Reducing maternal and neonatal deaths in rural Malawi: Evaluating the impact of a community-based women's group intervention

Sonia Odette Lewycka
Institute of Child Health
University College London

Supervisor: Anthony Costello

Co-supervisor: Marie-Louise Newell

Thesis submitted for the degree of Doctor of Philosophy October 2010

Declaration

I, Sonia Odette Lewycka, declare that the work presented in this thesis is my own. Where information has been derived from other sources, I confirm that this has been indicated in the thesis.

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Acknowledgement
I would first and foremost like to thank the women of Mchinji who gave their time to be interviewed in this study and took part in the project activities with enthusiasm. Thanks also to all the staff of MaiMwana who collected, checked and entered the mountains of data, and who supervised and managed the research process. In particular thanks to all the people who have worked with the M&E and data teams: Andrew Mganga, Sipho Jale, Tarcizious Phiri, Jones Kaudzu, Bruce Khonje, Mphatso Chauya, Feston Njuwaluwa and Matthews Chilambo for coordinating data collection in the field, and Bright Sinigini, Eldridge Mwangonde, Joseph Jaffu, Judith Katchoka and Lusungu Chipeta for management and entry of data in the office. Thanks for your dedication and hard work. And thanks to Sam Kalua and Kingsley Chikungwa for your hard work, as well as philosophical insights and good tunes.

I am very grateful to the project management team: Tambosi Phiri for her commitment and patience through challenging times, and to the project directors Dr Charles Mwansambo and Dr Peter Kazembe for their wise oversight. Thanks to Florida Malamba and the facilitation team, who ran the intervention and creatively navigated around many obstacles; thanks to Hilda Chapota and the health service strengthening team, who ran the peer counselling and PMTCT activities; and thanks to the District Health Officers of Mchinji, past and present, who supported the work and engaged with the communities in new forms of outreach.

I would like to thank my supervisors, Anthony Costello and Marie-Louise Newell, who provided many useful suggestions and read drafts at short notice, and thanks to Madeleine Green for organising them and me. Thanks also to friends and colleagues for technical advice and ideas of various sorts, and particularly Mario Cortina-Borja for his statistical support.

Thanks to my family and friends, and all the people who supported and motivated me along the way, in particular: my parents for secluded retreats at The Groves and Whanganui, Mina for the comforts of Abwenzi Palace, Sarah for the great room at Albert Road, Mahima for the extended Indian lunches and Edina Shaba for the exceptional beans and rice. And special thanks to Mikey for being my team sweeper, and being everywhere on the field all at once, and maintaining composure even during the third quarter of the Biggleswade defence.

And finally, to the memory of the late Mr Bernard Chimimba who planted lovely flowers in front of my office window, and my grandfather, Peter Lewyckyj, who would have been the most excited of all.

Abstract

Background: Maternal and neonatal mortality are high in Malawi, and cost-effective and sustainable interventions are needed in order to reduce mortality rates and make progress to achieve Millennium Development Goals 4 and 5 for mother and child health. Where health systems are weak and many women deliver at home, community-based interventions have the potential to make an important contribution to health improvements.

Methods: A cluster-randomised study with a factorial design was used to evaluate the impact of two community-based interventions on maternal and child health outcomes. A prospective pregnancy and birth monitoring system was developed to collect information on pre-specified pregnancy, birth and infant outcomes. The research presented here focuses on the women's group intervention, which uses participatory methods to mobilise communities to take actions for maternal and child health problems they identify.

Results: 18,562 pregnancies were followed up, resulting in 18,340 live births, 362 stillbirths, 434 neonatal deaths and 73 maternal deaths. 11,450 live births were identified retrospectively, resulting in 484 infant deaths. Statistically significant reductions in maternal and neonatal mortality as a result of the women's group intervention were not seen (adjusted odds ratio 0.94 (95% CI 0.56-1.61) and 0.95 (95% CI 0.71-1.28) respectively). There were significant improvements in antenatal care and immunisation, and reductions in births attended by traditional birth attendants, and there were non-significant reductions in mortality and increases in health-care seeking.

Discussion:

Although women's groups showed promising signs of community-level action for mother and child health, methodological factors, such as low power and baseline imbalance after randomisation, may have limited the ability of this study to detect an impact of the intervention on mother and child health outcomes. Design and implementation factors may also have caused delays and limited the measurable impact of the intervention at this time. Follow-up over a longer period may show greater impact.

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Additional material

A CD-ROM containing 'Umodzi' (Together) – a film about MaiMwana women's groups – has been attached in the back cover.

List of abbreviations

AIDS	Acquired Immune Deficiency Syndrome
ANC	Antenatal Care
ARV	Antiretroviral therapy
DC	District Commissioner
CHW	Community health worker
DHS	Demographic and Health Survey
EA	Enumeration Area
EBF	Exclusive Breastfeeding
ENC	Essential Newborn Care
FI	Field Interviewer
GVH	Group Village Headman
HIV	Human Immunodeficiency Virus
HMIS	Health Management Information System (Malawi)
HSA	Health Surveillance Assistant
IMCI	Integrated Management of Childhood Illness
IMPAC	Integrated Management of Pregnancy and Childbirth
IMR	Infant Mortality Rate
IPT	Intermittent Presumptive Treatment (of malaria)
ITN	Insecticide Treated Net
LBW	Low birth weight
LTR	Lifetime risk (of maternal death)
MCH	Mother and Child Health
MDG	Millennium Development Goal
MEO	Monitoring and Evaluation Officer
MTCT	Mother-to-Child Transmission of HIV
MMR	Maternal Mortality Ratio
NGO	Non-Governmental Organisation
NSO	National Statistics Office
NMR	Neonatal Mortality Rate
NVP	Nevirapine
PMR	Perinatal Mortality Rate

PMTCT	Prevention of Mother-to-Child Transmission (of HIV)
PNC	Postnatal care
RCT	Randomised Controlled Trial
SBA	Skilled birth attendance
SES	Socioeconomic status
SMP	Safer Motherhood Programme
SNL	Saving Newborn Lives
SP	Sulphadine-Pyrimethamine (used for malaria prophylaxis in pregnancy)
TA	Traditional Authority
TB	Tuberculosis
TBA	Traditional Birth Attendant
TTV	Tetanus toxoid vaccination
UN	United Nations
UNICEF	United Nations Children's Fund
VCT	Voluntary Counselling and Testing
VDC	Village Development Committee
VH	Village Headman
VMC	Volunteer MaiMwana Counsellor
WCBA	Woman of childbearing age
WE	Woman Enumerator
WG	Women's group
WHO	World Health Organisation
ZF	Zonal Facilitator

Chapter 1 : Introduction

1.1 Aim and chapter outline

The aim of this thesis is to evaluate the impact of a participatory, community-based women's group intervention in rural Malawi on neonatal and maternal mortality rates and other health outcomes. This intervention was implemented as part of a cluster randomised controlled trial, and available data will be used to evaluate the effectiveness of women's groups as a low-cost strategy for improving mother and child survival.

Chapter one will provide an outline of the thesis and an overview of the rationale for the research, setting the study in the context of international literature on safe motherhood and child survival. Chapter two will explore the background and setting for the study in more depth in order to provide context, and will review the quality and availability of existing literature on the epidemiology of maternal and neonatal mortality, with a focus on sub-Saharan Africa and Malawi. Chapter three will critically examine the literature on interventions to reduce maternal and neonatal mortality and discuss their potential as public health interventions in developing countries. Consideration will also be given to approaches for evaluating complex public health interventions. Chapter four will outline the methodology used to conduct this study and describe the processes undertaken in study design, implementation and analysis. Chapter five will present the results in terms of the characteristics of the study population, descriptive baseline data, main impact of the intervention on pre-specified outcomes, and sub-group analysis exploring variations in impact among different groups. Chapter six will discuss the findings in the context of current knowledge and make interpretations as to the broader meaning of these results. There will be discussion of the influence of methodological factors on the observed outcomes. Strengths and weaknesses of the study design, data collection, statistical analysis and intervention implementation will be highlighted, and alternative explanations for the findings will be explored. Chapter seven will summarise the main conclusions from the research and suggest ways that the findings could be carried forward with further research and policy recommendations.

1.2 Overview

Maternal and child mortality in Malawi are high. The most recent Demographic and Health Survey (DHS) estimates a national maternal mortality ratio of 984 per 100,000 live births (1), which represents a lifetime risk of maternal death during a woman's reproductive years of approximately one in 15. This is slightly lower than the previous survey (1,120 per 100,000) (2), but considerably higher than the figure reported in the first survey in 1992 (620 per 100,000) (3). Neonatal mortality is also high, though consecutive DHS survey estimates have shown a decrease, from 41 and 42 per 1,000 live births in the 1992 and 2000 surveys to 27 in 2004. Larger reductions in both will need to be made in order to achieve the Millennium Development Goals for maternal and child mortality (4). Neonatal mortality accounts for over one third of infant deaths (infant mortality rate 76 per 1000 live births), and although this is a smaller proportion than in Southeast Asian settings (5), it is still substantial. Efforts to reduce child mortality will have limited success if they do not target this high-risk neonatal period.

Studies differ in the exact proportions reported, but the most significant causes of maternal death in Malawi are postpartum haemorrhage, infections (including HIV) and complications of obstructed labour and abortion (6-8). The major causes of neonatal death in Malawi have not been reported, but the main causes of neonatal death estimated for sub-Saharan Africa (accounting for 88% of newborn deaths), are infections, preterm birth and intrapartum-related causes such as asphyxia (9).

Maternal and neonatal mortality and morbidity in Malawi are exacerbated by the high burden of human immunodeficiency virus (HIV) and malaria, and both have major direct and indirect effects on women and infants' health during and after pregnancy. An estimated 13.3% of women of childbearing age are infected with HIV (1), and routine health facility data reported 2,096,425 new cases of malaria infection among children under five years old in the year ending June 2007, (which represents an average of one case per child under five-years, or 94% of the under-five population), and 3,948 malaria deaths (10). The exact contribution of HIV and malaria is difficult to measure due to lack of widespread diagnostic testing (11), but some studies have suggested that both contribute significantly to the burden of maternal and neonatal illness and death in sub-Saharan Africa (9, 12-16).

Determinants of maternal and neonatal death may be socio-environmental, behavioural or related to quality of health care (17, 18). Safe motherhood and neonatal health programmes have typically focused on improving quality of obstetric services and increasing access to skilled care at delivery. However, almost half (45.6%) of women in rural areas of Malawi give birth at home in the community, with a traditional birth attendant or relative (1). In this context, focusing only on improvements in clinical quality of care may have limited immediate benefit. Community-level interventions are also needed to create awareness and demand for better services, and to tackle emergency situations when labour starts and becomes complicated a long distance away from a health facility. Vital signs of sick infants may deteriorate very rapidly, and delays in health-care seeking can be fatal. In addition, community-level interventions can be an effective way to promote preventative health behaviours, such as those related to hygiene, nutrition and malaria prevention (19-22).

In the context of limited access to good quality maternity, postnatal and child health services, interventions involving community mobilisation and participation have shown large reductions in both maternal and neonatal mortality in Asian and South American settings (23-25). The potential of such interventions in an African setting, where HIV and malaria are much more prevalent, has not been evaluated.

This PhD dissertation will evaluate the impact on mortality rates of a participatory community intervention using women's groups to mobilise communities to change mother and child care and health-seeking behaviours, and to take actions to improve their health. Furthermore, this thesis will explore the factors that predict coverage and uptake of the trial intervention, and will explore contextual influences on health and on the ability of the intervention to achieve a measurable effect.

Chapter 2 : Review of the epidemiology of maternal and neonatal mortality

Maternal and infant mortality are high in Malawi, and though there have been reductions in recent years, insufficient progress has been made so far to achieve the Millennium Development Goals (MDG) set out for maternal and child health (4). Neonatal mortality makes up a large part of child mortality (one out of every five deaths in children under five in Malawi (1)), and the MDG for child health will be difficult to achieve without focusing on this component.

The women's group intervention described in this study focused on improving maternal and newborn health, as well as looking at the wider effects on perinatal and infant outcomes. Implicit in our ability to evaluate the impact of this and other population-level interventions for mother and child health is the need to understand the epidemiology of maternal and neonatal mortality and to be able to make accurate measurements of mortality outcomes. Therefore detailed discussion is given to current levels and trends of mortality rates, focusing on sub-Saharan Africa and Malawi, as well as methods available for their estimation and the accuracy of such methods. This background will highlight the importance and policy-relevance of this study, and will also allow assessment of the validity and generalisability of the findings.

2.1 Methodological considerations in measuring maternal and neonatal mortality

Accurate data on mortality rates are important for monitoring progress towards Millennium Development Goals for health, and for evaluating the effectiveness of national and international strategies, programmes and policy-changes (26). In this study, reliable estimates of mortality were important for the design and sample size calculations, as well as to provide a reference against which to compare the findings.

Maternal mortality is notoriously difficult to measure. Underreporting of deaths or misclassification of reported deaths as non-maternal are common problems, especially

in countries with weak or non-existent vital registration systems. Neonatal mortality is also difficult to measure and often goes unreported. Misclassification may happen particularly in relation to the time of death, with early neonatal deaths being mis-reported as stillbirths or later neonatal deaths as post-neonatal.

There are substantial limitations in the availability and quality of information about maternal and neonatal health outcomes, especially in developing countries. In trying to understand the epidemiology of maternal and neonatal mortality in Malawi and to be able to estimate the impact of maternal and neonatal health interventions, it is important to understand the methodological difficulties involved in making mortality estimates. Baseline measures of mortality are also important for designing studies to evaluate the effectiveness of new interventions, and for the research presented in this thesis, consideration of the advantages and disadvantages of different methods of data collection was a necessary prerequisite.

Some of the difficulties in measuring mortality encountered include varying definitions and classification systems, incomplete identification and underreporting, misclassification of cause of death, large margins of uncertainty, varying sources of data, and use of 'selected' populations. This section will provide a basis for reviewing the literature on the epidemiology of maternal and neonatal mortality in Malawi discussed in section 2.2, and also for considering the quality of evidence for the effectiveness of interventions described in Chapter 3. Table 2.1 summarises the advantages and disadvantages of different types of study and forms of data collection for estimating maternal and neonatal mortality rates.

Table 2.1: Advantages and disadvantages of different types of study for estimating mortality rates

Type of study	**Advantages**	**Disadvantages**
Hospital-based studies	- Cheap, quick and easy	- Biased sample who use health facilities
Vital registration	- Provides ongoing data over long time period - Can monitor changes over time	- Biased sample who use health facilities - Still prone to misclassification of cause of death and underreporting
Population census	- Eliminates sampling error - Allows detailed breakdown of results by geographic and socioeconomic strata and over time - Retrospective estimates for 1-2 years before the survey	- Expensive - Infrequent, so can't be used for monitoring - Retrospective data prone to recall biases
Cross-sectional survey (e.g. using sisterhood methods)	- Relatively cheap, quick and easy	- Identifies pregnancy-related deaths not maternal deaths - Retrospective data prone to recall biases - Retrospective estimates for period some years before the survey - Require large sample sizes to achieve precise estimates - Difficult to monitor changes over time
Longitudinal (prospective) survey (e.g. demographic surveillance system)	- Prospective data less prone to recall biases - Prospective data provides current estimates	- Expensive and time-consuming - Losses to follow-up can introduce selection bias - May fail to identify maternal deaths due to indirect causes (e.g. malaria, HIV)

2.1.1 Case definition and classification systems

Although clear case definitions exist for both maternal and neonatal mortality (see Appendix 1 for a list of definitions), there are several slightly different, overlapping definitions that are used, and many studies do not report the definition used at all (27). This can lead to confusion in interpreting findings and in making comparisons between studies using different definitions. Comparisons between regions with different disease profiles and political situations may also be difficult to interpret.

Maternal mortality

According to the International Statistical Classification of Diseases (ICD-10) established by the World Health Organisation (WHO) as a general international standard diagnostic classification, a maternal death is defined as "*the death of a woman while pregnant or within 42 days of termination of pregnancy, irrespective of the duration and site of the pregnancy, from any causes related to or aggravated by the pregnancy or its management but not from accidental or incidental causes."* (28). However, the choice of 42 days as the cut-off point for maternal deaths was not based on a study of the timing of deaths in relation to pregnancy and delivery. In recognition of the fact that the 42-day limit is somewhat arbitrary and that both improvements in health care and malaria, anaemia and AIDS-related illnesses may result in later deaths that are still related to or aggravated by pregnancy, a 'late maternal death' category was also introduced (28). This includes deaths due to obstetric causes up to one year after termination of pregnancy. In addition, where it is difficult to ascertain cause of death, a category of 'pregnancy-related death' was introduced based more on the timing of death in relation to pregnancy than on the medical cause, and may include some non-obstetric deaths. Appendix 1 provides a list of definitions.

Although clear definitions exist, they are not always uniformly applied. In a WHO systematic review of maternal mortality, 2204 articles were reviewed and it was found that half of them did not report the definition used for maternal death and two-thirds did not use any method to confirm the death as maternal (27).

Whichever definition is used, the number of maternal deaths is then used to calculate indicators that are used internationally to monitor maternal mortality. The most

commonly used is the maternal mortality ratio (MMR), also referred to as 'obstetric risk' because it describes the risk of dying once pregnant. It is usually calculated as the number of maternal deaths per 100,000 live births.

The 42-day (6-week) maternal mortality definition is the most widely used to estimate MMR, and was used in the early rounds of Demographic and Health Surveys (DHS) (29). Recent DHS surveys (starting from the late 1980s) have used slightly different methods to estimate maternal mortality, and use a two-month rather than a 42-day cut-off for maternal death. This discrepancy is assumed to have little effect, with most maternal deaths happening during or soon after delivery (30). However, this may not be the case where the background adult female mortality rate is high, and the proportion of deaths due to non-maternal causes included is large (31). DHS surveys collect no data on cause of death, so include all pregnancy-related deaths rather than only true maternal deaths (32). Again, this is assumed to have little effect, but would have the largest effect where background adult female mortality rates are high, for example with high HIV prevalence or conflict (31).

Neonatal mortality

A neonatal death is defined as the death of a live-born baby within 28 completed days of birth (Appendix 1). A neonatal death is therefore defined solely by its timing in relation to birth rather than a specific clinical cause. It is sometimes difficult to determine whether a baby died during birth or immediately after, especially where the baby is very premature, asphyxiated or neurologically depressed. Misclassification of very early neonatal deaths as stillbirths could lead to underestimates of neonatal mortality (33). To avoid the problem of differentiating between stillbirths and live births, in the late 1940s stillbirths and early neonatal deaths (deaths within the first 7 days) were combined to form the category of perinatal deaths (34). Where most stillbirths and early neonatal deaths are due to asphyxia, this makes aetiological sense, though is less important where other causes are more prominent.

Aside from the difficulties of differentiating between live births and stillbirths, the case definition is relatively universally applied, though some studies have used a 42-day (six-week) cut-off rather than a 28-day (four-week) cut-off and others have preferred to confine outcomes to the perinatal period, which can make comparisons between studies

difficult. DHS surveys report both neonatal and perinatal mortality rates, but define neonatal mortality as "the probability of dying within the first month of life", so include deaths on the 29th, 30th and 31st days of life, thus slightly lengthening the period compared to the standard definition (29).

2.1.2 Incomplete identification and underreporting

In many countries, births and deaths are routinely registered providing reasonably accurate population and mortality estimates. However, most of the countries with the highest reported maternal and neonatal mortalities (5, 35-37) do not have vital registration systems to record events such as births and deaths. Attempts have been made in Malawi to launch national village health register and birth registration systems, but so far, coverage is patchy and data is unreliable (38). In the absence of vital registration systems most developing countries rely mainly on routinely collected health facility data or on surveys, like the retrospective DHS household surveys conducted by the international company ICF Macro, for making national mortality estimates. Health facility data is often poorly kept and provides a biased view as it only represents the proportion of the population with access to health services. Demographic and Health Surveys use cluster sampling to produce nationally representative estimates, and are widely used in international reports making comparisons between countries (5, 37). However, there are several methodological weaknesses of Demographic and Health Surveys discussed below.

