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INQUISIVI, BOLIVIA
TECHNICAL REPORT

September 24-October 6, 1990

Alfred Bartlett, Johns Hopkins University, INCAP

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**Report Prepared for the
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ACRONYMS USED

CDC	U.S. Centers for Disease Control
DJC	Proyecto de Desarrollo Juvenil Comunitario
JSI	John Snow Incorporated
NGO	Non-governmental organization
PROCOSI	Programa de Coordinación en Supervivencia Infantil
SCF	Save the Children Foundation

EXECUTIVE SUMMARY

At the request of Save the Childrens (SCF) Federation, Bolivia, with the support of the MotherCare Project and with the approval of USAID-Bolivia, the consultant visited Bolivia during the period September 24-October 6, 1990. The principal goal of the consultancy was to develop with field personnel responsible for community level activities related to the MotherCare-supported maternal and neonatal health project a retrospective study to identify risk factors and probable causes associated with maternal, perinatal and neonatal mortality in the area where this project will be implemented. An additional goal was to provide information regarding maternal, perinatal, and neonatal morbidity and mortality, derived from comparable studies in Guatemala, to the SCF headquarters staff, and key professionals from other non-governmental organizations working in Child Survival activities. Finally, the consultant was requested to assess the potential usefulness of the existing SCF data registration system for monitoring and evaluation of project activities.

The majority of effort during the consultancy was dedicated to participative group work with the field site study team to develop the basis, protocol, data collection instruments, sampling methodologies, definitions, and instructions necessary to implement a retrospective field study in the context of a field team enthusiastic but inexperienced in investigation. The study design incorporates elements of case-control, verbal autopsy, and "process diagnosis" methodologies. In addition, presentations were given to NGO representatives and to the Bolivian Pediatric Society to disseminate the results of the Guatemala studies and raise awareness of maternal/perinatal/neonatal health issues.

Key conclusions of the consultancy were: 1) that the retrospective methodologies could apparently be adapted for use by a field team with technical capabilities but without previous experience in investigation; 2) that successful execution of these studies would require close attention to coordination with other project activities and supervisory attention to demands on personnel time; 3) that the SCF data registration system has the potential capability to track indicators useful for project monitoring and evaluation, but that for it to fulfill this function, additional attention must be paid to identifying, defining, and including appropriate indicators and to data collection procedures at the field level; 4) that if the project should be successful in its community-level consciousness-raising and educational activities, demand for non-existent services will be generated.

In relation to these conclusions, the principal recommendations are: 1) that the ability of the field team to use the structure provided for study implementation be critically assessed, to evaluate the potential usefulness of this approach in other settings; 2) that consideration be given to activity schedules that will permit the two diagnostic components of the project to arrive at their results at about the same time (implying more effort dedicated to the retrospective studies in the next 2-3 months); 3) appropriate indicators for project tracking be immediately identified, included in new instruments, clearly defined, and communicated to field personnel; 4) that options for responding to life-threatening situations in the context of existing resources, and/or the possibility of developing additional resources for these situations, be explored beginning immediately, to avoid a counterproductive creation of demand for services without definition of what services will be available.

II. PURPOSE OF VISIT

A. Rationale

Experience gained in applying retrospective case-control and verbal autopsy methodologies to the study of intrapartum and neonatal mortality among traditional rural indigenous families in Guatemala, and subsequent validation, suggested that these methodologies might be useful in other developing communities. The MotherCare Project identified the Save the Children-Inquisivi Impact Area (SCF-Inquisivi) project as a site where these methodologies might provide information important in the development of the intervention phase of the project. It was also felt that exposure to the results of the Guatemala studies and to the interventions that have been designed based on these studies might help SCF and other NGO's working in child survival activities in Bolivia to focus their activities in maternal, perinatal, and neonatal health.

B. Scope of work

Work with Save the Children/Bolivia staff to plan and prepare for implementation of a retrospective case-control study of intrapartum/neonatal deaths in the Inquisivi impact area. To carry out this work the Consultant will:

1. Compile or adapt materials on the case-control methodology and the protocol developed and used in Guatemala in a form appropriate for the orientation of SCF medical and nursing staff.

2. Provide an initial briefing for SCF and other NGO and government officials on the case-control and prospective studies carried out in Guatemala and the interventions designed as a result of these studies.
3. Work with SCF staff in Inquisivi to adapt the Guatemala case-control protocol to the local reality. This will include developing a locally appropriate questionnaire (for verbal autopsy and investigation of maternal factors and mortality related events) and field testing it.
4. Develop the sampling procedure to be used for the study based on information available in the SCF information/family surveillance system and train SCF staff to select and supervise the case-finding effort.
5. Standardize SCF staff who will be involved in the collection of information to the sampling procedures and administration of the questionnaire(s).
6. Develop the workplan and schedule for data collection, data entry and data analysis with SCF staff and MotherCare's Bolivia Representative.

7. Provide SCF staff with the software used to create the study data base and either provide them with an orientation to its use. Or, if time does not permit or SCF staff are not judged capable of this task, identify and orient a local advisor who can work with SCF to supervise data cleaning and entry and data base management. Work with the MotherCare Bolivia Representative to develop a scope of work and estimated level of effort for this individual and submit to MotherCare with CV and Biodata Form.

8. Prepare and submit a written report of the consultancy including: 1) the materials used for orientation of SCF staff to the case-control methodology and protocol; 2) sampling procedure and justification; 3) workplan and schedule for data collection; 3) scope of work for data base manager, if necessary; 4) plan for analysis of study data; and 5) recommendations for use of prospective data collected through SCF information system for monitoring and evaluation of project interventions.

C. Objectives

1. Orient SCF-Inquisivi project staff to the steps required in development and implementation of a retrospective community-based study.

2. Assist SCF-Inquisivi staff in development of a protocol, procedure for identification and selection of study subjects, data collection instruments and guides, and standardization procedures, adequate to permit the realization of such a study in the SCF-Inquisivi Impact Area.
3. Review the SCF data management capabilities for support of such a study, and assist SCF data managers and study team in identification and utilization of appropriate software, data quality control procedures, data entry and cleaning routines, and analysis plan for study data.
4. Orient the SCF senior staff, and the representatives of other NGO's working in Child Survival activities in Bolivia, to the retrospective and prospective methodologies used in Guatemala, and to the results of these studies, to support the development of activities oriented toward maternal, perinatal, and neonatal health.
5. Evaluate the possible use of data presently being collected through the SCF community/family data registration system (or able to be collected through that system), for monitoring and evaluation of project activities.

III. BACKGROUND

Bolivia is one of the countries with the highest reported rates of maternal, perinatal, and infant mortality in the hemisphere. The recent Demographic and Health Survey identified an infant mortality rate of about 100/1,000 live births, with roughly 40% of this mortality occurring in the neonatal period. It is virtually certain that maternal, perinatal, and infant mortality are substantially underreported.

In general, Bolivia does not have a well developed health care delivery system in the areas outside the capital. The population is extremely disperse, living in wide areas of difficult terrain (dry altiplano areas, subtropical and tropical forest). Many births are reportedly attended at home by family members, including husbands; even empirical midwives are not commonly encountered attending births in many regions of Bolivia. However, especially since the 1952 revolution, Bolivia does have a strong tradition of community organization, especially of men's groups such as sindicatos and cooperativas.

Against this background, the Save the Children Foundation has developed several major integrated development projects in Bolivia, including one in the Impact Area of Inquisivi. This area, located about five hours south of La Paz at the margins of the altiplano region, has been selected as the site for a major MotherCare project focused on development of women's groups, trained community birth attendants, and broader community education programs to improve management of pregnancy,

labor and delivery. The implementation of these activities will occur through the strong community-based infrastructure which the SCF methodology encourages and reinforces.

As part of this project, two complementary approaches are planned for diagnosis of the principal existing maternal/perinatal/neonatal health problems in the area. One is the development and administration by mothers' groups in selected areas of a "self-diagnostic" survey for their own communities. The second, more technical in nature, is the elaboration of a case-control study of perinatal and neonatal deaths in the participating population, combined with a verbal autopsy study of cases to identify the principal conditions and illnesses resulting in this mortality.

This consultancy was concerned with the latter component of this diagnostic process.

IV. TRIP ACTIVITIES

The activities realized are best described in temporal sequence and in relation to the objectives described in Section II of this report, as follows:

- A. Preparation of materials to orient SCF and other personnel to the case-control methodology and to the Guatemala study protocol (Objective 1). Prior to departure from Guatemala, the consultant prepared a detailed, "user-friendly" guide to the case-control methodology, written in Spanish. This guide explained the basic principles of epidemiologic investigation as applied in the case-control methodology, and detailed the process and reasons for

definition of study objectives/hypotheses, definition of the study population, definition and selection of the cases and controls, instrument development and data collection procedures, sources of error and bias and how to avoid them, and general principles of analysis of case-control data. A resumé of the Guatemala case-control and verbal autopsy retrospective study was also prepared, following the framework elaborated in the guide, to serve as an illustration of how these steps were applied in an actual study. Copies of these materials are included as Appendix 1.

B. Orientation of SCF senior staff and personnel of other NGO's to the case-control and verbal autopsy methodologies and the results of the Guatemala studies (Objective 4).

On the second day in-country, the consultant gave a half-day workshop which included the SCF Director, the SCF staff physician in charge of maternal-child health activities, as well as representatives of other NGO's working in USAID-sponsored Child Survival activities. The workshop was organized by and held at PROCOSI, the umbrella coordinating group for these NGO's which is administered by SCF.

This workshop used the Guatemala studies to discuss the methodologies used and illustrate the types of results that can be obtained from such studies, as well as to present the actual results of these studies. The participants received copies of the

guide to the case-control methodology and resumé of the Guatemala studies. A list of participants in this workshop is included as Appendix 2.

As a product of this workshop, the consultant was offered the opportunity to present the same materials in a scientific session of the Sociedad Boliviana de Pediatría, the major professional association of pediatricians in La Paz. This presentation was given upon return to La Paz from the Inquisivi study site, and resulted in substantial interest and positive discussion of the applicability of the study findings and of perinatal and neonatal mortality issues to the Bolivian situation.

C. Development of study protocol, data collection instruments and guides, sampling methodology, and data management/analysis procedures for the SCF-Inquisivi project (Objectives 1-3).

This set of activities was the major focus, and accounted for the majority of time, of this consultancy.

On day 3 in-country, the consultant travelled to Inquisivi, site of the SCF Impact Area headquarters, in company with the JSI/MotherCare in-country representative and the physician recently hired as Project Coordinator for the MotherCare Inquisivi project. Upon arrival, a meeting was held with field site staff who will be principally responsible for implementation of the diagnostic and intervention phases of the project (physician in charge of Inquisivi MCH activities; project graduate nurse and health educator). This meeting focused on review of field

activities since the development of the annual work plan. These activities included several that were of importance in designing the case-control study, including focus groups and interviews with mothers and midwives regarding problems and treatments during pregnancy, labor and delivery.

The following day began a five day long process of group work to develop the study. This process was totally participative in nature and was intended to give the field team an in-depth understanding of the study design and methods and a sense of "ownership" of the study, as well as to assure that the study responded to the needs and realities of the Inquisivi situation. The process is described more completely in Section V of this report ("Methodology").

The products of this process were the study protocol (Appendix 3) and data collection instrument (Appendix 4); a question-by-question guide for standardization of the application of the instrument was developed simultaneously, and was being prepared in final draft at the time of the consultant's departure; this guide will also be forwarded to MotherCare when a copy is made available to the consultant. The data collection instrument and guide may be subject to (probably minor) modification based on the process of field testing which will immediately follow the departure of the consultant.

Based on the assessment of the JSI/MotherCare Bolivia representative and the consultant, it was perceived that, while technically excellent in their respective areas and enthusiastic

about participating in the diagnostic phase of the project, the field study team lacked a grounding in the basic principles of epidemiologic investigation which would serve to guide them in study development and in avoiding errors and bias during study execution. For this reason, this entire first day was spent in a "workshop" on basic principles of epidemiologic investigation and of case-control studies (following the guide, which was also provided to them for later reference). The Guatemala studies were again presented to illustrate the principles discussed and to show the team the types of results that could be derived from the case-control and verbal autopsy methodologies. The Guatemala results also served to bring into focus the degree of specificity (eg. specific practices, specific conditions of illnesses, specific characteristics) that would be most useful as diagnostic phase inputs to the intervention development process.

All the essential elements of the study design and execution plan, except for data management issues, are included in the protocol. Key elements are briefly described below:

1. Study objectives. Clearly defined objectives for the study in the context of the MotherCare project were developed with the group. This step was essential, because frequently (for enthusiasm and lack of experience in investigation) one or more group members would suggest elements of design or of data to be collected that would be extraneous to the central purpose of the study. The use of the defined, written

objectives as reference points in deciding about the appropriateness of such elements was repeatedly reinforced.

2. Study design: As planned, the study is designed to examine risk factors (including characteristics and practices) in relation to risk of prepartum, intrapartum and neonatal infant mortality using case-control methodology. The study is also designed to obtain retrospective diagnoses of probable causes of this mortality through the data regarding pregnancy, labor, delivery, and newborn condition at birth obtained in the case-control component, and the data collected during the verbal autopsy performed on cases.

In addition, the design incorporates a "Process Diagnosis" component which intends to identify the problem recognition, decision-making, logistic, or service delivery failures which were associated with each case. This operative evaluation component may provide important input in deciding which "system failures" are most prevalent in cases of maternal, perinatal, and neonatal mortality, and are thus expected to further inform the intervention phase. In addition, this component, combined with the verbal autopsy, can continue to be administered during the course of the intervention in order to monitor the success of intervention activities, identify areas where additional

attention is required, and identify the emergence of obstacles further along in the decision-making/response sequence as earlier obstacles are overcome.

The team was enthusiastic about this "process diagnosis" element, recognized its value in regard to the planned intervention as well as in evaluating other maternal child health "systems failures" (eg. child deaths due to diarrhea in their area, where an active ORT program has been in place for several years). The usefulness of such a systematic model in anticipating problems in the steps to receiving adequate care was also discussed with the field team and the SCF director and central staff.

3. Study Population. Based on estimates of numbers of cases anticipated, it was recognized that to give reasonable statistical power to the study, all cases from all three subareas of the Inquisivi impact area would have to be included, for the two preceding years. This recall period is the same as that used and subsequently validated in the Guatemala studies, and is believed by the consultant to be both acceptable and necessary. The basic source for identification of cases will be the sub-area registers of the SCF project. However, the project promoters and other resources will be used to identify and verify possible additional cases without slowing down study implementation.

