CITY INITIATIVE FOR NEWBORN HEALTH

MUMBAI

OVERVIEW AND PROTOCOL

A Collaboration Between SNEHA, MCGM, IPU AND ICICI Bank

SNEHA

The Society for Nutrition, Education and Health Action is a voluntary secular non-profit organization working to improve maternal and child health in the urban slums of Mumbai. Founded in 1999 by a team of committed health professionals from the neonatology department of Sion Hospital, SNEHA has grown into an organization serving the health needs of women and children through sustainable initiatives aimed at addressing problems in urban health.

MCGM

The Municipal Corporation of Greater Mumbai is a public body whose representatives are elected by the people of the city. Working through a number of sections, the MCGM is responsible for civic amenities (electricity and transport, water and sanitation, infrastructural improvement), primary health care and primary education. It runs a range of primary, secondary and tertiary level facilities in the city including three teaching hospitals.

IPU

The International Perinatal Care Unit, Institute of Child Health, University College London, is an academic research unit. IPU's mission is to promote the health, nutrition and welfare of children and their families in less developed countries. Its research aims to develop the scientific basis for improvement in clinical and public health management regimes using robust epidemiological, laboratory and social science methodologies focusing on perinatal health.

ICICI Bank

ICICI Bank through its non-profit Social Initiatives Group (SIG) invests in the areas of early child health, elementary education and micro financial services with a view to improving human capacity. In early child health, our work is organised around maximising the proportion of children born healthy and optimising growth and development in the first three years of life. In partnership with governments, NGOs academic and research institutions, the SIG co-develops and funds the development of evidenced-based models addressing key sectoral gaps in knowledge and practice, that have the potential to be mainstreamed through larger systems.

VISION

SNEHA is built on love, trust and commitment. We value every woman and child. We dedicate our energies, expertise and resources to ensure quality nutrition, education and health care of women and children in urban communities.

MISSION

We will look for innovative solutions to problems in nutrition, education and health in urban slums. Our services will build sustainable and replicable models of intervention and partnerships that will empower women to change their lives and the lives of those around them.

SNEHA Society for Nutrition, Education and Health Action for Women and Children

International Perinatal Care Unit

ICICI social initiatives.org

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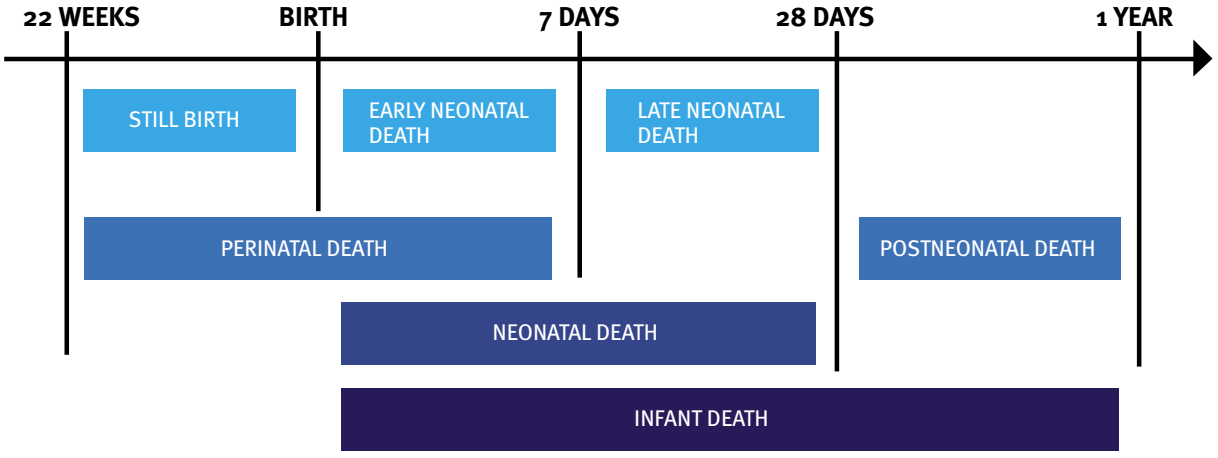
ABBREVIATIONS AND DEFINITIONS

AI	Appreciative Inquiry
ANC	Antenatal care
APH	Antepartum haemorrhage
BCC	Behaviour change communication
CBO	Community based organisation
CHV	Community Health Volunteer
DEHO	Deputy Executive Health Officer
EHP	Environmental Health Project
ENMR	Early neonatal mortality rate
ICDS	Integrated Child Development Scheme
IEC	Information, education and communication
IMR	Infant mortality rate per thousand live births
IPU	International Perinatal care Unit, Institute of Child Health, University College London
LBW	Low birth weight, < 2500 g
LMP	(First day of) Last menstrual period
LNMR	Late neonatal mortality rate per thousand live births
MDGs	Millennium Development Goals
MIRA	Mother and Infant Research Activities, Nepal
MIS	Management information system
MMR	Maternal mortality ratio per hundred thousand live births
MOH	Medical Officer of Health
NGO	Non-government organisation
NMR	Neonatal mortality rate per thousand live births
NNMB	National Nutrition Monitoring Board
NPP	National Population Policy
PMR	Perinatal mortality rate per thousand births
PNMR	Post-neonatal mortality rate per thousand live births
PPH	Post-partum haemorrhage
RCT	Randomised controlled trial
SAHAJ	Society for Health Alternatives
SBR	Stillbirth rate per thousand births
SC-US	Save the Children US
SEARCH	Society for Education, Action and Research in Community Health, Maharashtra
SNEHA	Society for Nutrition, Education and Health Action
U5MR	Under-five mortality rate per thousand live births
UN	United Nations
USAID	United States Agency for International Development
WCHP	Women Centred Health Project
YUVA	Youth for Unity and Voluntary Action



Stillbirth	**Stillbirth rate**	**SBR**
Death of a fetus after 22 complete weeks of gestation and before delivery	Stillbirths per 1000 births	
Early neonatal death	**Early neonatal mortality rate**	**ENMR**
Death of a live-born infant within 7 complete days after birth (the first week)	Early neonatal deaths per 1000 live births	
Late neonatal death	**Late neonatal mortality rate**	**LNMR**
Death of a live-born infant between 7 and 28 complete days after birth (weeks 2-4)	Late neonatal deaths per 1000 live births	
Perinatal death	**Perinatal mortality rate**	**PMR**
Stillbirth or early neonatal death	Stillbirths and early neonatal deaths per 1000 births live and still	
Neonatal death	**Neonatal mortality rate**	**NMR**
Early or late neonatal death (the first 4 weeks)	Early and late neonatal deaths per 1000 live births	
Post-neonatal death	**Post-neonatal mortality rate**	**PNMR**
Death of a live-born infant between 28 days and 12 complete months after birth (1 month to 1 year)	Post-neonatal deaths per 1000 live births	
Infant death	**Infant mortality rate**	**IMR**
Neonatal or post-neonatal death (the first year)	Infant deaths per 1000 live births	
Under-five death	**Under-five mortality rate**	**U5MR**
Death of a live-born infant within 5 complete years after birth	Under-five deaths per 1000 live births	
Maternal death	**Maternal mortality ratio**	**MMR**
Death of a woman while pregnant or within 42 days of termination of pregnancy, irrespective of the duration and site of pregnancy, from any cause related to or aggravated by the pregnancy or its management, but not from accidental or incidental causes.	Maternal deaths per 100,000 live births	

EXECUTIVE SUMMARY

GOAL

To improve the health and survival of mothers and newborn infants in underprivileged communities in Mumbai.

PURPOSE

To work with community members in urban slums to achieve improvements in maternal and newborn care practices and care seeking.

To work with municipal health service providers to strengthen decentralised primary care:

- To achieve provision of high quality antenatal and postnatal care at health posts.
- To encourage continuous quality improvement in maternal and neonatal services at maternity homes and hospitals and along the referral chain.

To test replicable and scaleable models of interventions to improve maternal and newborn health.

METHODS

The initiative's primary strategies are to encourage change through participation, self-sustaining group activities, ownership, and appreciative inquiry. The first phase of the initiative will run for 4 years. For the purposes of management and evaluation the package will be organised into three components. Within each component, strategies will be devised by groups convened to plan interventions to improve maternal and neonatal health. Intervention will take place at a number of levels, from community to tertiary.

EVALUATION, OUTCOMES AND INDICATORS

The initiative aims to have a series of impacts. In the community, these include improvements in home care for pregnancy, mothers and newborn infants. At health facilities, they include provision of good quality maternal and newborn care services. Both of these impacts should lead in turn to increased uptake of services and improvements in maternal and newborn illness and mortality.

The evaluation will make use of a range of designs, integrated to describe 4 broad types of outcome. (1) Indicators of achievement of project activities; (2) Indicators of success of interventions, compared with baseline indicators and with concurrent indicators in non-project areas; (3) Indicators of success of interventions, evaluated through a cluster-randomised controlled trial; (4) Process indicators describing the how and why of the initiative's effects, particularly the dynamics of group interventions within the MCGM and slum communities.