Maternal mortality estimates from DHS surveys

DHS surveys collect retrospective information about events some time after they have happened. Maternal mortality is usually estimated using the sisterhood method, which involves asking all women of childbearing age about their live born sisters, and collecting details of any sisters who died during or soon after pregnancy (30, 39). There is possibility for bias in the fact that only surviving siblings are interviewed, so where a deceased woman has no surviving sisters of childbearing age deaths of her other siblings (including maternal deaths) will not be counted. This can be particularly problematic where fertility rates are low. According to Stanton and colleagues, who compared DHS survey data on maternal mortality from 13 countries, sisterhood data is more likely to underestimate than overestimate maternal mortality (40). Adult female

mortality rates estimated using the same methods were consistently lower than mortality rates estimated using model life tables or census. However, DHS methods include all pregnancy-related deaths, and may overestimate maternal mortality where a high proportion of non-maternal deaths occur amongst women of reproductive age (31).

Discussion in the 2000 Malawi DHS suggests that over- or underestimation of maternal mortality may result from over- or underestimating all-cause adult female mortality due to misclassification of maternal deaths as non-maternal or vice versa; inclusion of all pregnancy-related rather than specifically maternal deaths; or omission of female deaths leading to underestimation of adult female mortality (2).

Childhood mortality estimates from DHS surveys

In retrospective surveys, underreporting of the births of deceased children and their subsequent deaths is also a concern, especially for deaths of children in the neonatal period and early infancy. Data from the 2004 Malawi DHS survey suggest that there may have been more underreporting of neonatal deaths compared to previous years (1). For example, the number of neonatal deaths as a proportion of infant deaths was lower in the immediate years preceding the survey compared to previous years – 39% in years 0-4 compared to 43% and 42% for the 5-9 and 10-14 years preceding the survey respectively. This is particularly strange given that where infant mortality is falling neonatal deaths tend to make up a larger proportion of the total rather than a smaller one (41). Because of these particular methodological concerns in the 2004 Malawi DHS, mortality rates and trends must be interpreted with caution.

Underreporting of infant deaths is usually greater for deaths that occur in very early infancy (42). In some cultures a pregnancy loss or very early death within the first few hours or days may not be reported at all. Completeness and accuracy of recall, especially of ages and dates, may deteriorate with time. In DHS surveys that ask about outcomes of pregnancies in the previous five years it may be difficult to adhere to WHO/ICD-10 definitions because gestational age is usually not known, menstrual periods can be irregular and women don't always have records to rely on (42).

Other possible biases in neonatal and child mortality estimates arise because only surviving mothers are interviewed about the birth history. If mothers that died have

systematically different birth histories, this will not be captured. Where adult female mortality is high this bias would be at its highest. It has been shown that children of women who die have a greater risk of dying themselves (14, 43), in which case mortality rates from retrospective surveys would underestimate the size of the problem. In the same way, women older than 49 are not interviewed in this survey, so their birth histories are not included. This presents more of a problem for estimating mortality rates 10 years prior to the survey (42).

Prospective data collection and surveys

Studies and surveys using prospective data collection tend to avoid many of the recall biases and problems of underreporting encountered in retrospective surveys, as they collect information about events as they arise. But they are usually costly and time-consuming to conduct as they require following up large populations over long periods of time. Following up participants who move out of the study area is also costly, and becomes a problem where there are high levels of in- out- and internal-migration, which is especially the case in urban areas (44, 45). Systematic differences between those lost to follow-up and not lost to follow-up can result in selection biases.

2.1.3 Misclassification of cause of death

Classification of maternal and neonatal deaths requires accurate medical histories for events leading to the death, including stage of pregnancy and dates of birth and death. Recall of such details can be difficult, especially in populations with little documentation on times and dates of events coupled with low literacy levels.

Maternal deaths

For maternal events, physician diagnosis is required for true classification of a death due to maternal causes, as well as an accurate history about the timing of events. Where deliveries commonly occur in the absence of a skilled health worker a reliable diagnosis may be difficult to get. Even in countries that have well-established vital registration systems it is still possible to find MMR underestimated, with misreporting of up to 70% of maternal deaths (46). This is especially the case where deaths in early pregnancy or several weeks after birth account for a large proportion of maternal deaths and where pregnancy status at the time of death is not known. Some vital registration systems

don’t include classification of cause of death, and as such maternal mortality estimates in these countries are usually made using statistical models (37, 46).

Neonatal deaths

Classification of neonatal death does not require clinical diagnosis, but depends on clear reporting of time of death in relation to birth, and thus requires detailed histories from parents or relatives including dates of birth and death. Misclassification of neonatal deaths happens as a result of imprecision regarding the timing of events. Cultural beliefs around stillbirths and early neonatal deaths sometimes make families reluctant to admit that a child was born alive and then died soon after birth, thus resulting in misclassification of a live born baby as a stillbirth. Infants that die during delivery also present a special problem, as it is often not clear at what stage the baby died, especially if the baby shows few signs of life immediately after it is born. ICD-10 states that “a stillbirth or foetal death is a death prior to the complete expulsion or extraction from its mother of a product of conception, irrespective of the duration of pregnancy” (28), but other studies have used the definition of a stillbirth as “fetal death after 28 weeks of gestation but before delivery of the baby’s head” (22). Furthermore, neonatal deaths might be misclassified as post-neonatal if the family reports that the baby died around one month of age and cannot provide accurate dates, in which case the death is often recorded as “30 days”, which is beyond the neonatal period.

Other methodological problems may arise through misreporting dates of birth and age at death. This may happen deliberately or just in the process of rounding dates to the nearest month or year. In the 2004 Malawi DHS, the dates of births for children that survived or had died were 32% and 82% higher respectively after the cut-off for requirement for interview compared with before it, suggesting that dates were deliberately misreported by interviewers to avoid having to do extra interviews (1). Similarly, neonatal deaths may be misclassified as stillbirths to avoid filling in death registration and survey forms. Digit preference and rounding of ages may also affect neonatal and infant mortality estimates, where deaths are reported as exactly 1-month rather than in days. This would have the effect of underestimating neonatal mortality, but over-estimating post-neonatal mortality (42).

Cause-specific maternal and neonatal deaths

Misclassification may particularly be a problem in large surveys like DHS where accurate clinical diagnosis is not possible. When trying to classify maternal and neonatal deaths by cause further problems arise. Where coexisting causes of death are found, rules for diagnosticians or coders are not always clear or consistently applied (47). Researchers have tried to develop algorithms to enable automated classification of large sets of data without the need for a physician (48). A study in Nepal comparing physician review with algorithm-based cause-of-death assignment for neonatal deaths showed high correlation for some conditions (prematurity and diarrhoea) but not for others (asphyxia and sepsis) (49). A study in Mozambique comparing clinical autopsy for maternal deaths to complete necropsy (gold standard), found very low sensitivity of clinical data and verbal autopsy, especially for infectious causes – HIV 33% and puerperal sepsis 50%. Eclampsia was the main source of false positives (57%) (50). In practice, classifications of cause of death often vary depending on the interests of the investigators. For example, whether HIV and malaria are classified as specific conditions or as general infectious conditions, or whether abortion-related mortality is classified as abortion or as post-abortal sepsis.

2.1.4 Large margins of uncertainty

Large margins of uncertainty around mortality estimates may arise due to non-sampling or sampling errors (37, 51). Non-sampling errors include systematic errors and random errors that are not due to sampling, such as recall error and misclassification as discussed above and other errors in the implementation of data collection, data entry and imputation of missing data. Efforts must be made at the implementation stage to avoid non-sampling errors, though they are difficult to avoid completely and difficult to evaluate statistically. Sampling errors arise as a result of chance when using a sample to estimate population mortality rates, and they reflect the degree of variability between all the possible samples that could have been selected. Sampling error can be reduced by increasing the sample size, and can be estimated from the standard error (45). The standard error can then be used to calculate confidence intervals within which the true value for the population can be assumed to fall.

Data from WHO reports are derived using inflation factors that try to account for the large margins of uncertainty inherent in estimating mortality rates. Margins of

uncertainty associated with MMR are very large (much larger than for other commonly used DHS/health indicators) (36). Even for countries with highly developed statistical systems an inflation factor of 50% was used in the WHO 2000 report (35), and the calculated MMR was multiplied by two in the WHO 2005 report (36). This was done to adjust for possible misclassification and underreporting, though inflation factors are based on fairly crude guesswork, and true figures could be higher or lower than these adjusted estimates. For countries that rely on surveys for mortality estimates, even with rigorous definition, identification and classification of deaths, maternal and neonatal mortality estimates are usually imprecise, due to the relatively small numbers of events used in calculating them, and the large associated random error. In the 2004 Malawi DHS survey only 240 and 289 maternal and neonatal deaths respectively were used to estimate the mortality rates, leaving large margins of uncertainty around the estimates (1). As such, apparent differences between regions or over time can be due to chance rather than real epidemiological differences. Sampling error is also of particular concern in epidemiological studies trying to make comparisons in mortality rates between populations exposed to different interventions or risk factors (52).

2.1.5 Varying sources of data

Data used to produce international reports tends to come from many different sources using different sampling and data collection techniques (5, 37, 53). Most data is collected retrospectively through surveys, and is thus prone to recall error as well as underreporting and misclassification. Prospectively collected data can minimise some of these sources of error, but is often costly and time-consuming so is seldom done on a large scale for long periods of time. Reports that make within-country national comparisons between regions and over time may also draw data from several different sources using different data collection techniques (54). Most research studies tend to use hospital-based populations, as it is usually easier to recruit a study sample and to collect follow-up data. Therefore, when seeking to describe patterns of maternal and neonatal health outcomes by country or region, or when looking at trends over time, it is important to take into account the problems inherent in measuring the magnitude and nature of the problem. It is worth considering whether apparent differences in mortality estimates between studies reflect chance, methodological, diagnostic or real differences, or in the case of facility-based data, differences in the use of health services.

2.1.6 Use of ‘selected’ populations

Hospital-based surveys or routine statistics only collect data from women who give birth in health facilities. In Malawi, this excludes the 43% of the population who give birth elsewhere (1). Women who give birth in health facilities are likely to be different from the general population in terms of various socioeconomic and demographic characteristics, which may also be associated with mortality risk. In addition, hospital deliveries usually include high-risk cases or emergency admissions, so are likely to provide a biased picture of the epidemiology of maternal and neonatal health at population-level. However, such studies are still useful in investigating the epidemiology of hospital-based deaths (55).

2.1.7 Summary of methodological considerations

In conclusion, different methodological factors result in over and underestimation of maternal and neonatal mortality, but few data exist in order to determine to what extent these errors compensate for one another (30, 42). The degree of over or underestimation may vary depending of the relative proportion of deaths happening at different stages of maternal and neonatal periods, which in turn depends on the maternal and neonatal epidemiology in that setting (31, 50). Comparisons between countries and over time should be made with caution due to potentially large errors and different data collection and estimation methods. As a result of these uncertainties, as well as contextual differences that affect implementation, several publications have described the limitations of mortality statistics (particularly maternal mortality) for measuring programme impact (56, 57).

2.2 Epidemiology of maternal and neonatal mortality

This section will explore available data for estimates of maternal and neonatal mortality from various sources such as routine data collection systems, surveys and research studies. Estimates in different geographic, demographic and socioeconomic settings and over time will be discussed, and some details of the aetiology will be explored. This will provide context for the research in this thesis, and give a reference against which the findings can be compared to assess their validity.

2.2.1 Frequency

The maternal mortality ratio (MMR) is the health indicator with the largest discrepancy between developing and developed countries and varies by a factor of over 100 between the poorest and least poor countries (51, 58). It is an important indicator for comparison of the performance of health-care systems between countries because it is generally assumed that maternal mortality reflects the quality of essential and comprehensive obstetric care. Maternal mortality has received increased attention since its inclusion in the Millennium Development Goals (MDGs) (4). Universal access to maternal healthcare is seen as the starting point to achieve the target of MDG 5, which is the reduction of maternal mortality by three-quarters between 1990 and 2015. This requires that births are attended by skilled birth attendants (doctors, nurses, or midwives) who are able to prevent, detect, and manage or refer women with obstetric complications. However, community-based action is also fundamental and has shown great promise as a means of improving home care with small but significant increases in uptake of services (22). Neonatal mortality rates (NMR) are less variable between developing and developed countries than maternal mortality rates, but are still high and vary by a factor of about 30 (59).

Global estimates of maternal and neonatal mortality

An estimated 358,000 maternal deaths occurred globally in the year 2008, representing an MMR of 260 deaths per 100,000 live births and a lifetime risk of maternal death of 1 in 140 (37). However, this burden is not distributed uniformly, and 99% of women who die during pregnancy, childbirth, or in the immediate postpartum period are from developing countries, and more than half of them are from sub-Saharan Africa. The

estimated MMR for sub-Saharan Africa is more than twice as high (640 per 100,000) as that for south Asia (280 per 100,000), and almost 50 times as high as that for developed regions (14 per 100,000). The same report estimates that the adult lifetime risk of maternal death is 1 in 31 in the sub-Saharan Africa region. The bounds of uncertainty for these estimates are large so they cannot be used as precise estimates, but they give an idea of the magnitude of the problem.

Worldwide, almost 11 million children under the age of five, and 4 million newborns, die every year. In a report using DHS, WHO and UN data sources, neonatal mortality is estimated to be 30 per 1,000 live births globally, with a rate of 44 per 1,000 in sub-Saharan Africa compared to 4 per 1,000 in developed countries (5). The authors highlight that newborn deaths are double the number of deaths due to HIV, but have received much less attention. As with maternal mortality, 99% of neonates that die are born in developing countries, and 28% of the global burden of neonatal deaths is in sub-Saharan Africa (5). Most newborns die immediately after birth as a result of premature birth or asphyxia, or subsequently from infectious diseases that can be prevented or treated by existing inexpensive means (60). The target of MDG 4 is to reduce the under-five morality rate by two-thirds, between 1990 and 2015 (4). Achieving the target requires a substantial reduction in newborn deaths, as they count for 38% of under-five deaths globally, and 24% in sub-Saharan Africa (5). The proportion neonatal varies depending on overall child mortality rates, with countries that have lower under-five mortality rates having a higher proportion of them being neonatal deaths (41).

Estimates of maternal and neonatal mortality in Malawi

Routine sources of data often only include births and deaths that occur at facilities, and where most women give birth at home these figures are likely to vastly underestimate mortality rates. In Malawi for example, the Health Management Information System (HMIS) is facility-based and does not include births and deaths that occur outside facilities, but only 57% of births happen in facilities so this is clearly not representative of the whole population (1). Attempts are being made to improve reporting of vital events at community level through community birth and death registration systems and facility-led maternal death audits (38). HMIS does not provide national MMR and NMR estimates, but gives a national case fatality rate of 2.5% for the reporting period July 2006 to June 2007 – that is the percentage of women with direct obstetric complications

in emergency obstetric care (EmOC) facilities that die from them (10). This gives an indication of the quality of care provided. The UN recommends that a CFR of less than 1% should be aimed for. A national population and housing census was conducted in 1987, 1998 and 2008, but this does not provide estimates of maternal or neonatal mortality. Infant mortality was estimated to be 121 per 1000 live births in 1998 and 87 per 1000 live births in 2008 (61, 62).

The most commonly cited national estimates of maternal and neonatal mortality in Malawi come from the Demographic and Health Survey (1, 63). In the most recent Malawi DHS report for 2004, maternal mortality was estimated to be 984 per 100,000 live births, neonatal mortality was 27 per 1,000 live births, perinatal mortality was 34 per 1,000 births and infant mortality was 76 per 1,000. Another more recent survey providing national mortality estimates is the Multiple Indicator Cluster Survey (MICS), which was conducted by the Malawi National Statistics Office and UNICEF in 2006 (63). This reports an estimated maternal mortality ratio of 807 per 100,000 live births, and neonatal and infant mortality rates of 33 and 72 per 1,000 live births respectively. Perinatal mortality rates were not determined in this study.

WHO model estimates are derived from adjusted national datasets available in 2008, including vital registration systems, national surveys and censuses. Using these data sources, the estimate for Malawi is 510 maternal deaths per 100,000 live births (with a range of uncertainty of 300 to 760), and a lifetime risk of maternal death of 1 in 36 (estimates are adjusted for age distribution and AIDS-deaths) (37). This is considerably lower than the WHO report for 2005, in which Malawi was estimated to have an MMR of 1,100 per 100,000 live births, and the highest proportion of maternal deaths as a fraction of all reproductive age deaths of any country in the world, with over two-thirds of deaths in women of childbearing age being due to maternal causes (36). This is also considerably lower than another model-based estimate of maternal mortality that gives an estimate of 1,140 for Malawi in 2008 (64). WHO sources estimate that Malawi's NMR was 40 per 1,000 live births and perinatal mortality rate (PMR) was 43 per 1,000 in the year 2000 (53, 59).

A summary of all population-based studies and surveys conducted in Malawi that reported maternal mortality estimates is given in Table 2.2, and summaries of all studies

and surveys reporting perinatal, neonatal and infant mortality figures are given in Table 2.3, Table 2.4 and Table 2.5. Most of these studies did not report margins of error for their mortality estimates, but these have been calculated from available data. Mortality rates from hospital-based studies were not included as they cover highly selected populations.

Estimated maternal mortality ratios range between 398 and 1,120. The range of estimates using prospective methods was somewhat narrower and lower (398 and 513) than those derived from retrospective surveys using sisterhood methods conducted around the same time (409 and 1,120). Perinatal mortality rates were estimated to be between 30 and 68 per 1000 births, neonatal mortality rates between 27 and 47 per 1,000 live births, and infant mortality rates between 55 and 165 per 1,000 live births.

It is evident that, whether using population-based or model-based estimates of mortality, considerable variability exists. This may be as a result of changes over time due to the different time periods represented, different study population characteristics, or different methods.

Table 2.2: Population-based studies estimating maternal mortality in Malawi (1981-2006)

Study/ primary author (Publication date)	**Date data collected** (Period refers to)	**Study design**	**Case definition**	**Population**	**Number of maternal deaths**	**MMR estimate (**per 100,000 live births) (95% CI)	**Maternal age** (Years)
Chiphangwi[1] (1992) (65)	1989 (reference period not given, approx 1976)	Retrospective sisterhood survey (indirect sisterhood)	Unknown	7 TAs in Thyolo District, Southern region	150	409 (349-480)	>=15
DHS (1992) (3)	1992 (refers to period 1986-1992)	Retrospective direct sisterhood survey	Deaths during pregnancy, childbirth and up to 6 weeks afterwards	Cluster samples across Malawi	71	620 (492-781)	15-49
McDermott (1996) (14)	Sept 1987 – July 1989	Prospective cohort (part of antimalarial trial)	All deaths during pregnancy, childbirth and up to 6 weeks afterwards (not excluding incidental/accidental deaths)	Antenatal attenders, Mangochi District, Southern region	15	398 (241-656)	Unknown
Kulmala[1] (2000) (66)	June 1995 – Aug 1996	Prospective cohort	Not given – not originally aiming to estimate MMR	Pregnant women identified at rural ANC, Mangochi District, Southern region	4	513 (200-1,311)	All pregnant
DHS (2000) (2)	2000 (refers to period 1994-2000)	Retrospective direct sisterhood survey	Deaths during pregnancy, childbirth and up to 2 months afterwards	Cluster samples across Malawi, with over-sampling for 11 districts	344	1,120 (1,008-1,244)	15-49
Van den Broek[2] (2003) (67)	2002 (refers to period 1998-2002)	Retrospective household survey asking about all births in the last year	"The death of a woman associated with child-birth". Timing not stated.	All households in catchment of rural health centre, Chiradzulu District, Southern region	9	413 (144-682)	>=10
DHS (2004) (1)	2004 (refers to period 1998-2004)	Retrospective direct sisterhood survey	Deaths during pregnancy, childbirth and up to 2 months afterwards	Cluster samples across Malawi, with over-sampling for 10 districts	240	984 (868-1,116)	15-49
MICS (2006) (63)	2006 (refers to period 2000-2006)	Retrospective direct sisterhood survey	Deaths during pregnancy, childbirth and up to 2 months afterwards	Cluster samples in all districts of Malawi	469	807 (737-883)	15-49

1 Complete paper not seen, abstract only. Other details from Geubbels 2006 (54).

2 Probably underestimated maternal deaths as most husbands left households after maternal death, and households headed by single women that died would be missed.

