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JSI THE JOHN SNOW PUBLIC HEALTH GROUP, INC

210 LINCOLN STREET, BOSTON, MASSACHUSETTS 02111 (617) 482-9485

RECOMMENDATIONS ON THE EVALUATION OF EGYPT'S NATIONAL DIARRHEAL DISEASES PROJECT:

TRIP REPORT

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by

Donald S. Shepard, Ph.D.

Associate Professor

Institute for Health Research
Harvard School of Public Health
677 Huntington Avenue
Boston, MA 02115
USA

Phone (617) 732-1060
Telex 710-320-0315 (c/o HIID)

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Partial List of Persons Contacted

Dr. Lutvi M. El Sayyad, Executive Director, NCDDP

Dr. Norbert Hirschhorn, Chief of Party, John Snow, Inc.
Dr. Jerry Russell, JSI
Ms. Susan Klein, JSI

Dr. Mevat El-Rafai, Chief of Evaluation, NCDDP

Dr. Wafik A. Hassouna, Sinai Consulation Group
Miss La Rue Davis, Sinai Consultation Group

Prof. Mahmoud El-Mougi, Al-Azhar Faculty of Medicine and Bab el Sharea Hospital

Dr. Hosni, Pharmacist, NCDDP
Dr. Ahmed Youssef, NCDDP
Ms. Linda Rowley, NCDDP

Dr. Youssef Tawfik, Strengthening Rural Health Delivery Project

I am grateful to these and other persons who gave their time and assistance during my visit. The fact that so many program activities and surveys were underway after only 1½ years is a tribute to the skills and efforts of all participants in the NCDDP.

SUBCLUSTER COVER PAGE

NUMBER OF SUBCLUSTER: _____

Governate:

Urban: City_____ Sheekha_____

Rural: Markaz: _____ Village:_____ Hamlet _____

Landmark used in center of village or city

Direction from landmark to first house in subcluster:

Distance, number of houses, or landmarks towards first house:

Number of houses counted along chosen direction:____
Number selected for first house in subcluster (from starting point):_____

Name of husband and wife in first house:

Is any household in this subcluster not adjacent to the house that precedes it?

If so, indicate which house(s) and describe their location.

Does this subcluster extend to other villages or hamlets? If yes, specify.

Remarks:

Name of supervisor (Round 1)
Other staff (round 1)
Date (Round 1)

IDENTIFICATION SUBCLUSTER _____ HOUSEHOLD _____ CHILD _____

Name of Father _____ Name of Mother _____

Complete one form for each living child under 3, proceeding from the youngest to oldest child.

0. What is the name of this child ? _____

1. How many birthdays had (child's name) had (what is the age of this child)? (Valid range : 0 to 2).

2. Is (child's name) a boy or a girl ?
   - Boy
   Girl

3. Are you breastfeeding (child's name) ?

4. Has (child's name) has diarrhea within the last 7 days ?
   - Yes
   No
   Don't know

5. If yes, did (child's name) receive ORS ?
   Yes
   No
   Don't know
   Not appicable
   (Interviewer : Show Packets)

GO TO QUESTION 0 FOR NEXT CHILD UNDER 3. WHEN COMPLETED FOR ALL CHILDREN UNDER 3, CONTINUE.

6. What is the highest level of schooling you (the mother) completed ?
   - Did not complete primary
   Primary
   Preparatory
   University
   Other, specify :

7. Have any children under 3 died since last the beginning of last Ramadan ?
   - Yes 1 died
   Yes, more than one died
   No (none died)

8. What was the name of the child that died ?
   IF MORE THAN ONE DIED, ASK : What was the name of the child that died most recently ? DO NOT CODE.

9. How many birthdays had (name of deceased child) had before he (she) died ? (What is the age ?) Valid range 0 to 2.

10. Did (name of deceased child) have diarrhea in any of the three days before he (she) died ?

COMPLETE BY OBSERVATION

11. What is your source of water ?
    - Private well or tap inside the home or directly in front.
    Private or shared tap outside the home
    Stream, river or drainage
    Other, specify :

12. How is water stored inside home ?
    - In covered container
    In uncovered container
    Not applicable (not stored).