COMPONENT 1	VULNERABLE SLUM COMMUNITIES	COMMUNITY MOBILISATION
COMPONENT 2	HEALTH POSTS	STRENGTHENING PRIMARY CARE
COMPONENT 3	MATERNITY HOMES, PERIPHERAL HOSPITALS, TERTIARY HOSPITALS	CONTINUOUS QUALITY IMPROVEMENT

CITY INITIATIVE FOR NEWBORN HEALTH

MUMBAI

BACKGROUND

Child survival and the Millennium Development Goals

10.8 million children under five die each year, making up 32% of global deaths.[1] Neonatal deaths account for about half of these,[2,3] and two-thirds of infant deaths,[4] proportions which have risen as mortality in later infancy has fallen.[3,5] Of an estimated 3.9 million annual neonatal deaths,[2,3] 98% occur in developing countries.[6]

After a decade of relative stagnation, the child survival agenda has been reinvigorated by a series of calls for action and the agreement of a set of United Nations Millennium Development Goals. There are eight goals, all of which have a bearing on maternal and child health, but goals four and five are most explicit: improvements in child survival (a reduction in U5MR by two-thirds) and maternal survival (a reduction in MMR by three-quarters) between 1990 and 2015.[7,8] Although many countries are unlikely to achieve the goals, the targets for India are not out of reach.[9]

Child survival in India

The consequences of maternal and child ill health and mortality are far-reaching, with profound effects on human capacity and economic development. The health of mothers, fetuses and newborn infants affects survival, growth and cognitive development throughout life. Indicators of early child health in India underline the poor nutritional and health status of women and children. About 30% of infants have low birth weight and over 45% of children between 6 months and 3 years are stunted.[10,11] The IMR is high at 67.6 per 1000 live births, and much of it is accounted for by deaths in the newborn period: the NMR is 44.4 per 1000 live births.[12] Achieving the objectives of India's National Population Policy, which calls for a reduction of IMR to less than 30 per 1000 live births by the year 2010, would require reducing NMR to about 20 per thousand.[12]

The challenge of urbanization

The World Bank estimates that half of the world's poorest people will live in urban conditions by 2035.[13] India's population has followed a 2-3-4-5 paradigm over the last decade: growth of the total population at 2%, the urban population at 3%, larger cities at 4% and slum populations at 5%.[14] In 1998, India's urban poor outnumbered the rural poor for the first time. The government's Ninth Development Plan suggests that the urban population will reach about 610 million by 2025, and it is estimated that within a decade much of the burden of child disease and malnutrition will fall on the urban poor.[15] Given this rapid increase, particularly within larger cities and slum communities, there is a growing recognition of the need to plan for the nutrition and health vulnerabilities of the urban poor. Slum populations rank among the poorest, most under-served and most vulnerable groups in terms of health.[16] They are further compromised by the often unauthorized status of vulnerable localities and the poor environmental conditions within them, and the disjointed care patterns that result from moving back and forth between city and natal home.

Problems with housing, sanitation, pollution, and physical space, as well as access to water, electricity and health services, make communities more susceptible to ill health.[17,18] Urban health and nutrition data are usually aggregates that mask inequalities between localities. Available indicators for the urban poor compare unfavourably with both urban and national averages. In vulnerable situations, women and children are often the most vulnerable. The IMR for urban infants with low standard of living index is 76.1 and the NMR 48.8 per thousand (compared with national figures of 67.6 and 43.4 per thousand). A recent study estimates that LBW prevalence in urban slum communities is as high as 56%,[19] as compared to a rural incidence of 38.1% and an all-India prevalence of around 33%.[20,21] Data from the National Nutrition Monitoring Board for 5 population groups across 15 cities suggest that slum populations have

A typical slum in Mumbai

the worst dietary and nutritional profiles, with only 13% of children having normal weight for age.[18]

Until recently, the health and nutritional status of the urban poor has received inadequate attention, but this has begun to change with the drafting of India's National Population Policy 2000, the National Health Policy 2002, the National Nutrition Policy and the Tenth Five Year Plan. The problem is highlighted by issues of care for newborn infants. Qualitative data suggest that families, community health workers and care providers do not view neonates as a particularly sensitive and vulnerable group. Moreover, even when poor families seek specialised care from doctors, it is unlikely that they will receive the necessary attention. According to a recent study of Delhi slums, only 13% of newborn infants with symptoms requiring hospitalisation were advised to visit a secondary or tertiary facility. Those arriving at hospitals are often turned away, or diagnosed, treated, or referred inappropriately.[22] LBW infants are more likely to be weak and have difficulty feeding. These vulnerable babies are more susceptible to infections and require special attention and care. Irrespective of the primary cause of death, over two thirds of neonatal deaths occur in LBW infants.[23]

Socioeconomic inequity, even between gradations of poverty, has significant effects on the health of the poor.[24,25] Even though its sources may lie outside the control of the health sector, inequity in provision and access is a challenge that needs to be faced [26]. Firstly, illness and healthcare expenses are powerful factors in the descent into and perpetuation of poverty.[27] Secondly, researchers have described clear links between living conditions and illness in mothers and children in urban slums in South Asia, with effects on perinatal, infant and under-five mortality [22,23,28-33].

This scenario calls for better understanding of and planning for vulnerabilities at various levels. Although urban India has a relatively strong health and nutrition infrastructure - with public sector investments coming from central, state and local bodies as well as a vast private sector - vulnerable urban communities continue to be poorly served. This is not only the result of under-provision: existing public infrastructure is often sub-optimally utilized. Rather, it is the product of a range of interrelated factors such as underdevelopment, inequitable distribution of primary healthcare services, poor referral systems, inadequate inter-sectoral and private sector linkages, vertical programming, human resource rationalization, attitudinal and management challenges, inappropriateness and inefficiency of data management systems.[15] This mesh of influences also includes socio-economic and cultural determinants, such as caring practices, the status of women, the nature of livelihoods, and food-security, in addition to social capital related to community participation and environmental factors.

THE CITY OF MUMBAI

With more than 16.4 million inhabitants, Mumbai is the most populous city in India. An increase of 50% is predicted between 1996 and 2015. Mumbai's residents are characterised by a social heterogeneity which cuts across regional, ethnic, cultural and linguistic lines. The Municipal Corporation of Greater Mumbai is the primary local body responsible for civic administration, covering about 12 million people across 6 administrative zones and 24 Municipal Wards. The existing infrastructure is overburdened, and rich, poor and diverse cultures coexist intimately.

More than half of Mumbai's residents live in slums and population density approaches a million per square kilometre in some areas. While the meaning of the word *slum* remains contentious, the 2001 census of India adopted an inclusive definition, including all areas notified as slums by state or local government and all areas recognized as such even if not formally notified. Within these parameters, slums were described as compact areas with populations of at least 300 (60-70 households), living in poorly built, congested dwellings in an unhygienic environment. Infrastructure, sanitary and drinking water amenities were usually lacking.

Slum residents are characterized by tremendous diversity in religion, language, race, caste, class, place of origin, livelihood, income levels, and practices. Information on maternal and child health indicators among slum-dwellers reveals that their health is 2-3 times worse than average urban statistics indicate. It is estimated that agencies are only reaching about 30% of the urban poor, and that these belong to comparatively less poor slums. A

study conducted by Nair Hospital in an urban slum located in E Ward (Byculla) found a LBW prevalence of 44%, as compared to 21% for urban Maharashtra in general.[34] In the slum of Cheeta Camp in M-East ward (Chembur), 74% of women in the reproductive age group were anaemic,[35] as against an average 49% in Maharashtra and 52% in India as a whole.[11] Public health data suggest that about 80% of neonatal deaths in Mumbai occur in the first week of life, primarily due to complications resulting from birth asphyxia and prematurity. However, the actual situation in slum pockets is unclear. Unplanned deliveries, delays in reaching facilities and deliveries by untrained personnel all contribute to injuries and loss of life during birth. These problems persist despite the concentration and proximity of public and private health facilities.

Participatory approaches have long been advocated in order to build links between primary services and their users,[36,37] and to improve service quality.[38,39] However, the evidence base for participatory models and their effectiveness remains scanty.[40,41] Didactic presentation of information does not seem to change infant care practices and care seeking behaviour,[42] and some other approach is needed.

STRATEGY PRECEDENTS: INTERVENTIONS TO IMPROVE URBAN HEALTH

A number of initiatives have attempted to improve the health of the urban poor though approaches that involve community and stakeholder participation as well as strengthening primary care.

The Women Centred Health Project, Mumbai

This collaboration between the MCGM, SAHAJ, and the Royal Tropical Institute, Amsterdam, gave rise to the Women Centred Health Project. The WCHP adopted a health systems approach with a view to strengthening health care services for women at all levels, enabling women to access gender-sensitive and user friendly services, raising awareness and sensitivity to women's health, developing materials on health rights and responsibilities, sensitising MCGM staff on these issues, and promoting quality assurance through research supporting development, monitoring and evaluation of interventions.