Table 2.3: Population-based studies estimating perinatal mortality in Malawi (1996-2004)

Study/ primary author (Publication date)	**Date data collected** (Period refers to)	**Study design**	**Case definition**	**Population**	**Number of perinatal deaths**	**PMR estimate** (per 1,000 births) (95% CI)	**Maternal age** (Years)
McDermott (1996) (68)	1987-1990	Prospective cohort	Stillbirths plus deaths within 7 days of delivery	Antenatal attenders, Mangochi District, Southern region	264	68 (61-76)	All pregnant
Kulmala (2000) (69)	June 1995 – Aug 1996	Prospective cohort	Stillbirths plus deaths within 7 days of delivery	Pregnant women identified at rural ANC, Mangochi District, Southern region	52	65 (50-84)	All pregnant
DHS (2000)[1] (2)	2000 (refers to 1995-2000)	Retrospective household survey of birth histories	Deaths after 7m gestation or within first 7 days of life	Cluster samples across Malawi, with over-sampling for 11 districts	568	48 (44-52)	15-49
Van den Broek (2003) (67)	2002 (refers to period 1998-2002)	Retrospective household survey	Not clear – seems only to include stillbirths	All households in catchment of rural health centre, Chiradzulu District, Southern region	66	30 (24-38)	>=10
DHS (2004) (1)	2004 (refers to 1999-2004)	Retrospective household survey of birth histories	Deaths after 7m gestation or within first 7 days of life	Cluster samples across Malawi, with over-sampling for 10 districts	372	34 (31-38)	15-49

[1] PMR estimate not available in 1992 DHS

Table 2.4: Population-based studies estimating neonatal mortality in Malawi (1992-2006)

Study/ primary author (Publication date)	**Date data collected** (Period refers to)	**Study design**	**Case definition**	**Population**	**Number of neonatal deaths**	**NMR estimate** (per 1,000 live births) (95% CI)	**Maternal age** (Years)
DHS (1992) (3)	1992 (refers to period 1987-1992)	Retrospective household survey of birth histories	Deaths during first month of life	Cluster samples across Malawi	188	41 (36-47)	15-49
McDermott (1993) (70)	1987-1990	Prospective cohort	Deaths during first 28 days	Antenatal attenders, Mangochi District, Southern region	135	47 (40-55)	All pregnant
Kulmala (2000) (69)	June 1995 – Aug 1996	Prospective cohort	Deaths within 28 days of delivery	Pregnant women identified at rural ANC, Mangochi District, Southern region	28	37 (26-53)	All pregnant
DHS (2000) (2)	2000 (refers to period 1995-2000)	Retrospective household survey of birth histories	Deaths during first month of life	Cluster samples across Malawi, with over-sampling for 11 districts	515	42 (37-48)	15-49
DHS (2004) (1)	2004 (refers to period 1999-2004)	Retrospective household survey of birth histories	Deaths during first month of life	Cluster samples across Malawi, with over-sampling for 10 districts	289	27 (23-31)	15-49
MICS (2006) (63)	2006 (refers to period 2002-2006)	Retrospective household survey of birth histories	Deaths during first month of life	Cluster samples in all districts of Malawi	Unknown	33 (29-38)	15-59

Table 2.5: Population-based studies estimating infant mortality in Malawi (1977-2010)

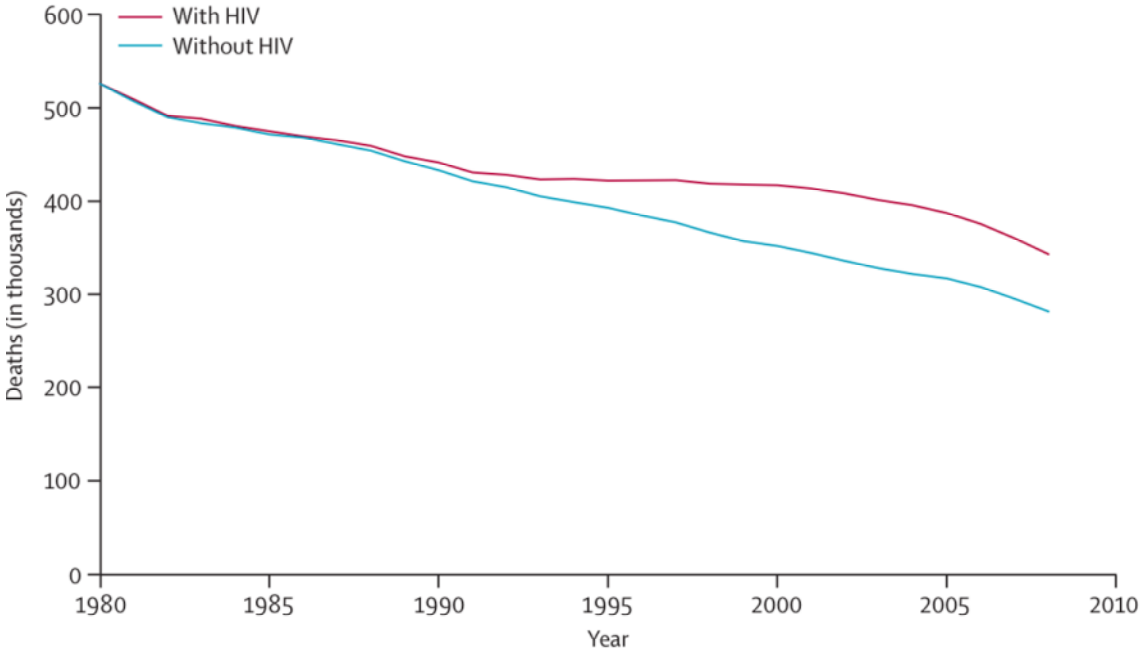
Study/ primary author (Publication date)	**Date data collected** (Period refers to)	**Study design**	**Case definition**	**Population**	**Number of infant deaths**	**IMR estimate** (per 1,000 live births) (95% CI)	**Maternal age** (Years)
Population and Housing census 1977 (71)	1977 (refers to period 1976-1977)	Retrospective household survey of birth histories	Deaths of infants under one year of age	All households in Malawi	Unknown	165	Unknown
Population and Housing census 1987 (72)	1987 (refers to period 1986-1987)	Retrospective household survey of birth histories	Deaths of infants under one year of age	All households in Malawi	Unknown	159	Unknown
DHS (1992) (3)	1992 (refers to period 1987-1992)	Retrospective household survey of birth histories	Deaths during first year of life	Cluster samples across Malawi	569	134 (124-145)	15-49
McDermott (1993) (70)	1987-1990	Prospective cohort	Deaths within first 365 days	Antenatal attenders, Mangochi District, Southern region	407	149 (136-163)	All pregnant
Population and Housing census 1998 (61)	1998 (refers to period 1997-1998)	Retrospective household survey of birth histories	Deaths of infants under one year of age	All households in Malawi	Unknown	125	Unknown
Vaahtera (2000) (73)	June 1995 – Aug 1996	Prospective cohort	Not specified (assumed deaths during first year of life)	Pregnant women identified at rural ANC, Mangochi District, Southern Region	100	136 (113-163)	All pregnant
DHS (2000) (2)	2000 (refers to period 1995-2000)	Retrospective household survey of birth histories	Deaths during first year of life	Cluster samples across Malawi, with over-sampling for 11 districts	1,159	104 (96-111)	15-49
DHS (2004) (1)	2004 (refers to period 1999-2004)	Retrospective household survey of birth histories	Deaths during first year of life	Cluster samples across Malawi, with over-sampling for 10 districts	742	76 (69-83)	15-49
MICS (2006) (63)	2006 (refers to period 2002-06)	Retrospective household survey of birth histories	Deaths during first year of life	Cluster samples in all districts of Malawi	Unknown	72 (68-77)	15-59
Population and Housing census 2008 (62)	2008 (refers to period 2007-2008)	Retrospective household survey of birth histories	Deaths of infants under one year of age	All households in Malawi	Unknown	87	>=12
Jahn (2010) (74)	2002-06	Demographic surveillance system (prospective data)	Deaths during first year of life	General population (32,000) in Karonga District, Northern Region	195	55 (48-63)	All pregnant

2.2.2 Temporal trends

Maternal mortality

For the reasons discussed in section 2.1, as well as changes in data collection methods over time, it is difficult to draw firm conclusions about temporal trends in maternal mortality globally, but there has been little sign of progress in reducing maternal mortality in sub-Saharan Africa over the past few decades (58). The smallest reduction in maternal mortality between 1990 and 2005 comparing WHO datasets was in sub-Saharan Africa (75). However, more recent reports suggest that greater progress has been made, and MMR has decreased by 41% globally since 1980 (Figure 2.1) (37, 64).

Figure 2.1: Trend in the number of maternal deaths globally, from 1980 to 2008



(From Hogan 2010 (64))

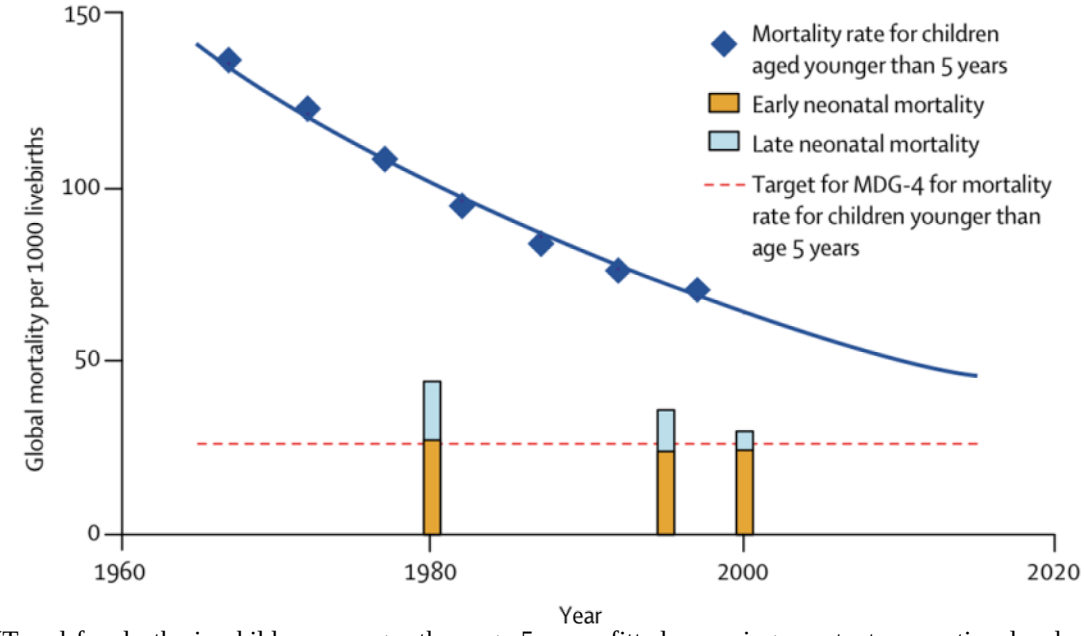
In Malawi, data in Table 2.2 do not show an obvious trend over time. There may have been an increase in maternal mortality in the late 1990s and early 2000s, followed by a slight reduction in recent years, but due to varying methodologies and wide margins of uncertainty it is difficult to tell. Consecutive DHS surveys have shown an increase from 620 per 100,000 live births in 1992 to 1,120 in 2000 and then a slight drop to 984 in 2004. As shown in Figure 2.1, the increase between 1992 and 2000 may reflect the emergence of HIV as an important contributor to maternal ill health in the 1990s, when global maternal mortality trends in the presence and absence of HIV started to diverge

(64). Although there was a rise in maternal mortality between the 1992 and 2000 DHS surveys in Malawi, there was a concomitant rise in all-cause adult female mortality, and the proportion of all female deaths that are maternity-related has remained constant at around 20%. This might reflect a true increase in maternal deaths that may be both direct (due to health service deterioration related to the HIV epidemic) and indirect (due to AIDS-related infections and sepsis) (54, 76, 77). It may also reflect errors in data collection. There may have been systematic underreporting or misclassification of maternal deaths in 1992 such that there were fewer reported maternal deaths, or systematic over-reporting or misclassification in 2000 such that there were more reported maternal deaths. Possible explanations suggested in the 2000 survey are that there may have been reporting of AIDS-related sibling deaths as maternal to avoid the associated stigma of AIDS, or general underreporting of AIDS deaths leading to underestimating all-cause female mortality (2). It has been suggested that it is inevitable that maternal mortality will be overestimated in household surveys using sisterhood methods where there is a combination of high non-maternal mortality (i.e. due to HIV) and high fertility, as all pregnancy-related deaths are included in estimations (31). In this context, failure to differentiate between direct and indirect maternal deaths, or maternal and non-maternal deaths, may lead to unrealistic conclusions about progress towards achieving reductions in maternal mortality (78). Increases in reported mortality rates due to HIV or methodological changes may have obscured any improvements in maternity care services over the same period.

Neonatal and infant mortality

Public health interventions have enabled faster reductions in child and infant mortality than in neonatal mortality, and neonatal deaths will make an increasingly larger contribution to the total burden of childhood deaths (Figure 2.2). However in countries affected by malaria and with high HIV prevalence rates, post-neonatal and child mortality have been declining more slowly (59). Temporal trends in neonatal mortality show an overall global reduction of 16% between 1996 and 2005. This reduction was not seen in sub-Saharan Africa though, with neonatal mortality rates staying at about the same levels during the same period (5). As for maternal mortality, temporal trends in infant and neonatal mortality should be interpreted with caution.

Figure 2.2: Trends in under-five and neonatal mortality rates globally, from 1965 to 2015



(Trend for deaths in children younger than age 5 years fitted assuming constant proportional reduction every year.)
(From Lawn 2005 (5))

A similar pattern is seen in Malawi, with large reductions in infant mortality over the last few decades, and a relatively smaller reduction in neonatal mortality (Table 2.4 and Table 2.5). The most recent DHS neonatal mortality estimate is much lower than all of the other estimates, and suggests that there might be a possible downwards trend in recent years. Although there were concerns about data quality in the 2004 DHS survey, and authors of the report suggest that there may have been some methodological problems that resulted in an underestimation of NMR for that year, such as: sampling constraints; transference of birth dates; and underreporting of deceased children (1). There is evidence that mortality rates for the period 0-4 years before the survey were underestimated in the 2004 DHS, but overestimated for the period 5-9 years before the survey, suggesting that the apparent reduction in 2004 may be an artefact of the data (1). However, the most recent estimate of neonatal mortality from the MICS 2006 survey (33 per 1,000 live births) is close to the 2004 DHS figure using similar nationally-representative sampling and survey methodology, which supports the hypothesis that the neonatal mortality rate has declined in recent years (63).

Mother and child health behaviours

In tandem with changes in mortality we would expect to see changes in related health behaviours, such as accessing skilled medical care. Little change has been observed in antenatal attendance or skilled delivery care between subsequent DHS surveys (1-3). Antenatal attendance has remained fairly static at around 90% in 1992 and 93% in both 2000 and 2004, while 55% of deliveries were attended by skilled personnel in both 1992 and 2000 surveys and 57% in 2004. There is some evidence that postnatal care coverage may have increased between surveys. Postnatal care attendance was not measured in 1992, but in 2000 7% of mothers reported that they received a postnatal check-up after birth. In 2004 31% of women received postnatal care within 42 days of birth (21% in the first 2 days). MICS data from 2006 reports similar figures to 2004 DHS figures, with 92% ANC attendance and 54% skilled delivery care, again suggesting little change in health care access over time (63).

Thus, unless the quality of skilled medical care got very much worse over time, the large apparent increase in maternal mortality between the 1992 and 2000 DHS surveys is unlikely to be due to an increase in the number of obstetric deaths. There may have been an increase in non-obstetric (indirect) maternal deaths, largely as a result of increasing HIV prevalence, but it is also likely that more of non-maternal deaths were included in the estimates. On the other hand, it is plausible that the increase in postnatal care attendance could potentially be related to the reduction in neonatal mortality seen between 2000 and 2004 DHS surveys.

2.2.3 Distribution

Geographical distribution

Comparisons of maternal and neonatal mortality rates between countries should be made with caution, and interpretation of data looking at geographical distributions must take into account differences in definitions, reporting systems, sources of data and accuracy and completeness of data.

For both maternal and neonatal mortality, rates appear to be highest where data is weakest, mainly in Africa and Asia. WHO reports have consistently shown higher

maternal and neonatal mortality in sub-Saharan Africa than any other region of the world (Table 2.6). Major contributing factors to poor health in Africa are weak health care infrastructure, drought and famine, endemic malaria, pandemic HIV and conflict. Khan describes the region-specific contributions to maternal mortality of sepsis and HIV in Africa, anaemia in Asia, abortion in Latin America and the Caribbean and other direct causes (related to caesarean section and anaesthesia) and embolism in developed countries (79).

Table 2.6: Global geographic distribution of maternal and neonatal mortality

UN region	**Maternal mortality ratio***	**Range of uncertainty of MMR estimates***		**Neonatal mortality rate****	**Perinatal mortality rate****
		Lower estimate	Upper estimate		
Developed regions	14	13	16	5	10
Countries of the commonwealth of independent states	40	34	48	33	50
Developing regions	290	220	410	42	61
Africa	590	430	850	41	62
Northern Africa	92	60	140	22	34
Sub-Saharan Africa	640	470	930	44	66
Asia	190	130	270	32	50
Eastern Asia	41	27	66	21	34
South Asia	280	190	420	43	65
South-Eastern Asia	160	110	240	19	33
Western Asia	68	45	110	28	39
Latin America and the Caribbean	85	72	100	15	21
Oceania	230	100	500	26	42
WORLD TOTAL	**260**	**200**	**370**	**30**	**47**

* from WHO 2008 (37)
** from WHO 2006 (59)

Comparisons of maternal and neonatal mortality rates between geographical regions within countries is usually limited by small numbers of deaths from each region. Due to these sampling constraints, maternal mortality data from the Malawi DHS reports and other population-based surveys is not broken down by geographic, socio-economic or demographic characteristics in order to identify high-risk groups, though data on infant and neonatal deaths is presented in this way. Thus, for sub-national data for Malawi, the focus will be on the distribution of infant, neonatal and perinatal mortality, as well as coverage of maternity care as a proxy for maternal mortality.

