

The MIRA Makwanpur Study

P r o t o c o l



M I R A

I C H



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Mother Infant Research Activities, Kathmandu.



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List of abbreviations

ARI	Acute Respiratory Infection	IMCI	Integrated Management of Childhood Illness
CDD	Control of Diarrhoeal Disease	IMPAC	Integrated Management of Pregnancy and Childbirth
CDO	Chief District Officer	IMR	Infant Mortality Rate
DDC	District Development Committee	MIRA	Mother Infant Research Activities
DFID	British Government Department for International Development	MWRA	Married Woman of Reproductive Age
DHO	District Health Office	NGO	Non-Governmental Organization
DPCP	Decentralised Planning for the Child Programme	NMR	Neonatal Mortality Rate
DPHO	District Public Health Office	NNIPS	Nepal Nutrition Intervention Project, Sarlahi
ENC	Essential Newborn Care	PMR	Perinatal Mortality Rate
EPI	Expanded Programme of Immunisation	SMP	Safer Motherhood Programme
FCHV	Female Community Health Volunteer	TBA	Traditional Birth Attendant
GDI	Gender sensitive Development Index	UNICEF	United Nations Children's Fund
HDI	Human Development Index	VDC	Village Development Committee
		WHO	World Health Organization

The study in brief

The MIRA Makwanpur Study is a cluster randomised, controlled trial of a community-based participatory intervention to improve the health of pregnant mothers and their newborn infants in Makwanpur district, Nepal.

Aims

There is an urgent need to improve the outlook for mothers and infants in developing countries. Policy makers are therefore seeking ways to reduce illness and prevent deaths by improving perinatal care in the home and at local health facilities. Building on experiences in Nepal and elsewhere, the MIRA Study aims to evaluate a community level intervention in Makwanpur, a poor rural district of Nepal. The study aims to examine the potential of community action cycles to bring about real improvements in health outcomes, and to serve as a model for sustainable replication.

Elements

The key elements of the intervention are the activities of women facilitators. Each facilitator will work within one Village Development Committee (VDC), covering an average population of 7500. She will facilitate the activities of women's groups within the VDC as they address the issues of pregnancy, childbirth and newborn health. Each women's group will move through a participatory planning cycle of assessment, sharing experiences, planning, action and reassessment with the aim of improving essential maternal and newborn care. The facilitation process will take place in 12 intervention VDCs, which will be compared with 12 control VDCs.

Outcomes

The study's primary outcome measures are Neonatal Mortality Rates (NMRs) and Perinatal Mortality Rates (PMRs). The study's secondary outcome measures include changes in patterns of home care, health seeking and referral. Other outcomes will include estimates of maternal mortality and neonatal morbidity, care practices in health and illness, and breastfeeding practices. The study will also generate a body of information on the process of introducing such an intervention in communities, and on the programme's experiences with planning and participation.



Background to the study

The neonatal period is the key to reducing infant mortality

Out of almost 800 000 annual births in Nepal, nearly 64 000 will die within one year and 40 000 will die within the first month of life. Interventions such as the expanded programme of immunisation (EPI), control of diarrhoeal disease (CDD) and treatment of acute respiratory infection (ARI) have successfully reduced infant mortality rates. To capitalise on this reduction, attention is now focused on the neonatal period. The continued decline in post-neonatal mortality means that the newborn period is growing in relative importance: neonatal mortality now accounts for up to 70% of infant mortality (Paul, 1999).

Essential newborn care

Essential newborn care (ENC) is based on the simple principles of perinatal hygiene, basic resuscitation, avoidance of hypothermia, early breastfeeding and a strong bond between mother and baby. It also emphasises the value of antenatal care and the treatment and referral of high risk or symptomatic infants. ENC is an integral part of WHO strategies for Safer Motherhood (SMP), the Integrated Management of Pregnancy and Childbirth (IMPAC) and the Integrated Management of Childhood Illness (IMCI). All of these strategies acknowledge the fact that improvements in health status in poor communities are strongly related to family and caretaking practices.

Mother and child health in Nepal

With a population of 23 million and a per capita gross national product of USD 220, Nepal is a poor country whose development challenges are exacerbated by its geography. Life expectancy is about 58 years and literacy rates run at 54% for men and 19% for women (UNICEF, 2000). Nepal's women have a total fertility rate of 4.4. Most babies are born at home: 94% in rural areas and 56% in urban areas (PRADHAN, 1997). Two-thirds of births are attended by relatives and only 10% by trained personnel. This lack of technical input is reflected in the high number of maternal deaths (a Maternal Mortality Ratio of over 500 per hundred thousand) and in poor infant outcomes. The reported Infant Mortality Rate (IMR) is 79, the NMR 50 and the PMR 57 per thousand (PRADHAN, 1997). A potentially effective perinatal health strategy must therefore recognise the realities of pregnancy and birth in rural Nepal. Primary and secondary care are deficient in rural areas and most women have no antenatal care and deliver their babies at home. The reasons for this include limited expenditure on public health, poor quality of care, a high turnover of service providers, a lack of drugs and supplies and a lack of ownership of health programmes by communities.