The WCHP worked in two adjoining wards of the city, G-North and H-East, covering a total population of 1.2 million. Key interventions included the establishment of gynaecological clinics at the health post level and a counselling centre at VN Desai hospital. The project also tried to involve men in women's reproductive health concerns and developed gender-sensitive IEC material. The project demonstrated the feasibility of expanding the range of reproductive health services at primary level. It reinforced the importance of capacity building, the need to move from the abstract to the concrete, the need for simultaneous infrastructure strengthening, and the need for a multi-pronged strategy that worked simultaneously with different levels of the healthcare hierarchy.

The Environmental Health Project, Indore

The Indore programme of the USAID-supported EHP aimed to bring about sustainable improvements in child health in the slums of the city through two primary approaches. The first was to build partnerships between NGOs and CBOs in identified slum localities with a total population of 125,000. NGOs worked with CBOs to build capacity, particularly in terms of conducting group meetings, community based monitoring and BCC. The intervention improved community adoption of appropriate behaviours, while increasing utilisation of services. The two types of organisation had complementary strengths that improved context-specific and participatory programming and implementation as well as sustainability.

The second approach was to develop a ward coordination model, in which key interventions included the formation of a ward level core group that included representatives from the Health Department, ICDS, the Municipal Corporation, elected representatives, charitable organisations, and local resources such as schools.

STRATEGY PRECEDENTS: INTERVENTIONS TO IMPROVE NEWBORN SURVIVAL

SEARCH, Gadchiroli, Maharashtra

This initiative reported a controlled study from a rural population of about 80,000.[43] At baseline,

almost half of newborn infants encountered high risk morbidity, commonly due to sepsis. In intervention villages, SEARCH trained traditional birth attendants, introduced health education, and developed a new cadre of supervised village health workers to visit newborn infants at home, identify warning signs and manage sepsis with a combination of injectable and oral antibiotics. By the third year of the intervention, the NMR was 26 per thousand live births in intervention and 60 per thousand in control villages. Whilst these findings were dramatic and important, their generaliseability and scalability have been interpreted with caution.

The Warmi project

This SC-US initiative was implemented in Bolivia in a poor, rural population of 15,000 with little health system infrastructure. The project worked with women's groups to encourage participatory planning for mother and infant care,[44] and documented a fall in PMR from 117 to 44 per thousand births over three years. Although the design lacked power and a control group, it suggested that a participatory approach might have more effect on perinatal care practices and might increase consultation in high risk pregnancies and for at-risk newborn infants.

The MIRA Makwanpur trial

Carried out by MIRA and IPU in a population of 170,000 in a mountainous rural district of Nepal, this initiative suggested that working with women's groups is an effective way of changing home-based perinatal care practices and care-seeking. One woman facilitator per population cluster of 7000 facilitated monthly meetings with women's groups to address the issues of pregnancy, childbirth and newborn health. Each group moved through a participatory planning cycle to explore perinatal care strategies and solutions.[45,46] A cluster randomized controlled trial showed that the group intervention could reduce neonatal mortality by 30%.[47]

CINH FORMATIVE RESEARCH

With a team drawn from clinical medicine, paediatrics, obstetrics, anaesthetics, public health, social sciences, social work and health systems management, SNEHA has a deep understanding of municipal health systems and a lasting relationship with the MCGM.

In order to understand the problems faced by families during pregnancy and childbirth, SNEHA commissioned a descriptive study of maternity practices and care-seeking in G-North ward. G-North includes Dharavi, familiar to many as one of Mumbai's oldest slum areas, and has seen successive waves of development and community action. The study was carried out by Monitoring and Research Systems (MaRS) in 2003-2004, and looked primarily at practices and care-seeking behaviour. A stratified random sample of households was taken from 58 slum, chawl and pavement communities in an estimated population of over 87,000. Interviews were conducted with women during pregnancy (389), within a year of delivery of a currently living infant (729) or of a newborn infant who had died (45).

The key findings of the survey are summarised below. The theme that emerges is one of adequate care provision in some areas, but specific gaps in quality. The women who were interviewed were poor and many were illiterate, had been married in later adolescence, had had a series of pregnancies, and worked largely in the environs of their homes. Few had been visited by health workers during their pregnancies, but most had eventually registered and delivered at an institution. Levels of antenatal care and tetanus toxoid administration were satisfactory, but few women completed a course of iron and folic acid supplements. The picture is one of minimal dietary or occupational concessions to pregnancy, late registration, late ultrasound (of questionable purpose), and late attendance for delivery. Discussions about these issues pointed to a number of determinants, such as a lack of awareness of a need for earlier registration and a preference for visiting tertiary institutions where clinics were crowded.

Delivery services at health facilities seemed satisfactory within the bounds of the available information, and most women recalled receiving some advice on the postnatal and neonatal periods. Home births were uncommon, but may be an underappreciated source of illness as a result of poor hygiene and delayed care seeking for problems. Breastfeeding rates were high, but exclusive breastfeeding was rare. Follow-up after birth was not as well attended as antenatal care, with few home visits and only a third of infants seen at health facilities.

KEY FINDINGS FROM THE FORMATIVE STUDY

Demographic factors

56% of women had been married before the age of 18 and 63% had 3 or more children

35% of women slum residents were illiterate

Only 9% of women worked outside the home

Recent pregnancies

95% of women had registered their pregnancies, but 50% had done so after 7 months

18% of women had been visited by a health worker during their pregnancies

98% of women had made an antenatal visit, and about half had made 5 or more visits

90% of women had received tetanus toxoid at least twice

30% of women had had an obstetric ultrasound at 4 months, but 70% had done so at 7months

About half of women had taken iron tablets, half of them for less than 2 months

21% of women reported fever in the first trimester, 23% reported signs of urinary infection, and 11% reported abnormal vaginal discharge

In case of illness, 52% of women had consulted private practitioners, 34% government services, and 14% had not consulted anyone

57% of women reported no change in their diet during pregnancy, and 35% reported eating less than normal

60% reported no change in the amount of rest they took during pregnancy

Recent deliveries at health facilities

33% of women had moved to their natal homes for delivery

91% of women had delivered in a health facility, of whom 29% reached the facility less than an hour before delivery

Most women had been attended to within half an hour of arrival at the facility

83% of deliveries were normal, 16% were operative and 1% instrumental

77% of women had been medically examined after delivery, and 88% of babies

85% of women had been advised on breast feeding, immunisation, baby care, the need for follow-up visits, and signs of illness before discharge

Recent deliveries at home

9% of women had delivered at home

Home births were assisted by family members in 31% of cases and traditional birth attendants in 55%

64% of women recalled birth attendants as having washed their hands with soap

70% of families had used a boiled blade to cut the umbilical cord and 58% a boiled thread to tie it

Recently newborn infants

33% of infants were recorded as having weighed less than 2.5 Kg

95% of infants had received BCG immunisation

98% of women reported breastfeeding their babies, 48% within the first day

Most women had given their infants complementary feeds within 4 weeks of birth

10% of women had been visited by a health worker at home after delivery

31% of women had taken their infants to health facilities in the first 2 weeks

COMPONENTS OF THE INITIATIVE

This section provides more detailed information on the 3 components of the City Initiative for Newborn Health. In order to develop and test potentially scaleable models for intervention, all 3 components will intervene through the activities of groups, using a process of Appreciative Inquiry and building ownership and potential sustainability. For component 1, groups will consist of community members; for component 2, they will centre on personnel involved with service provision at health posts; and for component 3, they will be built around representatives of the MCGM and clinical experts.

APPRECIATIVE INQUIRY

The history of Appreciative Inquiry is the history of a major shift in the practice of organizational development and transformation. Developed by David Cooperrider and Suresh Srivastva at Case Western Reserve University, USA, in the early 1990s, AI began as a theory-building process rather than an approach to organizational change. It was primarily conceived as a method for system intervention and transformation and was typically used in large corporate and educational organizations. While it has been hugely successful in this context and has transformed the way change is viewed and implemented, it has been applied with equal - if not greater - success in the development sector and at the community level.

The fundamental philosophy of AI is to shift the focus from a problem oriented approach to a possibility oriented one, to look at the existing strengths of an organization or community and focus on positive attributes as a basis for creating a desired future. This allows hope and is an energizing and life giving process, as opposed to a typical approach of "what is not", which creates negativity and a feeling of hopelessness and insurmountable problems.

It is also highly participatory and democratic, both of which encourage ownership and make for sustainability.

Whether it is used to help a multinational corporation position itself for the 21st century or a community to deal with HIV/AIDS, an appreciative inquiry usually proceeds through four stages: (1) Discovering periods of excellence and achievement, (2) dreaming an ideal organization or community, but based on existing strengths and grounded in reality, (3) designing new structures and processes to make this a reality, and (4) delivering the dream. Appreciative inquiry offers a genuinely new and rewarding way to tackle issues of sustainable change in a vast array of organizations, institutions and communities, from the relatively simple to the hugely complex; from the corporate to the not-for-profit; from metropolitan areas to villages. Its strength lies in the fact that it involves a wide range of stakeholders in assessing the past and planning the future, encourages transparency of organizational self-reflection, and is inclusive, valuing a wide dissemination of power and influence throughout the organization.