4. Definition of cases and controls. Exact definitions were developed for two subclasses of infant case ("born dead" and "neonatal death") based on the classification presently used in the SCF registry system. Once case data have been collected by the study, a more meaningful subclassification of cases may be developed. A case definition for maternal mortality was also established, since cases of maternal mortality will be studied to provide descriptive, cause of death, and "process diagnosis" information; these cases will not be included in the infant case-control study and will not have controls.

The definition of both cases and controls specified that they should be identified among families participating in the SCF-Inquisivi ("DJC") project. This is important because, although it might be possible to identify additional cases outside the project, there is no adequate register of non-project liveborn and neonatal survivor children from which to randomly select controls. Including such cases without an adequate source of controls could result in an important bias in the data.

5. Selection of controls. The team was instructed in the principles and the actual application of random sampling of controls from the SCF registers. To give additional statistical power to the only moderate number of cases, it was decided to select two controls per case, plus a reserve

sample (also randomly selected). The procedure and criteria for replacing a control to minimize bias in sampling were defined.

Because of differences between the three sub-areas, and (especially in the newest sub-area, Licoma) between the two past years, it was decided to use random selection of controls stratified by sub-area and by year.

Using a table of random numbers and the Inquisivi sub-area registers, the actual sample of controls for that sub-area for the period 20 November 1988 - 19 November 1989 was selected by the group with the consultant present. The control samples for the other year and sub-area strata will be selected by the group using the same procedure, once the sub-area registers are brought to Inquisivi (or they review them in the course of visits to other sub-area offices.)

6. Data collection procedures. As noted, a guide regarding the purpose, codes, and intent of each question was developed simultaneously with the development of the instrument. Since the group working in this study development process included the two persons (the nurse and health educator) who will be responsible for data collection through interviews with the mother of each case or control infant, this process served to orient them and clarify the use of each question and its associated codes.

In addition, a role-playing exercise was conducted with the group, in which one of the field interviewers (the health educator) conducted a complete interview of a "mother" (the nurse). This was an initial practice and standardization exercise, which will be repeated one or more times by the team immediately following the consultant's departure. Additional standardization and detection of needs for instrument modification will be developed through team interviewing of a number of non-study mothers, with feedback to the study team. Any modifications to the instrument will require restandardization and modification of the guide.

The physician Field Coordinator will develop definitions and standardization exercises regarding symptoms and conditions of pregnant women and newborns, especially for the health educator, whose clinical background is less extensive than that of the nurse.

Additional pretesting of the instrument will be carried out through interviews of non-study mothers, prior to implementing actual data collection.

Criteria for diagnoses. The specific (vs. open) content of the verbal autopsy is based on the groups' decisions regarding diagnoses that would likely be encountered and symptoms that mothers could probably identify with acceptable accuracy. Based on these elements, and on other

information regarding each case's clinical history that would be developed through the interviews, criteria were defined by the groups as guidelines for their own use in assigning each diagnosis.

8. Data quality control and management. Upon return from the study site to La Paz, the consultant met with the SCF information system manager to discuss study data management. The following points were concluded:

- a. The printed instrument was developed, and the data will be entered and analyzed, using the EPI-INFO 5.0 program developed by the U.S. Centers for Disease Control (CDC).
- b. Data will be reviewed at the field level for quality and assignment of diagnoses in small batches, approximately every two weeks (estimated 45-55 instruments per batch). These will be forwarded to La Paz, entered, and cleaned on a continuous basis to avoid backlog at the end of the study.

The EPI INFO 5.0 program is very user-friendly and is specifically designed to input and analyze epidemiologic and other study data. However, none of the SCF staff have direct experience using this program. Therefore, the

consultant met with Dr. Joel Kuritsky, a former colleague at CDC who is now working in Bolivia under the CDC-administered Technical Assistance for Child Survival (TACS) Program, and who is participating in the PROCOSI coordinating group. Programmers and managers of Dr. Kuritsky's program have received training in the use of EPI INFO 5.0 by CDC and are experienced in its use. Dr. Kuritsky offered to organize a short (about two day) training program for SCF staff in use of this program, and to provide problem-solving technical back-up. It was recommended to the SCF director and the data manager that key SCF professionals participate in this training, especially the data manager, the MCH headquarters physician, the Inquisivi MotherCare project Field Coordinator, and the Impact Area MCH physician (the JSI/MotherCare Bolivia representative and her secretary would also be welcome to attend).

Based on this offer, the consultant sees no reason to seek additional data management or programming support for the SCF project.

9. Data analysis. A general analysis plan is included in the protocol. The basic elements are:
 - a. Identification and classification (if necessary) of variables of interest.

- b. Description of study population in regard to prevalences of important characteristics, practices, etc.
 - c. Case-control analysis of risk factor data, beginning with univariate analysis followed by examination of significantly associated factors for potential confounding and for their significance in multivariate analysis with other significant factors.
 - d. Identification of important (from intervention perspective) subgroups of cases, and examination of possible subgroup-specific risk factors and practices.
 - e. Description of prevalences of specific diagnoses, and their frequency in the various subcategories of mortality.
 - f. Description of the frequencies of the various "process failures", in general and in relation to specific diagnoses and subcategories of mortality.
10. Work plan for study implementation. The work plan developed with the study team is attached as Appendix 5. Several aspects are of notice:

- a. Given the disperse nature of the study population, an estimate of two completed interviews per interviewer per day was judged to be realistic. DJC promoters in each community can be used to maximize the probability of completing scheduled interviews by establishing appointed dates for subject mothers to be available for interview in their homes.
- b. Based on this estimated rate of interview completion and number of cases, the data collection phase lasts approximately 9 weeks; with time for pretesting, instrument modification, and analysis, the total study duration is approximately 3.5 months if full time of the interviewers is dedicated to this activity.
- c. In reality, several additional MotherCare project-specific activities are scheduled for the nurse and health educator during the remainder of this calendar year (eg, two-week midwife workshop; workshop on mothers' group self-evaluation methodology development). In addition, occasional demands are made on them related to their professional roles within the Inquisivi Impact Area health infrastructure. For these reasons, assuming no

additional major commitments, it appears that the data collection phase will terminate in January, 1991, with analysis to be performed in February.

This workplan and schedule, and the issues deriving from it, were revised with the JSI/MotherCare Bolivia representative, who found them to be realistic and consistent with the needs and projected timetable of the Inquisivi project.

- D. Review of SCF data registration system and its potential use for project monitoring/evaluation. In two separate meetings (one before and one after the field site visit) the consultant met with the data systems manager responsible for the programming and management of the SCF information registration system. The field site visit provided the opportunity to review in a limited manner the actual utilization of the data registration system at the field level. It is noted that SCF, partly in response to the emphasis of the MotherCare project in Inquisivi, is in the process of developing revised instruments (which presently exist only in rough draft form) for maternal, perinatal, and neonatal health aspects of the program.

- E. Other activities. Briefing and debriefing meetings were held with the JSI/MotherCare Bolivia representative and with

the Director of SCF-Bolivia. A debriefing was held with the cognizant health officer of the USAID-Bolivia mission.

In addition, the consultant and the JSI/MotherCare Bolivia representative met at length with the wife of the U.S. Ambassador (Lic. Alene Gelbard), who has extensive professional training and experience in population data-based policy development and in development and applications of demographic data in the context of maternal child health programs. Lic. Gelbard is working with the USAID-sponsored Child Survival coordinating group (PROCOSI), and is in contact with other agencies in the country (including the Ministry of Health), to support the use of demographic data in public health planning and in development of useful indicators related to Child Survival and maternal/perinatal/neonatal health activities. Discussion in this meeting focused on these activities, on best possible indicators for maternal/perinatal/neonatal health outcomes, and on the possible relation of findings of the epidemiologic and verbal autopsy data from Inquisivi to the improvement of recognition and measurement of these activities.

V. METHODOLOGY AND APPROACHES

The methodologies used in these activities were the following:

A. Communication with health and public health professionals:

Presentation of Guatemala study methodology and results, followed

by open discussion. [This was the most time-effective mechanism for communication and consciousness-raising regarding these issues].

B. Focused information exchange with responsible decision-makers:
One-on-one meetings with key professionals, including SCF-Bolivia Director, data system manager, etc, often in company of JSI/MotherCare Bolivia representative.

C. Field study team orientation to applied epidemiologic research and development of study protocol, instruments, and guides:
Participative group "workshop" format. Taking advantage of the strong experience of all SCF personnel in such participative methodology, and utilizing this approach to provide in-depth awareness of study plan and implementation issues and "ownership" of the study, necessary to maximize the possibility of success in study execution by this team].

VI. RESULTS AND CONCLUSIONS

In the opinion of the consultant, all of the objectives of this consultancy were able to be satisfactorily addressed. The principal products of the consultancy are the attached study protocol and instrument, and the orientation and support materials provided to the study team for their utilization.

Based on this consultancy, the following conclusions are offered:

A. General

1. The participative methodology oriented around teaching and reinforcement of basic principles of applied investigation can yield a technically and contextually appropriate study design and plan when utilized with a group of interested persons without experience in applied research.
2. Such a process must produce the greatest amount of structure possible to maximize the likelihood of successful study implementation (objectives, protocol, instrument, instructions, criteria for diagnoses, sampling strategies and mechanism, standardization procedures, etc).

B. SCF and Bolivia-specific.

1. To successfully implement the case-control study component of the MotherCare project diagnostic phase, the study team will need support in the assignment of additional study-specific and other responsibilities. The sequencing and distribution of study team members' time needs to take into account the level of effort needed to conduct the case-control study, and the integration of this study into the overall activity plan.
 - a. Since the mothers' groups' "Auto-Evaluación" diagnostic phase will result in a much simpler and

easier to analyze data set, it may be appropriate to "front end load" the study team's level of effort dedicated to the case-control study, using over the next 2-3 months only the time needed to continue the methodology development process for the "Auto Evaluación". Executing the "Auto Evaluación" a bit later (eg. in January or early February) will result in the two diagnostic processes producing their results at about the same time.

2. The SCF data registration system is in general well-designed and has the capability to periodically identify, summarize, and cross-tabulate data items which may be useful in project monitoring/evaluation. This system will probably continue to organize data in the manner generally utilized by SCF, that is, with a basic register for each family and information modules (linked by unique identifier data) regarding important periodic events (pregnancy, infancy, immunization, etc.) Given the present system programs, this design offers no real constraints to utilization of this system for monitoring and evaluation.

However, to be useful in this regard, certain aspects of the system require additional attention:

- a. The variables that would be the principal indicators included in such a monitoring/evaluation process need to be identified now; their inclusion in a useful form in the present or proposed data collection instruments needs to be assured (for example, the draft of the new prenatal control, post-natal follow-up instrument did not contain an adequate data point to identify rates of neonatal mortality among liveborn children).

- b. Adequate definitions for these indicators and other critical variables need to be established. At the field level, it was found that substantial variability and subjectivity may exist in the application of a certain category of response (for example, mothers tend to use the term "aborto" only for first trimester fetal losses, calling later losses "nacido muerto"; field data collection personnel, for lack of tight definitions, may (or may not) apply the terminology of the mother, resulting in a category that is difficult to interpret).

- c. Greater attention must be paid to other elements of data collection at the field level. Review of a large number of past year (1989) data forms identified a substantial number of missing values (blanks). What impact or bias these missing results may produce is

impossible to determine. According to the data managers, more attention has been and will continue to be paid to this aspect of data generation.

3. Substantial interest and a positive attitude exist among at least some health and public health organizations in Bolivia, in regard to identifying and addressing the issues of maternal, perinatal, and neonatal health.
4. In terms of the level of awareness regarding these issues and appropriate response to high-risk or life-threatening maternal or neonatal situations, the population of the SCF Inquisivi impact area is not that different from that of the Guatemala projects. The SCF population actually has better community infrastructure through which to communicate with health promoters, midwives, families, and women. A basic element that is missing from the SCF setting in comparison with Guatemala is a reasonably functional health system at the community and area referral levels.

These similarities and differences have important implications for the MotherCare project and for SCF in the longer run: although the Inquisivi project is not at this point focused on impact, as in Guatemala the anticipated and hoped for effect of its successful training and communication activities has to be increased demand for services, at least for life-threatening situations.

Failure to deal at the present time with this issue, although at this moment outside the MotherCare project scope, could result in creation of demand that can not be met by the health system or by the presently available alternative (including community-level) resources. Such a situation could have medium and long-term negative consequences for the SCF Inquisivi project.

VII. RECOMMENDATIONS

- A. Evaluation of case-control/verbal autopsy/process diagnosis methodologies. In addition to review of the results of these studies in the Inquisivi project, the capability of field personnel not experienced in investigation to execute these studies successfully using the structure developed collaboratively should be critically assessed. These methodologies may prove very useful in other settings if the minimal criteria for their successful implementation can be determined (responsible: MotherCare Bolivia representative, Director SCF-Bolivia, JSI/MotherCare project staff-Washington, [consultant]).

- B. Identification of resource-appropriate responses to improve community/family recognition of high risk maternal and neonatal events. Substantial deficiencies exist in this health system's capabilities to respond to the high-risk situations which the project's community health worker and family education activities will help to detect. Thus, the project should begin examining

immediately the options for responding to these situations, within the context of resources realistically available. Several non-exclusive options exist for addressing this demand:

1. Identification of community-level practices that can respond to certain situations - examples:
 - a. Passive (and possibly if these fail, active) maneuvers to change fetal position in cases of malpresentation detected before labor [therefore, underscoring the importance of at least one third trimester examination and best possible midwife training and backup in diagnosis of fetal position].
 - b. Use of non-pharmaceutical (eg. nipple stimulation, uterine massage) and pharmaceutical (methergine) means to control post-partum hemorrhage.
 - c. Possibilities of treating certain cases of infectious diseases (puerperial infections, neonatal infections) at non-hospital facilities using intramuscular medications, family member participation, breastmilk (feeding by naso gastric tube), etc.

