

PW-ABP-543

THE JOHNS HOPKINS UNIVERSITY
SCHOOL OF HYGIENE AND PUBLIC HEALTH
INSTITUTE FOR INTERNATIONAL PROGRAMS

Manual for Conducting

Lot Quality Assessments

in Oral Rehydration Therapy Clinics

Mark C. Wolff, Ph.D.

Robert E. Black, M.D., M.P.H.

September 1989



OCCASIONAL PAPER NO. 9

PN-ABP-543

MANUAL FOR CONDUCTING
LOT QUALITY ASSESSMENTS
IN ORAL REHYDRATION THERAPY CLINICS

Mark C. Wolff, Ph.D.

Robert E. Black, M.D., M.P.H.

September 1989

The Johns Hopkins University
School of Hygiene and Public Health
Institute for International Programs
103 East Mount Royal Avenue
Baltimore, Maryland 21202
USA

a.

PREFACE

The Institute for International Programs, part of The Johns Hopkins University School of Hygiene and Public Health, brings together leading Hopkins experts in biomedical, environmental, social science, and health management fields. This distinguished group of professionals, together with collaborators from established research centers and major academic institutions throughout the world, provides a comprehensive approach to international development. The Occasional Papers Series of the Johns Hopkins Institute for International Programs was established as a means of disseminating information on advances in international health.

IIP OCCASIONAL PAPER NO. 9

September 1989

"Manual for Conducting Lot Quality Assessments in Oral Rehydration Therapy Clinics," by Drs. Mark C. Wolff and Robert E. Black, Department of International Health, The Johns Hopkins University School of Hygiene and Public Health.

Acknowledgements

This manual was originally prepared for the Programme for the Control of Diarrhoeal Diseases of the World Health Organization. The authors would also like to acknowledge the assistance of George Stroh, Jr. of the Centers for Disease Control.

Production Editor, Denise L. Harrison
Produced by JHU Design and Publications

Publication of this paper was funded by
the Agency for International Development
under Grant No. DAN 5057-G-SS-5088.

CONTENTS

Introduction	1
Overview of the Steps in an LQA	2
Detailed Steps in an LQA	3
Conclusions	15
References	16
Appendix	17

LIST OF FIGURES, TABLES, AND FORMS

Figure 1:	Illustrative Use of Form 1	8
Figure 2:	Illustrative Use of Form 2	12
Figure 3:	Illustrative Use of Form 3	14
Table 1:	Determination of Minimum Level, Sample Size and Acceptable Size	19
Table 2:	Random Number Table	20
Form 1:	Calculation of the Sampling Interval and Starting Number	21
Form 2:	Tally Sheet for Step 7	22
Form 3:	Summary of Results of Lot Quality Assessment	23

. C

I. INTRODUCTION

Lot Quality Assessment (LQA) is a method that was first developed to help manufacturers determine if the goods they were producing met a set standard of quality. It is often very costly to completely inspect every item produced. Therefore, it is necessary to select a sample of the manufactured items, test them, and make some decisions based on this sample.

Recently, LQA methods have been employed in public health programs to see if people are obtaining established standards of care. In this manual we will illustrate how LQAs might be used by the supervisor of diarrhea treatment clinics. It is not possible for the supervisor to examine how each person was treated, or to make an in-depth study of each clinic. LQAs provide a simple method for evaluating the quality of care based on examining how a sample of people were treated. The methods presented could easily be adapted to other clinic settings. They can also be adapted to the supervision of services given in the field. Supervision of field services is somewhat more complex because of the difficulty of collecting the necessary information in the community.

The specific problem we will examine is: "Is oral rehydration therapy (ORT) being properly used to treat children coming to diarrhea clinics?"

II. OVERVIEW OF THE STEPS IN AN LQA

In this example we will use LQAs to examine the question: "Is oral rehydration therapy (ORT) being properly used to treat children coming to diarrhea clinics?" We will base our answer on the information we find in a sample of clinic records. The basic steps are listed below. Each step is explained in section III.