Census of Children - Round 2

IDENTIFICATION

§ All identification items will be entered in advance from round 1
INTERVIEWER : Be sure to use correct form, correct identification detail necessary

SUBCLUSTER NO _____ § HOUSEHOLD NO _____ § CHILD NO _____

§ Name of father _____ § Name of mother _____

§ Name of Child _____

§ Age of Child (at the time of round 1) _____

§ Sex of Child : _____

1. INTERVIEWER : Did you locate the mother or other respondent for this child ?

   - Yes

   - No : Interviewer and supervisor explain below , as much information as possible to locate a respondent (city, adress, relatives, telephone, etc.)
   discountinue interview

2. INTERVIEWER : Determine whether this child is now living or not. (i.e. ask where the child slept, etc)

   - Alive
   Deceased (skip to question 7)
   Can't ascertain . INTERVIEWER : Explain, contact,supervisor, and document

3. If living , did this child have diarrhea within the last 7 days?

   - Yes
   - No

4. Were you breast feeding (name of child) just before(name of child) began having diarrhea ?

5. Did you continue breast feeding during the diarrhea ?

6. Did the child receive oral rehydration solution (ORS) ? (INTERVIEWER: Show Packets)

   GO TO NEXT CHILD

7. In which month did this child die ?

8. Did the child have diarrhea in the 3 days before he died ?

   - Yes
   - No
   - don't know

9. Were you breast feeding (name of child) just before name of child began having diarrehea ?

10. Did you continue breast feeding during the diarrhea?

11. Did the child receive oral rehydration solution (ORS) ?

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ESTIMATING CHILDHOOD MORTALITY

The National Control of Diarrheal Diseases Project (NCDDP) plans to assess the impact of the natioanl campaign against diarreal disease through yearly childhood censuses. Each census will be done in two rounds, covering children under the age of 3 in selected areas. Children will be identified at the first round in May, before the diarrhea season, and then followed up at the end of the summer season in a second round.

Cluster Sample: The NCCPD survey will use an adaption of the method of cluster sampling adopted by the Program for Control of Diarreal Diseases of WHO. The adaptations will be:

- A larger size population - on the order of 10,000 children.
- A narrower age range (children under 3).
- More clusters than 30.
- A plan to use 2 sub-clusters (2 starting points) within each cluster.

Recommended Sample Size. The sample size described below is the minimum recommended based on a combination of practical and statistical considerations. The statistical considerations are a 5% level of significance for a reduction in mortality ("one-sided") of 25% and an 80% probability power of detecting the expected 25% reduction (from 27 to 21 deaths per 1000 children during summer season). The practical consideration is that the survey must be done quickly (within the month of May), the numbers of experienced supervisors is limited, and funds have been budgeted for this census.

The recommended sample size is
9,840 children under 3
or approximately 7,000 households,
assuming 1.4 children under 3 in a household with at least one child under 3.
The sample structure is:
164 randomly selected clusters from all governates in Upper and Lower Egypt (excluding Cairo and ALexandria).
Each cluster (generally one village) will be divided into 2 sub-clusters (opposite sides of village or town).
In each subcluster information will be obtained on
30 children under 3 (i.e.0 through 35 months of age).
Each village entails about 43 households and will be completed by the teams in that village in one day.
Thus the total sample is
164 x 2 x 30 = 9,840 children.

The recommended size sample will have a standard error of .0019 (i.e. 1.9 deaths per 1000 children under 3) and a 95% confidence interval of ± 3.7 deaths per 1000. Thus, if the sample observed a rate of 27 deaths per 1000, we could conclude that the true rate was between 23 (~27 - 3.7) and 31 (~27 + 3.7) deaths per 1000. This error is the most that can be tolerated to detect the expected reduction in mortality 21 deaths per 1000. There will also be error in estimating the subsequent mortality.

Larger Sample Size. From a statistical veiwpoint alone, a larger sample size of 13,500 children is recommended (225 clusters, with 2 sub-clusters and 30 children per sub-cluster). With this size sample, the power would be 90%. That is, we will be 90% sure of detecting a reduction in mortality if it is at least as large as predicted. This larger size also provides a greater margin in case the "cluster factor" proves larger than our optomistic estimates. The higher power requires a 39% bigger sample. Its feasibility has not been assessed. Because Egypt's national campaign offers a practically unique experience to assess the effects of ORT on mortality, this larger survey should be carefully considered. While accuracy for detecting change beteen surveys could be increased somewhat ex post by taking a much larger sample for the second survey, the process faces rapidly diminished returns and escalating costs. For example, doubling the size of a second survey is equivalent to raising the size of the first and second surveys each by one third. The former alternative raises the number of interviews by 50%, whereas the more universal approach raises the number by 33%. Thus there are payoffs to good baseline data.