2. Collaborative development of management protocols for cases arriving for urgent hospital attention that can be accomplished without major surgery - examples:
 - a. Protocol for evaluation of post-partum bleeding - retained placental fragments, cervical tears, use of ergots.
 - b. Management of hypertensive diseases of pregnancy.
 - c. Management of major infections in pregnancy, puerperium, and newborn.
 3. Investigation of options to upgrade quality and utilization of possible hospital facilities at district level.
Responsible: Inquisivi project staff, SCF headquarters staff, JSI/MotherCare Bolivia representative.
- C. Identification and definition of key indicators for monitoring and evaluation of project activities using SCF data management system.
- As soon as possible, key indicators should be identified that serve both project-specific and longer-term SCF needs for monitoring and evaluation of maternal/perinatal/neonatal health related outputs and outcomes. Attention should be paid to assuring inclusion of these indicators in the data collection system (and defining the best source of measurement of these

indicators), to developing and communicating standardized definitions of these indicators, and to maximizing the quality of data collected in the field. The proposed strategy of data review feedback sessions with community-level health workers should contribute to these objectives and is endorsed.

VI. FOLLOW-UP ACTION

In addition to the recommendations above, it was agreed with the MotherCare representative that the study team would benefit from additional technical support in the analysis phase. The consultant would be willing to participate in this analysis phase. In addition, computer access and experienced data processing support with rapid turnaround should be lined up for the analysis, possibly through subcontracting a person experienced in analysis of epidemiologic data from the CDC or other group present in La Paz.

PERSONS MET

JSI/MotherCare

-Lisa Howard - Grabman, Bolivia Representative

Save the ChildrensLa Paz:

-David Rogers, Bolivia Project Director

-Robert Grabman

-Dr. Luis Guillermo Seoane F., Maternal-Child Health and Nutrition
Advisor

-Dra. Lilia Cespedes Claure, MotherCare Inquisivi Project
Coordinator

-Joaquín Flores, Data System Manager

Inquisivi:

-Dr. Adolfo Martínez, Physician-in-charge, Child Survival
Activities, Inquisivi Impact Area

-Elsa Sánchez (Graduate Nurse)

-Yolanda Fabon (Health Educator)

-Ignacio Chambi (Health Supervisor)

-Basilio Cach (Health Supervisor)

PROCOSI:

-Dra. Ana María Aguilar

-Meri Sinnitt

U.S.Embassy:

-Alene Geibard

USAID-Bolivia:

-Charles Llewellyn, Public Health Advisor, Div. of Health and
Human Resources

U.S. Centers for Disease Control (CCH/USAID):

-Dr. Joel Kuritsky

Sociedad Boliviana de Pediatría:

-Dr. Eduardo Mazzi G. de Prada (President)

APPENDICES

I. BASIC PRINCIPLES ON EPIDEMIOLOGICAL STUDIES

In general terms, the basic objective of epidemiological study designs and methodologies is to apply a structure which permits the scientifically valid gathering and assessment of information about events or diseases that affect groups of people. This structure, and the discipline's implementation itself, are fundamental to allow one to reach valid and useful conclusions about factors and events which we can study but very seldom control.

The basic elements for the structuring of epidemiological studies are: the application of current knowledge about the phenomena that are to be studied; the gathering of definite and well standardized data; the controlled comparison principle; the recognition of potential sources of error; statistics, and, finally, logic.

II. GENERAL DESCRIPTION OF CASE-CONTROL STUDIES

Among epidemiological study designs (which are structures or frames to apply the basic principles of this discipline), one of the more useful is the "case-control" design.

A. The most important elements of case-control studies are:

1. The identifications of several individuals who have suffered the disease or condition which we wish to study (the "cases").
2. The identification of a group of individuals, comparable to the "cases" BUT who have not suffered the disease or condition under study) the "controls"; and
3. The comparison of these two groups in respect to some factors which the investigator suspects may be related to the risk of suffering the disease/condition (looking for "risk factors").

It is important to note that, with this type of design, the study begins with people who have already suffered the disease or condition, and looks backwards into their past (and into the comparable persons past) for the presence of one or more of the factors under study. For this reason, this design is usually retrospective (looking for information from the past).

PAST	PRESENT	
— — — /// — — —	X	X = CASE O = CONTROL /// = FACTOR (event, circums- tance,
— — — — —	X	
— — — — —	X	
— — — /// — — —	X	
— — — — —	O	
— — — — —	O	
— — — /// — — —	O	
— — — — —	O	

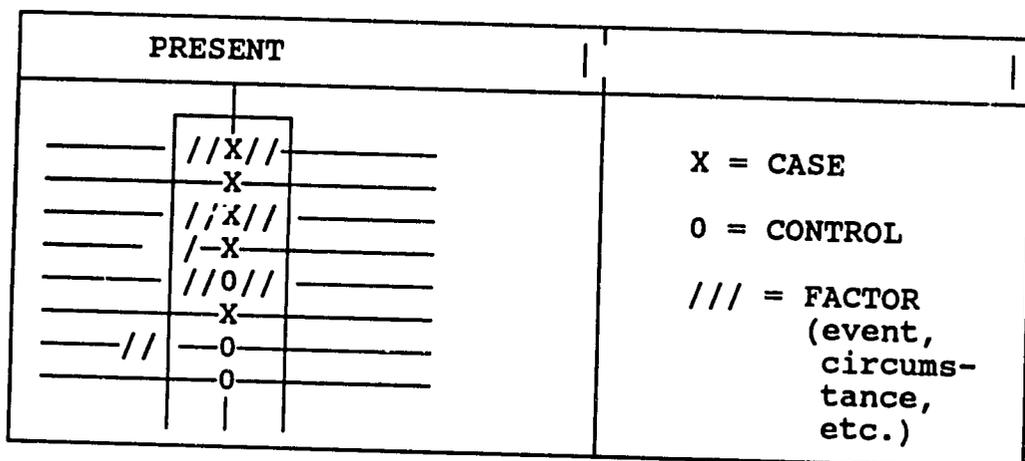
		etc.)
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B. Comparison with other types of epidemiological studies

A. There are other types of epidemiological studies designs. Each one has its advantages, disadvantages and appropriate applications.

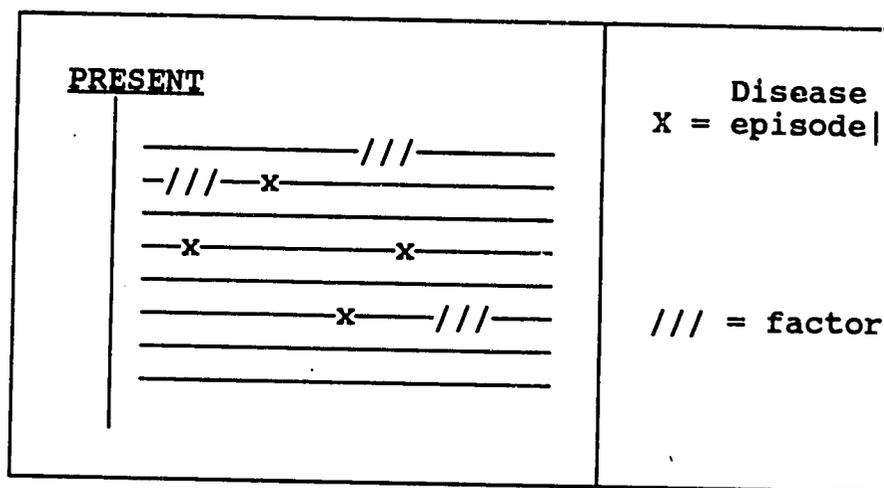
In relation to time, (and bearing in mind that case-control studies dwell on factors that exist in the past, and are therefore "retrospective") the other possible designs are: the "cross-sectional or transverse" and the "prospective" study designs.

1. The cross-sectional study gathers information about the existence of the disease/condition in the present and usually collects additional information about the presence of given factors in the same persons.



This study design DOES NOT begin with knowledge about who those who suffer the disease/condition are. If the disease/condition is not frequent among the population under study, a lot of time and effort is needed to identify or witness the occurrence of "cases". This study design allows us to know the "prevalence" of the disease/condition among the studied persons (i. e., what proportion of the study population suffers from the disease/condition at the time of the study), as well as the prevalence of other factors, and their association with the disease/condition of interest.

3. The prospective: first, a group of persons (the "cohort") is identified by the researcher, who has predicted that the disease/condition is relatively frequent among the members of the study group and expects to be able to study the relationship between the factors and the disease/condition.



MSA

Basically, this design differs from the case-control study design in that it begins with healthy individuals, identifies the presence of "risk factors" among them, and observes the occurrence of the disease/condition in those exposed to the risk factors as well as in those without exposure.

NOTE:

The case-control study helps identify certain factors among individuals with and without the disease/condition (also called "result")

In other words, case-control studies begin with the disease/condition.

On the other hand, prospective studies identify the disease/condition among people who have the risk factor as well as in those who do not have it.

The prospective study design allows us to define rates for the disease/condition (what number of cases occurs in a certain number of persons during a given interval of time?). Even more important, this design gives greater information quality control, because everything is happening during the study and not in the past as in the case-control study designs).

The prospective study design's benefits have their own cost. Because of the need to follow entire groups for relatively long periods of time, this design is more costly and lasts longer than the others. The disease/condition occurs less frequently in the population and the investigator has to deal with longer periods of observation time in order to be able to identify an adequate number of cases (this implies that a larger amount of resources must be invested and more people without the disease/condition must be included). Because of these reasons, the prospective study design seldom is the more indicated starting point for beginning research on a given health problem, even though it represents the "golden standard" among epidemiological study designs.

3. Another way to classify epidemiological study designs is the functional classification. According to this classification, studies can be:
 - a. Observational - the investigator merely collects information about the disease/condition and factors; the following are subclasses of this type of study design:
 1. Descriptive - whose only objective is to describe the problem within the population or study group.
 2. Analytical - which applies statistical tests

on the observations to identify factors which are associated with the disease/condition under study.

- b. Quasi experimental - whereby one studies population groups in which an intervention or action has been implemented that can affect the behavior of the disease/condition under study, even though this intervention is neither carried out nor controlled by the investigator. For instance, if the health authorities in a given region implement a new program, an investigator could examine the changes that occur in relation with the program and compare his observations with those made in a similar group that is not covered by the program in question. However, the investigator does not design nor does he implement the intervention; neither does he select the individuals who make up the study groups.
- c. Experimental - the investigator designs and implements the intervention, applying it in a manner such that all scientific requirements are fulfilled to the maximum possible, and evaluating its effect by comparison/contrast with a group of persons that is comparable in all aspects other than the intervention itself.

Considering the two classification systems above, it is clear that the case-control study design is retrospective, observational, and

usually analytic.

III. ADVANTAGES AND DISADVANTAGES OF CASE-CONTROL STUDY DESIGNS

A. Advantages - case-control studies have certain unique characteristics which give them an important role in the field of applied epidemiology. Among them are:

1. Quickness - this study design takes advantage of already existing cases with the disease/condition under study. (For instance, the cases that attend a given clinic or hospital). Cases can be identified from files (like the civil registry's death files or health center's records). This process is a lot more rapid than watching over a group of individuals in wait for the occurrence of the disease/condition.
2. Low cost: because of the short amount of time and effort involved, and because one counts with an important proportion of cases (subjects with the disease/condition), this studies frequently spend less resources than the prospective studies.
3. Infrequent events study - many very important events in public health (such as mortality, cancer cases, etc.) are typically infrequent. Because case-control studies deal with identified cases and

with a small number of comparable individuals as controls, they are excellent for doing preliminary research on this type of events.

4. Temporal association and relationship - the data allow the investigator to determine the presence of factors before the occurrence of the disease/condition. This temporal relationship is necessary in order to be able to assume that a given factor can be causally related to the disease/condition. The application of statistical tests permits the identification of important associations between factors and the disease/condition.

B. Disadvantages - despite its great advantages and the fact that the case-control design can yield very important information, it is worthwhile to acknowledge its limitations and disadvantages. Among these are the following:

1. Case selection bias - there are different types of bias that every researcher must know and try to avoid when applying any type of study design.. The different types of bias will be discusses below. However, the case-control studies do have an endogenous source of bias which stems from the fact that the source for the selected cases is almost

never representative of all the cases within a given population; the selected cases are usually part of a subgroup of persons who self-select themselves and for this and other reasons differ from the other members of the population. For instance, the cases that may be identified at a hospital or health clinic are representative of people who utilize these services when they are sick. The population segment that prefers to use other or no health service will not be represented by the selected cases. Another example of this form of bias may be that which occurs when case selection is made from civil registry's offices (in which case, the selected observations are not representative of those individuals or events that were not registered). If cases are selected from individuals who participate in a given health program, they would not be representative of the people who do not partake of the program's benefits.

2. Information quality - the quality of the information in retrospective studies can be limited by the quality of recall individuals experience about events in the past, or by the quality of the information that is available in the files or clinical records used by the investigator (such as

dates, symptoms, birth weight, etc.). This limiting factor can become one of the more important ones as far as the utility of this study design goes.

3. Disease/condition's rates - because from this study design there is no way the investigator can know how many cases exist that go undetected by his study, case-control studies only allow us to calculate proportions (Ex. "35% of the cases and 10% of the controls received "xyz" before the disease"). One cannot calculate rates, such as the incidence or prevalence of the disease/condition.
4. Inference of cause and effect relationship - case-control studies do not permit the investigator to draw conclusions about cause and effect between a factor and the disease/condition. As has been said before, this design allows one to identify the associations between factors and the disease/condition. A very important product from a case-control study can be the identification of such associations, which allow the investigator to formulate additional hypotheses that may afterwards give focus to other more in depth (and more costly) studies that must be designed differently in order to identify the causes of the disease/condition.

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IV. OBJECTIVES AND HYPOTHESIS

Frequently, the objectives of a study are initially so broad and ambitious that they cannot be reached with the available resources and study design. For this reason, it is important to define exactly the precise objectives of the study and to translate these objectives into hypothesis that can be tested statistically.

For instance, the investigator's general intention may be to "to understand the causes of maternal, peri- and neonatal morbidity and mortality in country "X". However, it is highly improbable that only one study could achieve this objective, and the case-control study design does not permit the identification of causes.

- B. Objectives: for a scientific study the investigator must be able to define objectives in a realistic and exact manner. These, in turn must include general as well as specific objectives. Some examples follow:

General objectives: "To examine the association of potentially related factors with the risk of neonatal mortality in a traditional rural community".

Specific objectives: "To describe age at death in weeks for the neonates that die in community X during the 1987-1989 period."

"To describe the social and demographic characteristics of these children's mothers".

"To examine the association of maternal social and demographic and obstetric characteristics, the type of birth assistance received, and some specific neonatal care practices with the risk of neonatal death."