In Malawi, health statistics are not uniformly distributed. Most health indicators tend to be worse in the Southern Region, better in the Central Region and best in the Northern Region. This pattern is thought to be due to higher education and literacy levels and lower population density in the north of the country. Key maternal and child health indicators from DHS and MICS surveys give slightly different geographic patterns, as shown in Table 2.7 and Table 2.8, and do not follow consistent north-to-south trends. Interestingly, the pattern of mortality distribution does not correspond with the pattern of coverage of health care services in and around pregnancy, with highest coverage of antenatal, delivery and postnatal care services being in the north where mortality is highest and the lowest coverage being in the central region where mortality is lowest (1). MICS 2006 indicators show a more consistent increasing north-to-south trend, particularly for post-neonatal, infant and maternal mortality (63). The picture for neonatal mortality is the opposite to DHS, with the highest mortality being found in the Central Region. However, most of the regional differences are small and regional estimates are likely to have large confidence intervals that overlap (though no data on denominators is available to calculate them), so differences due to sampling and non-sampling errors associated with the survey cannot be ruled out (42).

A DHS review of child mortality statistics found that neonates born to mothers in rural areas were 27% more likely to die than those from urban areas (80). A clear geographical pattern also exists between urban and rural areas in Malawi, with all mortality rates being higher in rural than in urban areas, and coverage of all health care services being lower in rural areas. The differences in mortality rates between urban and rural areas are much smaller in the MICS survey compared to DHS figures (1, 63). Maternal mortality is actually slightly higher in urban areas, although there were only 77 maternal deaths in urban areas, so this estimate is likely to lack precision. It is not clear whether the smaller urban-rural differential in the MICS survey is because estimates are centred on a later time point, or because of a different sample mix. There is some evidence that the ‘urban advantage’ in maternal health globally is diminishing, as high levels of urbanisation are associated with increasing exclusion of the poorest mothers (81). Higher HIV prevalence in urban areas may also account for some of the loss of ‘urban advantage’ in Malawi (77, 82).

Table 2.7: Geographic and socioeconomic distribution of selected DHS health indicators in Malawi

Region/district	Perinatal mortality rate	Neonatal mortality rate	Infant mortality rate	ANC attendance (%)	Skilled birth attendant (%)	Postnatal check-up within 42 days (%)
Northern	40	39	82	96	67	34
Central	32	34	90	91	52	27
Southern	34	39	98	94	59	34
Urban	15	22	60	98	84	42
Rural	37	39	98	92	53	29
Lowest	24	36	109	90	47	24
Second	45	41	100	91	47	27
Middle	35	40	95	92	52	29
Fourth	34	36	89	96	63	33
Highest	30	29	66	97	85	44
Total	34	27*	76*	93	57	31

* Refers to the five year period preceding the survey, whereas the other figures refer to a ten year period

Table 2.8: Geographic and socioeconomic distribution of selected MICS health indicators in Malawi

Region/district	Maternal mortality ratio	Neonatal mortality rate	Infant mortality rate	ANC attendance (%)	Skilled birth attendant (%)	Postnatal check-up within 42 days (%)
Mchinji	-	24*	65*	97	59	41
Northern	543**	33	57	82	58	27
Central	678**	35	73	92	51	34
Southern	1029**	31	75	94	56	33
Urban	861**	30	70	97	78	53
Rural	802**	34	73	91	50	29
Lowest	-	32	72	90	43	27
Second	-	34	79	89	48	29
Middle	-	30	76	94	52	29
Fourth	-	39	71	92	54	32
Highest	-	32	62	95	77	50
Total	807**	33	72	92	54	33

* Refers to the period 10 years preceding the survey

** Refers to the period 0-6 years preceding the survey

Other mortality estimates refer to the five-year period preceding the survey, and ANC, skilled attendance and postnatal care refer to the two years preceding the survey.

Distribution by socioeconomic and demographic characteristics

Few studies present maternal mortality figures broken down by age, though young age and first pregnancy are well known risk factors for poor maternal and infant outcome (5, 73, 80, 82, 83). In one prospective cohort study of 4,053 pregnant women in Malawi, no

association between age, pregnancy number and maternal mortality was found, though the number of deaths was small (14). Another later study looking only at infant outcomes found a strong relationship between maternal age, primiparity and infant mortality (73). Malawi DHS data suggest that complications in pregnancy are slightly higher among older women and women with more previous pregnancies. Coverage of maternity services is also lowest in this age group. Malawi DHS data also shows that much higher rates of neonatal death are found amongst mothers younger than 20 years or older than 40 (56 and 48 per 1,000 respectively) compared with women aged between 20 and 40 (29-34 per 1,000) (1). It is not clear whether or not this effect is independent of parity (as first born infants, or infants born 7^{th} or more, are at higher risk than those between 2^{nd} and 6^{th}). The same patterns are seen in the MICS data (63).

Coverage of antenatal, delivery and postnatal services is higher among the wealthiest groups of the population and the women with the highest level of education in both surveys (Table 2.7 and Table 2.8) (1, 63). The DHS review of child mortality estimates found that infants born to mothers with no schooling at all or only primary schooling (less than 8 years of school) were 58% and 45% (respectively) more likely to die in the first month than children whose mothers attended secondary school (more than 8 years of school) (80). Malawi DHS data similarly show that neonatal mortality is more likely for women with little or no education (36-39 per 1,000), compared to those with secondary education (25 per 1,000) (1). A markedly higher NMR in the poorest socio-economic groups is seen compared to the wealthiest (36 compared to 29 per 1,000). For post-neonatal mortality and infant mortality this socioeconomic differential is even more pronounced, with mortality rates in the poorest groups being almost twice as high as in the wealthiest. As with the urban-rural gradient, the socioeconomic gradient is less pronounced in the MICS survey (63), and it has been suggested that the HIV epidemic may be partly responsible for reducing the gap between the poor and the least poor, as HIV disproportionately affects wealthier households (74). Other studies have suggested that addressing inequity is a priority for any strategy that hopes to reduce neonatal mortality (5).

Analysis of the relationship between maternal mortality and poverty is difficult using survey data, as most surveys use the sisterhood method to identify maternal deaths (asking women about any sisters they had who died during or soon after pregnancy),

and this does not allow individual-linked data on cause of death and socio-economic factors. Prospective data would provide the best opportunity to explore the relationship between socioeconomic status and maternal mortality, but an alternative is the 'familial technique', which assigns socio-economic status for maternal deaths according to the socio-economic status of the sibling interviewed (84). Consistent trends of increasing maternal mortality with increasing poverty were shown, though these were not significant in countries with HIV prevalence over 2%. A study of trends in maternal mortality in Malawi showed a flattened socioeconomic gradient, which the authors suggest is due to higher prevalence of HIV amongst wealthier women balancing out the effects of lower access to skilled medical care amongst poorer women (85).

2.2.4 Aetiology of maternal death

Understanding the distribution and relative contributions of causes of maternal and neonatal death is essential to inform policy-makers and to inform the development of interventions to tackle these problems. Where health care systems are weak and over-stretched, reporting on causes of death is poor. In areas with low coverage and uptake of health services and poor diagnostic facilities, physician diagnosis at the time of death is uncommon. Therefore, population data on cause of death is largely dependent on verbal autopsy reports of variable quality (86). Studies that do report cause of death may use different systems for classifying them. For example, obstructed labour may require caesarean section that then results in post-operative sepsis and maternal death. The accepted classification system would identify the cause of death as obstructed labour, being the first complication, while other approaches would give sepsis as the immediate cause of death, with obstructed labour as an underlying cause. Definitions and diagnostic methods are often not reported, which makes comparisons across studies difficult (27). Global estimates of cause-specific maternal and neonatal mortality are generally generated through statistical modelling.

Distribution of causes of maternal death in Malawi

Maternal deaths can be categorised into two main groups; direct maternal deaths as a result of obstetric complications of the pregnant state (pregnancy, labour and puerperium) and indirect maternal deaths as a result of previously existing disease that

was aggravated by the physiological effects of pregnancy. A summary of studies with cause-specific maternal mortality data from Malawi, neighbouring countries and the region is given in Table 2.9 below.

Direct causes of maternal death

Direct maternal deaths arise from risks of pregnancy and childbirth as well as from poor quality health care and incorrect treatment. Globally, 80% of maternal deaths are attributed to direct causes, with 25% of all deaths due to haemorrhage and 15% to infections (53). The epidemiology of cause-specific deaths is different in high and low mortality countries, and population estimates are often based on very limited and relatively unreliable data. Verbal autopsy data is prone to misclassification (55, 58), but is often the only form of cause of death data in countries where the majority of women give birth and die at home. A recent WHO systematic review of population datasets reporting maternal deaths by cause found haemorrhage, hypertensive disorders, sepsis and abortion to be the leading causes of death worldwide (79), with haemorrhage accounting for a third of deaths in Africa and Asia, and hypertensive disorders for a quarter of deaths in Latin America and the Caribbean. However, reviews that have presented combined results for the African region as a whole often obscure sub-regional differences, for example the epidemiology of HIV and malaria related maternal deaths varies across Africa, with the highest prevalence of HIV being in the south and the highest prevalence of malaria being in sub-Saharan equatorial regions (87, 88). Such reviews may also be heavily biased towards countries that have better reporting systems – only 8 datasets were chosen to represent the whole of Africa in Khan et al's study and these did not include the countries with the highest maternal mortality (as reported in other sources (36, 37)). In general there is a paucity of data from sub-Saharan African countries. The precise proportion of maternal deaths attributable to unsafe abortion is not known, as restrictive abortion laws tend to compound the problem as well as increasing the likelihood of underreporting. In a multicentre hospital-based study in west Africa, it was found that a third of deaths during early pregnancy were caused by induced abortion (89).

Table 2.9: Distribution of causes of maternal deaths from Malawian and regional studies

Primary author **Study location** (date published)		**Direct deaths** (% of all deaths)					**Indirect deaths** (% of all deaths)				(%)
	N	Haem	Sepsis	R/U & ob labour	Abortion	Other	Anaemia	Mening	AIDS	Other	Unknown/ fortuitous
Hospital-based studies											
Wiebenga QECH, Blantyre 1992* (90)	78	4	13	7	17	5	5	9	4	24	15
Driessen 12 hospitals 1990* (54)	UK	10	12	14	18	6	8	3	2	17	10
Sangala KCH, Lilongwe 1992* (54)	UK	14	24	15	18	11	8	3	-	8	-
Lema QECH, Blantyre 2005 (8)	204	11	29	3	24	9	2	NC	NC	20	3
Safe Motherhood Project Hospitals, Southern Region 2003 (91)	304	11	20	15	6	13	9	7	9	9	3
Kongnyuy 9 hospitals, Central Region 2009 (6)	43	30	16	7	7	5	7	-	16	12	0
Community studies											
Hofman Mangochi, Southern Region 2004 (92)	UK	30	5	30	14	7	7	5	-	-	2
McDermott Mangochi, Southern Region 1996 (14)	15	27	0	0	0	7	7	0	0	0	60
Farish, community 2003* (54)	UK	33	7	7	-	7	7	7	7	13	7
Estimates from neighbouring countries											
Ahmed Tertiary hospital, Zambia 1999 (15)	251	5	8	2	14	13	NC	NC	NC	57[1]	-
Menendez Tertiary hospital, Mozambique 2008 (16)	139	17	9	-	-	13	1	7	13	36[2]	6
Department of Health, South Africa 2004 (93)	3296	13	8	-	4	28[3]	NC	2	20	23[4]	3
Regional estimates											
Khan Africa 2006 (79)	4508	34	10	4	4	17	4	NC	6	17	5
Khan Developed countries 2006 (79)	2823	13	2	0	8	57	0	NC	0	14	5

Percentages do not add up to 100% due to rounding

* Full article not seen. Abstract, and details from Geubbels 2006 (54).
QECH = Queen Elizabeth Central Hospital, KCH = Kamuzu Cebtral Hospital, UK = unknown, NC = not classified with this cause for this study
- = no deaths reported for this cause
[1] Classification in this study differed from other studies – of the 57% 'other' indirect causes of death, 14% of deaths were due to TB (92% AIDS-related), 17% due to malaria (37% AIDS-related) and 26% due to other indirect causes.
[2] This category included pneumonia (12%) and malaria (10%)
[3] This category included pregnancy-related hypertension, which accounts for 19% of maternal deaths in this study
[4] The largest other cause in this category was pneumonia, responsible for 10% of maternal deaths

The Confidential Enquiries study, which investigated the cause of death in 304 institutional maternal deaths in southern Malawi in 2001, found that roughly two-thirds of the deaths audited were as a result of direct obstetric causes. Of those direct obstetric deaths, 32% were due to sepsis, 24% due to obstructed labour and ruptured uterus, 17% to haemorrhage, 10% to complications of abortion, and 8% to eclampsia (91, 94). A more recently published retrospective survey (referring to a similar period) of 204 maternal deaths at Queen Elizabeth Central Hospital, a tertiary hospital in Blantyre, found that three-quarters of maternal deaths were as a result of direct causes, with the main direct causes being sepsis and complications of abortion. Though AIDS wasn't included as an indirect cause of maternal death in itself in this study, 19% of all the women who died were confirmed (with serological tests) or suspected (on clinical grounds) of having HIV, and over 70% of them died as a result of infections. The most recent study of the aetiology of maternal death in Malawi was conducted in nine hospitals in three districts of the Central Region (6). Again, two-thirds of the deaths were as a result of direct obstetric causes, but the most common single cause was haemorrhage, accounting for 30% of all maternal deaths. AIDS and sepsis both accounted for 16% of maternal deaths each.

Little data is available on causes of death at community level in Malawi. However, small localised studies have found that a high proportion of deaths were due to haemorrhage, ruptured uterus, obstructed labour and complications of abortion (92). In such cases early care-seeking is essential, and strategies that address community-level transport problems would be beneficial. Strategies that improve education for girls and increase the chances that a pregnancy results in a living child thus reducing fertility, are also likely to reduce mortality risks (67).

Indirect causes of maternal death

Indirect causes of maternal death are even less well documented in developing countries, due to poor diagnostic capabilities as well as failure to report pregnancy where the primary cause of death is a condition not unique to pregnancy. Inclusion or exclusion of conditions not unique to pregnancy can have a substantial impact on maternal mortality figures. The main indirect causes of maternal death globally are anaemia and HIV/AIDS (53, 79).

In studies where blood is not tested for infection (either during the course of the illness or at post-mortem), the contribution of infection to maternal death aetiology is underestimated. Two studies in African tertiary hospitals found the proportion of indirect maternal deaths to be much larger than in any of the Malawian studies. A prospective autopsy study in a tertiary hospital in Mozambique found that only 38% of maternal deaths were as a result of obstetric complications (16). Similarly, at a Zambian tertiary hospital only 42% of maternal deaths were as a result of direct causes (15). Infectious diseases, including malaria, pneumonia, HIV/AIDS, TB and meningitis accounted for over half of all maternal deaths in both studies. Thus infection can be a direct or an indirect cause. The marked difference in the contribution of infectious causes to maternal death in these studies may be due to the prospective nature, the availability of better diagnostic facilities, or simply the personal interests of the researchers.

HIV and AIDS

HIV is an important condition in most fields of health in sub-Saharan Africa. It was estimated in 2007 that 22 million people in Sub-Saharan Africa were HIV positive, which represents about two-thirds of all people living with HIV in the world (88). About 77% of all HIV-infected women and 77% of all HIV/AIDS orphans live in Sub-Saharan Africa (88). Malawi has one of the highest HIV prevalences in the world, with DHS estimating 11.8% of people aged 15-49 years are infected (1), and UNAIDS similarly estimating 11.9% of people aged 15-49 years are infected (88). Data from the national sentinel surveillance system (of women attending antenatal clinics) were modelled to estimate a national prevalence of 12.0% in 2007, with the lowest rates being in the Central Region and rural areas (95). In Malawi HIV is largely responsible for the decline in life expectancy from 42 years at birth in 1994 to 36.3 years at birth in 2004. More indirectly, HIV has depressed Malawi's GDP by at least 10% through larger societal effects on people of working age, impaired economic viability of most homes due to the loss of main income generators, and an increased burden on families caring for sick people and orphans. Health facilities are hugely over-burdened and under-staffed. 12.3% of pregnant women aged between 15 and 49 years are HIV positive in Malawi (95).

The relationship between HIV and maternal morbidity and mortality is complicated (32, 96), though HIV is becoming a leading cause of maternal death where HIV-related mortality rates are high (58). AIDS can itself be a cause of maternal death, increase the risk of obstetric complications (such as puerperal sepsis) and non-obstetric complications (such as malaria), or aggravate illnesses such as TB and anaemia. Conversely, biological changes in pregnancy may increase the incidence of HIV (97). Furthermore, the quality of care may deteriorate in the context of high HIV prevalence due to acute shortages of health professionals (96). In settings where HIV status is known, it has been suggested that women who are HIV-positive might receive a lower quality of care due to the stigma associated with infection (94).

The exact contribution of HIV to maternal deaths in Africa is not known. The most recent WHO estimates for 2008 suggest that 9% of maternal deaths in Africa are caused by HIV (37). However estimates vary widely between countries, with the same report estimating 32% of maternal deaths to be due to HIV in Malawi. A confidential enquiry in South Africa reported the cause of maternal deaths in 20% of cases as being HIV – the biggest single cause of maternal death in this population. 36% of all the women who died were known to be HIV-positive, which is similar to the proportion positive for all pregnant women in South Africa, but HIV status was unknown for 54% of women and the authors suggest that it could have been a primary or underlying cause for an even larger proportion of the deaths (93). A hospital autopsy study in Mozambique found that 53% of women that died a maternal death were HIV positive and HIV was reported as the main cause of death in 13% of maternal deaths (16). Another facility-based study in Zambia, using a different classification system, found that more than three quarters of all indirect deaths were due to three infectious causes – 30% were related to malaria, 25% to TB and 22% to respiratory tract infections of which 37%, 92% and 97% respectively were AIDS-related (15). In Malawi, the confidential enquiry found the main indirect causes of institutional maternal death were anaemia and HIV, each accounting for about a quarter of indirect maternal deaths (91). Another retrospective study at Queen Elizabeth Central Hospital in Malawi found over half of all deaths to be due to infectious causes, including puerperal sepsis, post-abortal sepsis and other infections, and 18.6% of women were thought to HIV-positive based on clinical symptoms or serology (8). The most recent maternal death review from Malawi attributes 16% of all maternal deaths to HIV (6). Although the methods and

classification systems are different, all five studies suggest a significant contribution to maternal mortality from both malaria and AIDS. Ahmed and colleagues describe an eight-fold increase in maternal mortality in Zambia over a 15-year period (from 118 to 921 per 100,000 live births), which they suggest is mainly due to non-obstetric causes such as malaria and AIDS-related illnesses.

Similar increases in maternal mortality were reported in several sub-Saharan African countries concurrent with the rise in prevalence of HIV in the region over the last two decades (98). The increases in both HIV prevalence and maternal mortality were higher in urban than in rural areas.

These hospital-based studies may still underestimate the contribution of HIV to maternal mortality. Many maternal deaths related to HIV might happen in the days or weeks after being discharged, so would not be counted among maternal deaths reported in hospital-based studies. A population-based study in Rakai, Uganda, where HIV status was known, found that the maternal ratio was five-times higher in HIV-positive women compared to HIV-negative women (1,687 compared to 310 per 100,000 live births) (99). In Nairobi, Kenya, Nduati and colleagues presented data from women enrolled at antenatal clinics that showed a three-times higher mortality rate among HIV-positive women who breastfed compared to those who used formula feed (100). However, this was a *post-hoc* analysis and had only small numbers of women who died. A prospective study in Malawi found no association between breastfeeding by HIV-positive women and mortality, but 1,800 per 100,000 of the women had died by 12 months post-partum (101). A population-based study in Malawi reported high mortality in the year following delivery (15 deaths classified as maternal and 12 non-maternal deaths). HIV and malaria were identified as important contributors to these deaths (14). Neither HIV nor anaemia were associated with increased mortality during the maternal period, but during the non-maternal period (up to one-year post-partum) the mortality rates were 1,852 and 145 per 100,000 women in HIV-positive and HIV-negative women respectively.

