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Monitoring a primary health care programme with lot quality assurance sampling: Costa Rica, 1987

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The Lot Quality Assurance Sampling (LQAS) method was developed in industry to determine at reasonable cost whether each lot of a shipment is acceptable, based on samples of a few elements from the lot. Acting as inspectors of quality control, the field supervisors of the Costa Rican primary health care programme used the LQAS technique to assess performance in all of the programme's 758 delivery points (lots). They selected probability samples of 20 households and classified the lot as unacceptable when the sample contained more than four unserved households. This 20–4 LQAS rule was aimed to identify lots with less than 70% coverage. Forty-three percent of lots were found unacceptable in their home visit schedule, and 25% unacceptable in vaccination coverage. The probability of accepting defective lots, or consumer risk, was estimated at 4%, and the probability of rejecting acceptable lots, or provider risk, was at 17%. As side results, it was found that 84% of children aged 1–2 years were fully vaccinated, and an estimated 58% of households had been visited in the last six months. A household survey showed that clinic records, which serve as both a sampling frame and source of information for the LQAS assessment, produce accurate estimates of vaccination coverage but contain biased information about home visit dates. Given the chronic lack of timely and accurate information from service statistics, and the high costs of conventional sampling surveys, the LQAS technique appears to be a cost-efficient alternative for monitoring delivery points of primary health care in some circumstances.

Introduction

One of the major obstacles in implementing effective primary health care (PHC) programmes is the lack of management information.[1-3] The Lot Quality Assurance Sampling (LQAS) technique is a cost-efficient alternative to weak routine service statistic systems or expensive sampling surveys, for providing information for management at local levels. LQAS was developed by industrial quality control engineers to determine whether or not each lot of a shipment is acceptable based on samples of a few articles.[4-7] The analogy of this lot-by-lot assurance of quality and the requirement of monitoring every single PHC delivery point is evident.

The Costa Rican PHC programme, launched in 1971, has been credited as the key determinant of the dramatic improvement in health conditions that occurred in this country during the 1970s.[8-9] The decline in infant mortality from 67 to 21 per 1000 between 1970 and 1980 is an example of this improvement.

The outreach activities of health workers (HWs) are critical to deliver PHC in Costa Rica. The HW is scheduled to visit approximately 500 households under his or her care every three or four months. In these visits the HW provides basic health care, including immunization and health education, refers cases to medical care, and collects information.[10-11]

In 1987 there were 758 HWs covering more than 60% of the Costa Rican population. The population not covered by the PHC programme was mostly urban, middle-class. The rural component of the PHC programme included 474 HWs based in 338 health posts, which in turn were supervised by 41 health centres; the rural programme covered about one million people. The urban programme reached about 600 000 persons with 284 HWs based in 67 health centres.

Despite the success of the PHC programme in improving the health of Costa Ricans, its information system has been chronically hampered by deficiencies. One of them is the lack of adequate information for monitoring performance of delivery points. However, each family covered by the PHC programme is supposed to have a record in the health post or centre, which usually contains a rich array of data. HWs use this information extensively on an individual basis to provide the services. The unsolved problem has been to summarize and aggregate this individual information for management purposes.

This article presents the results of an experimental use of the LQAS technique as a supervision tool in the PHC programme of Costa Rica. It also presents the results from a national survey aimed at validating the LQAS information.

Methods

LQAS consists basically of a rule used by quality control inspectors to reject or accept a homogeneous lot of products. The rule, in its simplest form, comprises two numbers: the sample size (n) and the maximum number of defective elements (c) tolerated in the sample. For example, a rule of 10–2 would say: 'Take a random sample of 10 from each lot. If the sample contains more than 2 defectives, classify the lot as defective; otherwise, accept the lot.' This approach uses the concept of random sampling in a non-traditional manner, to classify a lot as acceptable or unacceptable rather than to produce precise estimates of the lot quality. Detailed descriptions of the technique can be found in texts of statistical quality control, such as Dodge and Romig,[4] Duncan,[5] Grant and Leavenworth,[6] and Montgomery.[7]

The LQAS rule is based on the probability of lot acceptance; that is, the probability of finding c *or less* defective elements in a sample of n elements selected at random, given a proportion defective among the N elements of the entire lot. This probability is calculated using the *hypergeometric probability distribution*. For lots with a large N, however, it is appropriate to use the simpler *binomial distribution*.