- 1) Set up criteria to distinguish an acceptable record, showing proper use of ORT, from an unacceptable record.
- 2) Decide which records are to be included in the study, and make certain that they are all available for examination. Only a sample of these records will be selected.
- 3) Set a GOAL and a MINIMUM LEVEL. These are percents of the children receiving proper ORT for diarrhea. The GOAL is the percent of children we realistically hope will receive proper ORT in the clinic. The MINIMUM LEVEL is smaller than the GOAL. It is set so that the LQA method will almost always tell us if a clinic is not meeting the MINIMUM LEVEL.
- 4) Use tables to determine how many records must be selected, examined in each "lot" (sample size), and how many of the selected records must be "acceptable" (acceptable size) if we are to be satisfied with the ORT program in this "lot."
- 5) Select the sample of records.
- 6) Examine the selected records, and for each record decide if proper ORT was given based on the criteria established in step 1.
- 7) Tally the number of "acceptable" records. If there are at least as many as the acceptable size required by the tables used in step 5 then the level of treatment with ORT is acceptable. If not, then it is unacceptable.

III. DETAILED STEPS IN AN LQA

III.1 Set up criteria to distinguish an acceptable record, showing proper use of ORT, from an unacceptable record.

LQAs are useful when it is possible for someone to know when an individual product meets an established quality standard. In our example, the "product" is treatment of a child with diarrhea. We will base this judgement on treatment records. Ideally, these criteria would be simple enough that someone like a records clerk could decide if a record indicated that satisfactory treatment was given. The following steps should be taken:

- A) Review how diarrhea treatment is written on the records.
- B) Write brief, clear guidelines for deciding if a record shows that acceptable ORT treatment was given.
- C) Working with the people who will examine the records, test the guidelines. If more than one person will review the records, it is important that everyone will interpret them the same way. Select a few records, say five, and review them in a group to clarify when a record shows acceptable treatment and when it does not. Next, select a few different records, say five more. This time let everyone review the records by themselves. Then compare everyone's results. If there are disagreements, review these. Change or clarify the guidelines, if necessary. Be sure to return the test records to the files.
- D) Make a final decision on guidelines for acceptability.

III.2 Decide which records are to be included in the study, and make certain that they are all available for examination.

In order to select a sample of records for an LQA, it is necessary to decide which records are to be included in the study. For example, the clinic's ORT program may only be one year old. In that case we do not want to look at what kind of treatment a child received one and a half or two years ago. We might restrict ourselves to all treatment given to infants in the last six months. Not all of these records will actually be examined. But they are all "included in the study" in the sense that any one of these records might be selected.

It is also important to make sure that all the records are available for inspection. For example, if the files older than three months are stored away, then it will be necessary to retrieve these files to be sure they are available to be included in the study.

III.3 Set a GOAL and a MINIMUM LEVEL.

The GOAL and MINIMUM LEVEL are percents of the children receiving proper O.F.T for diarrhea. The GOAL is the percent of children we realistically hope will receive proper ORT in the clinic. The MINIMUM LEVEL is smaller than the GOAL. It is set so that the LQA method will almost always tell us if a clinic is not meeting the MINIMUM LEVEL. The ultimate goal of the program may be 100% coverage. Nevertheless, for management purposes, an intermediate goal might be set at 80%. That is, we will be satisfied with the progress a clinic is making if 80% of the infants requiring ORT treatment are receiving it. As supervisor of a number of clinics, we want to find clinics that are not meeting this GOAL of 80%. We want to be fairly certain that our sample finds any clinics that are far below this GOAL. For example, we want to be sure to know if a clinic is only treating a MINIMUM LEVEL of 60% or fewer children properly with ORT. Clinics that our samples show to be below the GOAL will then receive some type of special attention.

A) Set the GOAL.

If goals are set as part of the policy of the program they can be used as the GOAL for the LQA. If there is good reason to believe that the clinics are much higher or much lower, at least 10%, then some modification might be made. The GOAL should be a percentage between 20% and 95%, and should be a multiple of 5 (20%, 25%, 30%, 35%, 40%, 45%, 50%, 55%, 60%, 65%, 70%, 75%, 80%, 85%, 90%, or 95%.) If it is not a multiple of 5 then round it to the closest multiple. For example, 62% would be rounded down to 60%, and 63% would be rounded up to 65%. This rounding off is only necessary to simplify the tables that will be used in step 4.