Malaria and anaemia

A key component of Safe Motherhood is the eradication of anaemia during pregnancy. As with HIV, where serological tests during the illness or post-mortem are absent, the exact contribution of malaria and anaemia to maternal mortality is unknown. Anaemia

is a leading indirect cause of maternal death globally, and poor nutrition and malaria both play significant roles in this. Pregnant women are more susceptible than the general population to malaria and its consequences, and malaria-related maternal mortality can be very high (53). Brabin estimated that 6% of maternal deaths in Africa were attributable to anaemia in 2001, and that there would be 9 severe-malaria anaemia-related maternal deaths and 41 non-malarial anaemia-related deaths per 100,000 live births in holoendemic malarious areas (12). Placental malaria is associated with maternal anaemia, premature delivery, intra-uterine growth retardation, low birth weight and infant mortality (53, 102, 103). HIV infection can contribute to maternal anaemia directly and also through increasing the risk of higher frequency and higher parasite density of malaria infections during pregnancy (104). A systematic review of global data calculated the population attributable risk of anaemia associated with malaria in pregnancy to be 3-15% (105). WHO recommends that all women living in areas of stable malaria transmission receive intermittent presumptive treatment (IPT) for malaria during pregnancy. HIV infection reduces a woman's capacity to control *Plasmodium falciparum* infection and reduces the efficacy of IPT (104).

The WHO systematic review of causes of maternal death reports that 3.7% of maternal deaths in Africa are caused by anaemia (79), and a hospital-based autopsy study in Mozambique reported 10% maternal deaths as being due to malaria and 1% due to severe anaemia (16).

The range of estimates of the contribution of anaemia to maternal mortality in Malawi is fairly consistent, ranging from 2-9% (Table 2.9). The confidential enquiry in Malawi found that 9% of maternal deaths were due to anaemia (91), and the recent review in the Central Region found that 7% of deaths were due to anaemia (6). Though the retrospective review at Queen Elizabeth Central Hospital found only 2% of deaths as being due to anaemia and 1.5% due to malaria (8).

Little data is available on the distribution of indirect causes of maternal death at community-level, though three community-based studies in Malawi all estimated the contribution of anaemia to maternal mortality to be 7% (14, 54, 92). Most of the major indirect causes of maternal death can be addressed through improved quality and earlier

initiation of antenatal care, which includes provision of iron and antimalarial tablets, as well as HIV counselling and testing.

Timing of death

The majority of maternal deaths occur during labour, delivery or within 24 hours of giving birth, and thus the place of delivery, person attending and how quickly they can be referred in case of a problem are crucial factors that determine pregnancy and birth outcomes (106).

In Matlab, Bangladesh population-based data show that most maternal deaths happen during pregnancy or within the first day of birth (52%), 25% on days two to seven, and only 23% were between one and six weeks post-partum, suggesting that focusing on improving intrapartum care would substantially reduce the number of deaths in this population (83). Similarly, in Nepal 75% of deaths happened during pregnancy or the perinatal period, and the other 25% between one and six weeks post-partum (107). In both studies many deaths were also reported for several months following delivery, and increased understanding of the causes of death in the late post-partum period is needed, as well as a renewed focus on improvements in post-partum care (83). In Guinea Bissau, women who had recently delivered (0 to 42 days post-partum) had 16 times higher risk of death compared to women who delivered more than 6-months previously, and the risk was still 3 times higher up to 3 months post-partum (108). Hoj and Pradhan both suggest increasing the post-partum period for definition of maternal death to 12 weeks rather than 6 weeks. None of these studies were done in a population with a high prevalence of HIV, and in countries with high burdens of malaria and HIV, later deaths may be more common. A prospective cohort study in Malawi showed that mortality rates in the first year after birth were almost as high for the period six weeks to one year (341 per 100,000 live births) as they were using the ICD definition up to 42 days. (398 per 100,000 live births) (14). Most of these late maternal deaths were attributed to anaemia and HIV.

The confidential enquiry in Malawi found that nearly two thirds of institutional maternal deaths happened after delivery, and three quarters of these happened after the first 24 hours (91). Similarly, in a recent institutional review in the Central Region of Malawi, 70% of deaths happened after delivery, with 60% of these happening after the first 24

hours (6). This suggests that many institutional maternal deaths could potentially be prevented through better post-partum care. However, these studies did not follow women up after discharge, and they may not have included later maternal deaths.

Determinants and risk factors for maternal death

There are socio-environmental determinants that make a mother at higher or lower risk of maternal or neonatal death. These are interlinked cultural, demographic and socioeconomic factors that have an impact on access to services as described above, but also to medical causes of death through illiteracy, poverty, low status of women, inadequate access to information and essential reproductive health services (109).

Because of the relatively small numbers of maternal deaths in most studies, it is difficult to do sub-group analyses on the different risk factors for maternal death. No studies were found presenting the descriptive epidemiology of maternal death and its risk factors in general populations. Maternal deaths are also influenced by many different categories of events or conditions, making it difficult to disentangle them. These include biology, economics, culture, demography and the distribution and quality of health services (110). McCarthy and Maine developed a framework to help understand the mechanisms through which these factors lead to maternal death. Individual risk factors for maternal death include young or old age, low education, nulliparity, short stature, obesity, genetic factors, previous history of complication, HIV, malaria and nutrition. Household factors include poverty, gender imbalances and lack of decision-making power. Community factors include cultural beliefs and practices, long distance from health facility, lack of transport, and lack of community resources (e.g. clean drinking water). Health facility factors include availability, accessibility and acceptability, lack of trained personnel and poor organisation and management of health systems.

Previous experience and perceptions about quality of care might influence a woman's choice about whether to deliver at a health facility or not. Reports of unfriendly staff may deter women from using facilities (94). Cultural beliefs also play a part in decisions about where to give birth, who can be in contact with the mother and baby and things that should be done around delivery. Lack of knowledge about complications and danger signs can affect decision-making about seeking care, and gender imbalances can make it difficult for women to access household resources needed for care-seeking and

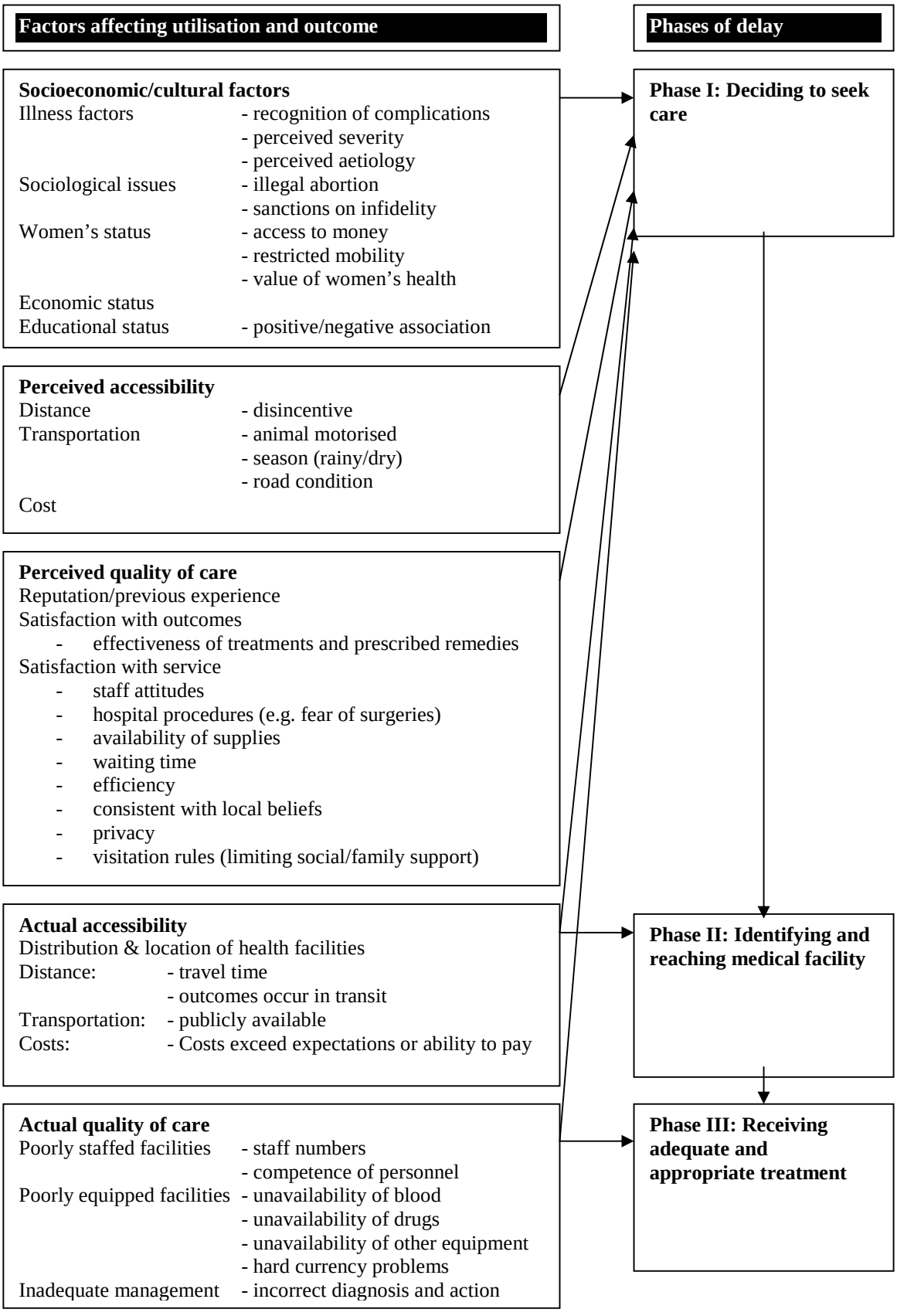
home care. Although lack of availability of transport and financial barriers affect the ability of women from poor households to seek care, regardless of who makes the decision. Health system factors may also contribute to poor outcomes. Facilities may be long distances away, especially those offering comprehensive emergency obstetric care (CEOC). Low staffing levels, poor motivation amongst staff and poor supervision contribute to poor quality of care. It has been suggested that HIV may have worsened this situation by increasing overcrowding in facilities, taking funding and attention away from other services and affecting the number of health workers directly through infections (94).

All of these factors tend to contribute towards delays in reaching a health facility and receiving appropriate medical care when it is needed. Thaddeus and Maine describe three important delays that contribute to maternal death (17). These delays and their contributing factors are outlined in Figure 2.3. The first delay is in recognising the problem and the need to seek medical help. The second delay is in reaching an appropriate facility, and can be due to weak referral systems, cultural, social or financial factors. The third delay is in receiving appropriate care on arriving at the facility. Delays can be considerable where facilities are understaffed and patient numbers are unmanageable. Inadequate equipment, training and supervision may also contribute to poor quality care. Factors that can cause delay include: failure to recognise danger signs; delay in decision-making (gender imbalances); use of traditional birth attendants; cultural beliefs; distance from health facility; lack of transport; poverty; poor perception of facility care; lack of resources for delivery at health facility; poor referral systems; shortage of skilled attendants; poor monitoring and treatment of patients; availability of emergency obstetric care; poor infrastructure; lack of drugs and equipment; lack of quality post-partum care (91, 111).

Individual risk factors for maternal death include caesarean section, abortion and multiple gestation. Maternal mortality is higher in women following a caesarean section compared to women having a normal vaginal delivery. 24% of women who died in a hospital-based study in Mozambique had delivered by caesarean section (16), and a large part of this was due to untreated infections, especially in HIV-positive women. In a multi-country study in Latin America increased rates of caesarean delivery in facilities were associated with greater maternal, perinatal and neonatal mortality even after

adjusting for demographic factors and limiting the analysis only to elective caesarean sections (112). In Malawi, a study of 8070 caesarean sections in 25 secondary and tertiary hospitals found that 1% of women died during or after the procedure (113). Mortality was two times higher in women having caesarean section who also had ruptured uterus compared to those who did not, and up to 38 times higher in women requiring transfusion for blood loss. Maternal deaths after abortion or stillbirth can be particularly common, accounting for about half of all maternal deaths in a study in Bangladesh (108)**.** Maternal deaths are also increased during multiple pregnancies, with a study in Malawi reporting a 6.93 (1.59-30.24) risk ratio for multiple gestations compared to singletons, and contributing to an estimated 11.5% of maternal deaths (114).

Figure 2.3: The three delays model (Adapted from Thaddeus and Maine, 1994 (17))



Summary of aetiology of maternal death

All the studies discussed above suggest that the epidemiology and aetiology of maternal mortality in sub-Saharan Africa is likely to be very different from Asia and will require different strategies for reducing it. In particular, focusing attention on the contributions of HIV and malaria in sub-Saharan Africa will be important.

As mentioned in section 2.1.3, it is difficult to compare studies that use different classification systems for cause of death and different rules for classifying coexisting causes. Perhaps the most striking finding from comparing the studies shown in Table 2.9 is the absence of any very consistent patterns at all, highlighting the challenges faced in measuring and understanding the epidemiology of maternal mortality. As well as the different classification systems used, the true aetiological profile is also likely to differ considerably in different settings, for example between community, health centre and referral hospitals and between rural and urban populations.

Misclassification of cause of death is a major problem in trying to understand the aetiology of maternal mortality, especially in Africa where HIV might account for a substantial proportion of maternal deaths but go undiagnosed due to lack of testing and stigma (50). Such incorrect diagnostic categorisation means that the course of clinical management chosen may be inappropriate to address the true cause. Focusing attention on HIV treatment and prevention for pregnant women in Africa will be an essential component in reducing maternal mortality and vertical transmission. Understanding the relative contributions of direct and indirect maternal deaths will also be important in guiding policy-makers (78).

2.2.5 Aetiology of neonatal death

Reliable data on causes of neonatal death are even more scarce than for maternal mortality. The limited presenting signs of neonatal illness makes diagnosis even in ideal clinical settings difficult, and almost impossible at community-level. Many estimates are generated from models and limited population data, and the data presented in this section summarises the best available evidence on the aetiology of neonatal death, but relies heavily on two main sources (5, 59).

Babies die after birth because they are severely malformed, born prematurely, suffer as a consequence of obstetric complications or because of practices that lead to infections. The risk factors for neonatal death and stillbirth relate to maternal health, care during pregnancy, management of pregnancy and delivery complications, hygiene and newborn care. Early neonatal deaths (during the first week of life) are mainly due to complications of pregnancy and childbirth, whereas later neonatal deaths (in the next three weeks of the neonatal period) are mainly related to infection (5).

In a review of the global epidemiology of neonatal death, the most common cause of death was reported to be severe infection (36% - including sepsis/pneumonia, tetanus and diarrhoea), followed by preterm birth (28%), and asphyxia (23%) (5).

No cause-specific neonatal mortality data were found for Malawi, though estimates for 2000 of the direct causes of neonatal deaths based on data from the World Health Report (53) suggest that 87% of neonatal deaths in Malawi may be due to three causes – infection, asphyxia and preterm birth (115). Indirect causes of neonatal death include low birth-weight, maternal infection (especially syphilis, malaria and HIV) and maternal complications in pregnancy (68, 69, 105).

Infections

Neonatal infections can be acquired in hospital as a complication of treatment, or at home. Some sources of infection include unhygienic cord care, feeding practices causing diarrhoea, and generally poor environmental hygiene. Prolonged labour or prolonged rupture of membranes is also the cause of many neonatal infections. Preterm infants are more vulnerable to infection, and neonatal tetanus is more common where maternal immunisation rates are low (5). Poor feeding practices lead to diarrhoea as well as poor growth (59). Most infections occur during or after birth, but infections such as syphilis and HIV can also be acquired during pregnancy, and result in many cases of stillbirth and neonatal death (68, 70, 73, 82).

The distribution of causes of neonatal death varies between countries, with countries with higher neonatal mortality rates having a higher proportion of deaths due to severe infection, tetanus and diarrhoea (5). Distributions of causes of death also differ within countries. For example, neonatal tetanus tends to occur within only a few districts in

countries that still have a higher rate. Tetanus deaths have been reduced by 50% globally since 1990, and two thirds of low and middle-income countries had eliminated neonatal tetanus. Most of the countries that remain with a high incidence of neonatal tetanus are in Africa.

HIV is a major cause of maternal morbidity and also has adverse consequences for the newborn. Prematurity coupled with low birth weight is the most common adverse perinatal outcome associated with maternal HIV infection (116, 117). There is no evidence that maternal HIV infection is associated with congenital abnormalities (117). Infants that are infected perinatally tend to progress to AIDS earlier than those infected later on, through breastfeeding. However, median age at onset of HIV-related symptoms is beyond the neonatal period between 5 and 11 months. In Uganda, infant mortality rates were over two times higher in infants born to HIV-positive mothers (209 per 1,000 live births) compared to HIV-negative mothers (98 per 1,000), irrespective of the infant's HIV status (99). HIV-infected infants have a seven-fold higher risk of infant death than non-infected infants (118).

Prematurity and low birth weight

Prematurity is responsible for around a quarter of all neonatal deaths globally (5). Prematurity is the main cause of early neonatal death, and resulted in 62% of deaths in a WHO multicentre trial of calcium supplementation (119). Prematurity causes death primarily as a result of immaturity of the organs, but is also an indirect risk factor for neonatal deaths caused by infection. Preterm birth results in infants being born with low birth weight. Low birth weight is not considered a direct cause, but is associated with many neonatal deaths. Globally, around 15% of infants weigh less that 2500g at birth, mainly as a result of being born prematurely (59). Maternal health and nutrition, as well as infections such as malaria, are important determinants of birth weight.

One study looking at preterm births in southern Malawi found that 20% of women who had attended ANC at either a health centre or district hospital delivered before 37 completed weeks (120). Preterm babies were twice as likely to die within 24 hours of birth compared to babies born at term. Another study reported a similar incidence of preterm births, and estimated that preterm was an underlying factor in 68% of neonatal deaths (69). Preterm delivery was associated with maternal malaria, and was more

common amongst primigravid women. Another study in Malawi found that preterm delivery was two to three times more likely when cord, placental or maternal peripheral paracitaemia were present (121).

A major underlying cause of newborn death is low birth weight (due to preterm birth and in-utero growth restriction), with an estimated 60-80% of all neonatal deaths occurring among low birth weight babies (5). In Malawi it was estimated that low birth weight contributed to 80% of neonatal deaths, 46% of perinatal deaths and 38% of infant deaths (122). However, few babies are weighed at birth in developing countries, and even fewer are of known gestational age, so it is difficult to estimate the precise contribution of low birth-weight to neonatal mortality. Efforts to reduce low birth-weight births at population level have met with limited success, but extra attention to warmth, feeding and prevention and early treatment of infections can reduce deaths in preterm babies without the need for high-tech equipment.

Malaria is one of the few contributors to low birth weight that is amenable to intervention through strategies such as intermittent presumptive treatment of malaria in pregnancy (IPT), chemoprophylaxis and use of insecticide-treated nets (ITN) (105). Concomitant HIV infection increases the risk of malaria and its adverse effects (123). As mentioned above, maternal HIV infection independently contributes significantly to prematurity and low birth weight in infants, and could also be tackled through PMTCT programmes that focus not only on the HIV status of the infant, but also on the health of the mother during and after her pregnancy (124). Steketee et al reviewed studies between 1985 and 2000 and found that the population attributable risks of low birth-weight associated with malaria and HIV were substantial (8-14% and 11-38% respectively) (105). They suggest that between 25% and 90% of these adverse events could be eliminated with full implementation of existing antimalarial and PMTCT interventions.