An operational characteristic curve graphically displays the probability of lot acceptance as a function of the proportion of defective elements in the lot for a particular LQAS plan. Figure 1 presents the operational characteristic curve for a 20–4 plan in a lot with $N = 150$. For example, the curve indicates that a lot with 10% defective elements has a 97% chance of being accepted, but a lot with 40% defectives has only a 4% chance of being accepted.

As in traditional sampling designs, LQAS plans are based on specified levels of Type-II and Type-I errors, which in the quality control terminology are called consumer and provider risks, respectively. The consumer risk is the probability of accepting defective lots, and the provider risk is the probability of rejecting acceptable lots. Assurance of proper standards of health requires that the consumer risk be kept as low as possible. Good management requires a low provider risk. Figure 1 portrays these risks with reference to a threshold, or tolerance standard, of 30% defective elements. Quality control engineers set this threshold according to technical and managerial criteria.

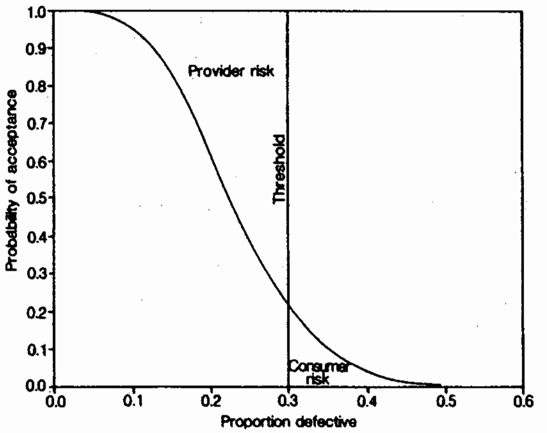

Figure 1. Operational characteristic curve for $n = 20$, and $c = 4$.

We used a 20–4 LQAS plan for classifying each delivery point, or lot, of the Costa Rican PHC programme. This plan was designed to identify lots with less than 70% coverage, keeping the consumer risk lower than 5% and the provider risk lower than 20%. A naive approach would have set the LQAS plan at 20–6, since the fraction 14/20 corresponds to the desired threshold of 70% coverage in a sample of 20. Such an approach is naive because it does not take into account the sampling error and the corresponding consumer and provider risks. Since this design would have resulted in an unacceptably high consumer risk (for example, the probability of accepting lots with only 60% coverage would be 23%), we opted for the more stringent LQAS rule of 20–4 in order to keep the consumer risk low.

Why was the 20–4 LQAS plan an efficient design? To answer this question Figure 2 presents estimated consumer and provider risks for alternative LQAS plans. The points with the same sample size are connected by iso-cost curves: the more external the curve the lower the survey costs. The shaded area in the Figure represents the constraints for selecting the LQAS plan – maximum consumer and provider risks of 0.05 and 0.20, respectively. Only those LQAS plans inside the shaded area are acceptable. The curve for a sample size of 10, though preferable from the point of view of survey costs, does not meet the risk constraints. The curves for sample sizes of 20 and 30 are acceptable since they have points inside the shaded area, but the most efficient approach is that of the 20–4 LQAS plan.