COMPONENT 1	VULNERABLE SLUM COMMUNITIES	COMMUNITY MOBILISATION
COMPONENT 2	HEALTH POSTS	STRENGTHENING PRIMARY CARE
COMPONENT 3	MATERNITY HOMES, PERIPHERAL HOSPITALS, TERTIARY HOSPITALS	CONTINUOUS QUALITY IMPROVEMENT

Children in Kalina, Santacruz (East)

1. COMMUNITY MOBILISATION

The apparent success of community interventions in Bolivia and Nepal begs the question of whether they might be effective in urban areas. The basis of intervention will be on the demand side. Work with community groups will aim to stimulate both improvements in antenatal, delivery, postnatal and neonatal care in the home and increased use of health care services.

PURPOSE

To improve maternal and neonatal health in vulnerable urban communities through a process of participatory action cycles with community groups.

OBJECTIVES

To test the effect of a participatory intervention using action research cycles with a range of community groups, on:

- Care practices and health care seeking behaviour for women in the antenatal, delivery and postpartum periods, and for infants in the neonatal period.
- Neonatal and maternal morbidity.
- Neonatal mortality.

DESIGN

The community mobilisation intervention will be evaluated through a cluster randomised controlled trial which will be integrated with the evaluation of the primary health care strengthening programme. A cluster design has been chosen because the allocation and loci of delivery of the interventions (community clusters) are groups rather than individuals. 48 vulnerable slum clusters will be selected from six municipal wards. 24 clusters will be allocated randomly to receive the intervention and 24 will act as controls. A surveillance system for births, birth outcomes and care seeking will be designed and implemented in all 48 clusters.

HYPOTHESES

Participatory work with community groups will lead to:

- Better home care
- Increased service uptake for routine antenatal, delivery, postnatal and neonatal care
- Increased care seeking at appropriate facilities for maternal and neonatal illness
- Reduced neonatal morbidity
- Reduced neonatal mortality
- Reduced maternal morbidity

ACTIVITIES

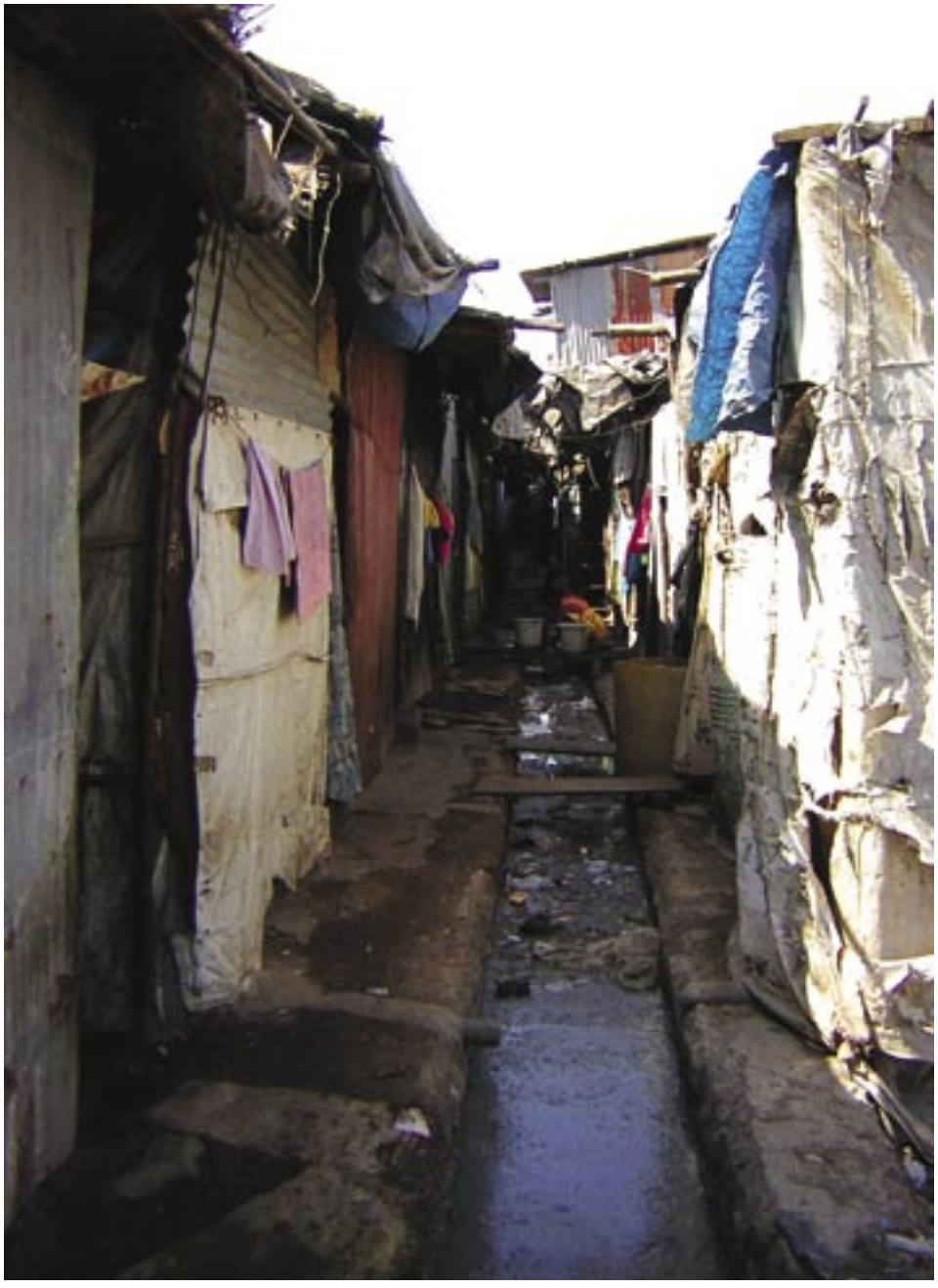
Cluster selection and setting

Within each ward, we aim to test the intervention in the most vulnerable communities. We have therefore conducted vulnerability and mobility studies to identify potential clusters. We developed a range of criteria for vulnerability through discussion with local and national informants and experts, and from sources such as a previous survey by the NGO YUVA. Vulnerabilities have been categorised in terms of common occupations, economic poverty, sanitation, transport, educational opportunities, health care infrastructure, religious and cultural groups, addictions, social cohesion and support, common beliefs, and perceived development priorities.

We have become familiar with wards by visiting ward offices and health posts and consulting ward and health post maps. The first phase identification of vulnerable slum localities was made after discussion with CHVs at each of 50 ward health posts. We triangulated their opinions with those of key informants such as political party leaders, members of CBOs and informal groups. In the second phase, we focused on 24 health posts selected for component 2 of the programme. We finalised vulnerability criteria and had a second round of discussions with CHVs. We then visited each potential vulnerable locality to triangulate the findings further and to confirm its suitability. The visits also afforded an opportunity to identify other vulnerable localities that had not been suggested at first pass. Using two tools, we gathered information about (1) community size, physical geography, economy, linguistic mix, cultural activities, religious composition and infrastructure, (2) details of CBOs, (3) demographic suitability for inclusion in a surveillance system, (4) the potential for contamination between areas, (5) the possibility of subdividing large localities into clusters along clear boundaries, and (6) availability of residents to work with the study.

Participants

The intervention focuses on improving the situation of pregnant women and their newborn infants, but will involve any participant who may affect this situation. Primary candidates will be young married women. Other key participants may be family members, members of CBOs, health workers and local opinion formers. Any woman who gives birth in



Chitah Camp, a slum locality selected in the project, M East Ward

the trial cluster will be eligible to provide information for the surveillance system for births and outcomes.

Details of the intervention

Within each intervention cluster, a facilitator will help to convene community groups to explore perinatal health issues. It is likely that the groups will have a range of origins: existing groups that meet to discuss issues such as microfinance, slum improvement, cultural issues and specific agendas, as well as newly convened groups. Likewise, group composition will vary. The primary target will be women of childbearing age, but it is likely that mothers-in-law, men and community leaders will be involved. Within the intervention cycle, groups will meet 2-4 weekly 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 cycle has four phases: identification and prioritisation of problems, planning strategies, implementing strategies, and evaluation. The role of the facilitator is to activate and strengthen groups, support them in identifying problems, help to plan possible solutions and support the 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 groups will discuss issues around childbirth in their own communities.

Larger cluster level meetings will be held periodically to build the community commitment and ownership essential to ensure implementation. Once a primary cycle of meetings has been completed, it can be repeated with appropriate modifications in other settings. Work with the original groups may continue, and new cycles may be set up with other groups. The exact form of the continued intervention cannot be defined in advance, since it is iterative and operates within an action research cycle. Similarly, the nature of the discussion, levels of involvement and potential solutions will differ from group to group.

OUTCOMES

The primary outcome of the trial will be NMRs in control and intervention clusters. We shall also examine neonatal and maternal morbidity reported by mothers and family members. More proximally on the pathway to survival are outcomes related to care practices, including routine care in the antenatal, delivery, postnatal and neonatal periods. We shall examine patterns of routine care uptake on the basis of reports by women under surveillance. In the event of illness, we shall document care at home and care seeking in both private and public sectors. As the community mobilisation intervention develops, we shall document context, group attendance and group activities, as well as interactions between groups, the community and service providers.