If there are no previously set goals use any available information that might help you guess what a good percentage of ORT usage would be. It might be helpful to first decide in

what range the GOAL should be set:

High: 95% to 80%
Medium-High: 75% to 60%
Medium-Low: 55% to 40%
Low: 35% to 25%

Then try to select a level within the range.

B) Set the MINIMUM LEVEL.

The next step is to select a MINIMUM LEVEL. This is set to be smaller than the GOAL, and is a level such that the LQA will be almost certain to find any clinic operating at or below this level.

In order to simplify this process, and to reduce the number of tables usually required for an LQA, this manual restricts itself to three possible MINIMUM LEVELs for each GOAL. Selection of the appropriate level is based on the answers to the following two questions.

- 1) Do you think there is a large difference in the proportion of children properly treated with ORT between clinics?

(YES = big difference, NO = small difference) _____

Differences in clinic performance can be caused by a number of different factors such as: experience and stability of the staff, ORT supply factors, and acceptability of ORT by clinic personnel. These, and other factors, should be considered in answering this question.

- 2) Do you wish to focus your efforts on finding the worst clinics for additional supervision, or are you interested in finding most of the clinics that fall short of the goal?

(YES = worst clinics, NO = most clinics) _____

In theory, one might hope to find all clinics that are operating below the program's GOAL. However, this information may not be of much practical benefit if there are only sufficient resources to take meaningful action at the clinics with the greatest problems. It will also require more LQA resources to find clinics that come close to but do not reach the GOAL. On the other hand, the clinics that come close to meeting the GOAL may benefit from a small amount of increased supervision, and therefore should be detected.

Once you have answered these two questions, your MINIMUM LEVEL is easily obtained from Table 1. If you answered "YES" to both questions then use column M 1. If you answered "YES" to one question and "NO" to the other then use column M 2. If you answered "NO" to both questions then use column M 3. Use the row of the table corresponding to your GOAL.

For example, let us assume that your GOAL is set at 75%. If you say "YES" to both questions you would use column M 1 and your MINIMUM LEVEL would be 50%. If you answer "YES" to question 1) and "NO" to question 2), or "NO" to question 1) and a "YES" to question 2) then you would use column M 2 and your MINIMUM LEVEL would be 55%. Finally, a "NO" for both questions would lead you to column M 3, which yields a MINIMUM LEVEL of 60%. If your GOAL were 40% instead of 75%, the three possible for your MINIMUM LEVEL would be 20%, 23%, and 25% respectively.

III.4 Use tables to determine how many records must be selected and examined in each "lot" (SAMPLE SIZE), and how many of the selected records must be "acceptable" (ACCEPTABLE SIZE) if we are to be satisfied with the ORT program in this "lot."

Once the GOAL and MINIMUM LEVEL have been determined, it is an easy matter to look up the SAMPLE SIZE and ACCEPTABLE SIZE. The SAMPLE SIZE tells us how many records we will have to select and review to see if acceptable ORT

treatment was given. The ACCEPTABLE SIZE tells us how many records in our sample must be acceptable for us to be satisfied that the clinic is reaching the GOAL. These numbers are picked so that a clinic operating at or below the MINIMUM LEVEL will rarely be mistaken for a clinic which is reaching our GOAL. We will also rarely make the mistake of saying a clinic is unacceptable based on the sample, when it is really meeting the GOAL. Clinics between the GOAL and MINIMUM LEVEL will be more likely to be detected if they are close to the MINIMUM LEVEL, and less likely if they are close to the GOAL.

SAMPLE SIZE and ACCEPTABLE SIZE are also found on Table 1. They are the two numbers immediately to the right of the MINIMUM LEVEL that you found in the previous step.