B. Hypothesis

A hypothesis is an objective formulated in such a way that it implies the collection of specific data and the fact that it can be tested through the application of statistical tests. Examples of a set of hypotheses could be as follows:

"There is a significant association between a neonate's gestational age and birth weight with the risk of his (her) death during the neonatal period."

"There is a significant association between one or more maternal social and demographic characteristics and her baby's risk of neonatal death."

"Independently from the effect of the maternal sociodemographic characteristics, there is a significant association between one or more neonatal care practices and the risk of neonatal mortality in children with adequate weight at term."

Objectives and hypotheses must serve as constant guides during the study's design and execution. If it seems that it is not feasible to reach one of the objectives with the available resources and/or design, then the objective must be revised and reformulated so that it becomes useful as a guide for the study's execution again.

V. THE STUDY SUBJECTS IN A CASE-CONTROL STUDY

Putting the methodology for a case-control study design implies following a series of steps that define which and how many individuals will be considered as study subjects.. The investigator normally has an idea of what people he will include in the study. However, the care and discipline that is applied while defining the study subjects frequently become the most important determinants of the quality of the results. Some of the more important steps to take are described below:

A. Definition of the study population

The size of the Case and control groups are usually small, but the investigator often wants them to represent a larger "population" or group of people. For this reason, before thinking about selecting the study subjects, the population one intends to study must be clearly defined beforehand. For instance, the investigators impulse may be towards understanding the relationship between several given factors and neonatal mortality. If he does not reflect carefully upon the

matter before, he might end up studying several isolated cases from a "health region" that is composed by urban as well as rural groups of individuals; well educated as well as less educated persons; people who use private health services as well as people who prefer the public system; different ethnic groups. Thus, it could be highly unlikely that the selected cases were adequate to allow the investigator to say or infer anything of importance about any of the subgroups just mentioned. For this reason, it would probably be better to define the population more precisely from the very beginning, in terms like "mothers from the rural area", or "mothers from villages and towns with more than 1,000 persons, where there are no public health services", or "nullipara from the peri-urban population".

With definitions such as this one, the investigator can focus his study better and choose cases and controls that do adequately represent the population of interest.

- B. Case definition and identification. Within a previously defined population, there will be several individuals that can be included into the study subjects. According with the study objective, not all of these will be appropriate enough to be included. For instance, "fetuses that are stillborn" may include different types of underlying pathology. If the investigator wants to

understand the relationship between certain obstetric practices and the risk of stillbirth, it would possibly be better to define the cases as "children who, according to their mothers, showed intrauterine movement immediately before labor and were born dead or died within the first 12 hours after birth." This definition may be refined to specify exclusion criteria: congenital defects (anencephaly, for example) and/or children who apparently die in utero before the beginning of labor.

The investigator may also wish to specify the diagnostic criteria that enable him to include study subjects into his study group. For instance, in a population that does not make frequent use of the health services, one could define pre-eclampsia as "a pregnant woman who develops hand and facial bloating or edema during the third trimester of pregnancy, regardless of the occurrence of headache". In a study with a population that receives adequate prenatal care, a more exact definition could be used, specifying for levels of arterial tension and proteinuria, etc.

Finally, the source for cases must be specified within the study population. For instance, there could be individuals with the disease/condition who look for the health services available at a clinic, or already-existing clinical records where the cases with the pathology or diagnosis of interest could be found.

c. Definition and identification of controls. Even though the identification and definition of the cases is obviously very important in this type of study, the investigator cannot be less careful or exact when considering those who will be controls.

It must be remembered that, in order to assess the effect of potential risk factors on the disease/condition, the basic tool would be the comparison of these factors' presence in the cases with their presence in individuals who are basically similar and comparable to the cases, but who have not suffered the disease/condition. If the controls are not basically comparable, the effect of a factor may be difficult to determine.

For instance, a pregnancy-induced hypertension study could define as cases those pregnancies that come to a prenatal care clinic and are found to have certain clinical findings; the corresponding controls could be other pregnancies that come to the same clinic and do not have hypertension. However, the selection of controls is not always easy. For example: cases defined as pregnancies that come to a health service with a very evident clinical sign (such as hemorrhage, fever, etc.) but have not received prenatal care should not be compared to controls that attend the same clinic for routine prenatal care. The second group could be different from the cases in many basic aspects, and any

difference detected between groups might not represent a valid association with the disease (sign); the difference could be a matter of chance derived from comparing two incomparable groups of individuals.

The definition of the controls frequently requires much care and reflection by the investigator in order to allow comparisons that really respond to the study's objectives.

D The selection of cases and controls. Once cases and controls have been defined, one has to select the population elements that will make up the study groups. In some studies, it is possible to study all the existing cases and controls (Ex., given a whole group of persons who attended a party, some will become ill, while others won't). To some extent, this is the ideal situation. However, in the majority of studies, it would be necessary to select some of the cases and some of the controls as study subjects.

If this is the case, the only adequate manner to select the calculated case sample size, and the controls afterwards, is aleatory selection (random selection). In order to carry out this mode of selecting cases and controls, a sequential number is assigned to each case. Then some of the assigned numbers are chosen from a random numbers table. The same procedure is followed when selecting controls. If some cases or controls cannot

be included in the study, they are then replaced through random sampling also. The basic principle involved in random selection is that, even though all eligible individuals are not going to be included in the study, at least all of them will have the same of being chosen. Any other way to draw the study subjects will almost surely introduce bias. For instance, including volunteers implies working with a very different set of characters (most people would not ordinarily offer to participate voluntarily, but if they are cases, they must be given the chance to participate). The selection of individuals who are more convenient for the investigators (like people who spontaneously come to a hospital during the day shift, in contrast with those who attend during the night shift, or who live closer to a health center) may result in the selection of a group of cases that do not necessarily represent the population under study. The selection of cases that have been identified and/or suggested by the study's personnel (not randomly) may run the danger of manifesting the personnel's own prejudices. In summary, if all cases and all controls cannot be included into the study, then the selection of the study subjects must be random.

- E. Sample size (samples of the controls and cases). There are several factors that affect the number of cases and controls that must be included in the study. The more

important ones are:

1. The level of confidence needed to accept a hypothesis. An association between a factor and the disease/condition can be either real or the result of chance. If one accepts a false result, one commits a "type I error". Statistics tells us how probable it is that we have of dealing with a true result, but we have to specify the level of probability at which we are willing to accept the result: 50% is like flipping a coin; 90% is more secure; and 99% is almost perfect reassurance. The more confident we want to feel about our results, the larger a sample we will need. The majority of studies use a 95% confidence level to accept a hypothesis.
2. The level of confidence needed to reject an important association. Once the level of confidence to accept a result has been defined, the investigator has to decide on the level of confidence that guarantees the study will not miss accepting a hypotheses as true when in fact it is true. Not accepting an association when it is in reality an important and true one is called a "type II error". This type of errors occurs when the sample size is not large enough to draw

At

statistically significant conclusions from the study results. Several studies accept a level of confidence (called "power") of around 80-90% that the type two error will not be committed.

3. The characteristics of the parameter's value in the population. Many of the factors that are examined in case-control studies are proportions; the study question is usually "what proportion or percentage of the cases has the factor present in comparison with the controls?" If this is the case, the expected proportion value for the whole population affects the sample size: the farther the value is from 50%, the smaller the sample size needed to detect a given difference between cases and controls.

If the study is going to compare the mean values of a certain parameter in cases and controls (like grams of hemoglobin), the parameter's variability will affect the sample size: the greater the variability, the greater the sample needed to detect a given difference between cases and controls.. For instance, if hemoglobin values varies from 10.0 to 16.5 gm/dL, the study would need a greater number of subjects than if the interval varied from 12.0 to 13.0 gm/dL.

4. The difference that the investigator intends to detect. Taking the aforementioned aspects, it is obvious that in order to detect very small differences one needs greater numbers of study subjects than to detect larger differences. The investigator calculates the sample size based upon his own estimate about the proportion or mean value that exists in a population, and also about the value's difference he (she) thinks must exist between cases and controls. This approximation exercise may only represent his own personal opinion about what he thinks he will observe. However, it is frequently more appropriate to calculate the sample size based on the capacity to detect a difference that would in reality be worth detecting. For instance, with large numbers of controls and cases, one could detect a 3% difference as statistically significant in regards to the proportions of cases and controls with factor present. However, it is highly unlikely and unusual that such a small difference would be of importance for a health program. For this reason, the investigator frequently calculates the sample size to detect differences that seem "important" from the operative point of view.

F. Patient enrollment and informed consent. In contrast to

an intervention study, the case-control study will not impose a change on the individuals. However, the information that will be collected may be sensible, and is the investigator's property. Any individual has the right to know the general study objectives (without introducing bias or prejudice into the response), the right to be certain that the information given will be kept confidential, and that his identification will not be disclosed in any manner. Individuals have the right not to answer a question, if they do not wish to do so. The subject's approval must be obtained at the moment of enrollment.

V. DATA COLLECTION

- A. What data are going to be collected? The data to be collected must be the same for cases and controls. The selected data itself as well as the manner in which it will be collected are important decisions to make. The investigator has to make sure that the information available for analysis at the end of the study is (1) complete; (2) adequate for the study objectives; (3) of the highest possible quality; and (4) comparable among subjects (that is to say, collected in a standardized manner).

The following are some important aspects to be considered on data collection and that will prove useful to expand this topic:

1. What variables? The study variables must be chosen accordingly with the study objectives, a good level of knowledge about the study's background and the results of other pertinent studies, as well as with sufficient understanding of other factors of potential interest that exist within the study population.

2. What sources of information? Selecting the sources of information usually depends on two basic aspects: quality and feasibility. The objective is to obtain the best possible information. Most of the information in case-control studies is gathered through personal interviews. Other data can be obtained from records, files, etc. The investigator has to decide which source offers the most reliable information. Occasionally, one must realize there are no sources reliable enough for analysis. This is the case when the only information source available is known to be unreliable, like a mother's recall of her baby's birth weight, and/or the weights recorded by the health services. If this happens, the investigator must find an indicator other than birth weight, or he could simply choose to accept that his study cannot evaluate this variable.

3. How to ask? how to take notes? There are several forms to obtain and to write down notes on any type of information. They vary from the very broad to the very specific:

(Open) "What diseases did the woman suffer during her pregnancy? _____".

(More specific) "Did the woman suffer from hemorrhage (bleeding) during her pregnancy?"

1 = yes 2 = no _____".

(Even more specific) "By trimester, write down the symptoms reported during the pregnancy.

0=absent, 1=present, 9=does not know).

Symptoms and signs	TRIMESTER		
	FIRST	SECOND	THIRD
Hemorrhage			
Edema or bloating			
Fever			

B. Organizing the questions/developing the instrument for data collection. To collect data, one needs a framework with the shape of an "instrument" (questionnaire, or formulary). This instrument provides the structure for collecting the data, (if used properly) it assures that the information will be complete, and serves as a source of information for recording, tabulation and statistical analysis.

The instrument must contain the question in a logical sequence that facilitates the interview or the data collection process itself. It is usually designed and organized in such a manner as to make data recording by computer easier.

The instrument must be accompanied by very specific set of instruction manuals that explicitly explains the objective and the forms to administer each question. Besides the instruction manuals, the investigator should have practical study sessions around the instrument with all the interviewers. All the study team members must reach an agreement on each of the study procedures in order to obtain the information in such a way that the informant will not feel coerced towards a specific answer. This process is called "standardization". Once the instrument has been fully developed, it must be tested through several real interviews. This allows one to identify those questions that are not clear, or easily misunderstood or even confusing. These instrument trials produce a more useful and exact data collecting tool. It is highly desirable to have the instrument fully developed and tested before the actual collection of the data; "on-the-road modifications" frequently result in a lack of comparability between the information collected before with the data collected after the

modification.

C. Data collection bias. Different forms of bias can be introduced into the study results through incorrect data collection. The investigator and the interviewers must recognize the possibility of introducing the following types of bias and try by all means to avoid them:

1. Question formulation bias: if an interviewer knows the hypothesis being tested (or if he has his own hypothesis) about the disease/condition under study, and if he knows which individual is a case and which one is a control, he could require the information in a suggestive manner so that the answer given is more likely to support his own hypothesis (thus the interviewer "puts his answer in the informant's mouth", so to speak).

2. Informant's bias. When a subject knows about the study and has his own ideas about it (or if he suspects the investigator's hypothesis, he (she) can modify his answer to conform with his opinion over the relationship that he thinks should exist between the questions being asked and the hypothesis.

VIII. STUDY IMPLEMENTATION

Once the designing process, selecting the study individuals, and organizing the collection of data finish, the investigator should not be negligent about carrying out the study. A study, as any other activity, is dynamic and can produce unforeseen problems and opportunities. Like any other matter that deals with human beings, it can have a lot of variability in the quality of its implementation. For these reasons, it is very important that the investigator revises the information and monitors some process indicators to ensure the quality of his results. This way, when the time for analysis comes, the investigator can be sure he is analyzing reliable information that will permit the examination of the aspects that make up the study's objectives and hypothesis.

PROGRAMA DE COORDINACION
EN SUPERVIVENCIA INFANTIL

MESA REDONDA
"AUTOPSIA VERBAL"

EXPOSITOR: Dr. Al Bartlett

COORDINADORA: Meri Sinnitt

LISTA DE PARTICIPANTES

<u>Participante</u>	<u>Organización</u>
1. Gonzalo Ramirez C.	CARE- Bolivia
2. Joel Kuritsky	CCH/USAID
3. Rolando Justiniano	Caritas
4. Luisa Mendizabal Valdin	CIEC.
5. Guillermo Zambrana Pérez.	CIEC.
6. Susan Bolman	Fundación Contra el Hambre.
7. Lisa Howard-Grabman	JSI/Mother Care
8. Martha Clavijo	Meals For Millions
9. Nelly Copari	Plan Internacional Altiplano.
10. Gualberto Guibarra Aliaga	Plan Internacional Altiplano
11. Juan José Villarroel	P.S.R.A.
12. Jennifer Luna	PROCOSI
13. Meri Sinnitt	PROCOSI
14. Ana María Aguilar	PROCOSI
15. David Rogers	Save The Children
16. Guillermo Secane	Save The Children
17. Lila Céspedes Claire	Save The Children

La Paz, 26 de Septiembre de 1990

MATERNAL, PERINATAL AND NEONATAL MORTALITY STUDY:
INQUISIVI PROJECT

I. OBJECTIVES

1. To identify characteristics associated with neonatal mortality (NN), maternal mortality (MM), and stillborns (NM).
2. To identify the relationship between birth and neonatal care (who attends? and specific practices) and maternal mortality (MM), NM, and NN.
3. To identify diseases and events that are probable causes of MM, NM, and NN.
4. To identify the moment when the decision-taking and health-care-seeking process (or the response) fails.