Community-based intervention

Most perinatal and neonatal deaths occur at home, and it is probable that many of them could be avoided with changes in antenatal and newborn care practice. There is also a well established need - a need spelt out in the Alma-Ata Declaration (WHO, 1978) to consolidate the links between primary health care services and their users. Where services exist, the reasons for their underuse are complex (STONE, 1986; CARLOUGH & LEMASTER, 1998; JUSTICE, 1999). The removal of physical barriers to access can only be expected to lead to a limited increase in uptake (HOTCHKISS, 2001), and there are issues of service quality (DHUNGEL, 1992; KUTZIN, 1993; TIPPING & SEGALL, 1995) and community perceptions of service providers (PARKER, 1988; CHALKER, 1990; BOLAM, 1998a). Supply and demand are intimately linked: poor service quality may be at least partly the result of users having little voice in the design and management of services delivered in their name (BRUCE, 1990; WEAKLIAM, 1994). The creation of a more demand-driven environment for service delivery might therefore be expected to increase rates of use. Concerned and involved users with palpable influence are more likely to use services knowledgeably and appropriately and to pay greater attention to health messages. In the context of improving perinatal health, this may increase the likelihood of high risk pregnancies and at-risk newborns being referred to health facilities more promptly.

Participation in health care

The growing interest in community participation in health care may be partly a response to the funding crisis in health care provision on the part of international agencies and national governments (ZAKUS, 1998), and partly a response to the failure of health education (BOLAM, 1998b) and primary health care to deliver substantial health benefits to those most in need of it (STANDING, 1996). Local health committees in Nepal may have little accountability to their communities and the level of representation of beneficiaries such as women is low (MANANDHAR, 1996; SEPEHRI & PETTIGREW, 1996). The community development literature identifies many reasons why beneficiaries are often passive in the face of service bureaucracies (RIFKIN, 1986, 1988 & 1990). Factors as diverse as lack of local ownership, different perceptions of priorities between officials and communities and capture of resources by powerful groups have been documented. It is particularly important, therefore, to find ways of involving those groups who have traditionally had the least voice in what is provided to them and how it is provided. One challenge is to develop strategies that encourage the growth of more focused forms of user involvement, capable of wielding influence over specific areas of service provision. User alliances may tap into more circumscribed areas of interest, where the potential for disruption by wealth and power differentials is less pronounced. Maternal and child health is potentially a fruitful area for developing such alliances (BERER, 1992). Although power relations - both of gender and seniority - are implicated in health decision making at the household level, a focus on improving the health of mothers and infants within communities is not inherently controversial.

Model strategies

Forest user groups

The experience of forest user groups provides some precedent for the development of health-focused user alliances. Community forestry interventions fall somewhere between top-down projects where the only community input is local labour, and grassroots initiatives aimed at the empowerment of women and the poor by giving them control over access and decision making. Such interventions are based on the active involvement of forest users in management, allied with continuing technical support from the Forestry Department and other agencies. The role of external facilitators as catalysts has been important in this process (HOBLEY, 1990 & 1996).

The Warmi experience

The Warmi Project - introduced in a rural area of Bolivia with little health infrastructure and widespread poverty - is the only published account of a community participatory intervention to improve perinatal care (HOWARD-GRABMAN, 1993a, 1993b & n.d.). It employed participatory planning methods and community action cycles focused on mother and infant care. The cycles began with the development of groups in which women worked together to identify key maternal and neonatal health problems (*autodiagnosis*). The women's groups went on to prioritise the problems and develop local strategies to address them (*planning together*). These strategies were aired in the wider community and adopted after a process of further planning. Within three years, the Warmi Project had achieved a substantial decrease in PMR, from 117 to 44 per thousand. The lack of a control group and the relatively low power of the study, however, make firm conclusions difficult to draw. The project also had many spin-offs in relation to increasing women's participation in the community. The local situation bore striking similarities to that of rural Nepal. The perinatal mortality rate in the area - 117 per 1000 births - was very high. Women had little decision making power and were isolated in dispersed settlements. Most deliveries were assisted by relatives and took place at home.

The SEARCH experience

The work of the SEARCH group in Gadchiroli, a poor rural district of Maharashtra state, India, has also achieved wide recognition (BANG, 1999). The group carried out a controlled study within a population of about 80,000. At baseline, almost half of newborn infants encountered *high risk morbidity*, of which over half was ascribed to sepsis. Village health workers were therefore trained to visit newborn infants at home, identify warning signs and manage sepsis with a combination of injectable and oral antibiotics. The case fatality rate was 17% before training and 2.8% afterward. By the third year of the intervention, the NMR was 26 per thousand births in the intervention areas and 60 per thousand in the control areas. Some caution is required in interpretation and generalisation, since the study was not randomised and the intervention involved workers paid and tightly managed by the SEARCH team, outside the government system and covering a relatively small population.

The MIRA Makwanpur Study

Aims

The MIRA Makwanpur study aims to test a low-cost, community-based perinatal care programme in a population of 170 000 in Makwanpur District, Nepal. An important part of the programme activities will be the development and evaluation of a model participatory intervention with an emphasis on sustainability. This model may influence policy at a national and local level, and also enable caretakers in resource-poor communities to practise the key elements of newborn care more effectively. The model has policy implications for most developing countries, especially where institutional birth is a limited option. The key role of trained local facilitators within the model brief is consonant with the Decentralised Planning for the Child Programme (DPCP) administered by UNICEF, Nepal. As a project partner, UNICEF aims to incorporate the perinatal model as a component of the DPCP and eventually to expand to national level.