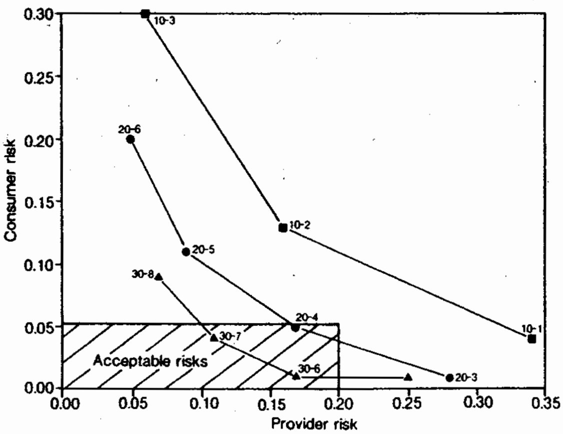

Figure 2. Consumer and provider risks in selected LQAS plans (70% coverage).

Three conditions framed the previous analysis: a threshold of 30% defective, a maximum consumer risk of 0.05, and a provider risk of 0.20. New risk levels could be considered in Figure 2 by modifying the shaded area. For example, a provider risk of 0.10, instead of 0.20, would result in a red ıced shaded area which would suggest an advantage for the 30–7 LQAS plan. Figure 2, however, is not suitable for threshold levels other than 30% defective. For example, a standard of quality tightened to 20% defectives requires the Figure 3 to study alternative LQAS plans. In this new Figure, no point with a sample size of 20 or 30 fits the risk constraints. The most efficient LQAS plan for a threshold of 20% nonvaccinated children is the 28–4 plan, which would result in a consumer risk of 0.048 and a provider risk of 0.188. In general, higher standards of quality control (lower thresholds) will require larger sample sizes.

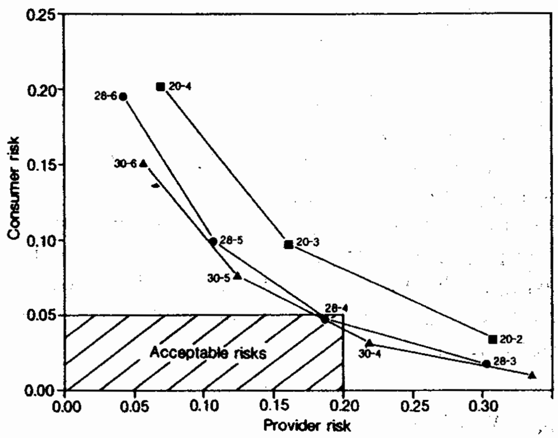

Figure 3. Consumer and provider risks in selected LQAS plans (80% coverage).

Two attributes were monitored:

- whether households had been visited in the last 6 months
- whether children aged 12–35 months were fully vaccinated

A child was considered fully vaccinated when he/she had received three doses of polio, three of diphtheria, pertussis and tetanus (DPT) and one of measles. The recommended age for completion of this schedule is 10 months in the Costa Rican programme. Households must be visited every three or four months.

We based the LQAS assessment on information in the family records kept in health posts and centres. The 84 field supervisors of the PHC programme were trained in 8-hour, regional courses to select a systematic sample of 20 family records per lot, to transcribe the information to the study form, to assess the lot performance according to the LQAS rule, and to interpret the result for the HW. Field supervisors were to make the LQAS assessment as part of their routine duties. They were also supposed to take corrective actions in defective lots after discussing with the HW the probable causes of poor performance.

Field supervisors conducted the study in all of the 758 lots of the programme in June and July 1987. We defined a lot as the cluster of households for which an HW had responsibility. The supervisor's time required for the LQAS assessment was about two hours per lot.

In addition to the data on home visits and vaccines, supervisors collected information on the characteristics of the lot, the HW, and the community. Lot by lot results were aggregated to produce estimates of coverage for the country, regions, and supervision areas, as well as for lots grouped by these characteristics. The results of each lot were weighted by the number of households in the lot for this aggregation.

A validation survey was conducted in a random sample of 60 lots. A probability sample of 28 households with children under 36 months of age was interviewed in each lot. To assure independence from the PHC information system, we used updated maps from the 1984 census as a sampling frame to select these households, and hired interviewers independently from the ministry of health. Household interviews lasted about 15 minutes, on average. After collecting the information from the 28 households in an area, the interviewers checked in the health post or centre that the households had a record on file, and they validated some relevant data.