Weekly meeting of the surveillance team, Urban Health Centre, Sion

Kumbharwada Health Post, G North Ward

Baseline assessment of health posts, Gokhale Road, G North Ward

'Training of trainers' in Appreciative Inquiry, The 'Dream' stage

2. STRENGTHENING PRIMARY CARE

Under India's Population Project V, basic antenatal services were built into primary care through an integrated approach. CHVs identify and monitor married couples for pregnancies, ensure that they access antenatal care, support institutional delivery, and follow up infants to ensure immunization and encourage family planning.

Each health post is allocated a population of 60,000, but the actual coverage is closer to 100,000.[48] A CHV is expected to reach 2000 people in her area, but the actual reach is more like 4000-6000. Unfortunately, the G-North baseline study suggested that 87% of pregnant women did not receive such a visit. When they did, they were often advised on iron and folic acid supplements rather than anything else. About a quarter of women experienced illness during pregnancy (particularly dysuria, breathlessness and fever), but only a quarter of these had consulted a doctor. Most women choose institutional delivery. 91% of respondents did so, but a quarter were not examined after delivery and half did not visit a health centre for a postnatal and newborn check-up. These statistics paint a picture of women who engage with the health care system only when it is perceived as essential.

PURPOSE

To improve maternal and neonatal health outcomes by increasing the availability and quality of decentralised antenatal, postnatal, and neonatal services at primary health care facilities.

OBJECTIVES

- To offer basic antenatal, postnatal, and neonatal services at health posts.
- To increase community uptake of these services.
- To promote timely and appropriate identification, referral, and treatment of high risk cases.
- To include effective behaviour change communication within routine antenatal, postnatal and neonatal care.
- To reduce the burden of routine check-ups at secondary and tertiary level facilities so that they are able to concentrate on the management of high risk cases.
- To evaluate the effects of the above activities on neonatal morbidity and mortality and maternal morbidity.

DESIGN

The primary care intervention will be evaluated through a cluster RCT which will be integrated with the evaluation of the community mobilisation programme. A cluster design has been chosen because the allocation and loci of delivery of the interventions (health posts and their clients) are groups rather than individuals. 24 health posts will be selected from 6 municipal wards. 12 will be allocated randomly to receive the intervention and 12 will act as controls.

HYPOTHESES (also see diagram below)

Participation in the planning process will lead to strategies for improving quality of care

Implementation of strategies will lead to:

· Introduction of new services
· Improved technical support and trained personnel
· Improved quality of care

Improved technical support will lead to:

· Increased provider satisfaction
· Improved quality of care

Improved quality of care will lead to:

· Better relationships between providers and clients
· Increased uptake of services
· Increased provider satisfaction
· Introduction of services will lead to increased uptake
· Increased uptake and better relationships will be mutually reinforcing

Consideration of quality of care by clients will lead to:

· Increased uptake of services
· Better relationships between providers and clients

ACTIVITIES

Health post selection and setting

Within the 6 selected city wards, we will conduct a preliminary assessment of all 50 health posts, after which specific health posts will be sampled. Each health post may be independent or attached to a dispensary, maternity home or peripheral hospital. We shall assess human resource availability (medical officers, public health nurses, auxiliary

nurse midwives, multipurpose workers and community health volunteers), population coverage and service provision.

Participants

The intervention is focused on improving services at health posts. Primary participants will therefore be health personnel, but the stakeholders and potential beneficiaries include administrative personnel, community leaders and community members.

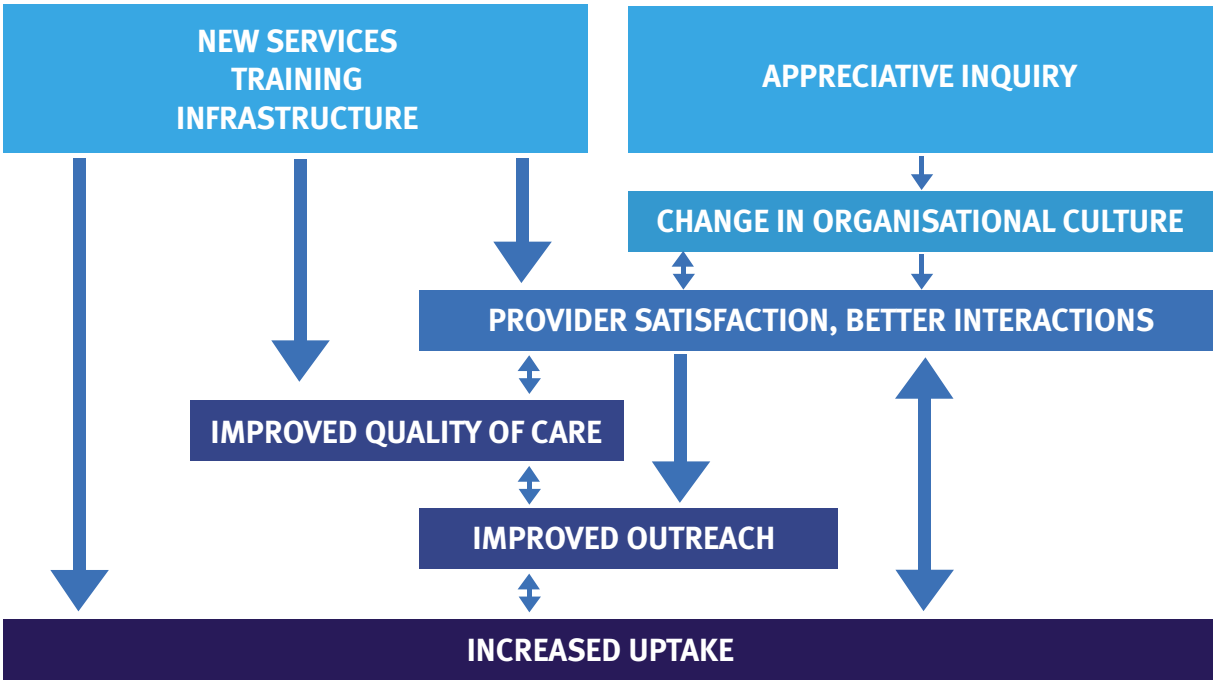
Details of the intervention

We shall attempt to build ownership of the programme by conducting orientation meetings with staff from the MCGM. A technical advisory committee will be convened, with representatives from the MCGM, NGOs, professional associations and research institutions. Participatory workshops with personnel from all selected health posts will be followed by a baseline assessment of upgradation needs organised by the participants themselves. Such needs may be structural or may involve increases in equipment, medications and personnel.

As with all arms of the programme, we shall catalyse the formation of action groups to assess the situation, plan strategic interventions, implement them and evaluate their effects. It is likely that action groups will cover facilities, human resource development, and training needs. Action groups will be involved in the assessment of facilities, development of clinical protocols for antenatal, postnatal and neonatal services, the process of facility upgradation, and the training of personnel. Our aim after an initial period of development will be the establishment of antenatal, postnatal and neonatal services at health posts, the implementation of a comprehensive IEC strategy, and the strengthening of a system of monitoring. The latter will require detailed assessment of the existing MIS and inputs into its improvement.

OUTCOMES

This component focuses on the provision of antenatal, postnatal and neonatal care within the municipal corporation health sector. As such, although morbidity and mortality outcomes will be available for pregnancies within surveilled slum clusters, we are also interested in indices of provision and uptake of care. Outputs will range from the existence or institution of services to their uptake and quality. Provision of care will be measured from both direct health post assessments and routine records (which will be improved as part of the intervention). We shall look at attendance and referral for pregnancy and newborn care, both routine and for problems. Using the surveillance of cluster pregnancies, we shall be able to document uptake of municipal routine and curative services by women in vulnerable slum clusters. We shall also be able to document changes in the share of public and private care, and to look at issues of accessibility.



3. CONTINUOUS QUALITY IMPROVEMENT
IN MATERNITY AND NEONATAL SERVICES AT THREE LEVELS OF FACILITY WITHIN THE MCGM

This component arose out of a need to rationalise care uptake at maternity homes, peripheral hospitals and tertiary hospitals. The existing system has become unbalanced in terms of care seeking, with a disproportionate burden of clients falling on tertiary hospitals. A lack of systematisation has also led to a high level of referral and transfer between facilities. Clients may be referred to another facility before admission, or transferred after admission. Initially, the objective of the intervention was to rationalise the referral and transfer system in order to improve client care and satisfaction and reduce unnecessary movement. However, the planning phase suggested that the referral and transfer issues were symptoms rather than causes of a lack of a non-systematic approach to service provision.

PURPOSE

To work with municipal health service providers to achieve continuous quality improvement for maternal and neonatal services at maternity homes and hospitals.

OBJECTIVES

The objectives of the intervention centre on availability, appropriateness and quality improvement. Of particular interest is the introduction of continuous quality improvement cycles, which include standardization, implementation, monitoring and evaluation, and feedback.