Asphyxia

Asphyxia is responsible for about a quarter of neonatal deaths and is the main cause of neonatal death in the first 24 hours (5). Asphyxia is mainly due to complications of birth such as obstructed labour and malpresentation. It is more common in the absence of good quality obstetric care. Complications of birth are also responsible for most

stillbirths where the baby was alive at the start of labour but was born dead (fresh stillbirth). Less severe asphyxia and trauma causes disability (40, 125).

Congenital anomalies

Congenital abnormalities are more common in developing countries and up to 1% of infants are born with a major congenital anomaly (59). Maternal syphilis and nutrient deficiency are both strongly related to birth defects. Lawn and colleagues estimate that 7% of neonatal deaths globally are due to congenital abnormalities (5).

Stillbirth

Foetuses may die in-utero, as a result of maternal illnesses or complications, but complications during birth are the cause of death for most infants that were alive at the onset of labour but die before birth (59). It is important to know at what point before birth the deaths occur so that appropriate interventions can be developed. Where women receive good care during childbirth, less than 10% of stillbirths are caused by labour complications.

Timing of death

38% of deaths in children under five years old happen in the first 28 days of life. In Africa this proportion is much smaller than in south-east Asia (24% compared to 50%), due to the larger contribution of post-neonatal causes of child mortality such as malaria and HIV in Africa (5). Even within the neonatal period there is considerable variation in daily risk of death, with most deaths happening in the first 24 hours after birth (25-45% of all neonatal deaths) and three quarters of deaths within the first week (5).

Determinants and risk factors for neonatal death

A framework for understanding the determinants and risk factors for child mortality, similar to that for maternal mortality (Figure 2.3), has been developed (18). This model combines social, environmental, and biological factors, by dividing them into five groups of ‘proximate determinants’ and exploring how they are determined themselves by ‘socioeconomic determinants’, and in turn how they relate to outcomes such as morbidity and mortality. The authors argue for the need for a multidisciplinary approach to the study of child survival, as childhood diseases have multifactorial origins. Many of the same pathways apply for maternal and child survival, and many of the individual

maternal, household, community and health facility risk factors are the same for neonates and mothers, as pregnancy and birth outcomes are often inter-related.

Intrapartum complications carry a high risk for neonates, with obstructed labour and malpresentation accounting for the highest risk (5), and perinatal mortality following caesarean section is particularly high (126). Intrapartum risks outweigh risks during the antenatal period or individual characteristics about the mother like age or parity. Skilled attendance and facility delivery rates are lowest in the countries with the highest NMRs (53). Skilled attendance at delivery is less than 40% in Africa and within countries it tends to be lower in rural areas than in urban areas (Table 2.7 and Table 2.8). As for maternal mortality, delays in receiving appropriate care for neonates can make a critical difference to the outcome. Thaddeus and Maine's three delays model outlined in Figure 2.3 (17) can be applied to neonatal death as well as maternal death, but additional cultural and social factors may create barriers to care-seeking for neonates. In many cultures babies are not named for several weeks or until the umbilical stump falls off, reflecting the hesitance to emotionally invest in a child in the face of high mortality rates, until it is definitely here to stay. A study in Guinea showed lower rates of health-care seeking for sick neonates compared to post-neonatal infants (60% compared to more than 90%) (127). In Malawi, dead newborns are buried in a separate, un-marked graveyard because they are "not yet considered a significant member of the community", and taboos and seclusion restrict postnatal contact with people other than the mother and close female relatives (128).

For infants, another important underlying cause of death may be that the mother has died or is too sick to provide adequate care. A study in Egypt found that infants whose mother died were at higher risk of dying themselves (43), and studies in sub-Saharan Africa in HIV prevalent populations showed that infants whose mothers are infected with HIV are at higher risk of dying, even when they are not infected themselves (82, 129), though this risk mainly affects children after the neonatal period (130).

Multiple pregnancies often result in higher rates of stillbirth, neonatal and maternal death due to complications in pregnancy and childbirth and higher rates of prematurity (114, 131). In a comparison of DHS datasets for 1990-2000 the risk of neonatal death was about six times higher for multiple births compared to single births (80). The

incidence of multiple births varies according to the region. In Malawi, infant deaths were twice as common and perinatal deaths were 3.6 times as common for multiple births compared to singletons (131).

Other biodemographic risk factors for neonatal death are mother's age at birth, length of preceding birth interval, birth order and sex of the child (80). When mothers give birth at a young age they are more at risk of complications and infants are more at risk of being born prematurely or with low birth weight. Older mothers are also at more risk of pregnancy complications and their children are more likely to have congenital anomalies. In the review of DHS datasets, mothers under the age of 20 and mothers aged between 40 and 49 are 45% and 30% respectively were found to have their child die in the first month of life (80). High birth order or high parity and first birth also contribute to this effect, and it is difficult to disentangle the effects of each. Birth intervals of less than 24 months also contribute a significant risk, with these infants being almost twice as likely to die in the first month as children born after an interval of 24 months.

More boys than girls are born globally, but girls have a biological survival advantage compared to boys in the neonatal period, (mainly due to lower vulnerability to infectious diseases) (59, 80). This may be offset by the effects of decreased care-seeking for girls, sex-selective abortion and female infanticide, especially in south Asia (5, 132-134). On average, boys are 28% more likely to die in the first month of life (80). Malawi DHS data show a higher neonatal mortality rate among males compared to females – 42 per 1,000 compared to 32 per 1,000 – and this female advantage persists to 5 years. This is the opposite to patterns seen in Asia, in countries with a strong preference for sons (135).

As described in section 2.2.3, poverty is a strong socioeconomic determinant of neonatal death. Poor children are more likely to die as they are more likely to be exposed to disease, less likely to receive preventive interventions, more likely to acquire disease, have lower resistance to disease, lower access to health facilities, are less likely to be managed appropriately in health facilities, less likely to get life-saving drugs and have lower access to secondary and tertiary care (136-138). Socio-economic differentials in neonatal mortality exist even within developed countries (139). Looking

at data from 23 countries in sub-Saharan African and Asia, one estimate suggests that if neonatal mortality rates for the whole population were equivalent to those seen in the richest socioeconomic quintile, mortality would be reduced by 19% in sub-Saharan Africa and 40% in Malawi (115). In the DHS review of childhood mortality estimates, urban/rural residence and mother's education were used as proxy measures of socioeconomic status. Place of residence also affects access to health facilities, transport, cash and opportunities for education. Malawi DHS and MICS data show an urban-rural gradient (Table 2.7 and Table 2.8). Data on the relationship between poverty and adverse infant outcomes in Malawi are more complicated, and some studies suggest that HIV may be closing the equity gap in infant mortality, through increasing mortality in less poor families rather than reducing mortality amongst the poorest (74, 82).

Cultural factors that may contribute towards neonatal health include women's status and decision-making power, early childbearing, birth spacing, cord care, wrapping and bathing practices, use of colostrums and when and what other foods are introduced (59, 140).

Reductions in late neonatal mortality will be possible through immunisation, breastfeeding and improved hygiene, but to prevent early neonatal deaths improvements in access and quality of skilled delivery care will be required. In Africa, prevention and treatment of malaria and HIV in pregnant women will also contribute to reductions in neonatal mortality rates as well as stillbirth and maternal mortality rates (5).

Chapter 3 : Review of evidence for community-based approaches to reduce maternal and neonatal mortality

Effective maternal and newborn health interventions exist, but they are too often not available to the poorest mothers and children amongst whom the highest mortality rates are found (5, 58, 136). Low uptake of interventions amongst the poorest and most at risk mothers may be related to difficulty accessing health services due to cultural, logistical or financial barriers. As described in Chapter 2, a large proportion of women in Malawi give birth at home, and this is higher in rural areas and amongst the poorest women (Table 2.7 and Table 2.8). This chapter will summarise the available evidence for the efficacy of key maternal and neonatal health interventions that can be delivered at community-level, and go on to explore factors related to maintaining their effectiveness at population level in poor communities. Several models for population-level, community-based approaches to health promotion will be reviewed. This will provide some further background to the rationale and development of the intervention in this study.

3.1 Review of interventions to reduce maternal and neonatal mortality

Several recent reviews have summarised the evidence for effective interventions that tackle maternal and neonatal health issues worldwide (60, 106, 138, 141-143). These reviews have suggested that maternal and neonatal mortality could be reduced by 74% and 41-72% respectively if universal coverage of these known interventions was achieved (60, 138). The review by Bhutta et al identifies antenatal, intrapartum and postnatal interventions for which the weight of evidence is sufficient to include them in maternal and neonatal health programmes. They focus only on community-based interventions for perinatal and neonatal outcomes, while other reviews consider the broader spectrum of health care settings, especially for many maternal care interventions that require skills and resources only normally available at health facilities (143).

The authors explored the global literature for evidence of the effectiveness of interventions, principally from randomised controlled trials, but also from studies using less rigorous designs, as well as from several Cochrane systematic reviews. A summary of the main findings is presented in Table 3.1 and will be discussed in the following section. Where Cochrane systematic reviews were available, references to these are included.

Table 3.1: Summary of evidence from meta-analyses and reviews of the impact of key interventions on maternal and neonatal outcomes

Interventions	**Maternal outcomes**	**Risk reduction on maternal outcome(s)** % reduction in maternal mortality		**Neonatal outcomes**	**Risk reduction on neonatal/perinatal outcome(s)** % reduction in neonatal mortality	
Preventive		Cause-specific mortality/morbidity	All-cause mortality		Cause-specific mortality/morbidity	All-cause mortality
Intermittent malaria prophylaxis in pregnancy (first/second pregnancies)	Placental malaria Severe antenatal anaemia	65% (53-73%) 40% (24-52%)	-	Perinatal deaths Low birth weight	27% (1-47%) 43% (28-54%)	38% (-5 to 63%)[1]
Use of ITN in pregnancy (first/second pregnancies)	-	-	-	Low birth weight Stillbirth/abortion	23% (2-39%) 33% (3-53%)	-
Iron and folate in pregnancy	Iron-deficiency anaemia (term)	67% (31-84%)		Neural tube defects	72% (42-87%)	-
Screening for pre-eclampsia	Deaths from hypertensive disorders of pregnancy	48%[2]	-	Preterm deaths	15%[2]	
Calcium supplementation	Pre-eclampsia	52% (31-67%)	20% (3-35%)	Preterm Low birth weight	19% (-3 -36%)[1] 16% (-3 -32%)[1]	-
Tetanus toxoid vaccination (2 or 3 doses)	-	-	-	Neonatal tetanus	98% (70-100%)	69% (45-83%)
Syphilis screening and treatment (Prevalence dependent)	-	-	-	Congenital syphilis	Low prev – <1% Moderate prev – 1-2% High prev – 4-5%	-
Detection and treatment of asymptomatic bacteruria	Deaths from sepsis (and cases of infertility)	10%	-	Low birth weight	34% (11-51%)	-
Antibiotics for premature (preterm) rupture of membranes	-	-	-	Neonatal sepsis	32% (13-47%)	-
Corticosteroids for preterm labour	-	-	-	Preterm	-	40% (25-52%)
Normal delivery by skilled birth attendant	Deaths from sepsis	40%[2]	-	Severe infection Neonatal tetanus	15% 60%	-
Detection and management of obstructed labour and breech (planned c-section)	Obstructed labour deaths (and fistula)	95%[2]	-	Asphyxia	40%	Perinatal/neonatal – 71% (14-90%)
Active management of third stage labour (including partograph)	Postpartum haemorrhage deaths and cases of anaemia	62%[2]	-	Asphyxia	-	Early neonatal – 40%[3]
Hygienic delivery practices	Puerperal sepsis	-	-	Neonatal tetanus	55-99%	58-78%
Breastfeeding	-	-	-	Diarrhoea, pneumonia	-	55-87%
Newborn temperature management	-	-	-	Hypothermia		18-42%
Kangaroo mother care (Low birth weight infants)	-	-	-	Infections	51% (7-75%)	-

Interventions	**Maternal outcomes**	**Risk reduction on maternal outcome(s)** % reduction in maternal mortality		**Neonatal outcomes**	**Risk reduction on neonatal/perinatal outcome(s)** % reduction in neonatal mortality	
Curative		Cause-specific mortality/morbidity	All-cause mortality		Cause-specific mortality/morbidity	All-cause mortality
Magnesium sulphate for treatment of pre-eclampsia/eclampsia	Eclampsia	59% (42-71%)	-	Asphyxia	-	-
Newborn resuscitation	-	-	-	Birth asphyxia	-	6-42%
Initial management of postpartum haemorrhage	Postpartum haemorrhage deaths and cases of anaemia	75%[2]	-	-	-	-
Referral care for severe postpartum haemorrhage	Postpartum haemorrhage deaths and cases of anaemia	75%[2]	-	-	-	-
Management of maternal sepsis	Sepsis deaths and cases of infertility)	90%[2]	-	-	-	-
Management of severe neonatal infections	-	-	-	Deaths from severe infection	50%	-
Management of low and very low birth weight babies (LBW and vLBW)	-	-	-	Preterm deaths - LBW - vLBW	 40% 25%	-
Community-based case management for neonatal pneumonia	-	-	-	Deaths from severe infection	40%	27% (18-35%)
Universal coverage of key interventions	-	-	74%	-	-	41-72%

(Source: Wagstaff, 2004; Bhutta, 2005; Darmstadt 2005 and Adam 2005, Gamble 2009, Barros 2010 (60, 138, 142-145))

[1] Borderline statistical significance – 95% confidence intervals overlap zero
[2] Based on expert panel assessment of available evidence (143)
[3] This evidence comes from a before and after trial (146). A Cochrane review found no significant effect of partograph on maternal or neonatal/perinatal outcomes (147).

3.1.1 Antenatal interventions

Prevention and management of health problems in pregnancy can be tackled through a wide range of antenatal interventions. In developing countries, problems during pregnancy are mainly related to nutritional deficits, infectious diseases and hypertension (142, 148). Antenatal care is one of the main pillars of the World Health Organisation's (WHO) Safe Motherhood package (149), but there is a lack of strong evidence as to the optimal content, frequency and timing of visits (150). Antenatal care varies in different settings, so systematic studies of 'standardised' antenatal care programmes on maternal and newborn health outcomes are difficult. The exact margin of reduction in maternal mortality after antenatal care is not known, and a WHO systematic review of antenatal care trials found no evidence of reductions in perinatal mortality (150). Some of the most important components of antenatal care are tetanus toxoid vaccination, iron-folate supplementation, detection and management of pre-eclampsia and screening and treatment for infectious diseases like syphilis and malaria. The evidence is mixed, but a review of the components of antenatal care suggests that quality antenatal care within a functional health system can reduce the risk of maternal mortality and adverse pregnancy outcomes (148). There is less consensus on the critical number of visits and the most cost-effective components. A WHO randomised trial found little difference in maternal or neonatal health outcomes for women having four antenatal visits compared to those having more frequent visits (151).

Nutrition-related interventions

Poor maternal nutrition in pregnancy is common in developing countries and contributes to anaemia, low birth-weight and other adverse pregnancy outcomes (152). Several nutrition-related, antenatal interventions have been tested that supplement the mother's normal diet, including supplementation with nutrients such as protein, iron, folate (periconceptual and antenatal), iodine, vitamin A (antenatal), zinc, calcium and multiple micronutrients.

A Cochrane systematic review found that high-protein supplementation alone (without energy supplementation) did not show any effect on pregnancy outcomes, but there was strong evidence in favour of balanced protein-energy supplementation in reducing

perinatal and neonatal deaths (153). Most of this evidence comes from efficacy trials, and there was no evidence from trials of community-level supplementation or home-available diets.

Oral iron supplementation is commonly included in antenatal care packages as it clearly reduces maternal iron-deficiency anaemia. However, there is a lack of evidence for a clear effect on maternal or perinatal/neonatal outcomes (154, 155). Pending the results of better-designed trials, reviewers recommended that continued iron supplementation to reduce the risk of adverse maternal outcomes is prudent, especially in malaria-endemic areas (142). There is strong evidence to support the use of folic acid supplements, given along with iron, for improving birth outcomes. Periconceptual folic acid also reduces the risk of neural tube defects.

Iodine plays an important role in cognitive development and evidence for its benefits is strong. Though much of this evidence comes from developed countries, its use is still advocated in maternal and child health programmes in developing countries (60, 106). There is some evidence for the benefit of vitamin A supplements taken before and during pregnancy in reducing pregnancy-related mortality (up to 12 weeks postpartum) through improvements of the immune and haematological status of the mother (156), though a recent cluster-randomised controlled trial in Ghana found no evidence of impact on pregnancy-related or all-cause adult female mortality (157). The effects of vitamin A supplementation for child survival have been clearly shown, but the effects of antenatal supplementation on perinatal/neonatal mortality are not clear (142, 158). Evidence for the benefit of isolated zinc supplementation in pregnancy is weak, and isolated zinc deficiency is unlikely to exist (159). Finally, there is emerging evidence of multiple micronutrient deficiencies in pregnancy in developing countries, and given the increased nutritional requirements during pregnancy, multiple micronutrient supplementation would seem to be a plausible means of improving pregnancy outcomes (142). The evidence of the benefits of multiple vitamin supplements for women in developing countries is unclear (160), and there is some evidence that increased birth weight increases the risk of obstructed labour and perinatal death (142). The widespread use of multiple micronutrients is not recommended until further trials have been conducted in developing country settings (142, 160).

The benefits of antenatal calcium supplementation to prevent pregnancy-induced hypertension and pre-eclampsia and consequent death or morbidity are strongly supported, especially for mothers living in communities with low dietary intake of calcium (141, 161). Screening women at antenatal visits to identify those at particular risk of pre-eclampsia may further enhance the effects of calcium supplementation and enable better management of pregnancy-related hypertension (143, 148).

Infection control and prevention

Malaria is a major problem in endemic countries and can cause severe complications in pregnancy, especially in primigravidae (first pregnancies) (123). HIV infection may impair the ability to acquire pregnancy-specific immunity to malaria, thus increasing the risk of complications (104). A Cochrane review reported that in malaria-endemic areas, malaria prophylaxis during pregnancy reduces maternal anaemia and improves birth weight. Benefits for the outcome of the infant were not clearly demonstrated, though perinatal mortality was reduced amongst low parity women (162). Continuing research into different prophylaxis strategies is necessary as resistance continues to emerge to new anti-malarial drugs (163). There is strong evidence for the benefits of using insecticide treated bed-nets on placental malaria, low birth weight, childhood mortality and on maternal anaemia, and some for improved pregnancy outcomes (144). Further operations research is needed into how to make this intervention feasible at scale, and longitudinal follow-up after social marketing and mass free distribution in Kenya showed increased coverage and sustained child survival effects (164). Hookworm infestation is associated with anaemia in endemic areas, and de-worming with mebendazole can reduce the prevalence of anaemia in pregnancy (165), but clear impact on maternal anaemia during the third trimester of pregnancy and other pregnancy outcomes has not been shown (145, 165). Further community-based effectiveness trials are needed to evaluate the benefits and possible complications.

Genitourinary tract infections may cause intrauterine infections or inflammatory reactions leading to preterm birth, and can be a significant underlying factor in late foetal deaths (145). Case identification and treatment of maternal syphilis can have significant benefits for perinatal/neonatal outcomes, though uncertainty remains about what the optimal treatment regimens are (142, 166). Implementing accessible, quality diagnostic and treatment services has been challenging, and further operational research

is needed to investigate ways to achieve this (166). Screening and treatment of asymptomatic bacteriuria (urinary tract infection without symptoms) has been associated with improved birth outcomes in developed countries, through reductions in low birthweight and preterm births, though the evidence is inconsistent (145, 167). Logistical and technical requirements are major barriers to widespread implementation in developing countries, and operational research would be needed to find ways to make such services more widely available (142, 167). Mixed evidence exists for the benefits of antibiotic treatment of bacterial vaginosis (145, 168). It may reduce low birth weight and other adverse birth outcomes, but may also increase the risk of preterm births (142). Once again, there is difficulty in operationalising this intervention through developing country health systems. Premature rupture of membranes is strongly associated with infection, and this infection is related to preterm birth (145). Routine antibiotic therapy for preterm labour where membranes are intact has no clear benefit, however, where membranes rupture prematurely, antibiotic therapy has shown to be clearly beneficial in improving neonatal outcomes (142, 169).