II. DESIGN

Objectives 1 and 2	-	Case-control study.
Objective 3	-	Verbal autopsy.
Objective 4	-	Process diagnosis.

III. HYPOTHESIS (Case-control study)

1. There are several maternal and neonatal characteristics that are significantly associated with the risk of MM, NM, NN.
2. There is a significant relationship between certain aspects of labor and neonatal health care (the person who assists and certain traditional practices) with the risk of NM, and NN.

IV. THE STUDY'S BASE POPULATION

Based on the estimation of the number of yearly cases that occur in the population covered by project DJC (Appendix 1), it was decided to take as base population all maternal deaths and all the children born to the families that make up the project in the three sub-areas (Inquisivi, Circuata, Licoma), during the two previous years (November 20, 1988 to November 19, 1990).

V. STUDY ACTIVITIES

A. DEFINITION OF CASE AND CONTROL

Case - Stillborn (NN): a child born to one of the DJC project's families no earlier than the completed sixth month of pregnancy and who showed no signs of life at birth (the approximate gestational age at birth should be calculated with the best available information, including the mother's own guess).

It is anticipated that this group of cases will be further categorized into "Obit fetal (in utero fetal death before labor begins)" and "Stillborn (fetal death that occurs during labor)". This additional categorization will be done according to systematically recorded data on fetal movements before labor and on the newborn's external appearance.

Case - Neonatal Death (NM): a child born to one of the DJC project's families who died before completing one full month of life.

The child's age in days after birth will be recorded in the instrument. If it comes out that the neonatal deaths that occur during the first day of life are principally related to labor events, then this category will be combined with the "Stillborn" category in order to focus the analysis more precisely on the different labor and delivery problems that result in mortality.

Case - Maternal Mortality: A woman who belongs to a family in Project DC, who died during a pregnancy, labor or the puerperium, and who did not die from another cause not related with these events (For example: a homicide or an accident). The mortality cases will be few and will be treated and analyzed separately. They will not enter the cases and controls analysis. However, it is expected that the data will be analyzed descriptively in order to better understand the characteristics, diseases or events, and the process of decision taking and health care seeking that are associated with these cases.

Control: a child who is born to one of the DJC project's families and survives the first month of life.

It is important to note that children who died after the first month of life have to be included as eligible into the list for selecting the controls. Excluding these children would result in an important bias on the results.

B. IDENTIFICATION AND SELECTION OF CASES AND CONTROLS

The cases will be identified from all available sources of information that are related to the DJC project's families. The most important source of information about cases will be the prenatal care records and the mortality files of the project for each community and sub-area.

However, it is possible that cases exist within these families that are not reported. For this reason, cases will also be sought through communication with the communities' promoters, traditional birth attendants (TBA's), and other community leaders. At Licoma, where there are no records before 1990, the 1989 cases will be identified through the January 1990 survey, where families were asked about neonatal deaths and stillbirths that occurred the preceding year. Retrospective information was also enquired from promoters, TBA's, and other community leaders.

The controls will be selected randomly from each existing sub-area record for the project's two years of duration (at Inquisivi and Circuata, the records of all the children born alive who survived the first two weeks in 1989, according to the January 1990 survey and the records for the same year). Two controls will be selected for each case in order to increase statistical power, considering the small number of cases. Because there are substantial differences between the three sub-areas, and because there can be important differences from 1989 to 1990 (specially at Licoma), the selection will be stratified by sub-area and by year, according to the following model:

<u>Sub-area</u>	<u>11/20/88 - 11/19/89</u>		<u>11/20/89 - 11-19-90</u>	
	<u>Cases</u>	<u>Controls</u>	<u>Cases</u>	<u>Controls</u>
Inquisivi	X1	2 (X1)	Y1	2 (Y1)
Circuata	X2	2 (X2)	Y2	2 (Y2)
<u>Licoma</u>	<u>X3</u>	<u>2 (X3)</u>	<u>Y3</u>	<u>2 (Y3)</u>

*Calendar years 1989, 1990.

It is important to note that if in reality a larger number of cases is found than expected by the project's personnel, time will probably not be enough to complete all the cases and controls. In this case, the most powerful statistical strategy to follow is to interview all the cases and then the largest possible number of controls (even though both controls per case), making sure there is at least one control per case.

C. REPLACEMENT OF CONTROLS

Because the purpose of the interview being done to all the cases, and not just a sample from them, the replacement of study subjects does not apply to them, In regards to the controls, it might very well be that replacements will be necessary. For instance, when a family emigrates from the project's area. If this happens, a new control will be selected randomly from the same records that were used to select the control sample.

However, the following matters related to replacing a controls must be emphasized:

1. As has already been pointed out, the fact that a child dies after the first month does not exclude him as a

candidate for being a control. Excluding these children could leave out a family with certain high risk characteristics, which would result in bias against the cases and blocking the identification of factors that are only associated with the risk of perinatal and neonatal mortality.

2. The fact that the mother of a control child is not at home when visited does not justify replacing this selected control. If it is replaced, the sample turns into a "sample of convenience" which includes a greater number of mothers who spend a longer time at home and who may not be representative of all the mothers in the base population.

Because of this reasons, once a child has been selected as control, every effort must be dedicated to include him in the study. Operationally, this would imply at least two tries at interviewing the "evasive" mother. The presence of promoters from the DJC project can facilitate the process significantly and must be taken advantage of in trying to set appointments with the mothers of control children or reaching out in other manners through the promoters to obtain an interview.

D. SAMPLE SIZE

The projections included in appendix 1 allow making an estimate of approximately 70 cases as total for all three sub-areas during the study's 2 years of duration. Assuming a 0.05 probability of an α type error (type I) and a) 0.80 probability of

β error (type II), with one control for each case, this number of 70 cases permits the detection of a difference in the prevalence of the factor of about 0.20 - 0.25 (For example, 0.05 - 0.025; 0.20 - 0.45; 0.40 - 0.65; 0.60 - 0.85). With two controls for every case, 30% smaller differences can be detected (For example, 0.05 - 0.18; 0.20 - 0.37; 0.40 - 0.57; 0.60 - 0.77). This level of difference is appropriate for studies that apply to public health.

E. DATA COLLECTION

All the data for each study subject will be included in the questionnaire that belongs to each subject. The data for identification (community number, home, family; record number) and the rest of the data already registered in the DJC project records (such as birth date, birth weight, etc.), will be the sources of this information in the formulary before the interview (with community validation, if deemed necessary).

Data collection will begin only after the instrument's testing, with modifications added to the instruments or the process itself if necessary, has been completed. The information will be gathered through a direct interview with the mother of each case or control. If dealing with a maternal mortality case, the interview will be done to a relative who was present during the event and who seems to be the most adequate source of information (in these cases, it could be necessary to obtain additional or confirmatory information from other persons who were also present during the event). If both the child and the mother died, or in twin births, one questionnaire will be filled for each case person.

Necessarily, the interview with the mother will have to be relatively "open", looking for the most adequate manner to obtain the information required in the questionnaire. However, the interviewer will do all that is within her (his) possibilities to follow the same order as the instrument and will have the responsibility of asking from the informant the most accurate answer to each of the questions. This process would have to be carried out in a neutral manner that does not lead towards certain answers. For each question, the answer must fit one of the categories indicated in the instrument, and has to be placed within the indicated spaces for the answer codes. With the exception of open question, which provide blank spaces to write down the answers or to describe events, other notes written on the instrument will not be analyzed (because it is not certain whether or not the matters treated by the notes were explored with the same standardized manner in the other interviews/subjects).

The data from the verbal autopsy will be collected during the interview with the mother (or another informer if dealing with a maternal death), in the manner of a clinical history . The interviewer will make sure that the presence or absence of the signs and symptoms in the questionnaire has been documented as well as their temporal relationship with the death of the case. Once the interview has finished (not during or before), the interviewer will write down a synthesis in narrative form of the events and symptoms associated with the death, in order to facilitate the process of assigning diagnoses; the interviewer will also write down her own impression as to the probable causes for this

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mortality case.

As frequently as possible (biweekly, for instance) the study team must meet, possibly with the participation of another professional who is not participating directly with the study's development in order to go over the data and the case syntheses and to assign diagnoses, taking the previously detailed criteria and guides to establish the probable cause(s) of death.

F. THE PROCESS DIAGNOSIS

The process diagnosis will be applied the same way as verbal autopsy, exclusively with cases. This component of the study is based on the model for decision making and health care seeking that is included in appendix 2. This component will examine the process as it relates to the event or disease that resulted directly in the death under study (not over previous processes or actions that possibly came from the same disease). For instance, if a newborn did not receive proper cord care and handling, which ended up in a case of omphalitis which turned into septicemia, then the process diagnosis will refer to the disease (omphalitis that developed into septicemia), not to the decisions related to cord care and handling. During the interview, the interviewer will have the responsibility to decide which is the event subject of this component (specially in reference to the data about the course of pregnancy, labor, delivery and the neonate's condition at birth in cases of stillborn children or to the data from the verbal autopsy in cases of maternal and neonatal mortality).

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G. DATA ANALYSIS

After the data has been cleaned, the analysis will be done by stages, according to the study component.

1. Data on the cases and the controls

- a. According to present knowledge and the examination of frequencies distributions, make categories for the continuous variables (like birth weight, duration of labor, etc.).
- b. Calculate the prevalence of several variables of interest about the total study sample (cases and controls together), to describe the population (for example, percentages of illiterate mothers, bilingual mothers and nulliparas; prevalence of certain practices and forms of treatment within the population).
- c. Do a univariate analysis for comparing cases and controls in relation to each groups proportions of the variables of interest. This is done to examine the association of these variables (factors) with the risk of being a case.
- d. For those variables which are significantly associated with high risk, examine this association more deeply in different ways:
 - Examine the association of other variables that are potentially confusing with the variable of interest by examining the association between the variable of interest

and the potentially confusing variables in the whole population as one (cases and controls together).

- If there are several factors significantly associated with the risk of being a case, examine the effects of these factors with a multivariate analysis test (like logistic regression).
- e. Make sub-categories of cases which make sense after examining the data (for instance, "obits", "stillborns and children who die during their first day of life", "neonatal deaths"). Use these sub-categories to carry out an analysis of their association with certain factors, using Chi^2 tests with multiple degrees of freedom.

2. Verbal autopsy and the process diagnosis.

The data analysis will be basically descriptive, indicating the frequency of each problem (event, disease, operative failure, etc.) in the cases. For those problems which appear more frequently, the data for the cases and controls component can be revised looking for associations with this particular, new problem (for example, to compare the cases with septicemia with the controls in regards to the duration of labor, practices in cord care, etc.; to compare the cases that decided not to look for adequate health care in regards to education, socioeconomic indicators, etc.). Because very

small numbers are expected within each category, it is probable that these analyses will not result in significant associations. However, they can be useful to indicate the areas in which there is a greater need for information and/or attention.

H. DURATION OF THE STUDY

Because the calculated sample size of cases that will be found in each subarea during the past two years will be relatively small it would be advantageous to obtain the additional statistical power of having two controls per case, the number of programmed visits can be calculated as follows:

70 cases (plus 8 maternal mortality cases, without controls)	_____	78 visits
140 controls	_____	<u>140 visits</u>
Total programmed visits:		218 visits

With two individuals (the nurse and the educator) working full time, the team personnel estimated that a mean of 2 daily interviews by each interviewer (taking into account the mother's absence the day the visit is done, the need to revisit, and other contingencies). With six working days per week, it is estimated that 24 visits per week can be carried out.

Because of this, the duration of the data collection phase (after the instrument's validation and the interview standardization trials) would be:

$218 \text{ visits} / 24 \text{ visits per week} = 9 \text{ weeks.}$

If the collected data is revised and recorded continuously, it

is estimated that the analysis could be carried out in approximately 4 weeks. Assuming 2 weeks for the testing and modifications of the instrument and for additional standardization, the total duration of the study would be 15 weeks, or 3.3 months. This estimations assume people will be working full time, fully dedicated to the activities preparation and data collection.

I. VALIDATION

The field team's supervisor will carry out interviews in a randomly selected sub sample of cases and controls.