Derivation of Sample Size. The required sample size (n) depends on the expected difference(s) the investigator wished to detect and the degree of statistical confidence he requires.

$$n = (z_\alpha - z_\beta)^2 \frac{\delta^2}{\sigma^2} CF.$$

Here Z_α and Z_β are the standard normal variables corresponding to a significance (one-sided) of α and power of β.

Here σ^2 is the variance in the mortality rates, R. According to the Poisson model σ^2 = R = mean rate (coverage of before and after). A slightly more precise formula is to replace $2\sigma^2$ by $p(1-p) + p^1(1-p^1)$ where p is the initial (higher rate) and p^1 is the subsequent (lower) rate.
Here CF = cluster factor, a factor that adjusts for the fact that cluster sampling is less precise than a simple random sample of the same size. It can be derived as CF = 1+ (n-1)K where K is correlation within a sub-cluster $1 + (n-1) Rcv^2$ where cv^2 is the coefficient of variation of means among sub-clusters.

We set + .05 (required level of significance one-sided z + 1.645) so the study would satisfy conventional levels of significance. We consider two alternative levels of statistical power: 80 percent and 90 percent, for a power β = 90%, $Z\beta$ + 1.282. For a power β = 80%, $Z\beta$ + 0.842. In the experience of WHO's CDD program, CF is 2 to 3*presumably with a cluster

* For derivation of cluster factor, see A. Donner, N. Birkett, and C. Buck. Randomization by Cluster. Am., J. Epidemiol. 1981; 114: 906-914. Setting n to 90 and CF to 2, we find K =.011.

size of N = 90 (letter from Dr. R.H. Herniman to Dr. Hirschhorn, 9 March 1984). With a smaller cluster size, CF declines. We set the baseline rate R = 27 per 1000 (70% of the annual diarrhea rate) and = (1/4R = 6.25 per 1000.

Tradeoffs between cluster size and number of clusters. For a power of 90%, a simple random sample of 10,220 would be required. With cluster sampling, a larger sample is required. Each of the following combinations has the same accuracy as a sumple random sample of 10,220 (the sample size corresponding to a 90% power):

Sub-Cluster size	Number of Clusters	Total Children	Additional Children to Avoid One Cluster*
30	225	13,480	
			27
40	183	14,606	
			44
45	169	15,208	
			66
60	142	16,997	
			123
90	114	20,442	

The latter column permits the choice of the most cost-effective sample design. In the opinion of Dr. Wafik Ashraf Hassouna, it is a sub-cluster size of 30. Use of an initial cluster factor of 3 but a lower power (= 0.8) gives similar results with N = 60, but the number of clusters decreases more slowly as cluster size falls. With a power of 80%, the number of clusters and number of children are each 28% smaller than for a power of 90%, but the tradeoffs in the last column are identical to those above except for rounding.

Selection of Clusters, Sub-Clusters, and Households

Clusters should be selected according to the standard WHO method and sequential sampling based on cumulative population. This method chooses clusters with probability proportional to total population of the cluster. Within each cluster, starting at the village center a direction is chosen at random, and a first house selected at random from among the houses along that direction. This is the first house in the first (odd numbered) sub-cluster within this cluster. While this method theoretically biases the choice of the starting house towards the central location (see footnote to D.S. Shepard below) the method has proved practical in many countries. The innovation in the present study is to pick a second subcluster. It should be diammetrically opposite the first sub-cluster. If the first was NW of the center, the second should be SE. If there are no houses in the chosen direction, a new direction should be selected at random. The sample

*This column is calculated by dividing the difference in number of children by the difference in number of clusters between successive rows. For example, $\frac{14,606 - 13,480}{183 - 225} = \frac{1126}{-42}$ = (ignoring sign) 27.

size calculations treat the sub-clusters as if they were completely independent.