The validity analysis is aimed at determining two types of biases: selection and classification biases.[12] Selection bias refers to the distortion resulting from the fact that the subjects with information available do not necessarily represent the target population. Since the study was based on clinic records, this type of bias was an important threat. Classification bias refers to the distortions due to errors in the information itself. We quantified these biases for the two monitored attributes and the three following sources of information:

- interviewee's answers (women's report)
- vaccination cards and visit cards kept within the homes
- clinic records

The bias was quantified by the difference of the observed minus the true coverage, expressed as the ratio to the true coverage.[12] The estimates of true coverage were based on 1) the information from subjects with consistent information in both the home and the clinic record; and 2) for the subjects with no records or with inconsistent records, the women's reports adjusted in a proportion derived from the subjects with consistent records.

Results

LQAS assessment

From the 758 PHC lots existing in Costa Rica in 1987, 43% had an unacceptable schedule of home visits and 25% an unacceptable vaccination coverage with the 20–4 LQAS plan (Table 1). Most (130/189, 69%) of the lots classified as defective in vaccinations were also deficient in home visits. However, only a minority (130/329, 40%) of those defective in home visits were also unacceptable in vaccinations. This discrepancy could derive in part from children immunized

Table 1. Lot classification by home visits and vaccination for a LQAS plan of 20–4.

Home visits	Vaccination		
	Total lots	Defective	Acceptable
Total lots	758 (100%)	189 (25%)	569 (75%)
Defective	329 (43%)	130	199
Acceptable	429 (57%)	59	370

Defective, both attributes: 130 (17%)

Acceptable, both attributes: 370 (49%)

Conflicting classification: 258 (34%)

Table 2. Estimate of provider and consumer risks for the 758 PHC lots, a LQAS plan of 20-4, and a threshold of 30% defective.

Percent defective	Household visits			Vaccination		
	Probability[1]	Total lots	Accepted lots	Probability[1]	Total lots	Accepted lots
0- 9	0.998	227	226.5	0.999	294	293.7
10-19	0.834	143	119.3	0.833	216	179.9
20-29	0.412	91	37.5	0.390	112	43.7
30-39	0.113	84	9.5	0.096	61	5.9
40-49	0.017	71	1.2	0.012	37	0.4
50-59	0.001	42	0.0	0.000	19	0.0
60+	0.000	100	0.0	0.000	19	0.0
Total		*758*	*394.0*		*758*	*523.6*
<30		461	383.3		622	517.3
30 +		297	10.7		136	6.3
Provider risk	1-383.3/461 = *0.169*			1-517.3/622 = *0.168*		
Consumer risk	10.7/297 = *0.036*			6.3/136 = *0.046*		

[1] Probability of lot acceptance for the central point of the interval (5%, 15%, and so defectives).

outside the PHC programme - in the private sector or in the social security system - especially in urban areas. Conflicting classification occurred in 34% of lots, whereas in 66% results were consistent for both attributes. In the 17% of lots deficient in both attributes, the likelihood of a classification error is lower and the need of a corrective action is clearer.

The consumer and provider risks estimated in Table 2 summarize the margins of random error for the previous figures. The estimating procedure described by this Table requires two inputs:

- the probabilities of accepting lots at different coverage levels
- the distribution of lots by coverage

The probabilities of acceptance in Table 2 were computed using the *hypergeometric distribution* for a 20-4 LQAS plan and $N=500$ for home visits and $N=150$ for vaccination. The figure of 500 represents the approximate number of households per lot according to administrative definitions (the average size of a lot was 460 households in this study). The figure of 150 estimates the population of children aged 1-2 years per lot, assuming 5 persons per household and an annual birth rate of 30 per thousand population (500 x 5 x 0.030 x 2 = 150). The distribution of lots by coverage was estimated by using the detailed results from the 20-household samples. For example, the number of lots with none or one defective element in the sample of 20 estimated the number with less than 10% defective in Table 2. This estimate was the best guess of the true distribution of lots by coverage, given the information available for the present study.