For example, if your GOAL is 75% and you answered "YES" to both questions in step 3, your MINIMUM LEVEL was found in column M 1 and was 50%. Your SAMPLE SIZE would be found in column S 1 and would be 23, while your ACCEPTABLE SIZE would be in column A 1 and equal 15.

III.5 Select the sample of records.

The next step in an LQA is the actual selection of records from the files. These records will be examined in accordance with the criteria set up in step III.1. In this step we concentrate on the actual selection of records. A procedure for the selection is described below.

It is crucial that the people selecting records follow this procedure as closely as possible. Most importantly, they must not include or exclude a record because of what it "looks like", "appears to say", or any other factors outside of the established procedure. A well meaning individual may skip over records where the handwriting is hard to read, or is damaged in some way. Even worse, someone might skip over records that appear to be incomplete. It is quite possible that they are records that also do not meet up to the standards set in step III.1. If someone is excluding these from the sample, the LQA will not be able to provide an accurate picture of ORT treatment in the clinic. The same problem would exist if someone were to include certain records, for whatever reason, which were not selected by the following procedure. Form 1 will be used in conjunction with the sample selection. Figure 1 illustrates the use of Form 1.

FIGURE 1: Illustrative Use of Form 1

FORM 1

Calculation of the SAMPLING INTERVAL and STARTING NUMBER

1) SAMPLE SIZE (S) 23 (from TABLE 1)

2) TOTAL NUMBER of RECORDS (T) 897

3) (TOTAL NUMBER OF RECORDS/SAMPLE SIZE) =

$$(S/T) = (\underline{897} / \underline{23}) = \underline{39.78}$$

4) SAMPLING INTERVAL (the results in 3 rounded down) 39

5) STARTING NUMBER (randomly selected from TABLE A) 22

- A) Enter the SAMPLE SIZE (N), which you found in Table 1 onto line 1 of FORM 1. This is the number of records that will be selected for determination of the use of ORT.
- B) Enter the total number of records from which the selection will be made on the line 2, marked "TOTAL NUMBER OF RECORDS", (T). It is important that this include all of the records, and only the records, which were decided to be included in the study in step III.2. It is not necessary to have an exact count for TOTAL NUMBER OF RECORDS.

If you do not have a good idea of how many records there are, then divide the records into a number of parts, each with approximately the same number of records. Count the records in one part, and then multiply by the number of parts you have. Say the records are kept in three file cabinets, each with five drawers, and each drawer containing approximately the same number of records. Count the number of records in one drawer, multiply this by five to get an approximation of the number of records in one cabinet, and then by three to get an approximation of the number of records in all three cabinets.

- C) On line 3 divide TOTAL NUMBER OF RECORDS by SAMPLE SIZE. Make this into a whole number by rounding down, or simply discarding the portion following the decimal point. Write the results on line 4, marked "SAMPLING INTERVAL".

For example, if your TOTAL NUMBER OF RECORDS is 897, and your SAMPLE SIZE is 23, then $(\text{TOTAL NUMBER OF RECORDS}/\text{SAMPLE SIZE}) = (897/23) = 39.78$. The SAMPLING INTERVAL is then 39. This is illustrated in Figure 1.

- D) Using Table 2, blindly pick a STARTING NUMBER by closing your eyes and pointing to a number. If the number you picked is greater than your SAMPLING INTERVAL, select a new number until you pick one smaller than your SAMPLING INTERVAL. Enter this number on line 5 marked STARTING NUMBER.

Continuing with Figure 1, let us assume that your first selection from Table A was 49. This is greater than 39, the **SAMPLING INTERVAL** in Figure 1, so we pick again. This time we get 22, which is less than 39, and this becomes our starting point and is written on line 5 of Form 1.

The next step in these instructions will explain how the **SAMPLING INTERVAL** and **STARTING NUMBER** completely determine which records will be selected. Carefully following these instructions will eliminate the problems discussed above, where the person selecting the records makes some judgement about which records to include.