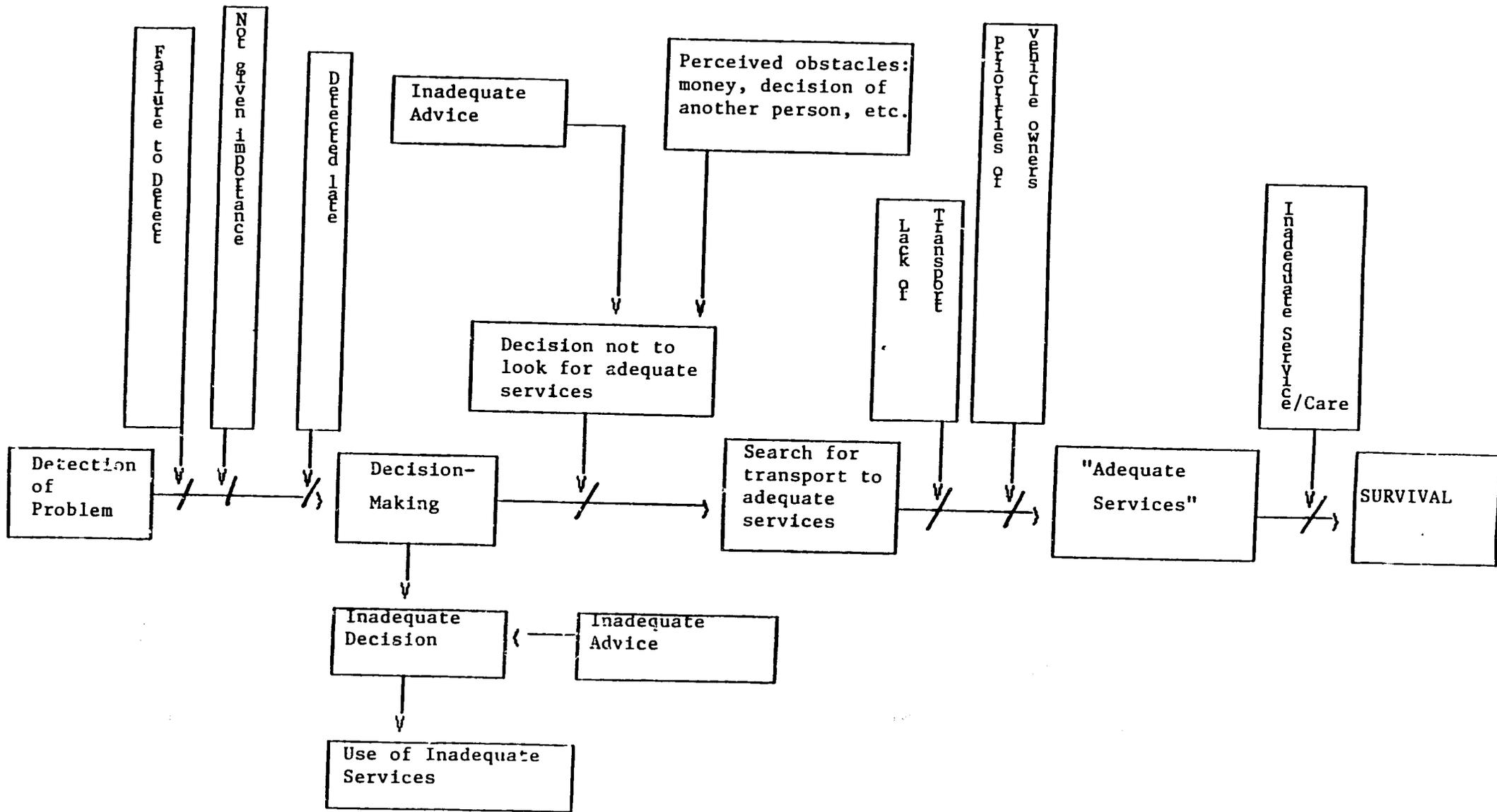
APPENDIX 1

Estimation of the number of cases available for the study

	<u>Inquisivi</u>	<u>Circuata</u>	<u>Licoma</u>	<u>Total</u>
Number of communities	15	15	21	51
Total population	3,024	3,953	2,921	9,898
Births/year*	234		130	364
Stillbirths and neonatal deaths	22		13	35

* Based on the number of children 0 to 1 year of age, according the most recent survey, plus 10% perinatal/neonatal mortality.

MODEL OF DECISION-MAKING AND SEARCH FOR HEALTH SERVICES



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QUESTIONNAIRE FOR THE "WARMI"-DJC PROJECT

1. Questionnaire number: _____
2. Family record number: _____
3. Community: _____
4. Date of interview: _____
Day / Month / Year
5. Interviewer: _____
6. Area code: _____
Zone code: _____
Community code: _____
House number: _____
7. Number of families living in the house: _____
8. Number of individual in family group: _____
9. Father's first and last names: _____
Mother's first and last names: _____
10. Category: _____
(1 = case 2 = control 3 = maternal death)
11. Case sub-category: _____
1 obit
2 stillbc.
3 Death during the first day of life
4 Death during the first week of life (after the 1st.day)
5 Death during the first month of life (after 1st. week)
9 control or maternal death
12. Birth date (dd/mm/yy): _____
(register date of maternal death if case corresponds)

COMMUNITY INFORMATION

13. Total population: _____
1=very small (<100)
2=small (100-199)
3=medium (200-499)
4=large (≥ 500)

14. Organization:
(0=none 1=yes)

Syndicate _____

Mothers' Club _____

Mother's organization _____

Cooperatives _____

Neighborhood committee _____

Other _____

15. Health resources
(0 = none 1=yes)

Health promoter _____

Trained empirical birth attendant _____

Untrained empirical birth attendant _____

Yatiri _____

Traditional healer _____

Health post _____

Medical post _____

Hospital _____

16. Basic services:
(0=none 1=yes)

School _____

Water source _____

1=river

2=well

3=watershed

4=Public faucet

5=Intradomiciliary faucet

FAMILY AND HOUSING INFORMATION

(NOTE: FROM HERE ON END THE DATA REFERS TO THE MOMENT THE EVENT OCCURRED)

17. How many families live in the house: _____

18. How many persons lived in the house: _____
19. Number of habitable chambers: _____
20. In case of an emergency, how many hours does it take you to get to the nearest center?

Walking _____

Other means of transportation _____

21. Characteristics of the house:

(0=no 1=yes)

False Stucco ceiling _____

Dubbed out walls _____

Mixed type _____

Dirt floor _____

22. Where do you bring water from for personal use?

1=river _____

2=well _____

3=watershed _____

4=public water faucet _____

5=private intradomiciliary water faucet _____

23. Sewage disposal (Drainage system)

1=open field

2=latrine

ECONOMICAL CONDITIONS

24. Land holding
(0 = no 1 = yes)

Legal ownership

Leasing

Sharing

Dependent (lodging in)

Borrowed

24. What was being produced?

Cereals and grains

Vegetables

Tubers

Fruits

Pastures

Others

26. What was being sold?

Cereals and grains
Vegetables
Tubers
Fruits
Pastures
Others

27. What was being used at home?

Cereals and grains
Vegetables
Tubers
Fruits
Pastures
Others

28. Amount of land that was farmed?

1=small (less than one "cato")
2=medium (1-3 "catos")
3=large (more than 3 "catos")

29. Maternal civil status:

1=single
2=formally united (not legally married)
3=legally married
4=separated, divorced or widow

FATHER'S INFORMATION

(If the answer to question No. 29 is 1 or 4, then write down "9").

30. Principal occupation or job:

1=farmer
2=cattle raiser
3=merchant
4=student
5=other occupation

31. Organizations to which he belongs:

Syndicate _____

DJC credit _____

Cooperatives _____

Neighborhood committee _____

Other _____

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32. Level of formal education:

- 0=none
- 1=basic
- 2=intermediate
- 3=medium
- 4=technical
- 5=higher

33. Does he know how to read?
(1=yes 0=no 2=a little)

34. Does he know how to write?
(0=no 1=yes 2=only signs his name)

35. What languages does he speak? (0=no 1=yes)

- Castellan
- Aymara
- Quechua

36. Were the following persons present at the birth (or event)?
(0=no 1=yes)

- Grandmother
- Grandfather
- Mother in law
- Father in law

37. Was the father present during the child's birth (or event)?
(0=no 1=yes)

MATERNAL INFORMATION

38. Principal occupation or job: (0=no 1=yes)

- Home chores
- Helps doing the farming
- Artisan
- Merchant
- Other occupation

39. Organizations to which she belongs (ed):

- Syndicate _____
- Mothers' Club (CARITAS) _____
- Mother's organization _____
- Cooperatives _____
- Neighborhood committee _____
- DJC credit _____
- Other _____

40. Level of formal education:

0=none
1=basic
2=intermediate
3=medium
4=technical
5=higher

41. Does she know how to read?
(1=yes 0=no 2=a little)

42. Does she know how to write?
(0=no 1=yes 2=only signs her name)

43. What languages does she speak?
(0=no 1=yes)

Castellan
Aymara
Quechua

OBSTETRIC HISTORY BEFORE THE SUBJECT PREGNANCY

44. Number of previous pregnancies:

45. Number of previous abortions (losses):

46. Number of stillborn children:

47. Number of children born alive:

48. Number of premature babies:
a) if there were premature babies, how many stillborn?
b) if there were premature babies, how many died before
the first month of life?

49. Number of children born full term with low birth weight?

50. Number of abnormal fetal presentations?

a) if there were abnormal presentations, how many were
stillborn?

b) if there were abnormal presentations, how many died during
the first day of life?

51. Number of previous caesarean sections?

52. Number of children who died during the first 7 days?

53. Number of children who died after the first week but not past
the first month?

54. Number of children who died during the first year but after the first month?
55. Number of children who died after the first year of life?

LABOR AND DELIVERY INFORMATION
(Here on we are talking about the event)

56. Birth date (event):
57. Month and year of the previous birth or abortion?
58. Interval between 56 and 57 (months):

PREGNANCY

59. Any problems during pregnancy?
(0=no 1=yes 9=does not remember)

hemorrhage
facial and hand edema (3rd. trimester)
strong and permanent headache (3rd. trimester)
urinary tract infection
seizures
fever
Hyperemesis

If any chronic condition was present during pregnancy, what was it?(0=none)

60. Prenatal care:

Number of controls by each provider:

Physician/Medical post
Health officer/Health post
Field supervisor
Trained TBA
Untrained TBA
Promoter
Other

61. What is your opinion about prenatal care?
(1=useful 2=not useful 3=did not give an opinion)

62. Number of tetanus shots received:

Before pregnancy
During this pregnancy

63. Any treatments or remedies taken during this pregnancy?

(0=none or no 1=yes 8=does not recall

Vitamins
Ferrous sulphate
Analgesics (sedatives)
Antihypertensives
Infusions

64. Practices
(0=no 1=yes 8=does not recall)

Mantling or handling with a mantle
Massage
External fetal rotation

Provoked abortion intent? (If yes,, how?)

65. Feeding during most of the pregnancy:
(1=less than normal 2=normal 3=more than normal)

66. Maternal work during pregnancy:
(0=none 1=yes)

Farming
Harvest/sowing
Carrying heavy loads over long distances

LABOR AND DELIVERY

67. Did the baby move during the days prior to labor?
(0=no 1=yes)

68. How many months did the pregnancy last?

69. Was this a multiple pregnancy?
(0=no 1=yes)

70. Where was the baby born?

1=at home
2=at the mother's mother's home
3=at a medical post
4=at another place

71. How did the mother know labor had begun?

(0=no 1=yes)

show
Pulse
contractions (pain)

72. How many hours did labor (pains) last?

73. How long before labor did the fetal membranes rupture?

1=during delivery

2=less than 6 hours before delivery

3=6-12 hours before deliver

4=More than 12 but less than 24 hours before delivery

5=More than 24 hours before delivery

74. Who assisted labor?

(0=no 1=yes)

TBA

Mother in law

Mother

Husband

Promoter

Physician

Nurse/Nurse aid

Nobody

75. Who assisted during delivery?

(0=no 1=yes)

TBA

Mother in law

Mother

Husband

Promoter

Physician

Nurse/Nurse aid

Someone else

Nobody

76. Who helped assist during delivery of the baby:

(0=no 1=yes)

TBA

Mother in law

Mother

Husband

Promoter

Physician

Nurse/Nurse aid

Someone else

Nobody

77. Delivery route:

1 = vaginal

2 = caesarean section

3 = was not born

78. How long before delivery did you begin to push down?
- 1 From the very first moment the contraction started (pushing down all through labor).
 - 2 Only when the baby was about to come out (be born)
 - 3 A few hours before birth.
 - 4 Started to push but stopped later.
 - 5 She did not push.

79. Any problems during labor and delivery:

0 = none 1 = yes

Abnormal breech (buttocks) presentation
Abnormal breech (podalic) presentation
Prolapse of extremity(ies) (hand)
Meconium staining of amniotic fluid:
 the liquid was dark brown or green.
Transverse lie
Umbilical cord wrapped around baby's neck
Umbilical cord prolapse
Hemorrhage
Fever
Seizures
Another problem

80. Any treatments performed during labor or delivery?
(0= NONE RECEIVED 1 = YES)

Handling the abdomen with a mantle
Massage
Putting the baby back in normal position (external rotation)
Girdle
Pelvic examination (vaginal)
Oregano, chua-chua, kinsa k'uchu infusions
Pill 1 for pushing (white and gray capsule)
Pill 2 for pushing (yellowish white tablet)
Another "pushing pill" _____
Injection for hastening labor
 "Peturitina"
 Methergine
 Ignores the name
Large tablet
Other treatment

81. In what maternal position was labor and delivery conducted?

1=lying down on her back
2=Kneeling down
3=On hands and knees
4=Squatting down

82. What was the baby born on to?
1=sheep skin

- 2=animal carcass
- 3=old and dirty bed
- 4=bed or leather plus clean cloth

DELIVERY OF THE PLACENTA STAGE

83. How long before the placenta was ejected?
- 1=fast
 - 2=less than one hour
 - 3=more than one hour
84. What assistance was performed to help eject the placenta?
- 1=blowing, coughing or provoking nausea
 - 2=other
 - 3=none
85. Was there bleeding immediately after delivery of the placenta?
(0=no 1=yes)
86. How long did the blood loss last?(hours)
87. Approximate amount of blood lost?
- 0=nothing
 - 1=a little
 - 2=a lot

NEONATAL CARE PROVIDED

88. Birth weight (grams):
89. Was the baby immediately cared for or until after the placenta came out?
- 1 = care provided immediately after birth.
 - 2 = care provided after the placenta came out.
90. Baby's condition at birth:
- Crying:
- 0 = none
 - 1 = weak
 - 2 = strongly
 - 3 = cannot tell (cannot remember).

Movements:

- 0 = none
- 1 = very little
- 2 = fairly active
- 3 = cannot tell (cannot remember).

Skin color:

- 0 = pale
- 1 = blue (cyanotic)
- 2 = pink
- 3 = cannot tell (cannot remember).

Breathing:

- 0 = did not breathe
- 1 = very little
- 2 = with grunting (moaning)
- 3 = normal
- 4 = cannot tell (cannot remember)

91. Baby's condition a few moments later (about five minutes after birth).
92. Were there other abnormalities noticed in the newborn?
(0 = none 1 = yes)

Bad odor (stench).

Bruises: any purple lesions or excoriations derived from trauma.

Maceration: the baby with characteristics similar to those found in a "wet baby".

Deformities: if the answer is affirmative, describe the abnormality (ies) in the blank space below_____.

93. Suction reflex immediately after birth:

- 0=baby did not suction
- 1=suctioned weakly
- 2=suctioned vigorously
- 3=baby was not offered breast

94. Who assisted the baby:
(0=no 1=yes)

TBA

Grandmother

Father

Promoter

Physician

Nurse

Someone else_____

Mother

Nobody

95. How long did it take to have the umbilical cord cut?

1=immediately

2=Not immediately (but before the placenta came out)

3=After the placenta was delivered.