Among the expected 136 vaccine deficient lots in Table 2, an estimate of six lots would be misclassified as acceptable under the 20-4 plan; that is, a consumer risk of 0.046. In home visits, an estimate of 11 out of 297 deficient lots would be misclassified as acceptable, for a consumer risk of 0.036. The estimates of acceptable lots misclassified as defective were substantially higher: 105 in vaccination and 78 in home visits, for a provider risk of 0.17 in both attributes. It should be pointed out that classification errors in Table 2 are concentrated in the vicinity of the threshold level (30% defective). Those lots with very low or very high proportion defective are seldom misclassified.

Estimates of coverage

A side product of the LQAS assessment was the estimates of coverage obtained from the aggregation of lot results weighted by lot size. The proportion of households visited in the previous six months was 71% overall, with 74% in the rural programme and 68% in the urban programme (not shown in Tables). The proportion of children aged 1–2 years who were fully vaccinated was 84% and, as with home visits, the rural programme had higher coverage (86%) than the urban programme (81%) (Table 3). The urban programme performed better than the rural programme only in two regions (North Huetar and Atlantic), and in particularly large lots with 600 households or more.

Table 3. Percent of children aged 1–2 years fully vaccinated,[1] by selected variables. Urban and rural areas covered by the PHC programme, Costa Rica, 1987.

Variable	Total		Urban		Rural	
	(N*)	Percent	(N*)	Percent	(N*)	Percent
Total	*(758)*	*84*	*(284)*	*81*	*(474)*	*86*
Region						
South Central	(216)	87	(117)	83	(99)	92
North Central	(110)	81	(76)	80	(34)	83
North Huetar	(72)	89	(8)	90	(64)	89
North Pacific	(159)	89	(47)	85	(112)	91
Atlantic	(83)	70	(19)	72	(64)	70
South Pacific	(118)	82	(17)	71	(101)	84
Time since HW started in the lot						
<2 years	(219)	82	(105)	81	(114)	84
2–4 years	(236)	84	(104)	82	(136)	86
5 + years	(246)	89	(55)	87	(190)	89
HW position						
Vacant	(50)	70	(18)	64	(32)	76
Filled	(708)	85	(266)	83	(442)	87
Households per HW						
100-299	(105)	85	(21)	78	(84)	86
300-599	(547)	86	(215)	82	(332)	89
600 +	(106)	76	(48)	79	(58)	75
Travel time from supervisor's office						
None	(290)	81	(259)	81	(31)	84
< 1 hour	(343)	88	(19)	87	(324)	88
1 + hours	(119)	81	(1)	85	(118)	81
Community support[2]						
Weak	(132)	82	(41)	80	(91)	83
Good	(490)	84	(201)	82	(289)	86
Excellent	(123)	88	(32)	86	(91)	90

[1] Children were considered fully vaccinated when had three doses of DPT, three doses of polio and one dose of measles vaccines.

* N = number of lots. Each lot includes 20 observations. Observations were weighted by the lot size (number of households).

[2] Assessment of field supervisors.

The three lowest levels of vaccine coverage occurred in lots where the HW position was vacant (64%) and in the Atlantic (70%) and South Pacific-urban (71%) regions. Outstanding coverages of over 90% were found in the rural programme in two regions (South Central and North Pacific), as well as in areas with 'excellent' community support. The time the HW had been in charge of the lot and the level of community support had a favourable effect on vaccine coverage. Very small or very large lots had lower coverage, as well as lots very close or very far away from supervisors' offices (Table 3).

Several variables were not associated with vaccine coverage (not shown in Tables): age and sex of HWs, HW type (assistant or auxiliary nurse), year of creation of the lot, frequency of supervision visits, and infrastructure in the health post or centre. The differentials in home visit coverage (not shown in Tables) were analogous to those described for the vaccination variable.

Table 4. Indicators of validity of household and clinic records from the validation survey in 60 lots.