Availability of services

- Reduction in referral and transfer of clients because of unavailability of a designated level of service at a given facility.

Appropriateness of services

- Reduction in referral and transfer of clients because of lack of appropriate care for their conditions.
- Increased proportions of referral and transfer following designated protocols.
- Improved user satisfaction with maternal and neonatal services.

Continuous quality improvement

- Introduction of a system for continuous quality improvement at facilities.
- Satisfaction of health service personnel with the system.

DESIGN

The evaluation will have a plausibility design, comparing (a) the situation at the beginning of the project with the situation at midline and endline, and (b) indicators from Sion region with indicators from other municipal regions. The evaluation aims to use MCGM data if at all possible, in order to feed in to data quality and the organisation of the municipal MIS. The process will begin with the development of an indicator framework and a review of the existing record systems. This will be followed by standardisation of record systems.

HYPOTHESES

Action group work on clinical and administrative protocols, systems and advocacy will:

- Increase the standardization of administrative services
- Increase the standardization of clinical services
- Increase the proportion of facilities using continuous quality improvement
- Increase appropriate protocol-based care
- Increase the proportion of clinically skilled providers
- Increase the proportion of facilities providing designated essential services
- Increase the availability of technical support for facilities
- Reduce the transfer and referral of mothers and newborn infants between facilities as a result of unavailability of designated services
- Reduce the transfer and referral of mothers and newborn infants between facilities as a result of inappropriate care
- Increase work satisfaction in health care providers
- Increase client satisfaction with services
- Reduce neonatal morbidity and mortality

OUTCOMES

These will be grouped under 4 headings. (1) Availability: improved availability of technical support, work satisfaction and motivation of health service personnel, infrastructure according to designated level of care, and technical knowledge and skill of health service providers. Specific indicators include the proportion of facilities where technical support is available around the clock,

the proportion of facilities displaying problem solving abilities, work satisfaction at facilities, the proportion of facilities satisfying the infrastructure requirement of essential according to facility designation standards, and the proportion of facilities with appropriately skilled providers. (2) Appropriateness: improved infrastructure, technical, administrative and communication knowledge and skill of health services providers; improved systems to ensure geographic distribution of health facilities. Specific indicators include the proportion of facilities with essential levels of infrastructure and support services, the proportion of facilities with human resources with technical, administrative and communication skills, and the proportion of transfer and referral to appropriate centres according to transfer and referral guidelines. (3) Continuous quality improvement: improved support systems for sustainable quality of health care services, standardization of major clinical and administrative services, and an enabling environment for the continuous quality improvement. Specific indicators include the proportion of human resources satisfied with available support systems, the proportion of standardized clinical and administrative services, and the proportion of human resources willing to participate in continuous quality improvement .

ACTIVITIES

Setting

The partnership between CINH and the MCGM has elected to begin the intervention in Sion region. The region covers 7 city wards: G North, F North, M West, M East, N, S, and T. The intervention will involve three types of facility: maternity homes, peripheral hospitals and tertiary hospitals. Sion region includes 10 maternity homes, 4 peripheral hospitals, and 1 tertiary hospital.

Participants

The brief for maternity homes in terms of maternal and neonatal health will be to manage normal deliveries, recognise risks and undertake appropriate referral or transfer. For peripheral hospitals, the brief will be to manage high risk and complicated deliveries, and undertake appropriate referral or transfer. The brief for tertiary hospitals will be to manage sick newborn infants and mothers requiring specialty support.

Details of the intervention

The intervention will centre on the creation of action groups and the introduction of continuous quality improvement systems. Action groups will bring together cadres of health care providers (doctors, administrators, nurses, and paramedical staff) in a non-hierarchical setting. We shall endeavour to include senior colleagues and opinion formers in the groups so that their outputs are respected. The groups will adopt an appreciative position and will be tasked with improving knowledge, defining needs and implementing strategies for change. They will assess and develop common clinical and administrative protocols to cover maternal and neonatal health care, recognition of risk, referral, transfer, procurement, and human resources, as well as working on cost analysis for strategies and the development of standards against which progress can be judged. The groups will drive continuous quality improvement cycles both within and across institutions, with an emphasis on participation.

The first phase will bring together information on the existing system. Groups will develop and implement self-assessment tools in order to document maternal and neonatal services. Simultaneously, studies will examine (a) the perceptions of clients who have been transferred, through a series of semi-structured interviews and focus group discussions, (b) a review of causes of neonatal mortality at LTMG hospital, and (c) a cost analysis of the options for maternity homes.

After identification of the particular problems of service delivery, a problem tree will be developed and the situation framed through the 5A concept of quality: availability, accountability, accessibility, acceptability, and appropriateness. The problem tree will be converted into an objective tree and specific objectives rated according to their merits, difficulty and risks. This will allow prioritization of objectives.

The second phase will be driven by action groups, who will work in several areas. Strategies developed during group discussions will be categorised into short, medium and long term.

Standardization of clinical protocols

Action groups of clinicians and nurses will review and prepare clinical protocols for maternal and neonatal care at maternity homes, peripheral hospitals and tertiary hospitals. Development will involve consultation with key members of the MCMG and

review of protocols by an expert committee. The group will then catalyse the piloting and implementation of the protocols.

Standardization of facilities

Action groups will prepare and conduct assessments at each facility level. Upgrade needs (for staff, equipment, drugs and supplies) will be categorised into vital, essential and desirable for human resources, equipment, medications and supplies. This will be followed by costing of requirements, discussion with members of the MCGM and discussion of potential sources of funding.

Standardization of administrative protocols

Action groups will review existing administrative processes in discussion with members of the MCGM. Profiles of the required steps will be constructed through case studies and subsequently streamlined. Administrative tools, particularly for staff appointment, procurement and maintenance, will be developed.

Training and IEC

ction groups will identify and prioritize training needs for staff at each level of facility. These may include clinical training, understanding of administrative processes and developing awareness of vital, essential and desirable benchmarks. Existing IEC and training materials will be reviewed, priorities examined, master trainers identified, and training methodologies developed and implemented. It is likely that much of the training will be skill-based.

Other activities: in order to improve communication between facilities, group meetings will be convened across a range of institutions and cadres. Information technology requirements will be reviewed and sources of support for upgrade identified.

Action Group meeting, Facility Upgradation and Designation

EVALUATION OF THE INITIATIVE

The implementation of public health programmes is a point at which the need to for evidence meets the need to justify expenditure. The first phase of the City Initiative for Newborn Health will run for 4 years and will evaluate its activities with a range of methods.

Traditionally, biomedical studies evaluate efficacy: the effect of an intervention under ideal conditions. This is not always the question, however, for public health interventions, which may be better addressed in terms of their effectiveness: the effect of an intervention under normal conditions in field settings. In evaluating a public health intervention, the aim is to influence decisions. The precision and complexity of the evaluation depend on the requirements of decision makers,[49,50] as well as the context, aims and finances.[51] The objectives of a sound evaluation design are to minimize selection and information bias, to control confounding, and to attempt to rule out chance.[52] The following table summarises the available choices: adequacy, plausibility, probability and process.[50]

Community Mobilisation activities will be evaluated through (a) process documentation, and (b) a randomised controlled trial involving 48 vulnerable slum clusters (for details see Annex).

Strengthening Primary care activities at health posts will be evaluated through (a) process documentation, (b) comparison of the situation at health posts before and after intervention, and (c) a randomised controlled trial involving 24 health posts (for details see Annex).

Continuous Quality Improvement activities at maternity homes and peripheral and tertiary hospitals will be evaluated through (a) process documentation, (b) comparison of the situation in Sion zone before and after intervention, and (c) comparison of the situation in Sion zone with other municipal zones.

Because the intervention will operate at a regional level, it will not be possible to control the comparison beyond the remit of the implementing organisation. The evaluation aims at a stepped wedge design, useful when it is not possible to randomise allocation over a large number of areas and when the exigencies of public health systems demand a more reactive approach. Of particular interest will be the spread of the intervention activities beyond Sion zone. It is conceivable that, once action groups are working and protocols and systems introduced or improved, there will be a demand for uptake beyond the project's initial area. We aim to track the spread of the intervention and uptake of its tools as part of