Elements

The location

Makwanpur District occupies about 2500 sq km and lies to the south of Kathmandu in the Central Region, Narayani Zone. It has a population of about 376 000 (NEPAL RESEARCH ASSOCIATES, 1999), a Human Development Index (HDI) of 0.31 - half way between the highest and the lowest in Nepal - and a Gender sensitive Development Index (GDI) of 0.23. Topographically, Makwanpur includes both hill (*pahaad*) and plain (*terai*) areas. Most residents are engaged in agriculture and the ethnic composition is mixed: of at least 15 ethnic identities, the largest group are Tamang, a predominantly Buddhist, Tibeto-Burman group. The district centre is Hetauda, the site of the MIRA Study office, a growing town with good road connections and developing infrastructure.

95% of deliveries in Makwanpur occur at home and the provision of maternity services at the district hospital in Hetauda is of limited quality, with caesarean section not available. Perinatal health care is provided by personnel from Sub-Health Posts or Health Posts at VDC level, as well as by Primary Health Centres and the District Hospital. Traditional Birth Attendants (TBAs) are also available in all localities. In 1998, the Ministry of Health identified Makwanpur as a future Safe Motherhood Programme district. The obvious synergy between Essential Newborn Care and Safer Motherhood provides opportunities for collaboration.

Local relationships

A national workshop held in 1998 discussed the aims and design of the study. This was followed by a series of meetings with members of the District Development Committee (DDC) and Chief District Officer (CDO). The MIRA Hetauda office was set up in late 1999, from which point local visits – both formal and informal – increased. This helped to cement links between the MIRA team and local actors such as community leaders, district health services and non-governmental organisations (NGOs). In early 2000, the chairpersons of all 24 VDCs involved as either *intervention* or *control* areas agreed to take part in the study and provided signed consent. All community based team members were recruited locally and carry out their activities in their home VDCs.

The study design

The randomised, controlled trial is the accepted gold standard for evaluating the effect of health interventions. The MIRA Study has a cluster randomised controlled design predicated on the need to demonstrate the impact of the intervention on neonatal mortality rates. The 42 rural VDCs of the district were matched into 21 pairs on the basis of geography, population and ethnicity. 12 pairs were then randomly selected to produce a study area with a population of about 170 000. Finally one VDC per pair was randomly allocated to receive the intervention and one to act as a control.

The study will run for three years. If a valuable effect is shown at the end of this period, the intervention model – refined on the basis of experience - will be implemented in the 12 control sites. Moreover, all VDCs within the district will receive training and service strengthening inputs throughout the study cycle.

Participants

Married women aged 15 to 49 years are classified for study purposes as *married women of reproductive age* (MWRA). All MWRA within the study area have been identified, and each is visited monthly by study personnel. From the beginning of the study period, all pregnancies occurring within the cohort of MWRA are followed until at least six weeks after delivery. The ages of women in the cohort were established for a specified point in time. The cohort members are listed in a master document to which no new names can be added: the cohort is closed and no other participants will be enrolled during the study period.

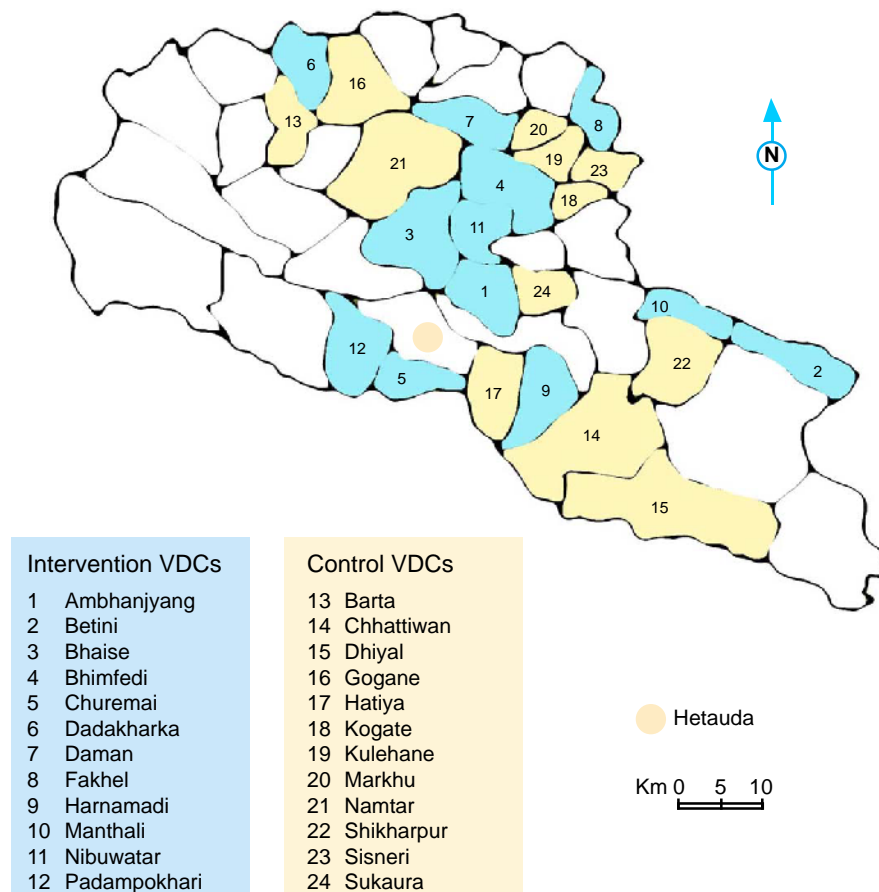
Inclusion criteria

The criteria for enrollment into the closed cohort were: that a woman was aged between 15 and 49 years inclusive; that she was married; and that she could potentially conceive within the period of the study.