Indicators	Total	Urban	Rural
Visit card at home	48%	21%	63%
Vaccine card at home	89%	88%	89%
Family record located in the Post/Centre	84%	75%	88%
Child in family record	93%	91%	95%
Consistency between home and clinic records in the date of:			
Last home visit	64%	60%	65%
BCG vaccine	69%	64%	72%
Third dose of DPT	80%	72%	85%
Third dose of Polio	76%	71%	84%
Measles vaccine[1]	89%	88%	90%
All vaccines[2]	70%	63%	74%

[1] Consistent dates for measles vaccine alone *or* measles-rubella.
[2] Consistent dates for the third dose of DPT *and* for the third dose of polio *and* for the measles dose.

Validation survey

The validation survey showed that 89% of children aged 1–2 years had their vaccination card at home, whereas only 48% of households kept the record of HW visits (Table 4). The interviewers were able to locate 84% of clinic records of the families in the sample. Assuming that half of the missed family records were really not in the clinic, we estimated a 92% completeness of clinic files. In 93% of clinic records the surveyed child aged 1–2 years had been registered. This proportion reduced to 74% for infants under one year of age, which justifies their exclusion from LQAS assessments based on clinic records. The estimated proportion of households with clinic records (92%) multiplied by the proportion with the child in the record (93%) results in an estimated 86% of children aged 1–2 years with a record in the PHC clinic.

Among the families with home and clinic records, the percentage of consistent information ranged from 64% for the date of the last HW visit to 89% for the date of the measles vaccine (Table 4). In general, the information on vaccination dates appeared more accurate than that of home visits, and the information in the rural programme was superior to that of the urban programme. The urban/rural contrast was most marked for the proportion of households with visit cards available (21% versus 63%).

The estimated selection, or non-response, bias in the data from clinic records was 5% for the coverage of home visits and 1% for the proportion of children fully vaccinated (Table 5, under 'Selection bias, clinic records'). These biases are small primarily because of: 1) the high completeness of clinic records, and 2) the similarity of subjects with and without clinic records in terms of vaccination and home visit coverage.

The selection bias in the data from home records was small for the proportion fully vaccinated (6%), but it was extreme for the variable home visits. Indeed, since only 48% of households had a visit card (and they were the most frequently visited households), measuring the coverage of home visits with this information over-estimates the true coverage by 32% (Table 5, under 'Selection bias, home records'). The women's reports were free of non-response bias.

The classification bias was almost null in the information on home visits reported by the

Table 5. True and observed proportion covered, selection bias and classification bias by source of information. Estimates from the validation survey.

Indicator and source of information	Home visits	Vaccination				
		BCG	DPT	Polio	Measles	All[1]
True proportion covered (estimated)	*0.58*	*0.90*	*0.89*	*0.89*	*0.94*	*0.84*
Observed proportion covered						
Women's report	0.57	0.94	0.70	0.63	0.91	0.64
Home records	0.69	0.89	0.93	0.93	0.95	0.90
Clinic records	0.71	—	0.85	0.85	0.91	0.87
Selection bias						
Women's report	0.00	0.00	0.00	0.00	0.00	0.00
Home records	0.32	0.00	0.04	0.05	0.01	0.06
Clinic records	0.05	0.00	0.02	0.02	0.00	0.01
Classification bias						
Women's report	-0.02	0.05	-0.22	-0.29	-0.03	-0.24
Home records	-0.10	-0.01	0.00	0.00	0.00	0.02
Clinic records	0.17	—	-0.01	-0.01	-0.01	0.02

[1] Children fully vaccinated, ie with three doses of DPT, three doses of polio, and the measles dose.

interviewees from women's reports and in the data on vaccines collected from clinic and home records (Table 5). In contrast, the information about visits contained in home records under-estimated the coverage by 10% and that contained in clinic records over-estimated coverage by 17%. Mothers' answers about their children's vaccination produced coverage estimates substantially biased downwards by 24%.

