtain the minimum target sample size in 14 cases is concerning and should be addressed in future studies. However, even in cases with smaller than ideal sample sizes, we were able to calculate precision levels and establish requisite caveats for generalizing from these samples.

Design effect and clustering

The factor having by far the largest impact on the actual precision obtained in these surveys, especially in Niger, was clustering as measured by the design effect. The higher the design effect, the lower the precision of the estimates. Whereas a design effect of 3 had been used as an estimate for planning, actual design effects observed averaged 5.3 (range, 0.8–12.0) in Burkina Faso, where 6–7 clusters were used; 5.8 (range, 3.1–12.4) in Uganda, where 30 clusters were used; 11.6 (range, 3.7–14.6) in Ghana where 12 clusters were used; and 38.7 (range, 3.3–92.3) in Niger, where 6–7 clusters were used (Table 1). Higher design effects were observed when there was a wide variation in coverage rates between villages for a given district. For example, in the Kollo district in Niger, with a design effect of between 56 and 92 for the different drugs administered, 5 of the 6 clusters sampled had coverage rates of above 77%, but 1 cluster had a very low coverage rate of 11% (Table 1). The low coverage in this cluster—due mainly to a drug distributor failing to visit assigned houses—contributed substantially to the variability of coverage rates. Removal of this cluster from the analysis resulted in design effects below 4.6 for all drug packages and demonstrates the large impact 1 cluster can have on overall precision when as few as 6 clusters are selected.

Precision obtained for age- and gender-specific categories

A secondary aim of the survey design was to track equity between genders and across age groups. In examining gender- or age-group–specific coverage rates, a less conservative estimate of ±10% was deemed to be desirable. We examined the confidence intervals by gender and by age group in data from Burkina Faso, Ghana, and Uganda. We did not examine data from Niger in any more detail given the already wide confidence intervals observed around total population coverage estimates. Confidence intervals by district, drug, and gender ranged from ±<1–10 percentage points in Burkina Faso, ±4–8 percentage points in Ghana, and ±2–15 percentage points in Uganda. Of the 44 coverage rates obtained by gender, the confidence intervals did not exceed ±10 percentage points in 42 (95%) cases. Overlapping confidence intervals for males and females indicated no significant difference between genders. Confidence intervals obtained in this study by district, drug, and age group ranged from ±2–9 percentage points in Burkina Faso, ±3–13 percentage points in Ghana, and ±2–13 percentage points in Uganda. Of the 60 coverage rates obtained by age group, 58 (97%) had confidence intervals less than or equal to ±10 percentage points.

Comparison of statistical software

Comparison of data analysis by using Epi Info, SUDAAN, and SAS software showed that all 3 programs provided the same point estimates, standard errors, and design effects with some variation in 95% confidence interval estimates. Epi Info estimates tend to provide smaller margins of error based on the fact that Epi Info calculates the 95% confidence interval by using the standard normal (Z) distribution, whereas SAS and SUDAAN calculate the 95% confidence interval by using the Student t distribution. However, these differences in width of confidence intervals were marginal and programmatically acceptable except where design effects were unacceptably high, such as in the case of districts in Niger.

DISCUSSION

Impact of design effect

In this survey, we sought a precision of ±5 percentage points. This means that for a survey result of 50%, one can be 95% confident that the true result lies between 45% and 55%. Although a precision of ±10 percentage points was obtained in the majority of cases, a precision of ±5 percentage points was obtained in only about half of the cases. The questions of how much precision (e.g., 5% vs. 10%) is required in neglected tropical disease coverage surveys and whether required precision is dependent on the program goal being elimination versus control need to be discussed.

The factor that had by far the largest influence on precision was clustering as measured by the design effect. Observed design effects ranged from <1 to 14.6 in Burkina Faso, Ghana, and Uganda and were especially high in Niger where design effects were higher than 25 in 5 of 9 cases. These design effects are all much higher than the design effect of <2 reported for surveys measuring smallpox immunization in children aged 1–4 years in the United States (31), between 1.5 and 2.5 reported for expanded program on immunization coverage surveys (24), and between 0.8 and 5.7 reported for quality of care in health facilities in Benin (32).