- E) This step assumes that all the records are presently stored in some type of order, either alphabetical, based on an identification number, or based on the date of the last contact with the child. Any ordering will be fine. If the records are not ordered by such a procedure, then simply think of them as being ordered by the way they are stored in files cabinets or boxes. If they are in more than one drawer, or box, number these. In that way the records will be ordered, with all the records in the first drawer coming first, followed by the records in the second drawer, then the records in the third drawer, etc.

Starting with the first record, count records until you reach the **STARTING NUMBER**. This is the first record selected for review. Be sure to take this one no matter what it "looks like". Remove this record. Start counting from one again, beginning with the record immediately after the one you just selected. This time count records until you reach the **SAMPLING INTERVAL**. This is the second record selected for review. Remove this record. To find the third record, repeat the process you used for the second one. That is, starting with the record immediately following the second record selected, count from one to the **SAMPLING INTERVAL**. This is the third record. Continue in this way, always counting up to the **SAMPLING INTERVAL**, and selecting a record, until you have selected exactly as many records as called for by your **SAMPLE SIZE**.

In the example in Figure 1, we have a SAMPLING INTERVAL of 39, and a STARTING NUMBER of 22. Therefore, we would start with record 1, count until the 22nd record, and select it. Then you would start counting again with the record immediately following the 22nd record. Count up to 39, and select this record. This newly selected record could also be found by counting from the beginning to the 61st record, as $22 + 39 = 61$. Similarly, the next record, which is 39 records further into the file, is the 100th ($61 + 39 = 100$) record from the start.

III.6 Examine the selected records, and for each record decide if proper ORT was given based on the criteria established in step 1.

Each record selected in step 5 must be reviewed to determine if it is acceptable on the basis of the criteria set up in step 1. A simple tally sheet, such as the one in Figure 2, should be created, and each record should be scored. It must be emphasized again that this scoring should be based solely on the criteria of step 1. If there is some ambiguity in the record, it should probably be considered to be unacceptable. One should not go back to the individual who entered the information and "double check" what they "meant." The records should be judged without such additional "commentary." It would be best to have someone other than the person who wrote the information into the record do this scoring.

Figure 2 continues the example started in the preceding figures. Therefore, it contains space for 23 entries, the SAMPLE SIZE derived in Table 1.

Be sure to refile the selected records. After the records have all been reviewed and scored, further action or clarification of a record can be made prior to refileing.

FIGURE 2: Illustrative Use of Form 2

FORM 2 TALLY SHEET for STEP 7

Sequence #	ACCEPTABLE	
	<u>YES</u>	<u>NO</u>
1	✓	
2		✓
3	✓	
4	✓	
5		✓
6	✓	
7		✓
8		✓
9		✓
10	✓	
11		✓
12	✓	
13	✓	
14	✓	
15		✓
16	✓	
17		✓
18	✓	
19		✓
20		✓
21	✓	
22	✓	
23		✓
TOTAL	<u>12</u>	<u>11</u>

III.7 Tally the number of "acceptable" records. If there are at least as many as the acceptable size required by the tables used in step 5, then the level of treatment with CRT is acceptable. If not, then it is unacceptable.

The final step is to summarize the LQA results on Form 3. The GOAL, MINIMUM LEVEL, SAMPLE SIZE, and ACCEPTABLE SIZE, are all obtained from TABLE 1. The number of acceptable and unacceptable records in the sample are found from the tally sheets of the preceding step. If the number of acceptable records, line 5, is greater than or equal to the ACCEPTABLE SIZE, line 4, then the clinic is considered to be acceptable, i.e., it is meeting the GOAL, line 1. If not, i.e., the number of acceptable records, line 5, is less than the ACCEPTABLE SIZE, line 4, then the clinic is judged to be short of its GOAL.

Figure 3, illustrates the use of FORM 3 and completes the examples started in the preceding figures. The two crucial numbers are the ACCEPTABLE SIZE, which was found to be 15 in TABLE 1, and the number of acceptable records, which was 12. This comes from the tally in Figure 2. Since 12 is less than 15, the clinic in the illustration is considered to be operating below the GOAL of 75% CRT coverage.¹

¹ We can get an estimate of the actual percent coverage by computing; $100 * (\text{number found to be acceptable}) / (\text{SAMPLE SIZE})$.