There is overwhelming evidence for the benefits of tetanus toxoid immunisation on neonatal outcomes (170). In addition, clean delivery practices and clean umbilical cord care contribute to infection prevention (19, 171, 172). Clean delivery kits may help promote hygienic practices in the community, but general behaviour-change interventions are necessary alongside the kits. Research into maternal immunisation for pneumococcal infection is in its preliminary stages, but could provide a promising means of protecting young infants from infection (142).

Maternal education

Finally, general maternal educational level is associated with better perinatal and neonatal outcomes, even after correction for socioeconomic status (80, 142), though there is little available evidence for effective strategies to improve educational capacity of mothers. A Cochrane review of studies in developed countries found little evidence for benefits on maternal and neonatal health outcomes of health promotion interventions targeted at women before pregnancy (173), and another review of group or individual antenatal education was inconclusive (174). In one study in Nepal an individual health education intervention to promote behaviour change in relation to newborn and infant care and breastfeeding failed to achieve any significant improvement in knowledge or

behaviour outcomes (23), and it has been suggested that community participatory learning can be a more effective way to change behaviour (22).

3.1.2 Intrapartum interventions

Community-based interventions

Interventions targeting prevention and management of complications during delivery are usually developed and tested for use in health facility settings. Although community-based interventions have been used as a means of promoting the use of these services (175), few interventions have been developed for the management of complications of delivery in communities, despite the fact that many births happen at home. Some interventions such as caesarean section obviously cannot be adapted to community settings, however, model-based predictions suggest that it may be possible to augment health-facility care by providing drugs for emergency treatment of postpartum haemorrhage and sepsis in the community, as a back-up for women who are not able to reach a health facility in time (176). Other intrapartum interventions that have the potential for use at community-level relate to infection prevention. One such intervention is maternal vaginal and newborn skin antisepsis, though meta-analyses have not shown significant reductions in postnatal infections or neonatal deaths in a hospital-based setting using chlrohexidine (177, 178). Other community-level methods of infection prevention during delivery might include use of clean razor blades and cutting surfaces, plastic sheets to lie on, soap for hand-washing (or latex gloves), and clean threads to tie the umbilical cord. In some settings these have all been combined to form ‘clean home delivery kits’ or ‘birth kits’ (19, 171). Kits such as these have been tested in community settings, and there is strong evidence for the benefits of hygienic delivery practices in reducing deaths from sepsis and tetanus in mothers and neonates (60, 142, 143).

The assistance of a skilled birth attendant during delivery is highly desirable (175), but the majority of women in developing countries give birth at home, without access to medical care. Training traditional birth attendants (TBAs) for improved maternity care is controversial, and evidence in support of continued TBA training programmes is inconclusive for maternal outcomes (179). Training TBAs or community health workers

(CHWs) to provide advice and support for newborn care after delivery may be more acceptable to policy-makers as the skills and equipment for managing the most common problems are less technical. Studies have shown that training TBAs has been beneficial for perinatal and neonatal outcomes, and little evidence was found to suggest no benefit (179). Further research is needed in this area, and also to investigate other interventions that TBAs and CHWs could deliver in the community.

Facility-based interventions

Some obstetric complications cannot be managed or treated at community-level, and effective interventions in health facilities are included as components of basic and comprehensive emergency obstetric care (BEmOC and CEmOC), such as active management of labour by a trained health worker, caesarean section, blood transfusion, magnesium sulphate, antibiotics for premature rupture of membranes and corticosteroids for preterm labour. When deliveries are attended by trained health workers, interventions such as management guidelines can help to improve the quality of care provided. However, a Cochrane review found no evidence that using a partogram to monitor the progress of labour makes any difference to the likelihood of caesarean section and delivery complications (147). On the other hand, active management of third stage of labour (especially use of drugs like oxytocin or misoprostol) is associated with a reduction in deaths from anaemia and post-partum haemorrhage (180-182).

In a comprehensive emergency obstetric care setting (CEmOC), caesarean section is possible. According to a panel of experts, management of obstructed labour (including external cephalic version for breech presentation, and vacuum extraction, forceps or caesarean section for persistent breech) is expected to have a large impact on maternal deaths (95% of deaths due to obstructed labour prevented) (143). Breech birth can result in poor outcomes, and there is clear benefit for perinatal and neonatal mortality with planned caesarean section for breech, though slight increase in maternal morbidity (183). If appropriately managed in accordance with clinical protocols in a modern labour setting, vaginal delivery of breech can achieve a similar level of safety as caesarean section (184). In developed countries, caesarean delivery is the main risk factor for postpartum maternal infection (185). Antibiotic prophylaxis following

caesarean section significantly reduces the incidence of fever and infection in mothers, but there is uncertainty about the consequences for the baby (186).

For the treatment of pre-eclampsia/eclampsia, there is clear evidence for the benefit of magnesium sulphate, as compared to placebo or other drugs such as phenytoin or diazepam. Three Cochrane reviews of magnesium sulphate found evidence for significantly reduced maternal deaths and reduced risk of further fits (187-189).

3.1.3 Postnatal interventions

There are many interventions to improve postnatal care that could be applied at community-level. Even apparently quite sophisticated interventions such as newborn resuscitation, hypothermia prevention and care for preterm or low birthweight infants have been adapted and tested in community settings.

There is preliminary evidence for the capacity of trained TBAs or CHWs to learn resuscitation skills and save newborn lives (179). However, in a six-country effectiveness study using the WHO Neonatal Resuscitation Programme to train TBAs, no impact on perinatal or neonatal mortality rates was seen, though the incidence of stillbirths was reduced (190). Simple drying, stimulation and warming as a part of routine neonatal care might be more straightforward as a way of promoting the basic elements of newborn resuscitation at community level (142).

Few studies have evaluated the prevention, recognition and management of hypothermia in the newborn in developing country settings. A Cochrane review including mainly studies from North America, found that inexpensive interventions such as plastic wraps and skin-to-skin contact showed reductions in heat losses, though no evidence was available for mortality outcomes (191). Simple, routine care practices could be carried out at community-level, such as immediate drying, wrapping and breastfeeding, delayed bathing and close contact with the mother. Thus, development and evaluation of culturally appropriate behaviour-change interventions is required to promote these practices at home.

Skin-to-skin contact for preterm low birthweight infants after birth also promotes increased weight gain and reduces the risk of nosocomial infection. All newborns in the community may benefit from this intervention, but especially high-risk infants. A Cochrane review of Kangaroo Mother Care (skin-to-skin contact between mother and newborn) found evidence that it reduced infant morbidity in low birthweight infants, but not infant mortality, though the quality of the evidence was poor and further research was recommended (192). Another intervention that has only been tested in hospital-based settings so far, but has the potential to be adapted to community settings, is the application of topical emollients (193). Serious bacterial infections can enter through the skin of newborns, especially preterm infants whose skin is not fully developed, so emollients can be applied to enhance skin-barrier function. As mentioned above, evidence for the benefits of neonatal skin antisepsis for infection prevention is limited. Benefits of antisepsis of the umbilical cord has similarly limited evidence, though might be useful just as a way of replacing harmful practices such as cow dung application (142, 172).

Other important neonatal infections with prevention and treatment interventions include ophthalmia neonatorum and pneumonia. Gonorrhoea and Chlamydia are the main causes of ophthalmia neonatorum and can be treated or prevented with prophylactic application of with silver nitrate, tetracycline or erythromycin ointments. The benefits of routine prophylaxis in areas endemic for gonorrhoea have been shown, though the evidence for Chlamydia is less clear (142). The impact of training CHWs to recognise and manage neonatal pneumonia in communities in developing countries is significant (194). Case management is superior to no case management, though the impact is limited given that distinguishing pneumonia from sepsis can be difficult and use of oral antibiotics alone may lead to under-treatment of infections. However, research in India showed that training of CHWs to identify and treat sick newborns with parenteral antibiotics was feasible and effective in reducing neonatal mortality due to pneumonia (195).

Nutritional interventions can be easily applied at community-level, and the benefits of breastfeeding have been extensively reviewed, showing reduced neonatal and infant morbidity and mortality with early and exclusive breastfeeding in community settings in developing countries (196). Lack of exclusive breastfeeding is also linked with

increased risk of neonatal sepsis (197), and based on a systematic review of the optimal duration of exclusive breastfeeding, WHO and UNICEF recommend exclusive breastfeeding for the first six-months of life (198, 199). The benefits of vitamin A supplementation on child mortality in developing countries are also well known, and there is interest in the potential benefits for neonatal and infant outcomes. There is some evidence for the benefits of neonatal vitamin A administration, but further research is needed (200).

3.1.4 Summary of evidence and gaps in knowledge

On the basis of their review, Bhutta et al recommend several interventions for immediate inclusion in programmes. These are shown in Table 3.2. These closely resemble interventions advocated by WHO (201, 202) and identified by the Saving Newborn Live Initiative of Save the Children/USA (203), suggesting that there is a convergence of expert opinion. Effective interventions span maternal and newborn care, illustrating the importance of a coordinated approach to both. To prioritise the highest impact and most appropriate interventions for sub-Saharan Africa and Malawi, an evidence-based approach based on local epidemiological, coverage data and contextual considerations is needed (9).

The pillars of essential newborn care are: resuscitation where necessary, immediate breastfeeding, warmth, hygiene (especially for delivery and cord care), and prevention, early detection and management of major diseases (204). These in addition to effective pregnancy, childbirth and postnatal care will be the most important strategies to reduce neonatal and perinatal mortality. “Basic” and “Comprehensive” emergency obstetric care (BEmOC and CEmOC) care at facilities will also be essential. BEmOC facilities should offer skilled attendance at birth, administration of intravenous fluids, antibiotics, anticonvulsants and oxytocics, manual removal of the placenta, provide help for retained products of conception and carry out an assisted delivery when necessary. CEmOC facilities should include all the basic functions, in addition to the ability to perform blood transfusions and caesarean sections (205). Good maternal nutrition, the prevention and management of anaemia (and malaria) and high-quality antenatal care will reduce the incidence of complications and thus perinatal, neonatal and maternal deaths.

Table 3.2: Summary of antepartum, intrapartum and postnatal interventions recommended for inclusion in programmes

Antepartum care	Intrapartum care	Immediate newborn care	Postpartum care
• Tetanus toxiod immunisation • Nutrition: iodine, iron/folate (periconceptual) • Maternal infections: syphilis, malaria (endemic areas) • Breastfeeding counselling • Birth preparedness • Danger signs	• Clean delivery • Skilled care at delivery • Danger signs	• Newborn resuscitation • Prevention of hypothermia: drying, warming • Prevention of hypoglycaemia: immediate breastfeeding • Prophylactic eye care (areas endemic for gonorrhoea)	• Exclusive breastfeeding • Clean umbilical cord care • Maintenance of temperature • Pneumonia and sepsis management • Early postpartum visit • Birth spacing

Adapted from Fig 1. Bhutta 2005 (142)

As well as specific maternal and neonatal interventions, general public health interventions like immunisation, improved nutrition and water and sanitation also make important contributions to maternal and child survival. Treatment and management of diarrhoea, respiratory infections, malaria, malnutrition, HIV/AIDS and pregnancy complications contribute to general improvements in the health of mothers and children.

Knowledge gaps

Community-based strategies have the potential to achieve higher coverage than facility-based interventions where health service use is low, and they may be a means of both changing behaviours related to prevention and care as well as increasing awareness and uptake of health services (206). There is a paucity of evidence from community-based trials of maternal and newborn health interventions in developing countries, particularly RCTs (142). Gaps identified in the knowledge base of mother and child health include the need for better understanding of family and community practices and to develop tools to build individual, household and community capacity for appropriate self-care and care-seeking. Critical questions remain on how to operationalise effective interventions, such as which cadre of health worker to deliver the interventions, how they can be linked efficiently to referral systems and how they will be trained and supervised (142). The main question is how to effectively deliver services in an integrated way within existing mother and child health programmes, and maintain high levels of coverage in various epidemiological contexts and populations (206).

Strategies, packages and combinations of interventions need to be tested through effectiveness trials in health systems settings.

Poverty, illiteracy, gender imbalances and dysfunctional health systems are underlying factors in all maternal and child health issues (142). However these cannot be addressed by public health interventions alone, but require national and international level strategic changes to bring about social development, economic growth and reduce inequity over a longer period of time (207). Implementation of evidence-based, cost-effective health programmes is critical in the shorter term to bring about reductions in mortality.

None of these reviews evaluated the evidence for the impact of HIV prevention and prevention of mother-to-child transmission of HIV interventions on maternal and neonatal mortality. There is accumulating evidence for the impact of such interventions, with five Cochrane reviews looking at reduction of MTCT (208-212). They describe considerable benefits for the mother and newborn of interventions such as ARVs, caesarean delivery, complete avoidance of breastfeeding (if affordable and feasible) and exclusive breastfeeding (where access to clean water is limited) as well as longer-term benefits, especially in countries with high HIV prevalence. Vaginal disinfection and vitamin A supplementation were not found to be effective ways of reducing MTCT (208, 211, 212).

Similarly, none of the reviews evaluated the benefits of family planning interventions for maternal and neonatal health. Availability of family planning is likely to reduce attempts at unsafe abortion and thus the incidence of complications of abortion (106). Other obstetric and neonatal conditions would also be avoided, due to the reduced number of pregnancies and physiological burden on the mother. A recent review provides strong evidence for the benefits of contraception in reducing not only the number of deaths through a reduced number of total pregnancies, but reducing the proportion of high-risk births and associated maternal deaths (213).

3.2 Complex interventions for complex populations

Most of the interventions described above are single clinical interventions, but single interventions on their own cannot tackle the complexity of prevention and treatment for maternal and neonatal health problems at population level. Combined packages of interventions are required to address the spectrum of disease conditions and their determinants. Population dynamics and behaviours are also complex, and interventions and evaluations that take into account complex population factors such as coverage, adherence and quality are also needed.

3.2.1 Complex interventions

Maternal and neonatal health strategies

As described in Chapter 2, the epidemiology and aetiology of maternal and neonatal health is complex. An added level of complexity is that individuals are not only at risk of one disease condition, though they may be more at risk of one or another, and sometimes several related pathologies may arise – e.g. obstructed labour, ruptured uterus, neonatal death from asphyxia, maternal death from haemorrhage or sepsis. Because of this complexity of aetiology and causal pathways, people are simultaneously exposed to multiple risk factors for multiple diseases, so approaches that combine several interventions in one package, programme or public health strategy are likely to be more successful at reducing mortality rates on a population level (141). The health of the newborn is inextricably linked to the health of the mother, so many strategies to improve the health of women improve both pregnancy and neonatal outcomes.

In practice, interventions are rarely applied in isolation. Safe motherhood and integrated management of childhood illness (IMCI) strategies are examples of such public health approaches (214). Interventions for both mother and child health span antenatal, intrapartum and postnatal periods, and the integration of maternal and neonatal care is important. Maternal care packages not only improve the health of mothers, but also improve the outcomes for infants. Using integrated approaches and interventions that

benefit mothers and newborns simultaneously, and avoiding vertical programmes that focus on one or the other is likely to be more cost-effective.

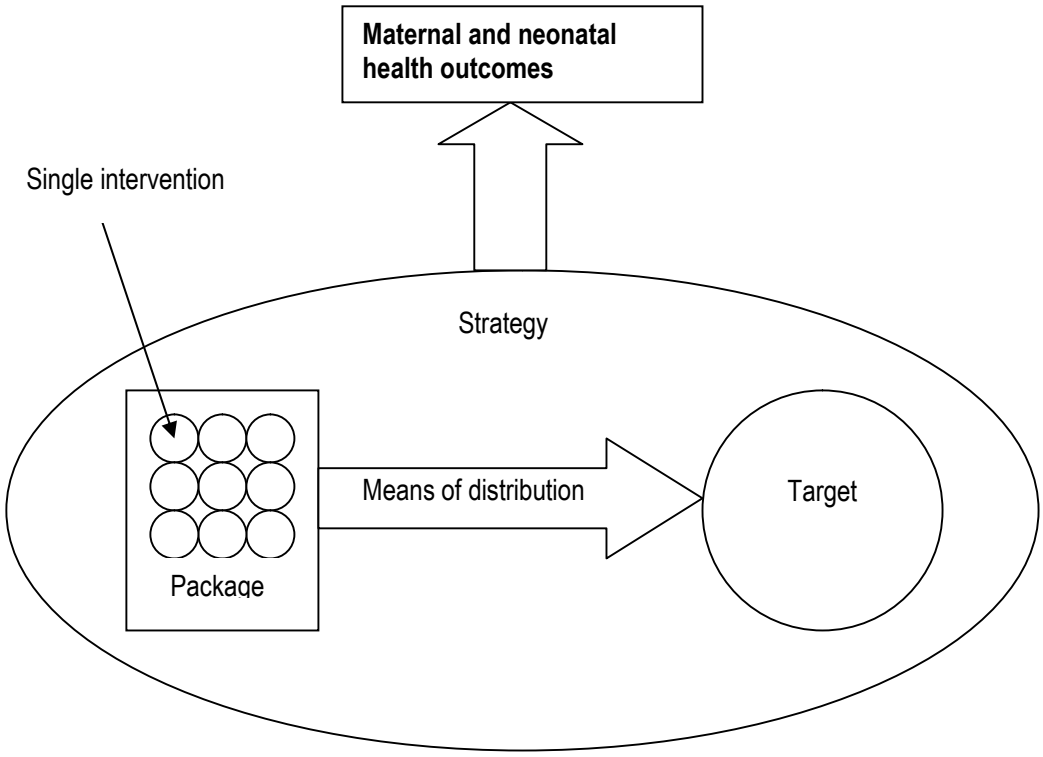
A review of packaged interventions for neonatal health found that evidence for the effectiveness of mother and newborn health strategies, as opposed to single interventions, is limited (215). Interventions were largely combined together out of convenience rather than anticipated synergistic effects. There is some evidence for the benefit of antenatal care packages that combine some of the interventions into one package (150), but a large-scale effectiveness trial to determine the magnitude of effect would now be unethical (142). Community-based case management of neonatal pneumonia was identified as the most cost-effective intervention for sub-Saharan African countries with high mortality to achieve mother and neonatal health millennium development goals (216). Several studies have shown that packages of newborn care in settings where health services are limited can be beneficial, but few of the studies reviewed were done with existing staff and infrastructure, so concerns about replicability and sustainability arise, and the cost-effectiveness at larger scale is not clear (142, 217, 218). A recent multi-country study looking at the impact of TBA training on perinatal and neonatal outcomes found no effect of training TBAs with either general essential newborn care or specific newborn resuscitation skills on neonatal mortality, but a significant reduction in stillbirth rate (relative risk 0.69 (95% CI, 0.54 to 0.88; P=0.003)) (190).

Skilled care during delivery is a major long-term goal for improving mother and child health outcomes, and health system capacities need to be developed. Since health systems are currently struggling in many developing countries, the question arises as to whether large reductions in mortality can be achieved in the shorter term by focusing mainly on preventive behaviour-change interventions, without investing in active management of illness and curative interventions (142). Understanding what the added benefit and cost-effectiveness would be of interventions for active identification and management of illness is an important next step.

Campbell et al have summarised the key decision points for policy-makers: a suitable package of interventions needs to be defined, a means of distributing this package needs to be developed and the most appropriate target population needs to be identified (106).