Exclusion criteria

Reasons for non-inclusion in the cohort were: that a woman was aged under 15 or over 49 completed years; that she was unmarried, permanently separated or widowed; and that there was no potential for conception within the period of the study.

Makwanpur District: the intervention and control VDCs



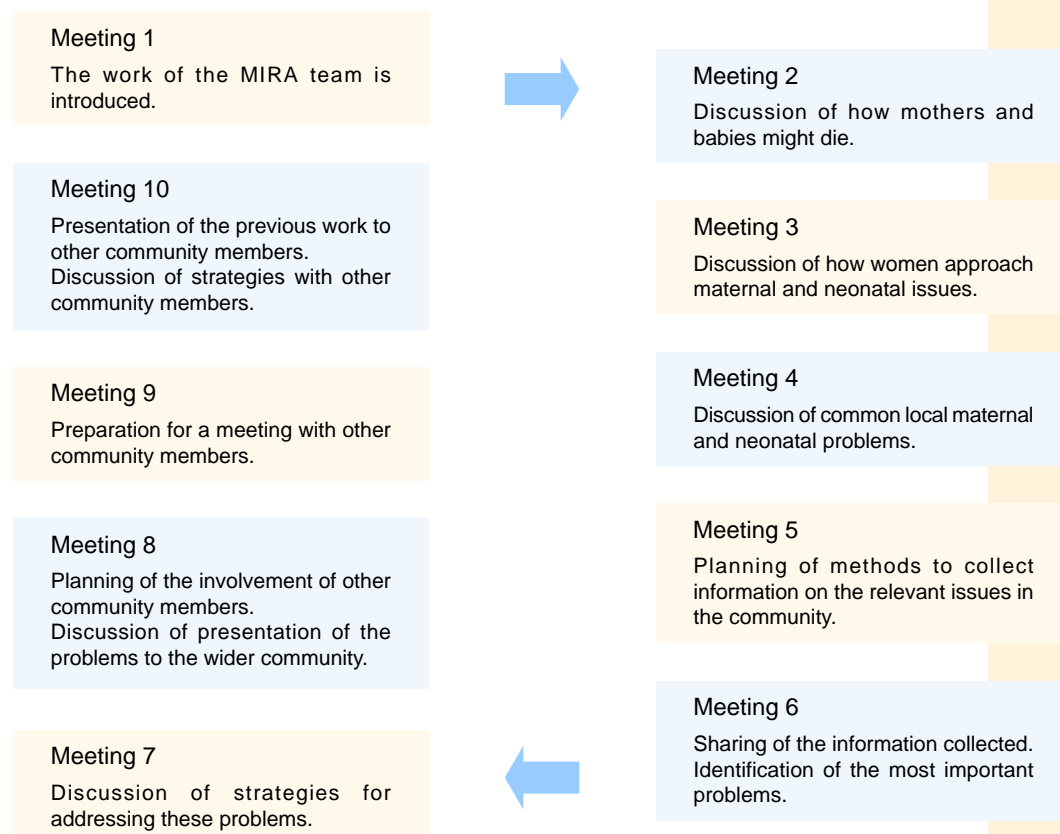
The intervention: Working with women's groups through an action research cycle

Twelve local female facilitators explore perinatal health issues, one in each of the twelve *intervention* VDCs. Mothers' groups convened by local Female Community Health Volunteers (FCHVs) exist in each VDC, but their degrees of activity and performance vary. The role of the facilitator is to activate and strengthen groups, support them in identifying and prioritising maternal and neonatal problems, help to identify possible solutions and support the planning, implementation and monitoring of the solution strategies in the community. The intervention requires a facilitator rather than a teacher, a change agent with experience in participatory modes of communication. She needs to have a grasp of perinatal health issues and some knowledge of potential interventions, so that she can act as a broker of information and a catalyst for change.

In the first phase of the programme, the facilitation team explored the issues around childbirth in the communities in which they were to initiate the intervention. This exploration served as a prolonged induction and training period for the facilitators, and generated a body of ethnographic information on pregnancy and childbirth of considerable breadth and depth. The team examined both normal practices and beliefs and practices relevant to problems in either mothers or babies. Within the intervention cycle, mothers' groups meet monthly to work on the identification of maternal and neonatal problems, the identification of possible solutions, planning, implementing and monitoring potential solutions and sharing information with others. The groups are also involved with other health-related activities in their communities. The primary cycle consists of a series of ten meetings.