In a cluster sample, the total population is divided into subpopulations. These subpopulations, referred to as clusters, are ideally designed to be as heterogeneous as possible; that is, the subjects within each cluster are diverse, and each cluster is somewhat representative of the population as a whole. However, in practice, clusters are chosen to reduce the travel time and costs associated with the survey, by using, for example, geographical boundaries. With the goals of reducing the variance and designing an efficient sample, it is desirable to lower the number of observations per cluster, which necessarily means increasing the number of clusters to reach the given sample size. Conversely, selecting more clusters also increases travel for the field staff and makes the study more costly. Selecting the ideal number of clusters for a study is therefore an important part of achieving optimal cost effectiveness. Sensitivity ("what if") scenarios can help establish an optimal balance between these 2 opposing objectives.

The lowest design effects in this study occurred in Burkina Faso, where only 6–7 clusters were used (average design effect = 5.3), followed by Uganda, in which 30 clusters were used (average design effect = 5.8). On the other hand, Niger, in which 6 clusters were also used, observed a very high design effect of 38.6 because of 1 cluster with a very low coverage rate.

In the surveys reported in this study, populations were clustered by village. The delivery of drugs is the responsibility of approximately 2–4 distributors in each village. Thus, it is easy to see how the success or failure of even 1 distributor would result in a large part of the cluster either receiving or not receiving the medication. This in turn affects the homogeneity levels within each cluster, and when the number of clusters is small, it takes only 1 village that behaves differently to result in a high design effect. To reduce the design effect, one could increase the number of clusters sampled and/or define the clusters in a way that increases the potential for intracluster variation. A review of village-level reported coverage rates should help inform the decision of how many clusters to select. Intracluster variation for post–mass drug administration coverage surveys could be increased by increasing the number of drug distributors represented within a cluster.

It is recommended that a design effect of 6 be used when calculating sample size. As national organizations gain more experience with these surveys and as survey designs become more sophisticated, these estimates can be refined.

Sample sizes

Assessing the coverage of treatment of neglected tropical diseases with an integrated survey potentially poses the challenge of calculating sample size requirements where the population targeted with 1 treatment is not the same as the population targeted by another treatment (29). In this study, <100% geographical overlap of populations targeted for treatment was observed in only 3 districts, which were all in Burkina Faso. Here, treatment with albendazole for soil-transmitted helminthiasis was targeted at school-age children only, and treatments for trachoma and schistosomiasis were targeted to all ages. Although the sample size obtained for persons treated with albendazole was significantly lower, precision was still acceptable because of high coverage rates and smaller design effects. High program coverage rates for school-based programs treating soil-transmitted helminthiasis are in fact routinely reported (33). This may reflect the relative ease of accessing school-age children through school-based programs in countries where school attendance rates are high. Oversampling of populations where treatment targets only school-age children therefore may not be necessary in areas where school attendance rates are high.

Health systems implications

In considering the role of integrated treatment coverage surveys in what is a rapidly expanding, global neglected tropical disease control initiative, consideration should be given to the role of survey implementation in building health systems capacity and the need for appropriate survey designs that balance complexity and accuracy. Skill building should focus on increasing local ability to use and adapt survey protocols to country-specific situations and capacity to conduct appropriately weighted analysis. The level of statistical knowledge and skills required for adapting survey protocols to country-specific programs can be reduced by the provision of sample framework builder software such as Survey Sample Builder (34).

The choice of data analysis software has implications in terms of levels of training required and the cost of purchasing and maintaining the software. The results of this study support the use of Epi Info, which is free and widely used within the ministries of health of less developed countries. Similar findings have also been reported by Brogan, et al. (26).

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(Appendix follows)

Appendix Table 1. Drugs Used to Treat Neglected Tropical Diseases

Drug Names	Form	Diseases Treated
Albendazole	Tablet	Soil-transmitted helminthiasis Lymphatic filariasis (used in combination with ivermectin)
Azithromycin	Oral solution or tablet	Trachoma
Ivermectin	Tablet	Onchocerciasis Lymphatic filariasis (used in combination with albendazole)
Praziquantel	Tablet	Schistosomiasis
Tetracycline	Ointment	Trachoma (in children <6 months of age and, in some countries, pregnant women)