In the example this would be:

$$100 * (12) / (23) = 52.2\%$$

Keep in mind that this is only an estimate, as it is based on a sample of records, not the complete set. Estimates of percent covered can be used to rank the clinics to help establish priorities among the clinics not meeting the GOAL. These estimates they will not be very useful in distinguishing clinics that are only a few percentage points apart. Differences of 10 percentage points or more probably reflect a true difference, and differences of 20 or more almost certainly arise from true differences in CRT coverage.

FIGURE 3: Illustrative Use of Form 3

FORM 3

Summary of Results of Lot Quality Assessment

1) SAMPLE SIZE (S) 23 (from TABLE 1, column S 1, S 2, or S 3.)

2) ACCEPTABLE SIZE (A) 15 (from TABLE 1, column A 1, A 2, or A 3.)

3) Number of Acceptable Records 12 (from last line of FORM 2.)

4) Number of Unacceptable Records 11 (from last line of FORM 2.)

IV. CONCLUSIONS

This manual has attempted to provide its users with a highly simplified version of LQAs. In order to achieve this simplification we have refrained from using standard statistical terminology and tried to use more descriptive English terms wherever possible. We have reduced the number of tables that would normally be included in a manual on this subject.

Even in this simplified form, it is the authors' belief that the introduction of a carefully planned, structured review of the outcome of health delivery will be a valuable supervisory tool. At minimum it will provide a framework for supervisors to review records and to try and establish appropriate standards. Carried out on a regular basis, LQAS will help supervisors detect clinics in need of special attention and generally help direct their resources to improve service delivery.

The example given in this manual is for an ORT clinic. Clearly LQAs can be adopted in a wide variety of settings. The reference by Lemeshow and Stroh given in the next section discusses LQAs in evaluating vaccination coverage. The reader will no doubt think of many other possibilities. In addition, the reference is provided for a previous Occasional Paper that discusses uses of LQAs and other industrial sampling methods. Unmarked copies of Forms 1, 2, and 3 are provided in the Appendix.

We hope that this manual will prove useful to those facing the difficult job of assessing health care delivery in circumstances where few resources are available for such activities.

REFERENCES

Sampling Techniques for Evaluating Health Parameters in Developing Countries. Lemeshow, Stanley, and Stroh, George Jr. National Academy Press, Washington, D.C., 1988. This working paper contains an introduction to the general concepts of sampling, including LQA. This paper also contains a good bibliography for those interested in further reading in this field.

Industrial Sampling Plans: Prospects for Public Health Applications. Reinke, William A. The Johns Hopkins University, School of Hygiene and Public Health, Institute for International Programs, Occasional Paper No. 2, Baltimore, M.D., 1988.

APPENDIX

16

TABLE 1

Determination of Minimum Level, Sample Size, and Acceptable Size Based on Differences Between Clinics, Need to Focus on Worst Clinics, and Pre-Established Goal

1) BIG DIFFERENCE		YES		YES or NO			NO			
2) FOCUS ON WORST		YES		NO or YES			NO			
	M1	S1	A1	M2	S2	A2	M3	S3	A3	
GOAL	MINIMUM LEVEL	SAMPLE SIZE	ACCEPTABLE SIZE	MINIMUM LEVEL	SAMPLE SIZE	ACCEPTABLE SIZE	MINIMUM LEVEL	SAMPLE SIZE	ACCEPTABLE SIZE	GOAL
95%	70%	13	12	75%	18	16	80%	28	26	95%
98%	65%	16	13	70%	24	20	75%	40	34	90%
85%	60%	19	15	65%	29	23	70%	49	39	85%
80%	55%	22	16	60%	33	24	65%	57	42	80%
75%	50%	23	15	55%	36	24	60%	63	43	75%
70%	45%	25	15	50%	38	23	55%	66	43	70%
65%	40%	25	14	45%	40	23	50%	70	41	65%
60%	35%	25	12	40%	40	20	45%	72	38	60%
55%	35%	40	18	38%	55	26	40%	72	35	55%
50%	30%	38	16	33%	54	23	35%	70	30	50%
45%	25%	36	13	28%	51	19	30%	67	25	45%
40%	20%	33	10	23%	48	15	25%	63	21	40%
35%	15%	29	7	18%	43	11	20%	57	16	35%
30%	10%	24	5	13%	36	8	15%	49	11	30%
25%	5%	28	3	8%	29	5	10%	40	7	25%