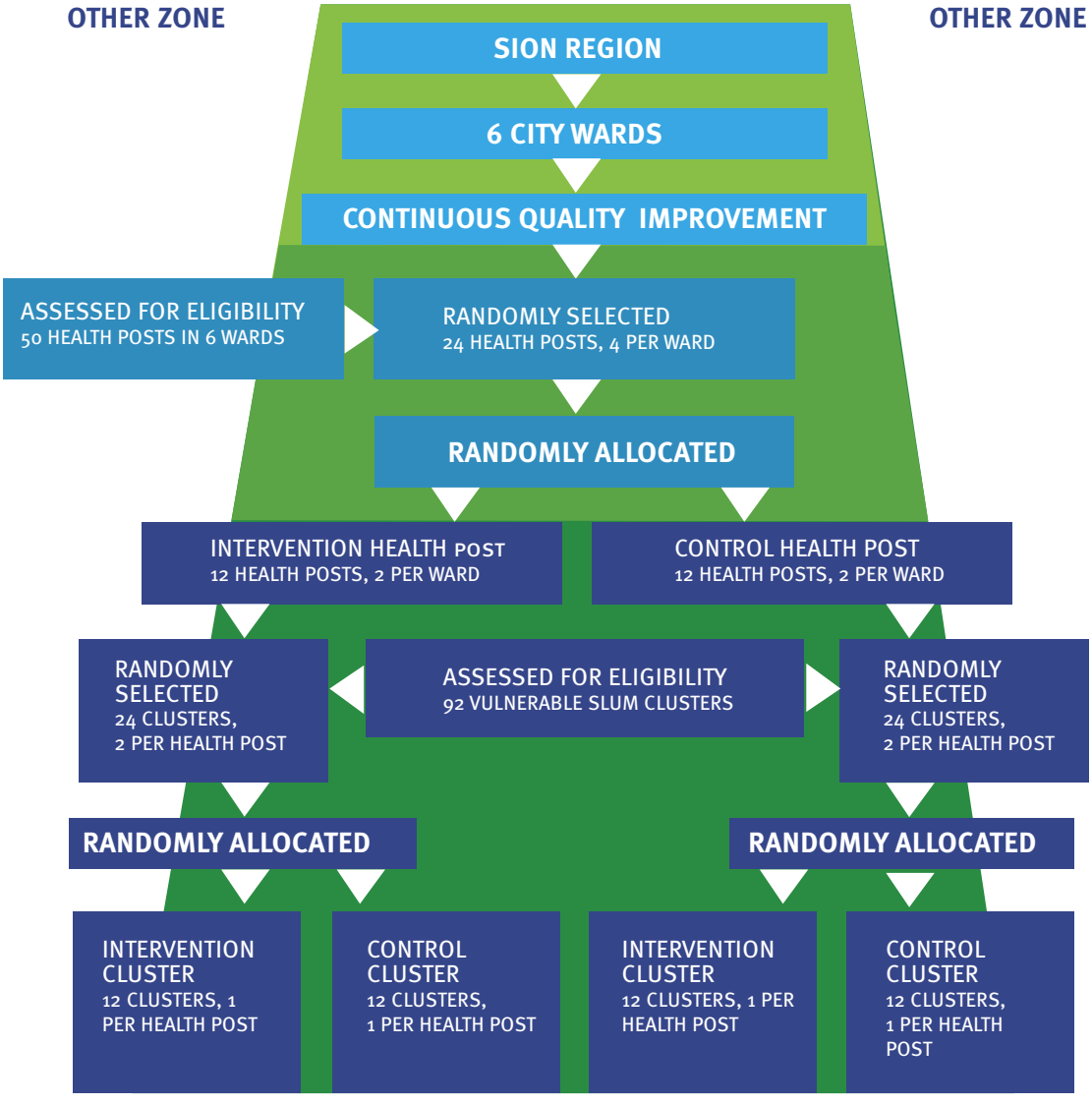
Type of evaluation	Evaluation question	Example	CINH component
Adequacy	Was the intervention implemented as planned?	Assessment of activities against a logical framework.	All components.
Plausibility	Does the intervention seem to have been effective?	Comparison of an area before and after intervention. Comparison of an intervention area with another area.	Continuous quality improvement.
Probability	Was the intervention effective in statistical terms?	Randomised controlled trial.	Strengthening primary care. Community mobilisation.
Process	How and why did the intervention operate?	Documentation of the context in which projects were implemented.	All components.

the process evaluation. We shall also conduct case studies and undertake detailed documentation of the processes involved, such as those for procurement of equipment, administrative changes, human resource management, and the introduction of continuous quality improvement.

The evaluation designs are summarised in the figure below. All three components will be implemented in central, northern and eastern Mumbai. The RCT will be implemented in 6 wards, selected on the basis of 2 criteria: (1) feasibility of intensive access for the research team; and (2) IMRs reported by existing MCGM systems. Citywide, reported IMRs range from 11 to 57 per thousand live births. Two wards were selected as examples with high IMRs (M-East, 57.5, and P-North, 55.8), two with middle-range (F-North, 39.9, and K-West, 44.4) and two with low (G-North, 20.3, and H-East, 32.7). Component 3 will be implemented in Sion region.

Interpretation of outcomes

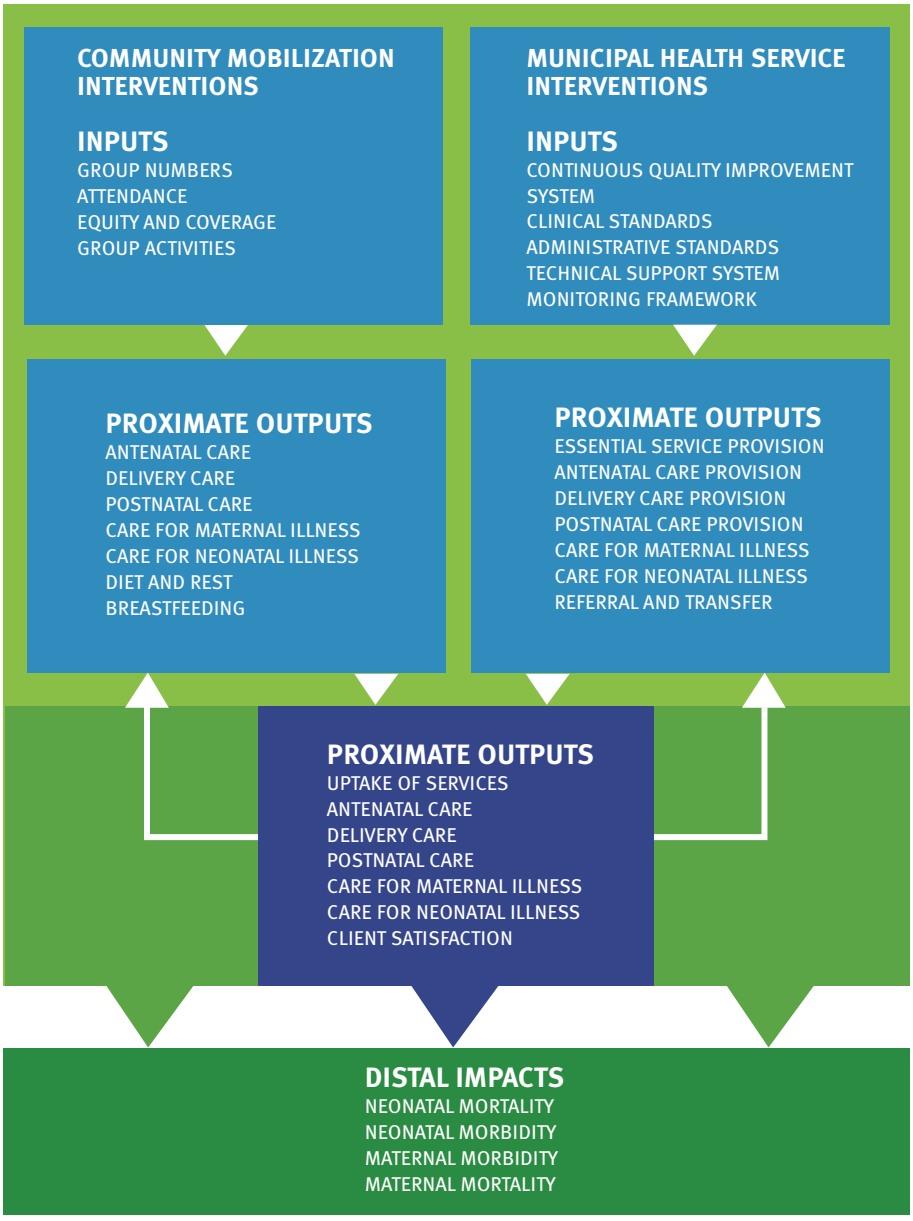
The RCT has a factorial design and is powered to detect differences in outcomes between intervention and control groups for each component. In principle, it will provide a probabilistic answer to two questions: (a) is strengthening primary care associated with a reduction in neonatal mortality rates (?), and (b) is community mobilisation associated with a reduction in neonatal mortality rates? Beyond this analysis, the study has been designed so that equal numbers of health posts and community clusters will receive no intervention, one of the two interventions, or both interventions. Although power will probably be insufficient to demonstrate significant differences at this level of stratification, it will be possible to comment on the interaction between the two interventions.



OUTCOMES

Health care in urban settings can be assessed against a number of outcomes: provision (availability of services, accessibility, quality), utilization (use of services), coverage (the degree to which the target population is reached), and impact (improvements in disease patterns or behaviours).[50] The City Initiative for newborn health will monitor indicators in each of these categories, summarised in the diagram below.