In summary, Table 5 shows that the best estimate of the true proportion covered by home visits (58%) was that from the women's reports (57%), and the best estimate of the proportion of children fully vaccinated (84%) was obtained from clinic records (87%).

Conclusions

This paper reports an experience of monitoring PHC with a technique developed for quality control in industry: the Lot Quality Assurance Sampling (LQAS) method. Acting as inspectors of quality control, field supervisors of the Costa Rican primary health care programme took a probability sample of 20 households at each delivery point and classified the lot as 'unacceptable' when the sample contained more than four unserved households. This 20–4 LQAS rule produced 43% unacceptable lots for home visit coverage, 25% unacceptable lots for vaccination coverage, and 17% of lots unacceptable for both attributes. Overall, an estimated 84% of children aged 1–2 years were fully vaccinated, and 58% of households had been visited in the last six months. Lower coverages were found in the urban programme, the Atlantic region, and in lots with a vacant HW position. Health coverage was positively associated with level of community support and the length of time the HW had been in charge of the lot. There was also a curvilinear association of coverage with lot size and travel time from the supervisor's office.

The supervisors used clinic records as both a sampling frame and a source of information for the LQAS assessment, which was evidently inexpensive. A parallel validation survey showed that there is no gain in data quality when the information is collected from records kept at homes instead of from clinic records. Both sources produced unbiased estimates of vaccination coverage, but both were misleading on home visit coverage. In contrast, mother's answers during home interviews were accurate for studying home visit coverage but produced biased estimates of vaccination coverage.

A critical aspect of the LQAS technique is the use of a small sampling size, which can produce large lot classification errors, called consumer and provider risks. The 20–4 LQAS plan was designed to identify lots below a 70% threshold of coverage. An estimated 4% of lots below that threshold were not correctly classified as unacceptable (consumer risk), and 17% of lots above that threshold were misclassified as defective (provider risk). In the vicinity of the threshold, the risks of classification error were extreme. However, for lots with clearly high or clearly low coverage, that is, far away from the threshold, the risk of classification errors was minimal. Luckily, only a fraction of the evaluated lots clustered around the threshold.

It was demonstrated that a 20–4 LQAS plan is the most efficient design given:

- the distribution of lots by coverage in the Costa Rican programme
- a threshold of 70% coverage
- a maximum consumer risk of 0.05
- a maximum provider risk of 0.20

If the threshold of coverage were tightened to 80% coverage, a LQAS plan of 28–4 would be required.

Even though the application of a LQAS rule by field personnel is straightforward, the design of a LQAS plan is a somewhat complex task that has to be done at central levels. Microcomputer programmes for calculating the hypergeometric probabilities of lot acceptance and the consumer and provider risk facilitated the choice of the LQAS plan in the present application.

Given the chronic lack of timely and accurate information from service statistics and the high costs of conventional sampling surveys, the LQAS technique appears to be a cost-efficient alternative for monitoring delivery points of PHC in some circumstances. The strength of LQAS is that it can be used by local decision-makers (that is, field supervisors) to assess objectively every PHC service point. In addition, aggregating the results of several lots generates estimates of coverage for use by higher-level decision-makers, such as at regional and national levels.

LQAS uses the stratified random sampling concept in a non-traditional manner. The purpose of the technique is not to produce an estimate of each lot's quality, but rather to classify each lot as acceptable or unacceptable. The use of LQAS is particularly appropriate if corrective courses of action are taken at the local level. LQAS is thus an action-orientated technique and a useful tool for local managers, rather than an instrument for research. Consequently, the main outcomes of the present LQAS application were not the statistics reported in this paper but the actions the supervisors took to improve those lots identified as deficient, as well as their learning of a technique they could use in the future. Corrective actions ranged from administrative steps to accelerate the filling of vacant HW posts to the discussion with HWs about more efficient schedules for home visits. The very existence of an accountability mechanism has the potential of improving performance by itself. Repeated LQAS assessments over time will allow evaluation to see whether this monitoring technique has generated improvements in the programme.

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