96. What was used to cut the umbilical cord:

1=A broken piece of new ceramic ("juk'illa)

2=Broken glass

3=Knife or switchblade

4=Scissors

97. How was this material disinfected?

(0=no 1=yes 8=cannot recall)

With alcohol or other antiseptic

Washed with water

Boiled

With a piece of cloth

Did not disinfect at all

Cannot tell (cannot remember)

98. What was used to tie (ligate) the cord?

1=Sack cloth thread

2=Mantle thread

3=Nothing

4=Other material

99. How was this material disinfected?

1=with alcohol or another antiseptic

2=Washed with water

3=Boiled

4=Did not disinfect

8=Cannot tell (cannot remember)

100. What was used to cure?

1=Mercury

2=Sulfa-

3=Alcohol

4=Other material: _____

101. Immediate care given to the newborn?

(0 = none given

1 = yes, immediate care given)

Bathed

Coated

Stimulated

Resuscitated
Pharyngeal aspiration
Placed next to mother
Other care: (write down) _____

POST PARTUM AND PUERPERIUM MATERNAL CARE

102. What was done to control post partum bleeding?
(0=no 1=yes)

There was no hemorrhage: normal blood loss.
Transabdominal uterine massage: massage to help uterine contracture
Methergine administration
Nipple massage or stimulation by friction.
Other _____

103. What was done to correct placental retention?
(0=no 1=yes)

There was no placental retention
Pulling of the umbilical cord
Blowing
Making the mother cough
Provoke nausea reflex
Manual extraction: was this done by an empirical birth attendant or by another person?

104. Immediate care to the mother after delivery given?
(0 = none 1 = yes, care given)

Coated or sheltered for warmth
Girdled: belt woven with sheep hair.

105. Lochia?
(0 = none 1 = yes)

How many days did they last (up to ten days for white lochia).
Bad odor(0=none 1=yes):

106. Fever after delivery? (0=no 1=yes)

107. If the answer to the preceding question if "yes", specify the number of days after birth the symptom began as well as the number of days it lasted.

108. How was the fever treated?
(0=no 1=yes)

antibiotics
local remedies
putting the baby to the breast
It was not treated

109. How many days after birth did the mother get out of bed?
110. How many days after birth did the mother wash herself (or was washed)?

NEONATAL CARE DURING THE FIRST MONTH

111. Was the baby given colostrum?
(0=no 1=yes)

112. How many days after birth did breast feeding begin?

1 = immediately after birth
2 = on the first day
3 = on the second day
4 = on the third day
5 = after the third day: not early neonatal
6 = never breast fed (when dealing with congenital malformations or other maternal/neonatal problems)

113. Did the mother stop breast feeding her baby?
(0=no 1=yes)

114. What was used to cure the umbilical cord?
(0=no 1=yes)

Mercurochrome
Burned piece of cloth
"Mantizan"
Other materials
Nothing

115. How many days after birth was the baby cleansed?

116. How often was the baby bathed or cleansed?

117. Who was the baby taken to for check ups (health-wise) during the first month of life?
(0=no 1=yes)

TBA
Promoter
Traditional healer
Physician
Nurse

118. Did the newborn receive a BCG shot during the first month?
(0=no 1=yes)
119. Did the baby suffer any illness during the first month of life?
(0 = no 1 = yes)
120. What illness was this? _____
121. Who cared for the child while he was sick?
(0=no 1=yes)

Physician
Nurse
Promoter
TBA
Traditional healer
Someone else
Nobody

CHILD'S VERBAL AUTOPSY:

122. At what age (in days) did the child die?
123. Symptoms of the terminal disease:
(0 = absent 1 = present during the episode)

<u>Symptoms/Signs</u>	<u>Absent/present</u>	<u>Number of days before death</u>
-----------------------	-----------------------	------------------------------------

GENERAL

Stopped suctioning
Irritable
Too much crying
Weak crying
Difficulty breast feeding
Weak suctioning
Suctioned without strength
Lethargic (sad)
Fever
Hypothermia
Grunting/moaning
Apnea (moments without breathing)

(Question 123 continued)

<u>Symptoms/Signs</u>	<u>Absent/present</u>	<u>Number of days before death</u>
NEUROMUSCULAR		
Trismus		
Could not swallow	---	
Muscular spasm	---	
Muscular rigidity		
Seizures		
Abnormal movements		
RESPIRATORY		
Coughing		
Nasal secretion		
Nasal fluttering		
Noisy breathing		
Rapid breathing (gasping)		
Thirst for air		
Intercostal retraction (collapsing between ribs)		
DERMATOLOGIC (SKIN)		
Cyanosis (purplish, bluish)		
Pale skin		
Jaundice (sclerotica and skin)		
Erythrodermia (red skin)		
Red umbilicus		
Pus from umbilicus		
Stench from umbilicus		
Blisters		
Petechia		
Rash		
BLOOD		
Hemorrhage (Where? _____)		
GASTROINTESTINAL		
Abdominal distention		
Constipated completely		
Describe in narrative form a synthesis of the lethal disease's		

history (evolution) and give your personal opinion (diagnosis):
124. Final diagnosis codification:

Probable cause:

- 1 probable
- 2 possible
- 9 not applicable

Contributing factor:

PROCESS DIAGNOSIS

125. nature of the event/disease:

126. Who participated actively in response to this event?
(0=no 1=yes)

- TBA
- Mother in law
- Mother
- Husband
- Promoter
- Physician
- Nurse
- "Yatiri"
- Someone else _____
- Nobody

127. At what moment was the existence of a problem (this problem) noticed?

- 1=detected at adequate moment
- 2=detected too late
- 3=passed unnoticed
- 4=was detected but considered unimportant
- 5=another moment _____

128. Once the problem was detected, what was done about it?

- 1=they looked for adequate care
- 2=they looked for inadequate care
- 3=they did not look for helps (tried to treat at home)
- 4=something else _____
- 0=question does not apply

129. If adequate resources were sought, why did you decide for them?

- (0=no 1=yes 9=not applicable question,

Because of the cost of adequate care

Because of transportation cost
Because we trusted in the inadequate care
Lack of trust in adequate care
Because of advice given by someone
Because of the distance from adequate care (too far)
The indicated person was not in the community
Another reason _____

130. Who participated in deciding for inadequate assistance?
(0=no 1=yes)

TBA
Mother in law
Mother
Husband
Promoter
Physician
Nurse
"Yatiri"
Someone else _____
Nobody

131. What treatment was administered by the inadequate resource?

a: _____
b: _____
c: _____

132. Were adequate resources for assistance sought after the inadequate resources for assistance?

0=no
1=yes, an adequate person was called
2=the case was taken to health services
3=the case had already passed away
9=question not applicable

133. If an adequate person was called for, what did this person do?

1=adequate response
2=inadequate response
3=not applicable

134. When it was decided to look for adequate resources (persons), did you reach them?

1 = yes
2 = no, because there was no transportation
3 = no, because the owner of the transportation did not give importance to this matter.
4=the case died before arrival
5=No/another reason _____

9=Not applicable

135. When you reached the health services, what type of care was given? Codify this answer at the end of the workshop.

1=adequate care

2=inadequate care

9=not applicable

INSTRUMENT FILLING GUIDE

Questionnaire number: it is a unique sequential number for each record and it will be written before the interview in order to ensure the questionnaire is not repeated.

Date of interview: all the data like the questionnaire, area, zone, community, house and family are registered in the family questionnaire.

Interviewer's number: each interviewer must register his number when filling the questionnaire. (1=Yolanda; 2=Elsa; 3=Adolfo).

Parent's first and last names: In this questionnaire the wife's paternal last name will be kept, the same way it was done with the family record. In maternal mortality cases, the wife's name whose mortality case it is will be registered, even if the widower has remarried and has other children.

case = 1 control = 2 maternal mortality = 3

At the space provided the appropriate code number is written down. If both mother and baby died, then two questionnaires will be used.

Case subcategories

- 1 "obit" (intrauterine death before labor starts)
- 2 stillborn
- 3 death on first day
- 4 death the week after the first day
- 5 death the month after the first week
- 9 control or maternal mortality case

1. Obit: death before labor.

The usual characteristics are: the child stopped moving in utero, upon birth he looks macerated (he looks wet and burnt brown color), the mother refers block displacement.

2. Stillborn: according to the mother the baby showed signs of life until labor began; the baby was born without life signs.

Signs of death:

- no movements at all
- no respiration
- pale or blue color

3. Death on the first day of life: a child who was born with any sign of life and died during the first day (before completing 24 hours).

4. Death on the first week after the first day: the child who lives through his first day and dies before completing a full week.

5. Death on the first month after the first week of life: a child who lives through his seventh day of life and dies before completing one calendar month since his birth date.

9. Control: if the instrument belongs to a control or to a maternal death case, it will be marked with code 9.

Birth date: (or date of death if dealing with a maternal death case). Register here the date the child (case or control) was born and, if the case is a maternal death, then write down her death date.

Community characteristics that can be quantified and say something important about the community.

Why was DJC not accepted?

Characteristics of RPS.

Post characteristics

population number

Maternal group

School

COMMUNITY DATA

10. Population number: this datum will be obtained from the family survey for the february-march 1990 period. Each category's codes will be used.

11. Community data:

Does the community have social

Organization

0 = no

1 = yes

This datum will come from the general secretaries, agro-pecuary health promoters, DJC field supervisors and the Health Unit. The pertinent code will be annotated on the questionnaire.

code 0 = negative answer

code 1 = positive answer

12. Health resources: these are data present at the community. Register only that which exists at the community.
13. Services: register all services found at the community.
14. Water supply/sources: this refers to the presence, type and highest number of water sources at the community. Register the highest number of water sources found in the community. For instance: if the majority of persons in the community still use watershed and also have a water faucet installed (that is working), the interviewer must register within the answer box the number "4" (take the more sophisticated source for the answer even if it does not get to the individual. (This information only describes the degree of development of the community).

HOME AND FAMILY INFORMATION

15. How many families live in the house: this refers to the number of families that live there at the moment of the event.
16. How many individuals used to live in the house: this refers to the number of persons that used to live in the house at the moment of the event, taking into consideration all the families.
17. Number of habitable chambers: the number of chambers that are used permanently (dormitory, kitchen), excluding store rooms and/or empty chambers or those inhabited by domestic animals.
18. Characteristics of the house:
"tumbado" if the majority of the habitable chambers have a false ceiling made of stucco. Do not consider it as "tumbado"

if it is built with cloth.

"dubbed out walls" ("revocado"): walls with stucco; do not take as such if the dubbing out is done with mud.

mixed: if there is more than one type of the above characteristics within the same house.

dirt floor: self-explanatory.

19. Where is the water consumed brought from?

20. Sewage system:

Economic conditions: know the economic characteristics of a family.

21. Land ownership:

Proprietor or legal owner: (self explanatory).

Leasing: a rent is paid to use the land for cultivation.

Sharing: the crop is divided with other person regardless of the proportions.

Lodging: the people (a single mother or a married son who lives at the house) lodge at the place and do not produce income. They depend from other individuals or from a relative for sustenance.

22. What did they produce?

Grains and cereals: wheat or corn.

Traditional horticulture:

Tubers: potatoes, waluse, cassava, racacha.

Fruits: peaches, oranges, mango, chirimoya.

Pastures:

Others:

23. What did they sell? Answer according to question 22.

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24. What did they consume?: this question should be answered according to question 22.
25. What extension of the land was farmed or cultivated? this is a direct question to the mother and should be answered according to the categories described in the 1987 instrument.
26. Mother's civil status?:
1. Single
 2. Stable union without legal marriage
 3. Legally married
 4. Separated - Divorced - or Widow.

Husband's information (if the answer to the preceding question was 1 or 4, then answer this question with code "9")

27. Occupation?: what was the husband's main occupation when the event occurred?
28. Organizations to which he belongs:
- Syndicate: (This means the community's natural organization; specify function).
- Neighborhood committee
- Cooperative
- DJC credit (potato, lemon, beekeeping credits)
29. Level of formal school instruction:
- Basic: includes any complete academic year from 1st. to 5th.
- Intermediate: from 1st. to 3rd. year.
- Middle
30. Do you know how to read?: (in case the informant is the wife, ask if the husband knows how to read:
- NO A LITTLE VERY WELL

100

31. Do you know how to write?

32. Language:

What language does your husband speak?

- Quechua
- Aymara
- Castellan (Spanish)

33. Was the husband present at the baby's birth?(event for the 6-8 cases of maternal mortality).

MATERNAL INFORMATION

35. Principal occupation:

- Home chores
- Cooperates with husband at farm work
- Artisan
- Merchant
- Other

36. Organization(s) to which she belongs:

- Syndicate
- Neighborhood committees
- Mothers Club
- Maternal organizations
- Cooperative
- DJC credits

Mothers Club: CARITAS organized groups to which food is distributed as incentive.

Maternal organization: groups of women organized by DJC and religious groups that do not receive food.

37. Level of formal school instruction:

- 0 = none
- 1 = basic
- 2 = intermediate
- 3 = middle

38. Does the mother know how to read? write the answer down at the top box: "0" if the answer is negative, and "1" if it is positive. "A little" means that she does not know how to write or read.

39. Does the mother know how to write?

40. What language does she speak?

**MATERNAL OBSTETRIC HISTORY
BEFORE THE SUBJECT PREGNANCY**

41. Number of previous pregnancies: if the mother was nullipara use code "0".

42. Number of abortions (or pregnancy losses): in what sequential number of pregnancies did the loss of the baby occur, if it occurred before 6 months of gestation.

43. Number of stillborn babies: (Refer to _____).

44. Number of live births: (premature babies and at term babies).
(The same as _____).

Historical information, events and deaths must be elaborated on through a placid and candid conversation that inspires intimacy; if conflict is reflected in the data, the interviewer must return to clarify the answer.

45. Number of premature babies: a child is considered premature from 6 complete months of gestation to 8 complete months.

45.a. Of the reported previous premature children which one (sequential) was born dead (before the subject)?

45.b. Which one was born alive and died before one month of life?

46. Number of term, live children with low birth weight? this is a subjective datum. It will be estimated considering the mother's description of the baby's appearance (skinny, small, slender).

47. Number of births where the baby came in abnormal presentation: only births before the subject will be taken into consideration.

47.a. If there was a child with abnormal presentation, what number was born dead?

47.b. How many and what number was born alive and died during the first day of life (before the subject or before the last pregnancy whose product died or still lives if dealing with a control).

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NOTE: 42, 43, and 44 must add up to the number of previous pregnancies (No. 41).

NOTE: Questions 41 to 47, if dealing with a nullipara (who only had one pregnancy) leave them blank.