Stratification and Weighting. Weighting of samples from different parts of Egypt is not recommended in this survey. In a note*, I showed elsewhere that if expected mortality rates differ among groups, it is theoretically desireable to oversample the group with higher mortality, because it also has higher expected variance. If one group has twice the mortality of another, the higher group should be oversampled in proportion to the square root of its variance (i.e. $\sqrt{2}$), or oversampled by 41%. In this application, however, using two possible strata (Upper and Lower Egypt), the gain in efficiency is only 3% assuming the relative mortality estimates are correct. In my opinion, this gain does not justify the added complexity. Furthermore, the gain would be offset by the higher cost of more of the sample in Upper Egypt, where poorer communications might raise the cost per cluster.

To show why the gain from weighting is so samll, assume that the populations of Lower (excluding Cairo and Alexandria) and Upper Egypt are approximately equal. The unweighted sample allocates half of the 164 clusters (82 clusters) to each area. Let R be the expected diarrhea mortality weight in Lower Egypt, 2R be the rate in Upper Egypt, and 1.5R be the average rate. Then the variance in the estimated mortality rate is:

$$1.5\left(\frac{1}{82} + \frac{1}{82}\right) \quad R\frac{1}{2}\left(\frac{1}{\text{sub-cluster size}}\right)\left(CF\right)\left(\frac{1}{\delta^2}\right)$$

$$= .0019^2,$$

obtained by setting R = 18 per 1000 (so 1.5R = 27 per 1000), sub-cluster size = 30, and CF = 1.319. The weighted analysis would allocate 66 clusters to Lower Egypt and 93 to Upper Egypt for an identical variance of

$$1.0\left(\frac{1}{66} + \frac{2}{93}\right)(\text{other factors}) = .0019^2.$$

The reduction in 5 clusters (from 164 to 159) would require 11 additional clusters in Upper Egypt, plus additional analytical complexities.

Comparison With Preliminary Calculations. A previous calculation suggested that the sample size for such a survey required only 9,000 children, based on the same power (β = 0.8) but on a higher significance (two-tailed level of α = .05), and on the assumption that a weighted stratified sample could have allowed a one-third reduction in sample size. As discussed above, stratification according to expected risk in fact would have afforded only a 10% reduction in sample size, but probably little or no savings in cost, as more interviews would have been needed in Upper Egypt under more adverse conditions.

*Shepard, D.S. "Cluster sampling for estimating total and diarrhea-associated mortality rates." Mimeo. Boston: Harvard School of Public Health, July, 1982.

If the sample size were restricted to 9000 using the cluster structure above, the power would be only about 75%. That is, the project might spend over 0.5 million L.E. on household mortality surveys but still face a 25% risk that the evaluation shows no "significant" change in mortality because the sample size was too small. The recommended sample size limits the risk to 10% (higher size) or 20% (minimum).

Procedures for Identifying Households for Household Censuses. As this is a two-round census, households need to be identified with sufficient precision that the identical household can be revisited approximately six months later. Suggested procedures are:*

1. Fill out the cover page for each sub-cluster very carefully, completely, and legibly. It gives directions to the first household in the sub-cluster, and to any other house not adjacent to its predecessor. As soon as possible, make a photocopy of this page and store separately.

2. Code the identifying names into the computer or handcopy them onto forms for round 2. (This includes names of parents and the child under 3).

3. Give a present to the household (e.g. some household utensil) not related to the project. Write the household number on the present and paint the household number on or near the door of the house (with the household's permission). Assuming that 25 households will suffice to yield 30 children in most sub-clusters, these gifts can be pre-printed with the numbers 1 through 25. The team will be given some blank items with a waterproof marker to use when needed (numbers missing or outside expected range).

4. Sketch a map of the village showing the location of each house in the sub-cluster.

5. Make the survey forms and cover sheet available to another contractor hire to do KAP studies. The latter contractor should choose a random sub-sampl (of approximately 500 households) and verify the household location, names and the items from Round (except those that change (such as history of diarrhea). Any sub-cluster found to have serious error should be recorded or resurveyed immediately.

6. Consult demographers, epidemiologists, or census takers for additional suggestions, and incorporate where appropriate.