Table 2: Random Number Table

03 47 43 73 86	36 96 47 36 61	46 98 63 71 62	33 26 16 80 45	60 11 14 10 95
97 74 24 67 62	42 81 14 57 20	42 53 32 37 32	27 07 36 07 51	24 51 79 89 73
16 76 67 27 66	56 50 26 71 07	32 90 79 78 53	13 55 38 58 59	88 97 54 14 10
12 56 85 99 26	96 96 68 27 31	05 03 72 93 15	57 12 10 14 21	88 26 49 81 76
53 59 56 35 64	38 54 82 46 22	31 62 43 09 90	06 18 44 32 53	23 83 01 30 30
16 22 77 94 39	49 54 43 54 82	17 37 93 23 78	87 35 20 96 43	84 26 34 91 64
84 42 17 53 31	57 24 55 06 88	77 04 74 47 67	21 76 33 50 25	83 92 12 06 76
63 01 63 78 59	16 95 55 67 19	98 10 50 71 75	12 85 73 58 07	44 39 52 38 79
33 21 12 34 29	78 64 56 07 82	52 42 07 44 38	15 51 00 13 42	99 66 02 79 54
57 60 86 32 44	09 47 27 96 54	49 17 46 09 62	90 52 84 77 27	08 02 73 43 28
18 18 07 92 46	44 17 16 58 09	79 83 46 19 62	06 76 50 07 10	55 23 64 05 05
26 62 38 97 75	84 16 07 44 99	83 11 46 32 24	20 14 85 88 45	10 93 72 88 71
27 42 40 64 74	82 97 77 77 81	07 45 32 14 08	32 98 97 07 72	93 85 70 10 75
52 35 28 19 95	50 92 26 11 97	00 56 76 31 38	80 22 02 53 53	86 60 42 64 53
37 85 94 35 12	83 39 50 08 30	42 34 07 96 88	54 42 06 87 98	35 95 29 48 39
70 29 17 12 13	46 33 20 38 26	13 89 51 03 74	17 76 37 13 04	07 74 21 19 30
56 62 18 37 35	96 83 50 87 75	97 12 25 93 47	70 33 24 03 54	97 77 46 44 80
99 49 57 22 77	88 42 95 45 72	16 64 36 16 00	04 43 18 66 79	94 77 24 21 90
16 08 15 04 72	33 27 14 34 09	45 59 34 68 49	12 72 07 34 45	99 27 72 95 16
31 16 93 32 43	50 27 89 87 19	20 15 37 00 49	52 85 66 60 44	38 68 88 11 80
68 34 30 13 70	55 74 30 77 40	44 22 78 84 26	04 33 46 09 52	68 07 97 06 57
74 57 25 65 76	59 29 97 68 60	71 91 38 67 54	13 58 18 24 76	15 54 55 95 59
27 42 37 86 53	48 55 90 65 72	96 57 69 36 10	96 46 92 42 45	97 60 49 04 91
00 39 68 29 61	66 37 32 20 30	77 84 57 03 29	10 45 65 04 26	11 04 96 67 24
29 94 98 94 24	68 49 69 10 52	53 75 91 93 30	34 25 20 57 27	40 48 73 51 92
16 90 82 66 59	83 62 64 11 12	67 19 00 71 74	60 47 21 29 68	02 02 37 03 31
11 27 94 75 06	06 09 19 74 66	02 94 37 34 02	76 70 90 30 86	38 45 94 30 38
35 24 10 16 20	33 32 51 26 38	79 78 45 04 91	16 92 53 56 16	02 75 50 95 98
38 23 16 86 38	42 38 97 01 50	87 75 66 81 41	40 01 74 91 62	48 51 84 08 32
31 96 25 91 47	56 44 33 49 13	34 86 82 53 91	00 52 43 48 85	27 55 26 89 62
66 67 40 67 14	64 05 71 95 86	11 05 65 09 68	76 83 20 37 90	57 16 00 11 66
14 90 84 45 11	75 73 88 05 90	52 27 41 14 86	22 98 12 22 08	07 52 74 95 80
68 05 51 18 00	33 96 02 75 19	07 60 62 93 55	59 33 82 43 90	49 37 38 44 59
20 46 78 73 90	97 51 40 14 02	04 02 33 31 08	39 54 16 49 36	47 95 93 13 30
64 19 58 97 79	15 06 15 93 20	01 90 10 75 06	40 78 78 89 62	02 67 74 17 33
05 26 93 70 60	22 35 85 15 13	92 03 51 59 77	59 56 78 06 83	52 91 05 70 74
07 97 10 88 23	09 98 42 99 64	61 71 62 99 15	06 51 29 16 93	58 05 77 09 51
68 71 86 85 85	54 87 66 47 54	73 32 08 11 12	44 95 92 63 16	29 56 24 29 48
26 99 61 65 53	58 37 78 80 70	42 10 50 67 42	32 17 55 85 74	94 44 67 16 94
14 65 52 68 75	87 59 36 22 41	26 78 63 06 55	13 08 27 01 50	15 29 39 39 43
17 53 77 58 71	71 41 61 50 72	12 41 94 96 26	44 95 27 36 99	02 96 74 30 83
90 26 59 21 19	23 52 23 33 12	96 93 02 18 39	07 02 18 36 07	25 99 32 70 23
41 23 52 55 99	31 04 49 69 96	10 47 48 45 88	13 41 43 89 20	97 17 14 49 17
60 20 50 81 69	31 99 73 68 68	35 81 33 03 76	24 30 12 48 60	18 99 10 72 34
91 25 38 05 90	94 58 28 41 36	45 37 59 03 09	90 35 57 29 12	82 62 54 65 60
34 50 57 74 37	98 80 33 00 91	09 77 93 19 82	74 94 80 04 04	45 07 31 66 49
85 22 04 39 43	73 81 53 94 79	33 62 46 86 28	08 31 54 46 31	53 94 13 38 47
09 79 13 77 48	73 82 97 22 21	05 03 27 24 83	72 89 44 05 60	35 80 39 94 88
88 75 80 18 14	22 95 75 42 49	39 32 82 22 49	02 48 07 70 37	16 04 61 67 87
90 96 23 70 00	39 60 03 06 90	55 85 78 38 36	94 37 30 69 32	90 89 00 76 33