The facilitators assist the women's groups in devising local strategies to realistically tackle the issues in a resource-constrained context. Community commitment and ownership are essential to ensure implementation. Once a primary cycle of meetings has been completed, it is repeated with appropriate modifications in other settings. Work with the original groups continues, and new cycles are set up with other mothers' groups and with groups such as mothers-in-law and husbands. The exact form of the continued intervention cannot be defined in advance, since it is inherently iterative and operates within an action research cycle. Similarly, the nature of the discussion, levels of involvement and potential solutions differ from group to group.

The intervention: The action research cycle for women's groups



Institutional perinatal health care strengthening: Training and support for health service providers in all cadres

The experience of the team during the three year preparation phase for the study suggested that – aside from the intervention itself - there was a need for health service strengthening. This need was underlined by a service audit carried out in the first phase of the programme, which focused specifically on the provision of antenatal care, delivery and newborn care. The team therefore made a commitment to improving service delivery at all levels within the district, and to improving referral links between them. The key inputs are training and the provision of some equipment and consumables. Perinatal care training is provided at all levels of the primary health care system, in partnership with the District Public Health Office (DPHO). Training is cyclical and subject to follow-up evaluation. Shortfalls in basic equipment and essential drugs are also remedied, but strategies for securing resupply are addressed in order to optimise sustainability. However, because the study aims to test the effects of the facilitatory process, service strengthening activities are carried out across the whole district and their effects are not explicitly evaluated through the study design and surveillance system. This is both ethical and beneficial to VDCs acting as controls (EDWARDS, 1999).



Outcomes

The study was designed to detect changes in NMRs (deaths in the first 28 days per thousand livebirths). PMRs (deaths from 22 weeks of gestation to 7 days after birth per thousand births) will also be examined.

The surveillance system also gives us the opportunity to look at a range of other issues. These include demographic factors, antenatal care service use, perinatal illness, birthing practices, newborn care practices, health seeking behaviour, breastfeeding practices and infant mortality. We shall examine trends in light of the intervention, particularly in caretaker practices, early and exclusive breastfeeding, the use of prelacteal feeds, hygiene behaviours, care-seeking, referral patterns and clean delivery kit usage.

For the women and communities involved in the process, the hoped for results will be awareness of perinatal problems and an understanding of ways to approach them in the community, knowledge of danger signs in pregnancy and after birth, knowledge of available services and when to use them, and demand for the appropriate services. The team also hope to improve the knowledge and skills of health workers. Desirable outcomes include improved availability and quality of antenatal care, clean home delivery kits and newborn referral services, as well as an increase in the levels of skilled attendance at delivery.

For the wider community, we hope to develop a generalisable methodology to identify and facilitate participation with user groups, a methodology that could be incorporated into other strategies such as UNICEF, Nepal's DPCP. The nature of the intervention has mandated a complex process of community entry, as well as a flexible approach to planning. The team feel that good descriptive information on the practicalities of managing community interventions and trials is hard to find. A further output of the programme will therefore be a body of appropriate information in the form of papers and manuals. The collation and presentation of this sort of information will be important for groups that seek to replicate the process elsewhere. The depth and breadth of the surveillance will also allow us to produce descriptive statistics of high quality to inform further research and policy: this is an output that accords with the emphasis on good quality data in recent statements made by the British Government Department for International Development (DFID, 2000).

Ethical issues

Community consultation

The process of informed consent has already been mentioned (see *local relationships*, page 6). DDC, VDC, DHO and DPHO representatives have ongoing access to the research programme and will be the first to be briefed on study findings and outcomes through written and verbal reports.

Benefits to the control communities

The study is designed to test the efficacy and cost-effectiveness of a new and unproven community level initiative to reduce neonatal mortality in rural Nepal. For demand-side interventions to work, the supply side of perinatal care services must reach a minimum standard. The study team considers it unethical to strengthen primary care facilities in intervention but not control areas, especially given the weakness of primary perinatal care services in Nepal. Control communities will benefit from low-cost improvements in equipment and training provided at all levels of the health system in Makwanpur.

Treatment of illness in participating communities

When the study surveillance team identify minor illness in mothers or infants in either intervention or control areas, they will encourage their referral to the appropriate health facility. In severe cases of illness, the team will have access to an emergency fund to assist in the rapid and appropriate treatment of patients in the study area, regardless of whether the VDC is an intervention or control area.

Confidentiality of information

All information provided by participants will remain confidential. Access to information is limited to interviewers and their supervisors at sites of collection, to auditors and datafeeders at the collation point and thenceforth to the Senior Data Management Officer and Technical Advisors at the analytical level. No analyses or outputs will include the names of participants.

Data monitoring

The nature of the intervention means that the MIRA study, though randomised, is not blinded. Until the definitive analysis of the study outcome, analysts will be blinded to the distinction between intervention and control VDCs. Subsidiary analysis will be performed on exported datasets whose origin is likewise blinded. An independent Data Monitoring Committee will meet to discuss issues of quality, confidentiality and analysis on a regular basis. The Trial Steering Group will be informed if, at any time, the randomised comparisons in this study have provided both (i) proof beyond reasonable doubt of a difference in mortality rates between the intervention and control groups, and (ii) evidence that would be expected to alter substantially the decision of policymakers to implement community-based perinatal care programmes. Exact criteria for proof beyond reasonable doubt are not specified, but it should generally involve a difference of at least three standard deviations. Using this criterion has the practical advantage that the exact number of interim analyses is of little importance: no fixed schedule is proposed.