There are two major axes of intervention: community (demand side) activities and health service (supply side) activities. The first group of indicators – inputs - will describe the achievement of planned activities. In the community, these will include process indicators describing group activities. In the health service, they will include similar indicators about professional group activities, as well as achievements in terms of putting in place the planned systems and standards. The second group of indicators – proximate outputs – will describe the effects of intervention on practice. In the community, these will include routine care practices and care-seeking behaviour. In the health service, they will include service provision, quality of care and patterns of referral and transfer. A linked set of indicators will describe the points at which community care-seeking and health service provision intersect: uptake of services. The third group of indicators – distal impacts – will describe the downstream effects of the intervention on the health of mothers and newborn infants.



Systems for data collection

Indicators will be collected from 5 general sources. (1) A surveillance system will document births, birth outcomes, care practices and care-seeking in the vulnerable slum clusters involved in the randomised controlled trial. The system will provide most of the data for the evaluation of the community mobilisation component. It will also provide data on uptake of government health services. Women resident in specified clusters will act as identifiers for all births in their allocated areas. Interviewers will visit families in which a birth has taken place and administer questionnaire tools to family members. (2) Facility records will be used to document service provision and uptake. The improvement and streamlining of recording systems will be addressed as part of the initiative, in order to reduce work for health service personnel, improve the quality and utility of data, and build capacity for both outcome evaluation and audit. (3) The municipal MIS will provide information on care patterns within the city, and will also be used to triangulate data from other sources. The improvement of inputs to and feedback from this system will be addressed as part of the initiative, with a particular view to sustainability. (4) Process documentation will be carried out for all components, with an emphasis on context, challenges, successes and lessons learned. (5) Specific assessment exercises will be carried out when required to augment existing knowledge. For example, the upgrading needs of facilities will be examined, quality of care will be assessed periodically, and client perceptions of services will be examined through rounds of qualitative research.

The sources of indicators are summarised in the table below.

ECONOMIC EVALUATION

An economic evaluation will be carried out alongside the community mobilisation intervention from a provider perspective (including all costs incurred by SNEHA). Efforts will be made to monitor the costs of the strengthening primary care and continuous quality improvement in maternity and neonatal services at the three levels of care. Cost data for the interventions will be collected prospectively where possible from project accounts. Staff time will be allocated using time sheets. The values of donated or subsidised items and volunteer time will be documented and included.

	COMMUNITY MOBILIZATION INTERVENTIONS	MUNICIPAL HEALTH SERVICE INTERVENTIONS
INPUTS	Process documentation	Process documentation Maternity home records Peripheral hospital records Tertiary hospital records Specific assessment exercises
PROXIMATE OUTPUTS	Slum cluster surveillance system	Health post records Maternity home records Peripheral hospital records Tertiary hospital records Municipal MIS Specific assessment exercises
DISTAL IMPACTS	Slum cluster surveillance system	Slum cluster surveillance system Health post records Maternity home records Peripheral hospital records Tertiary hospital records Municipal MIS

Cost-effectiveness will be defined as the cost per neonatal death averted and the cost per life year saved (LYS). If time and resources allow, efforts will also be made to: 1) estimate the costs of the three intervention components to the health system in terms of health staff time spent participating in related activities and changes in the way they work (through operationalisation of new protocols and referral practices) as well as savings from efficiency gains; 2) estimate the costs and savings to households.

ETHICAL CLEARANCE

The City Initiative for Newborn Health has been permitted to work in urban slums by the Municipal Corporation of Greater Mumbai. Its activities are being undertaken in partnership with the MCGM and corporation staff are involved in all interventions. Benefits to trial control areas will be improvements in services at all levels of the public health care system. Participants will give verbal informed consent to interview and data will be treated anonymously. All community-based members of the study team will be recruited locally. Team members who encounter illness in mothers or infants will facilitate attendance at an appropriate health facility, and in cases of severe illness will have an ethical responsibility to assist with rapid and appropriate transport and treatment, irrespective of allocation.

End of a great planning session! Appreciative Inquiry workshop with action groups

ANNEX: DETAILS OF THE RCT

Sample size

For the RCT, sample size was calculated with the equations of Hayes and Bennett,[53] assuming two treatment groups, unmatched clusters of approximately equal size, a value of k – the between-cluster coefficient of variation – equal in intervention and control groups, and the addition of 2 to the estimated cluster number to account for loss of degrees of freedom consequent on stratification. The value of k was set at 0.3 on the basis of (a) estimates of IMR in 24 wards of Mumbai from 2003 MCGM data, and (b) estimates of NMR from data from the MIRA Makwanpur study in Nepal.[47]

We estimated sample size for a range of numbers of births per cluster (200-350) and a range of possible reductions in NMR. At 80% power and two-tailed 5% significance level, a sample size of 48 clusters with 300 births each would allow us to detect a reduction in neonatal mortality rate from 30 to 20 per thousand. We aimed to attain 300 births per cluster over 3 years, which implies a cluster size of 900-1400 households on the basis of municipal demographic data. The surveillance of births and birth outcomes will therefore be carried out over 3 years in 48 clusters of approximately 1500 households.

Randomisation and allocation of health posts and slum clusters

4 health posts will be selected randomly from each of 6 wards, giving a total of 24 health posts. 2 health posts from each ward will be allocated randomly to the intervention group and 2 to the control.

8 slum clusters will be selected randomly from each of 6 wards, giving a total of 48 clusters. 4 clusters from each ward will be allocated randomly to the intervention group and 4 to the control.

Allocation will not be concealed. Because of the nature of the trial, there can be no official masking. However, evaluation teams and intervention teams will conduct their activities independently and no primary outcome results will be fed back to implementation staff.

Statistical methods

The analysis will be undertaken as intention-to-treat at both cluster and participant levels. Participants who begin the trial as residents of a given cluster will be retained as residents even if they move to another cluster during the trial period. Within the prospective cohort, we shall compare NMRs, SBRs, and PMRs between control and intervention groups, taking account of clustering and possible pairing, with hierarchical logistic models. We shall estimate intraclass correlation coefficients from preliminary surveillance of neonatal mortality and stillbirth data by analysis of variance. Secondary outcomes and process indicators will also be compared with adjustment for clustering. All estimates will be presented with 95% confidence intervals.

Interim analysis

We shall conduct an interim analysis of birth rates and neonatal mortality rates after the first few months of surveillance, in order to make sure that they are of an order likely to be sufficient to yield results to the study questions. If the birth rate is inadequate, we shall expand the cluster size from its initial level of 1500 households.

It is unlikely that a community mobilisation intervention will have adverse effects. From our experience in other, similar studies, we do not intend to institute stopping rules. However, if there are social or political problems in specific clusters, each situation will be judged on its merits and the trial can be stopped if necessary.

WARD	HEALTH POST	VULNERABLE SLUM CLUSTER
H East	SV NAGAR	Navjeevan Rahivasi Sangh (Dhobighat)
		Agripada, Chakkikhan and Jaku Club
	GOVERNMENT COLONY	Pathar Nagar
		Islampura and Yasim Nagar
	VN DESAI	Milansar and Masjid Galli
		Golibar (4th-6th Roads) and Bismillah Galli
	KALINA	Chunabatti and Radhakrishnan Nagar (Shastri Nagar)
		Dongar Basti and Kinchikurve Nagar
K west	JUHU CHURCH	Indira Nagar
		Moregaon
	VERSOVA	Tere Galli, Buddha Galli, Patil Galli, Dongri Galli and Shiv Galli
		Sagar Kutir
	ANAND NAGAR	Vikas Nagar
		Anand Nagar
	AJIT GLASS	Shastri Nagar
		Gulshan Nagar
P North	TANK LANE	Ban Dongri A
		Ban Dongri B
	PATHANWADI	Indira Nagar
		Kokani Pada and Gautam Nagar
	DINDOSHI	Srikrishna Nagar
		Jai Bhim Nagar and Ganesh Nagar
	VELNAI	Kaanch Pada 2
		Shivgami Nagar, Shival Nagar and Ambedkar Nagar
G North	KUMBHARWADA	Vijay Nagar and Kamal Nehru Nagar
		Azad Nagar wards A, B and C
	UHC	Indira Nagar, Badnam Basti and AKG Nagar
		Kamala Nagar (old and new)
	PILLA BUNGALOW	Naik Nagar
		Mukund Nagar – Dambar compound
	WELKAR WADI	Naya Nagar and Ambedkar Nagar
		Janata Sevak (Praja Nagar)
		Kokari Nagar
F North	RAWLI CAMP	Jai Maharashtra Nagar
		Kokari Nagar
	ANTOP HILL	Azad Mohalla Khadi and Hindustan Nagar
		Bhartiya Kamala Nagar
	DON BOSCO	Kamla Sunder Nagar
		Mahatma Gandhi Nagar
	KORBA MITHAGER	Anandwadi, Panchsheel and RG Nagar
		Giridhar Tambe Nagar and Adarsh Ramai Nagar
M East	CHITAH CAMP	Mahatma Phule Nagar
		Khadi area of Sector D
	LOTUS COLONY	Durga Seva Sangh and Lotus Colony
		Rafiq Nagar and Baba Nagar
	BAIGANWADI	Adarsha Nagar
		Indira Nagar
	SHATABDI HOSPITAL	Gautam Nagar (Panjarapole)
		Samrat Ashok Nagar

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