Source: WHO/CDD/Series81.5, Appendix B, page 31

FORM 1

Calculation of the SAMPLING INTERVAL and STARTING NUMBER

1) SAMPLE SIZE (S) _____ (from TABLE 1)

2) TOTAL NUMBER of RECORDS (T) _____

3) (TOTAL NUMBER OF RECORDS/ SAMPLE SIZE) =

$$(S/T) = (\text{_____} / \text{_____}) = \text{_____}$$

4) SAMPLING INTERVAL (the results in 3 rounded down) _____

5) STARTING NUMBER (randomly selected from TABLE A) _____

FORM 2
TALLY SHEET for STEP 7

Sequence #	ACCEPTABLE	
	<u>YES</u>	<u>NO</u>
1		
2		
3		
4		
5		
6		
7		
8		
9		
10		
11		
12		
13		
14		
15		
16		
17		
18		
19		
20		
21		
22		
23		
TOTAL	_____	_____

FORM 3

Summary of Results of Lot Quality Assessment

- 1) SAMPLE SIZE (S) _____ (from TABLE 1, column S 1, S 2, or S 3.)
- 2) ACCEPTABLE SIZE (A) _____ (from TABLE 1, column A 1, A 2, or A 3.)
- 3) Number of Acceptable Records _____ (from last line of FORM 2.)
- 4) Number of Unacceptable Records _____ (from last line of FORM 2.)

11