Economic evaluation

Since the study aims to produce a replicable and scalable model for intervention, it is important that all inputs are audited and cost-effectiveness analysis is carried out. The collection of economic data and analysis of cost-effectiveness of the study intervention, is being conducted in collaboration with Dr Julia Fox-Rushby at the London School of Hygiene and Tropical Medicine.



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Annex 1

The surveillance system

In order to examine differences in neonatal mortality in matched pairs of VDCs, births and birth outcomes will be quantified prospectively. A community surveillance system will monitor pregnancies, births, deaths and a number of secondary indicators over the period of the study. Many of the procedures that underpin the surveillance system were developed after consultation with the Nepal Nutrition Intervention Project, Sarlahi (NNIPS). This group have been carrying out high quality surveillance in the Terai for over a decade, and have unsurpassed experience in the relevant areas (PRADHAN, 1994). The implementation of the surveillance system was carried out in three phases.

Phase 1 Mapping and enumeration

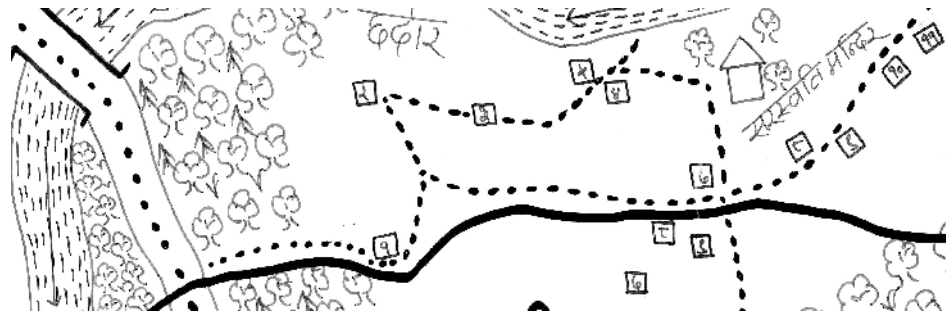
The 24 study VDCs have been mapped in detail to locate all households and allocate to each household a unique identification number. All MWRA within these households eligible for entry into the study have been identified and each has been allocated a unique, personal identification number. At each household a questionnaire has been completed, covering ethnicity, occupational and socioeconomic status. This information will help in (a) describing the backgrounds of MWRA within a household, and (b) assessing baseline comparability of matched pairs of VDCs. A household has been defined as a group of individuals sharing one kitchen; a MWRA as a married woman aged between 15 and 49 completed years, whose husband was alive on enrollment and whose husband either lives with her or makes visits that allow for the possibility of conception within the study period.

Phase 2 Describing the cohort

After generating a list of all MWRA residing in the study area, each MWRA has been interviewed to document her educational status, work activities and details of previous pregnancies. The information provided at this stage will allow us to determine retrospective infant mortality rates, patterns of antenatal care, rates of morbidity during pregnancy and postpartum and patterns of health care seeking for maternal and neonatal problems.

Phase 3 The surveillance process

Each of the 24 VDCs is divided into nine wards. Each ward is further divided (for study purposes only) into four sectors. Each VDC has a VDC Interviewer who is responsible for managing nine Ward Enumerators, one for each ward of each VDC. Each Ward Enumerator is a local woman whose role is solely to monitor menstrual status in MWRA in her ward. Every week, a Ward Enumerator visits all MWRA in one sector of her nominated ward. Each sector (and thus each MWRA) is therefore visited once per month. At each visit, a MWRA is asked about her menstrual status. The Ward Enumerator records the response on a preprinted chart on which the names and numbers of her allotted MWRA appear. The chart is then scrutinised by the VDC Interviewer at a weekly VDC-level meeting. A MWRA who has not menstruated for three visits (three months) is presumed to be pregnant. A memo to this effect is written on a standardised form which is transmitted to the central office. Subsequent to identification of pregnancy, the first formal study interview is carried out by the VDC Interviewer at as near to seven months gestation as possible. At seven months, there are three possible outcomes for a pregnant woman: she may be progressing through pregnancy, she may have had a miscarriage or she may have died. Clearly, the first of these outcomes is by far the most likely. Since the Ward Enumerator continues to visit each woman on a monthly basis, it is possible to know in advance (in most cases) which of the three outcomes is relevant. The Ward Enumerator appraises the VDC Interviewer of the situation and the first interview is taken. There is a specific questionnaire for each of the three possible outcomes. The second interview is carried out by the VDC Interviewer at as near to one month post-partum as possible. At one month post-partum, there are two possible outcomes for a woman: she may have delivered her baby and progressed to one month, or she may have died. There are likewise three possible outcomes for her infant: progress to one month of age, stillbirth, or neonatal death. The Ward Enumerator again appraises the VDC Interviewer of the situation and the second interview is taken. There is a specific questionnaire for each of the two possible maternal and each of the three possible infant outcomes.



Section of ward map

The interview tools

The analysis of the surveillance data will be quantitative, using information derived from closed questionnaires. The general content of each questionnaire is outlined below.