7. Assure that the investigator has the supervisors to execute a survey of the size planned. If necessary, subdivide the work so that different organizations can work in different parts of the country. A preliminary estimate suggests that this survey requires 32 teams in 8 groups of 4. Each group of 4 teams can cover two subclusters with 60 children in one day. Altogether, the work requires 20½ working days, doing 8 clusters per full day (20½ x 8 = 164).

* Some procuedures can substitute for others. For example, preprinting of names onto the forms can probably avoid painting of numbers on the house.

ANALYSES OF TWO-ROUND CENSUS OF CHILDREN

Mortality Estimates. The most important results are mortality rates prospectively determined during the summer diarrhea season. These rates are:

Diarrhea-associated death rate =

$$\frac{\text{The number of children who reportedly died between Rounds 1 and 2 with diarrhea present in the 3 days preceding death}}{\text{number of children covered (i.e. household interviewed on Round 2)}}$$

Child mortality rate (all causes) =

$$\frac{\text{Number of children who died between rounds 1 and 2}}{\text{Number of children covered on Round 2.}}$$

Child loss rate (all reasons) =

$$\frac{\text{Number of children not found (dead, lost, not known)}}{\text{Number of children covered on Round 2}}$$

Additionally, the survey will provide retrospective estimates of mortality from the respondent's self report on Round 1. (This corresponds to the method being tested by WHO.) Comparing results for these two methods will indicate whether the one-round census is usable in Egypt or whether there is substantial underreporting.

Predictors of Mortality. Predictors of mortality can be examined one at a time by computing the mortality rate within each respnse category of a variable. Taking the category with the lowest mortality rate as the reference, a risk ratio can be calculated. Multivariate analyses can be made through multiple regression analysis by transforming predictors to "dummy" (0 or 1) variables. Responses must be combined, and non-responses excluded or grouped with the most likely response. Outcomes: child died; child died with diarrhea present. Predictors: age, sex, area (Upper or Lower Egypt), mother's education, breast feeding, source of water, storage of water. If project officials wish, they could send the data to the U.S. for more sophisticated statistical analyses using logit, Cox regression, or log-linear contingency tables.

Other Analyses. The questionnaire has been developed to provide data for the following additional analyses:

- Incidence of diarrhea (in 1 week) in May (Round 1) and November (Round 2)
- Prevalence of breast feeding
- Relation between breast feeding and incidence of diarrhea

- Rate of reported use of ORS before and after summer campaign (use living children in Round 2)

- Effect of breast feeding and its continuation on case-fatality rate of diarrhea-associated illness.

- Distribution of baseline predictors (water source, water storage, mother's education, etc) by one area and for entire sample.

- Case-control study of effect of ORS on case-fatality rate of diarrhea (from Round 2)

- Bias in the procedure for selecting the first house in a sub-cluster.

The location of the starting house in each of the 328 sub-clusters will be determined as a proportion of the distance to the edge of the village. It is the number of the randomly selected house divided by the total number of houses along the chosen direction, a fraction between 0 and 1. If bias is present, lower fractions will be associated with more favorable conditions (more education, better access to water, lower incidence of diarrhea, etc). One comparison is deliberately excluded because it would be misleading: change in breast feeding between Rounds 1 and 2. All the children in Round 2 will be older at Round 2 and some will have been weaned. In this census, no younger children are being entered at Round 2, so the reported rate of breast-feeding will be lower. Another comparison could have been made by adding additional questions: whether a change occured in the extent to which women stopped breast feeding during diarrhea. A series of knowledge - attitude-practice (KAP) surveys could get at this change. We have not added them to the census of children, however, because these issures are being covered in greater depth (though over a more limited geopgraphical area) in other surveys.

COST OF ORT ACTIVITIES

The subject of a "cost-benefit" or "cost-effectiveness" analysis divided into several parts.

> Cost-benefit would entail assigning monetary values to health outcomes. This process is problematic and not appropriate for the NCDDP.
>
> Cost-effectiveness entails quantifying the impact of the NCDDP. I believe the "chain of events" in the "evaluation framework" provides the appropriate approach. Among the important indicators of success are:
> - number of diarrhea - associated deaths averted annually (derived from mortality surveys)
> - number of cases of diarrhea treated with ORT annually (and increase over baseline).
>
> Cost analysis entails computing the cost per case and cost per capita of a diarrheal disease treatment program.