49. Deaths during the first week of life: any child who was born alive and died during the first week of life.
50. Number of deaths that occurred during the month after the first week of life: any child who was born alive and lived up to 7 days and then died between the eighth and thirtieth day of life.
51. Number of children who died during the first year, but after the first month of life: any child who was born alive and lived up to the first month and then died at any moment between the 31st. and 365th. day of life.
52. Number of children who died after the first year of life:

INFORMATION ABOUT THE PREGNANCY AND LABOR

FROM THIS QUESTION FORWARD, THE QUESTIONS REFER TO THE EVENT

53. Event's birth date: register the birth date of the child under study.
54. Month/year of the previous birth or abortion: before the last pregnancy. This will be used to calculate termination of the previous pregnancy.
55. Interval (months): Calculate the difference between the months and years for the next-to-last and the last births.
56. (NO TEXT IN SPANISH COPY)

NOTE: QUESTIONS 49 THROUGH 52 DEAL WITH THE SUBJECT CHILD OR EVENT.

P R E G N A N C Y

57. Any problems during pregnancy:

0=no 1=yes 8=does not remember

- Hemorrhage: any amount of blood loss noticed by the mother.

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- Face and hands edema: this means a constant and notorious sign from 6 months of pregnancy and forward.
- Headache (strong and permanent): this deals with head pain noticed during the last months or last trimester of pregnancy.
- Urinary tract infection: fetid urine, presence of mucous and phlegm in the urine and a sense of burning pain upon urinating.
- Seizures: refers to tonic/clonic seizures during which the mother becomes unconscious or dies.
- Fever: if the mother refers high temperature.
- Hyperemesis: persistent vomiting.

Did a chronic condition exist that could have any negative effect on the pregnancy? _____
 (The interviewer will register the answer in the blank space provided).

58. Prenatal care: number of prenatal care visit by each prenatal care provider. If there was no prenatal care at all, write down "0"; if there was some, write down the real number of controls or visits received.
59. What do you think about prenatal care?:
60. Number of tetanus shots received: verify the answer with the local record.
61. Any treatments and remedies received during pregnancy:
 0=none 1=yes 8=does not remember
- remedies: any remedies, such as antibiotics, antimycotic, antidiarrheics, antiparasitic, and flue medicines, analgesics (sedatives) (aspirin, novalgine, acetaminophen), antihypertensives (aldomet, lasix, hygroton), infusions (any "mate" for pregnant women).
62. Practices: 0=none 1=yes 8=does not remember
- "manteo" (mantling or handling with a blanket): soft or abrupt movements done by an empirical birth attendant and a third person.
- massage: hand friction applied to the maternal abdomen.

External fetal rotation: abrupt or delicate maneuver?

provoked abortion intent: write down the mother's answer in the provided space. This question must be made subtly.

63. Feeding during most of the pregnancy: try to estimate how the mother feed herself in relation to her normal (non pregnant) eating pattern.

64. Maternal work during pregnancy:

0=she did none

1=she did work

LABOR, DELIVERY AND PLACENTAL EXPULSION

If the mother died during pregnancy, the question will be carried out with the maternal verbal autopsy.

65. Did the child move in utero the days prior to labor?

66. How many months did the pregnancy last? calendar months will be taken into consideration. If the mother indicates 10 months, register as "full term". It is advisable to ask for the date of the last menstrual period and to calculate the expected day of delivery just to make sure.

67. Was this a multiple pregnancy? 0=no 1=yes.

68. Where was the child born?: (specify on the provided blank space) _____

69. How did the mother know labor had begun?

This question must be a bit directed without offering alternative answers.

70. How many hours did labor (pains) last?

The interviewer will ask how long the pain lasted and calculate in days, then convert to hours.

71. How long before labor did the fetal membranes rupture?

It is necessary to ask in as much detail (mornings, nights, hours, days, etc.) as the mother can remember. Convert the answer to hours.

72. Who assisted labor?

The answer is non excluding.

10/11

73. Who else assisted labor?

The answer is non excluding.

74. Who assisted during delivery?

The answer applies to domiciliary as well as hospital births, after referral.

75. Who helped assist during delivery of the baby:

Others: it is necessary to register who assisted and the corresponding code.

76. Delivery route:

1 = vaginal

2 = caesarean section

3 = was not born (in case the mother died with the fetus still within the uterus).

77. How long before delivery did you begin to push down?

The answer is excluding.

1 From the very first moment the contraction started (pushing down all through labor).

2 Only when the baby was about to come out (be born)

3 A few hours before birth.

4 Started to push but stopped later.

5 She did not push.

78. Any problems during labor and delivery:

0 = none 1 = yes

Abnormal breech (buttocks) presentation

Abnormal breech (podalic) presentation

Prolapse of extremity(ies) (hand)

Meconium staining of amniotic fluid: the liquid was dark brown or green.

79. Any treatments performed during labor or delivery?

0 = NONE RECEIVED

1 = YES

80. In what maternal position were labor and delivery conducted?
Answer is excluding.

81. What was the baby born on to?
The answer is excluding.

DELIVERY OF THE PLACENTA STAGE

82. How long before the placenta was delivered?
83. What assistance was given to help deliver the placenta?
84. Was there bleeding immediately after delivery of the placenta?
85. How long did the blood loss last?
86. Approximate amount of blood lost:

NEONATAL CARE PROVIDED

87. Birth weight: this datum comes from the roster record that belongs to the woman in reproductive age and children under five years of age. The codes will include one decimal (Example: 3.5, 2.8). If there is no datum, write down 9.9.

88. Was the baby immediately cared for or until after the placenta came out?

1 = care provided immediately after birth.

2 = care provided after the placenta came out.

89. Baby's condition at birth:

Crying:

0 = none

1 = weak

2 = strongly

3 = cannot tell (cannot remember).

Movements:

0 = none

1 = very little

2 = fairly active

3 = cannot tell (cannot remember).

(Question 89 continued)

Skin color:

0 = pale

1 = blue (cyanotic)

2 = pink

3 = cannot tell (cannot remember).

Breathing:

0 = did not breathe

1 = very little

2 = with grunting (moaning)

3 = normal

4 = cannot tell (cannot remember)

Very little: this sign means the baby was dying.

Grunting or moaning: this means the baby breathed the same as a if he (she) were sick.

90. Baby's condition a few moments later (about five minutes after birth). Answer using the same parameters as in the previous question: crying, movements, color, breathing.

91. Were there other abnormalities noticed in the newborn?

0 = none

1 = yes

Bad odor (stench).

Bruises: any purple lesions or excoriations derived from trauma.

Maceration: the baby with characteristics similar to those found in a "wet baby".

Deformities: if the answer is affirmative, describe the abnormality (ies) in the blank space below.

92. Suction reflex: ask the mother if she put the child to her breast immediately after delivery; if the answer is positive, do the rest of the questions.

93. Who assisted the baby: register data about the person who took care of the baby immediately after he (she) was born. A "no" answer is excluding.

94. How long did it take to have the umbilical cord cut?

Immediately

Not immediately (but before the placenta came out)

When (after) the placenta was delivered.

95. What was used to cut the umbilical cord:
A broken piece of new ceramic ("juicily)
Broken glass
Knife or switchblade
Scissors

96. How was this material disinfected?

- 1 With alcohol or other antiseptic
- 2 Washed with water
- 3 Boiled
- 4 With a piece of cloth
- 5 Did not disinfect at all
- 8 Cannot tell (cannot remember)

97. What was used to tie (ligate) the cord?

- 1 Sack cloth thread
 - 2 Mantle thread
 - 3 Nothing
 - 4 Other material
-

98. How was this material disinfected?

The answer is excluding.

- 1 With alcohol or another antiseptic
- 2 Washed with water
- 3 Boiled
- 4 Did not disinfect
- 8 Cannot tell (cannot remember)

99. What was used to dress the umbilical cord?

Register the material used for dressing.

Mercury

Sulfa-

Alcohol

Other material: write down the name of the material used.

100. Immediate care given to the newborn?

0 = none given

1 = yes, immediate care given.

Bathed

Coated

Stimulated

Resuscitated

Pharyngeal aspiration

Placed next to mother

Other care: (write down) _____

POST PARTUM AND PUERPERIUM MATERNAL CARE

101. What was done to control post partum bleeding?

There was no hemorrhage: normal blood loss.
Transabdominal uterine massage: massage to help uterine contracture
Methergine administration
Nipple massage or stimulation by friction.
Other _____

102. What was done to correct placental retention?

There was no placental retention
Pulling of the umbilical cord
Blowing
Making the mother cough
Provoke nausea reflex
Manual extraction: was this done by an empirical birth attendant or by another person?

NOTE: IF THE FETUS WAS BORN DEAD, CONTINUE WITH THE REST OF THE SECTION ON MATERNAL CARE; THE VERBAL AUTOPSY WILL NOT BE CARRIED OUT. THE PROCESS DIAGNOSIS WILL BE DONE INSTEAD.

103. Immediate care to the mother after delivery given?

0 = none 1 = yes, care given

Coated or sheltered for warmth
Girdled: belt woven with sheep hair.

104. Lochia?

0 = none 1 = yes

How many days did they last (up to ten days for white lochia).
Odor: do not disregard the sui generis smell of normal lochia. If there is a fetid, it will be considered as a sign of risk.

105. Fever:

Enquire about the presence of fever within the 40 days after birth.

106. If the answer to the preceding question is "yes", specify the number of days after birth the symptom began as well as the number of days it lasted.

107. How was the fever treated? (antibiotics, local remedies,

putting the baby to the breast.

108. How many days after birth did the mother get out of bed?

109. How many days after birth did the mother wash herself?

NEONATAL CARE DURING THE FIRST MONTH

This section refers to care provided after the first day (or immediate care).

110. Was the baby given colostrum?

This refers to the first moments after birth.

111. How many days after birth did breast feeding begin?

- 1 = immediately after birth
- 2 = on the first day
- 3 = on the second day
- 4 = after the third day: not early neonatal
- 5 = never breast fed (when dealing with congenital malformations or other maternal/neonatal problems)

112. Did the mother stop breast feeding her baby?

113. What was used to cure the umbilical cord?

The answer is not excluding

Mercurochrome Alcohol
Sulfa-
Other materials
Nothing

114. How many days after birth was the baby cleansed?

After the first day; the exact number of days between birth and the first bathing will be registered.

115. How often was the baby bathed or cleansed?

116. Who was the baby taken to for check ups (health-wise)?

This question refers to controls.
The datum is answered for both surveys.

117. Did the newborn receive a BCG shot during the first month?
look for the information at the right upper corner and in the roster for children under 5 years of age.

118. Did the baby suffer any illness during the first month of life? find any illness that was not the cause of death (does not refer to the lethal illness; in case the disease or illness resulted in the baby's death, this question is not valid. Furthermore, if the baby survived the disease, the disease was not lethal).

For instance, if a child had a cold, afterwards he had meningitis and died with meningitis, we are interested in the respiratory infection and not in the cause of death.

0 = no

1 = yes

119. What disease was this?

120. Who care for the child's disease?

<p>CHILD'S VERBAL AUTOPSY: Identification of basic characteristics</p>

121. At what age (in days) did the child die?

122. Symptoms of the terminal disease:

0 = absent

1 = present during the episode

<u>Symptoms/Signs</u>	<u>Absent/present</u>	<u>Number of days before death</u>
GENERAL		
Stopped suctioning	---	---
Irritable	---	---
Too much crying		
Weak crying		
Difficulty breast feeding	---	
Weak suctioning		
Sectioned without strength		
Lethargic		
Fever		
Hypothermia		
Grunting/moaning		
Apnea		
NEUROMUSCULAR		
Trism		
Could not swallow	---	
Muscular spasm	---	
Muscular rigidity		
<u>Seizures</u>		

* NOTE ON PRECEDING TABLE: for stillborn children, write down the descriptive history and the diagnosis. Minimal criteria for each case. Once the interview finishes, leave the house. Narrate the history of the lethal disease (about ten lines). It is important to leave a space for the interviewer's personal impressions and to go over the data about 15 days later to ensure the diagnosis.

123. Final diagnosis codification:

Probability:

1 probable

2 possible

9 not applicable

Principal --- Neonatal sepsis

Contributing factor --- Omphalitis

Contributing factor: the data can also be looked for during analysis.

PROCESS DIAGNOSIS

124. nature of the event/disease: this refers to the disease event that resulted in death (intrapartum, neonatal, etc.). The event will be registered in the blank space and the code will be used (develop codification for this number). For instance: the child was born almost asphyxiated and there was a labor complication and it is necessary to explore the whole process around this event. If it regards the child, one knows from the disease.

125. Who participated actively in response to this event?

126. At what moment was the existence of a problem (this problem) noticed?

127. Once the problem was detected, what was done about it? write the answer in the blank space.

Does not apply: problem not detected; data exploration does not apply because there was anything to do or look for.

128. Were adequate resources were sought, why were inadequate resources or support sought?

0 = no 1 = yes 9 = does not apply

Other people: this refers to other people who participated,

like TBA's, Rural Health Promoters, etc.

This question will preferably need guidance or stimulation.

129. Who participated in deciding for inadequate assistance?
130. What treatment was administered by the inadequate resource?
A (resource) _____: for codes a list must be developed before sending to La Paz.
131. Were adequate resources for assistance sought after the inadequate resources for assistance? (Was an adequate person summoned like a TBA or a Rural Health Promoter?)
132. If an adequate person was called for, what did this person do?
Write the family's response in the blank space.
133. When it was decided to look for adequate resources (persons), did you reach them?
1 = yes 2 = no, because there was no transportation
3 = no, because the owner of the transportation did not give importance to this matter.
134. When you reached the health services, what type of care was given? Codify this answer at the end of the workshop.

Adequate care: whatever corresponds to the situation; this depends largely on the interviewer's criteria; justify why the care is thought to be adequate.

Does not apply: any case that could not reach the health services.

APPENDIX 5

PLAN DE TRABAJO

1. Prueba del Instrumento	Médico/Educadora/ Enfermera	Inquisivi	8-12 oct
2. Orientación a Síntomas/ Estandarización	Coordinadora	Inquisivi	8-19 oct
3. Desarrollar listados de casos y registro para selección de con- troles Inquisivi 11/89-10/90; Circunata Licoma, 2 años); Selección de muestras de controles.	Educadora/Enfermera	Inquisivi	8-18 oct
4. Modificaciones y foto- copias de instrumentos	Coordinador	La Paz	15-18 oct
5. Ejecutar entrevistas (validación)	Educadora/Enfermera (Médico)	Todas las áreas	23 oct- 31 enero
		(Tienen varias otras activida- des ya progra- madas)	
6. Análisis	-Equipo/Médico de la Sede. -Encargado de sistema de información -Consultor	Inquisivi/ La Paz	1-28 feb.