Contact 1: at seven months gestation

either...

Pregnancy questionnaire

contains questions about illness in early pregnancy.

or...

Miscarriage questionnaire

contains questions about illness in early pregnancy and health seeking behaviour.

Contact 2: at one month postpartum

either...

Maternity questionnaire

contains modules for antenatal care, illness during pregnancy, delivery, illness in the postpartum period and health care seeking behaviour.

or...

Maternal verbal autopsy questionnaire

contains modules for antenatal care, illness during pregnancy, delivery, illness in the postpartum period and health care seeking behaviour.

either...

Infant one month questionnaire

contains modules for birth, newborn care, breastfeeding, neonatal illness and health seeking behaviour.

or...


Perinatal verbal autopsy questionnaire

contains modules for birth, newborn care, breastfeeding, neonatal illness and health seeking behaviour.

Data handling


After completion, each questionnaire passes through a four-stage checking process, the first stage of which is as near to the interview site as possible, and the last stage of which is at the point of data entry. All data are double entered. Further checks are carried out internally within the electronic data handling environment, which comprises a dedicated server and workstations running a relational database management system in Microsoft SQL Server. The system is outage protected and has multiple levels of backup. Basic analyses can be run within the system itself. For more complex treatment, the modular structure of the database allows flexible export to statistical packages.

Annex 2



Nepal Health Research Council

Estd. 1991



NHRC September 8, 1998

Date: Dr. D.S. Manandhar
President, MIRA
GPO Box 921
Thapathali.

Ref: १७३ Fax: 977 1 278522

Subject: Approval of the research proposal entitled "Impact of a Community Based Participatory Intervention to Improve Essential Newborn Care (ENC) in Rural Nepal."

Executive Committee

Chairman
Prof. Mathura Prasad Shrestha

Vice-Chairman
Dr. Sunder Mani Dixit

Member-Secretary
Dr. Kamal Gyawali

Members
Prof. Sanu Maya Dali
Dr. Basant Lal Shrestha
Dr. Rishi Ram Koirala
Dr. Madhu Ghimire
Dr. Ram Kewal Shah

Representative
Ministry of Finance
National Planning Commission
Ministry of Health
Chief, Research Committee, IOM
Chairman, Nepal Medical Council

Dear Dr. Manandhar:

We are pleased to inform that the above mentioned proposal submitted by you has been approved by NHRC Board following the recommendation of the Technical Review Committee (TRC) and Ethical Review Committee (ERC). This also certifies that the proposal is ethically cleared.

As per NHRC regulation you are to follow strictly the protocol stipulated in your proposal finalized after the interaction of TRC and ERC with you. Any change in objectives (st. problem statement, research question or hypothesis, methodology, implementation procedure, data management and budget that may be necessary in course of the implementation of the research proposal can only be made so and implemented after prior approval from this council. You are thus strongly advised to submit to NHRC the details of such changes intended or desired with justification prior to instituting actual change.

You are also to abide by the ethical guidelines of NHRC strictly during the implementation of your research proposal. In addition, in course of investigation of any medical health problem feeding immediate care, further investigation, or expert consultation you are obliged to inform the subject-study or control clearly in writing from within seven days of detection. However, during the transmission of such information confidentiality must be maintained.

Lastly, you are obliged to submit periodic progress reports every 3 months and submit three copies of the final research report, and financial statement after completion of the research. If an article based upon that research is published, you should submit two copies of that article.

If you have any question, please contact our research officers.

Thank you.
Yours truly,
Dr. Kamal Gyawali
Member-Secretary

Ethical agreement

Agreement from VDC

यो भन्नुको के हो त ?

२४ वटा गा.वि.स. हरलाई १२ वटा जाँडीमा बाँडिने छ । प्रत्येक जाँडीको एउटा गा.वि.स.मा माथि भनिए अनुसारको रणनीतिहरू सुट देखी लागू गरी अध्ययन गरिने छ । कार्यक्रम लागू भएको दुई वर्ष पछि मात्र यसको महत्त्व बारे जानकारीहरू प्राप्त हुने छ ।

कुन कुन गा.वि.स.मा रणनीतिहरू तुरुन्त लागू गर्ने भन्नुको लागि मोलाप्रसाद निर्णय गरिने छ । २४ वटै गा.वि.स.हरू मध्ये १२ वटा गा.वि.स.मोलाप्रसाद ज्ञान सुदपार पढी रणनीतिहरू लागू गरिने छ र नतिजाबारे अन्य १२ वटा गा.वि.स. संग राखिने छ । यसको लागि २४ वटै गा.वि.स. का गर्भवती आमाहरू संग भेटघाट गरी गर्भवती र नवजात शिशुहरूलाई के कसरी हेरचाह तथा समस्या समाधान गरिन्छ र के के समस्याहरू आईपरेकै ज्ञान आवश्यक छ ।

हामीले विस्तारगर्ना नवजात शिशुहरूको मृत्यु, आमाहरूमा नवजात शिशु हेरचाह बारे चेतना, उपयुक्त आचारगर्ना तालिम प्राप्त स्वास्थ्य कार्यकर्ताहरूलाई सुत्कोरी, स्वास्थ्य कार्यकर्ताहरूको ज्ञान र सीप, गर्भवती सेवाको उपलब्धता र प्रयोग साथै सुत्कोरी सामग्रीको उपलब्धता र प्रयोग र पैसा (टिफर) को बारेमा टेकडै राख्ने छौ ।