The following model shows guidelines, discussed with Dr. Mevat to the extent that time permitted, for obtaining cost information from at least two health facilities in each governate.

Hiring of Cost Analyst. A person experienced in health of public administration needs to be hired as cost analyst. That person will guide the cost analysts nominated by each coordinator in a governate and carry out studies in Cairo. Dr. Mevat does not have time for such tasks herself.

Model for Estimating Costs

1) Ask directors general to nominate a co-worker "cost-data coordinator" from his governate attend mtg in Cairo. (rural health units)

2) Coordinator selects two government health facilities from his governate
   Fully implemented: -center has equipment, trained personnel, functioning well.
   Not fully implemented: -similar center, but with less use of ORT
   Coordinator asks center to keep detailed records about diarrhea cases. (separate record developed).

3) Data from each center.
   a) salaries for one year: (e.g. year ending June 30, 84)
      -type and number of personnel and annual regular salaries.
      -bonuses if any
      -overtime and other payments, if any.

   b) other expenses (excluding food and excluding drugs).

-water
-electricity, etc.
Note: food not relevant and drugs analyzed separately.

c) ORS:
quality of ORS used in aggregate:
compute by determining total amount supplied.
less quantity on hand at end of season.

d) Other drugs used for cases with diarrhea (including conmitant problems).
-antibiotics e.g* chloramphenicol
-antipyretic
-antiemetic

1. need the limit cost to RHC per course of therapy (available NPCCCD protocol)

*e.g. ampicillin, Keflex, Teramycin, chloramphenicol

2. need to determine: drug, mode of administration, total

3. amount given by RHC

e) Total visits of all types to RHC.

f) Number of diarrhea visits to RHC.

4) Proposed form for gathering cost informatio The register on the following page, designated to be used at <u>selected</u> imp ent and outpatient facilities that treat diarrhea, provides a mechanism for utilization of services hospitals (days and visits) and major supplies (ORS and drugs). To obtain costs average per case, multiply average utilization by corresponding unit costs.

Proposed Registers for Computing Costs of Treating a Case of Diarrhea

Instructions: Use register in a health facility in which ORT activities have been extensively implemented, and in a similar facility in the same governate in which ORT activities are not yet extensively implemented:

	OUTPATIENT REGISTER				Other drugs			
Name, age, sex, date	Number of outpatient treatment visits		Number of ORS cups at facility	Number of ORS packets for home	Name	Dose	Quantity	Unit Cost	Total Cost
	[space, totals]								

	INPATIENT REGISTER				Other drugs			
Name, age, sex, date of admission	No. of Days stay	Cups of ORS	Number of ORS packets for home	Number of IV bottles	Name	Dose	Quantity	Unit Cost	Total Cost
	[space, totals]								

Computations: For cost analyst: Compute cost of a treatment visit and a day of stay from annual (or monthly) salaries and volume of services. Determine unit costs of ORS and drugs from supply manuals. Compute cost of a cup of ORS by adding cost of packets of ORS used at facility (valuing UNICEF 1-litre packets at international cost of $0.08/packet) and dividing by cups administered. Use average over a day or week.

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COMMENT OF MEDIA EVALUATION

The "chain of events" in the evaluation framework provides an appropriate basis for media evaluation. It suggests the following steps:

Task	Criteria	Evaluator
1. Were messages and materials of adequate quality and quantity provided? Produced on schedule?	contract between producer and NCDDP to spell out.	NCDDP to monitor contract compliance. Can withhold, delay, or reduce payments for non-compliance.
2. Were messages distributed, printed, broadcast on schedule in right quantity, etc.?	same as above	same as above
3. Did messages transmit desired knowledge and lead to changes in behavior (regarding ORS, etc.)?	Goals of project. Change from baseline.	An evaluation contractor should conduct KAP surveys on randomly chosen households.*

*Preliminary suggestion on household surveys.

1. Use cluster survey method.
2. Conduct in 2 areas - good TV reception and poor TV reception (mixture of several clusters for each). to see separate contribution of TV.
3. Two rounds in each area (before and after) but do not revisit earlier households. Choose new ones.
4. Sample size of M =400 households per area. Gives max width of confidence interval of I5%.
5. Will try to have further thoughts by early June '84.