हामीलाई आशा छ यो कार्यक्रमले नकवानपुर जिल्लाका आमाहरूलाई मात्र नभई नेपाल अधिराज्य भरिका आमाहरूलाई सहयोग पुग्ने छ । त्यसकारण हामीले श्री ५ को सरकार स्वास्थ्य मन्त्रालय संग मिनेर काम गर्ने छौ ता की यस अध्ययनको नतिजा श्री ५ को सरकार स्वास्थ्य मन्त्रालयलाई दिनु सकियोस ।

हामीले गा.वि.स. अध्यक्ष ज्यूहरूको भिटिडमा वि कुण्ठर छलफल गरीसकेका छौ र पुन बाह्रैको प्रश्नको जवाफ पनि हामी दिने छौ ।

हामीले यस अध्ययन पहचान यसको नतिजा प्रत्येक गा.वि.स. मा तुरुन्त उपलब्ध गराउने छौ । तपाईं यो कार्यक्रमको लागि २४ वटा गा.वि.स. भन्ने एउटा गा.वि.स. छानिई कार्य संचालन गर्न सहमत हुनु हुन्छ भने कृपया तब बल्लश्वत गरीविनूहन अनुरोध गरिन्छ ।

म श्री अमल न बिजु गा.वि.स. अध्यक्ष हरीमणि गा.वि.स. के नवजात शिशु स्वास्थ्य कार्यक्रम (मिरा) बारे छलफल गरीयो अध्यक्ष अमल न बिजु गा.वि.स. हर नयाँ मेरो गा.वि.स. मा पनि लागू गर्न मेरो सहमती छ ।

अध्यक्ष
गा.वि.स. हरिमा

२०२०/११/४
मिति

सहायक अध्यक्ष
गा.वि.स. हरिमा

२०२०

Annex 3

Sample size calculations

Calculating sample size in a cluster randomised trial with neonatal mortality as the main outcome variable requires a number of assumptions (DONNER, 1992). In essence, the calculation depends upon the estimation of the following variables: the projected size of the reduction in neonatal mortality; the statistical power of the study; the k value (a measure accounting for the design effect, the possibility that clusters may systematically differ one from another rather than being random collections of people. This may also be described as either intracluster correlation or intercluster variation); the number of births generated in each cluster; the number of clusters in the intervention and control groups.

The primary unit of randomisation is the VDC, rather than a smaller geopolitical unit such as a ward. This decision was made by participants at the national planning workshop in 1998, and was endorsed by the DFID Safer Motherhood Programme based on their experience in three districts. Randomisation at the level of the VDC simplifies the management of the participatory intervention. VDC health and women's development committees will also be key points of liaison. The maximum number of clusters considered feasible in either intervention or control groups was 12.

The NMR was estimated as 60 per thousand livebirths. We hypothesise a maximum reduction of this figure to 40 per thousand. Whilst we believe that this target is achievable, we acknowledge that it is ambitious within the time frame of the study. In practice, the intervention will have a longer term impact and we envisage that the mortality reduction will be lower in the first two study years and gain momentum over time.

Calculation of the variation in mortality rates between clusters represented by the value of k is critical, yet there is an absence of randomised controlled trials using neonatal mortality as an outcome variable in poor communities (KIRKWOOD, 1997). One available estimate of k for community health studies is around 0.25 (HAYES, 1995). This is recognised as fairly conservative and is based upon the measurement of outcomes such as HIV seroprevalence and infectious disease mortality. We believe that there will be less variability in neonatal mortality between clusters in rural Nepal: exposure to risk factors such as poor hygiene and lack of a birth attendant is likely to be fairly uniform within Makwanpur district. We estimate that each VDC will generate on average - but with considerable variation - about 250 births per year. This will provide sufficient power to draw adequate interim conclusions about the mortality decline associated with the intervention. For example, assuming a k value of 0.20, a sample size of 11 pairs of VDCs generating a mean of 480 births per VDC over two years would enable us to detect a reduction in neonatal mortality from 60 to 43 per 1000 at a power of 80%. Since starting the study, the number of VDC pairs has increased from 11 to 12, an increase that will be associated with a marginal increase in power. If – as we believe – the design effect turns out to be lower, the power of the study and its ability to detect smaller mortality reductions will improve.



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Project partners

The MIRA Study has a five-year, written memorandum of understanding with His Majesty's Government, Nepal, Ministry of Health. The British Government DFID, UNICEF, Nepal and WHO have been involved since the inception of the study. A key objective is to take lessons learned quickly to scale in other districts through our partners. At local level, we shall work closely with the DDC, DHO, DPHO, Women's Development Office, VDC representatives and locally active NGOs. The MIRA Study principal investigators are also working in close collaboration with the Saving Newborn Lives Initiative, directed by the Save the Children Fund (US) and funded by the Bill and Melinda Gates Foundation. The findings of the study will be communicated promptly to the network of partners developed by this initiative, and also to the south Asia network of perinatal societies.