This combination of package, delivery mechanism and target population makes up a health 'strategy' (Figure 3.1). Similar emphasis on the importance of distinguishing between biological and behavioural interventions and the mechanisms through which they can be delivered has been made in child survival literature, and the need for better understanding and evidence for successful delivery mechanisms (206).

Figure 3.1: Schematic representation of a strategy aimed at maternal and neonatal health outcomes (adapted from Campbell, 2006 (106))



Maternal, perinatal, neonatal and infant care in developing countries requires an integrated and holistic package of interventions at various levels, including direct health-related measures as well as poverty alleviation, improved educational opportunities, gender balancing and empowerment. These need to be intentionally combined in evidence-based packages, and delivered through context-specific and cost-effective mechanisms (206, 215, 219). One approach for selecting components for community-based neonatal mortality reduction packages has been to use models such as the Lives Saved Tool (LiST), that predict mortality effects with inclusion of different components (220).

Focusing on supply or demand

There is a tendency to dichotomise the choices about how to focus interventions, such as the debate about the relative merits of health-facility strengthening and community-based interventions, but most often interventions, strategies and programmes fall along a continuum (141). For example, the questions relating to whether it is better to focus on improving supply or creating demand for health services are often posed. Traditional health interventions focus mainly on improving availability and quality of formal health services – the 'supply' of health care. Meanwhile, community-based health interventions have often focused on creating 'demand' for health services through greater recognition of danger signs and improved health care-seeking patterns, using methods such as community mobilisation. However, issues relating to supply and demand are closely linked and changes in one can influence the other. Focusing on either supply or demand alone is unlikely to achieve great impact on health outcomes – creating demand without good quality services (and vice versa) cannot meet people's health needs.

Current international opinion suggests that both facility and community approaches are important to ensure the continuum of care throughout pregnancy, childbirth and the postpartum periods (221, 222). The Making Pregnancy Safer initiative recognises that availability of quality health services will not produce desired health outcomes unless the capacities and awareness of individuals, families and communities are improved, and linkages between them and the health care delivery system are built and strengthened (223).

Focusing on prevention or treatment

Another question commonly posed by policy-makers is whether it is better to focus on prevention efforts or to develop good facilities to treat illnesses and complications (141). Promotion of family planning is an example of a primary prevention strategy for maternal mortality, by preventing unwanted pregnancies, moving births into lower risk categories and reducing the total number of births. Family planning alone may have an impact on the maternal mortality rate, by reducing the total number pregnancies and deaths, but it might have little effect on the maternal mortality ratio unless the risk of dying once a woman becomes pregnant is also addressed. However, a recent review

suggests that by reducing high-risk births increased use of contraception can avert additional maternal deaths and reduce the maternal mortality ratio (213).

Another preventive approach that is increasingly popular among public health decision-makers is micronutrient supplementation. It is perceived to be cheap, safe and relatively easy to implement. However, the evidence base for its effectiveness is weak. There are many trials and Cochrane reviews related to micronutrient supplements, and there is some evidence for the benefits of antenatal vitamin A and calcium supplements (for maternal outcomes) and iron-folate and protein-energy supplements (for neonatal outcomes) (153-155, 158, 161).

It is believed that antenatal care offers an opportunity to detect early signs of, or risk factors for, morbidity and mortality. However, this risk assessment approach may not in fact be a cost-effective use of resources, and emphasis has shifted from universal access to antenatal care to universal access to professional delivery care (141). However, antenatal discussions have other benefits and are still an important part of pregnancy and birth planning. Skilled attendance at delivery is a preventive strategy at normal deliveries, but when complications arise emergency obstetric care (EmOC) provides a package of interventions focused on direct obstetric complications that cause the majority of maternal deaths.

Improving quality of services

Effective facility-based interventions need to be delivered through high quality health systems, and the improvement of obstetric services is one of the key elements of the Safe Motherhood programme (141). Making improvements to existing health services within the constraints of tightly limited health budgets is a challenge in many developing countries, and will require long-term government investment and support from the international community (221). Long-term planning for the training and deployment of additional health workers, especially midwives, will be a crucial part of this.

One way of improving the quality of existing services is through auditing. Confidential enquiries into maternal deaths were developed as a way of identifying the causes of maternal deaths and the avoidable factors contributing to them (224). A confidential

enquiry in Malawi found that the quality of care had been “sub-standard” in 62% of deaths. Deficient hospital care was the principal avoidable factor in 38% of deaths, and hospital and health-centre care is reported to have deteriorated since a previous audit in 1989 (94, 225). Recommended improvements included strengthening supervision, regular reviews of maternal and perinatal deaths, maternity waiting homes to reduce delays in reaching health facilities, and better telecommunication and transport systems to reduce barriers to timely care and referral.

Another approach to auditing is facility-based maternal death review, which reviews each case of maternal death that occurs so that lessons can be learned from the management of the case to improve future practice (141). In a maternal death review in nine hospitals in Malawi, the main factors that contributed to maternal deaths were grouped into health worker factors, administrative factors, patient/family factors and TBA factors (6). Of those, health worker factors were the most prevalent, and they included inadequate resuscitation, lack of obstetric life-saving skills, inadequate monitoring, incomplete assessments and delays in starting treatment. Major institutional problems were encountered with shortages of staff and equipment. A study of the process of maternal death review in Senegal concluded that it was a beneficial strategy for improving maternal health, and had a marked effect on resources, management and maternal outcomes (226).

3.2.2 Complex populations

As described in Chapter 2, the epidemiology of maternal and neonatal mortality is complex and many inter-related factors determine health outcomes for mothers and neonates. As such, approaches to tackling maternal and neonatal mortality are also complex, and must take into account the important contextual factors that determine health outcomes in different settings (57). ‘Vertical programmes’ take single disease conditions and identify straightforward clinical actions to prevent or treat the disease (e.g. screening test, drug, vaccine, nutritional supplement). In a setting, where access to quality health care can be limited, a public health intervention would, in addition to the clinical action itself, have to take into account different geographic, socioeconomic and cultural barriers to uptake and adherence, as well as health system management factors affecting implementation. Though an intervention may be known to be efficacious in

ideal settings, contextual and confounding influences might obscure the evidence of its effect when implemented in a population setting. Interventions may fail to achieve significant reductions in mortality at a population level due to factors such as incomplete or patchy coverage, low uptake among some groups, limited diagnostic accuracy, ineffective application of interventions, or low adherence to treatment.

Strategies that enable communities to benefit more efficiently from existing evidence-based interventions have the potential to achieve large reductions in mortality. For example, one study of malaria treatment in Burkina Faso reported that although the treatment drug was 85% effective, the true community-effectiveness was only 3%, due to factors such as low uptake of health services in case of illness (21%), poor diagnosis and management by clinicians (31% sufficient history taken, 69% complete examination, 81% correct dosage prescribed), and patient adherence (68% took drugs as prescribed) (227). Addressing barriers to uptake of such services is essential, alongside the necessary improvements in clinical skills.

Coverage and access

Reviews have suggested that effective interventions for maternal and neonatal health exist, and large reductions in mortality could be achieved by increasing their coverage (60, 138). But coverage is a complex issue and many factors must be considered in order to improve it. These include, widening the provision or distribution of services/interventions, increasing uptake and use of interventions and ensuring consistent and optimal use (138, 219). Provision and distribution of services and interventions is usually the responsibility of health care providers, and depends on personnel, training, infrastructure and consumables, which make up the 'supply-side' of intervention coverage. On the other hand, uptake and use of services and interventions depend on a host of community factors such as distance, cost, acceptability and culture, which make up the 'demand-side' of intervention coverage. Improving coverage therefore requires understanding of both the supply-side and demand-side barriers, and consideration of mechanisms to address each.

Many public health interventions have the potential to achieve a high coverage at a relatively low cost – such as vaccinations, comprehensive antenatal care (including iron folate and antimalarial prophylaxis). Alternatively, interventions can target specific

diseases that cause high morbidity or mortality, or target particular population groups (e.g. the poorest, or the furthest from health facilities) who are at higher risk of disease. Packages of care that tackle multiple risk factors (e.g. antenatal care, skilled delivery care, or community-based women's groups) and have a high coverage amongst the poorest groups, can be more cost-effective than single interventions (60).

Inequalities and barriers to health care

Better coverage does not necessarily happen evenly across a population (136). The inverse care law described in the 1960s in the UK states that, ""The availability of good medical care tends to vary inversely with the need for it in the population served." (228). This means that the poorest people in society are the ones who are most vulnerable to health problems but often have least access to appropriate health care.

Inequalities in health exist within and between countries, even in developed countries (229). Internal variations may be masked by national figures, but large geographic, economic and social variations exist. Urban-rural differences can be substantial. MMR is usually higher in rural areas, in part due to large distances between health facilities and poor transport infrastructure (85). The pattern may be reversed where quality of health care is poor and urban areas may have more overcrowding and higher prevalences of HIV and unsafe abortion. In Peru maternal mortality was found to be more than six times as high in the poorest quintile of the population compared to the wealthiest (more than 800 per 100,000 compared to less than 130) (58). Part of the explanation may be differences in uptake of antenatal, delivery and postnatal care services between rich and poor women, but societal factors and group characteristics such as ethnicity, caste, race and religion, and individual factors such as marital status, self-esteem and psychosocial wellbeing are also important pathways through which disadvantage can exert an effect on health.

Mother and Child Health (MCH) interventions often reach people in better off groups more frequently and faster than they reach poorer groups, even when they were intended to benefit primarily the poor (137). The World Bank Reaching the Poor programme evaluated a sample of interventions to see how their benefits were distributed across different socio-economic groups. Comparing coverage rates of 8 basic MCH interventions in 56 developing and transition countries, coverage was found

to be higher in the best-off 20% of the population compared with the poorest 20%. Government expenditure on health was also shown to benefit the best-off 20% more than the poorest 20% (230). Approaches that were successful in reaching the poorest groups included; paying rather than charging poor families for clinic attendance, targeting interventions at the poorest groups, contracting with NGOs to run rural primary health services, and targeted bednet distribution in rural areas.

Strategies such as conditional cash transfers, now popular with donors, have been introduced in an attempt to reach the poorest and reduce the cost barriers for them to access health care (231). Examples of this have been seen in Mexico, Honduras and Nepal, where cash transfers are made conditional on a woman delivering at a health facility. However, women from the most remote areas are still at a disadvantage because they have the longest distance to travel and may only set off once labour has already started. These women may deliver en-route to the health facility, where they are arguably worse off than if they had delivered at home. The financing scheme in Nepal also provided transport costs in order to further reduce the barriers to health care for the poorest women, but this was challenging to implement (232).

3.3 Community-based interventions to reduce maternal and neonatal mortality

In the past most programmes targeting maternal and neonatal health have focused mainly on improving the quality of health service provision (antenatal care, skilled delivery care and emergency obstetric care), where quality may have been compromised by lack of adequately trained health workers, lack of medicines supplies and equipment, overcrowding and poor hygiene. However, in populations where most mothers deliver at home and the capacity of health services is severely stretched, the impact of interventions focusing on skilled attendance and improved obstetric care at facilities alone is likely be limited.

The rationale for using community-based interventions is based on the fact that many maternal and neonatal deaths occur at home, and could potentially be avoided by

changes in antenatal and newborn care practice. Consolidation of the links between primary health care services and their users – a need spelt out in the Alma-Ata Declaration (233) – is an essential part of this process, and involves both improving the quality of the services and creating a demand and awareness among the community to use them. As described in the previous section, reasons for under-use of existing services are complex, and in order to increase the uptake of services, not only must physical barriers to access be removed, but issues of service quality and community perceptions of service providers must be addressed.

Supply and demand are intimately linked: where users have little say in the design and management of services, services are unlikely to be successful in meeting their needs. Creating a demand-driven environment for service delivery therefore, might not only improve the quality of the services, but also increase uptake. Users who are concerned and involved with planning service delivery and have an obvious influence are more likely to use services knowledgeably and appropriately and to pay greater attention to health messages. In the context of maternal and newborn health, this may mean that women with high-risk pregnancies and at-risk newborns may be referred more promptly to the right health facilities.

3.3.1 The importance of community participation in health interventions

The fourth article of the Alma Ata Declaration stated that, “people have the right and duty to participate individually and collectively in the planning and implementation of their health care” (233). But even where work to improve health has been done at community level, decisions have not always been made by the people most affected by those health issues. Decisions may be made by certain individuals who control resources, or by people who do not even come from the community. This has generally been because the interventions have lacked local ownership, there have been different perceptions of priorities between officials and communities, and because powerful groups have captured the necessary resources (234-236). Groups most consistently excluded from decision-making have been women and children.

Involving groups who have traditionally had little influence in decision-making is very important for a number of reasons. Firstly, it can lead to better and more appropriate decisions being made – people in the community have a lot of experience and insight into what works, what does not work, and why. Secondly, it can increase community commitment to planned work and thus ensure its sustainability. Thirdly, it can enable the community to gain some power and control over any planned work and can lead to their empowerment. Finally, it can increase the resources available for the planned work, as local materials and manpower can be used

Uninformed community decision-making may lead to inappropriate choices, so increasing knowledge is also important, but simply providing passive recipients with interventions or information about health risks is not always enough to change behaviour (237). Understanding the social context in which behavioural messages are delivered is extremely important. Experience in Nepal of providing basic information on infant care and family planning, showed that this did not result in significant changes in behaviour (23). A review of behaviour-change research in the field of HIV prevention also found that impact on only one in four participants on average can be expected through individually focused behavioural interventions (238). Recent cluster randomised trials in Tanzania, Zimbabwe and South Africa found no effect of school-based sexual health education interventions on HIV prevalence, though some knowledge and attitude measures improved (239-241). In the South African study, the authors concluded that the lack of success may have been in part to do with the inability of individuals to challenge cultural norms (241).

More success with health promotion and behaviour change has been achieved through health alliances or partnerships, and the stronger the representation of the community and the greater the community involvement in the practical activities of the health promotion, the greater the impact and the more sustainable the gains (238). Campbell argues that a social change approach that takes the focus away from individuals and encourages community responsibility for action may have the best chance of success. Community-based programmes can "*help to provide enabling conditions for the renegotiation of [behaviour] at the collective level, rather than attempting to persuade people to make an individual decision to change their behaviour by simply providing them with information about health risks*" (242, 243).

In a review of packages of community-based interventions for neonatal health, it was found that strategies that used community mobilisation elements reported the highest declines in perinatal and neonatal mortality (215). Community mobilisation and empowerment provide fertile ground for facilitating uptake, effectiveness and sustainability of other beneficial interventions (244, 245). Deployment of private community members as intervention providers in the absence of community mobilisation may limit the potential effectiveness of interventions (215).

Despite this evidence, the use of community participatory approaches to improve mother and child health in Africa has so far been limited. Thus the challenge remains to develop strategies that encourage the growth of more focused participation of community members in decision-making about health issues that affect them. Maternal and child health is potentially a fruitful area for developing such participation.

Community mobilisation, participation and empowerment

Community mobilisation may be perceived to work simply by bringing about changes in behavioural risk factors such as home care practices and health-care seeking. But as described above, studies of health education suggest that simply providing key messages to improve health behaviour do not have the biggest impact, and processes that engage communities may be more successful.

Community mobilisation and participation are closely related concepts and may be used to describe processes along a continuum with communities participating passively in health initiatives implemented by governments or organisations at one end, or actively as priority-setters and decision-makers at the other (237, 246). Greater active community engagement with the problem-posing and problem-solving process leads to recognition that community members could collectively change their circumstances, and thus leads to greater community empowerment. According to Freire's theory of cultural action, new interventions, technologies and information may be insufficient to change behaviours, unless they are introduced in conjunction with changes in the existing systems of power and control (247).

Community mobilisation may be defined as: “a capacity-building process through which community individuals, groups, or organisations plan, carry out, and evaluate activities on a participatory and sustained basis to improve their health and other needs, either on their own initiative or stimulated by others” (237).

3.3.2 Model strategies for participatory, community-based interventions

Studies in Bolivia, India, Nepal, Bangladesh and Ethiopia have shown that it is possible to achieve significant reductions in mortality using cost-effective community-based interventions that reach the poorest people (20, 22, 24, 25, 195, 218). These approaches emphasise the importance of active community participation in tackling health problems, rather than achieving high coverage of interventions in populations through more passive means. The design and results of these studies are shown in Table 3.3 and Table 3.4.

The Warmi experience (Bolivia)

The Warmi Project – introduced in a rural area of Bolivia with little health infrastructure and widespread poverty – was the first published account of a community participatory intervention to improve perinatal care (24). 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*) (248). The women’s groups went on to prioritise the problems and develop local strategies to address them (*planning together*) (249). 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. However, this study lacked a control group and had relatively low power, so the quality of evidence it provides is limited.

The SEARCH experience (India)

The work of the SEARCH group in Gadchiroli, a poor rural district of Maharastra State, India, has also achieved wide recognition (195). The group carried out a controlled study with 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

heath 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.

Follow up some years later found that the neonatal mortality rate had increased slightly in control areas between 1993–1995 and 2001–2003, but fell by 70% in intervention areas (250). Early neonatal mortality decreased by 64%, late neonatal mortality by 80%, and infant mortality by 57%. The stillbirth rate decreased by 49% and perinatal mortality by 56%. Cause-specific neonatal mortality for sepsis decreased by 90% (1995–1996 vs 2001–2003), for asphyxia by 53%, and for prematurity by 38%.

These findings suggest a large impact of community-based sepsis management on neonatal outcomes, though some caution is required in interpretation and generalisation of the findings from this study. The study had a control group but was not randomised, and the intervention involved workers paid and tightly managed by the SEARCH team, outside the government system and covering a population in which numerous previous community interventions may have sensitised them to more rapid behavioural change (195). The contribution of community mobilisation to the mortality reductions is difficult to estimate.

Community groups in Tigray (Ethiopia)

A community-based approach to malaria management was developed in Tigray, Ethiopia, to overcome the limitations of the existing community health worker approach, which had limited coverage and low of uptake amongst the youngest and most vulnerable children (20). Mother coordinators were selected and trained to teach all mothers to recognise and treat the symptoms of malaria, and this strategy was evaluated through a cluster randomised controlled trial. Under-five mortality was reduced by 40% in intervention areas (95% CI 29·2–50·6, $p<0·003$). Verbal autopsy data suggested cause-specific mortality reductions related to malaria, with 13 out of 70 (19%) of deaths in intervention areas being consistent with possible malaria compared with 68 out of 120 (57%) control areas.

This study supports the evidence for the effectiveness of participatory, community-based interventions, though did not include any data on maternal, neonatal or infant outcomes.

The MIRA Makwanpur experience (Nepal)

The MIRA Makwanpur study is the main operational model for this study – 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, central Nepal (22). MIRA built on experiences in Nepal and the studies mentioned above to examine the potential of community action cycles to bring about real improvements in perinatal health outcomes. They demonstrated a 30% reduction in neonatal mortality in intervention clusters compared with controls over a two-year period (adjusted odds ratio 0·70 (95% CI 0·53–0·94)). Maternal mortality was reduced by 78% (adjusted odds ratio 0·22 (0·05–0·90)), though this was not a specified *a priori* primary outcome of the trial. Secondary outcomes included changes in patterns of home care, health seeking and referral, and showed small, but significant improvements.

The intervention used trained local facilitators as change agents to assist mothers' groups to bring about perinatal care behaviour change. Each facilitator worked within one Village Development Committee (VDC) covering an average population of 7500. She facilitated the activities of women's groups within the VDC as they addressed the issues of pregnancy, childbirth and newborn health, using an action-learning cycle. The first cycle of the facilitation process was completed in 12 intervention VDCs and 12 control VDCs in October 2003. Married women of reproductive age (15-49 years) within the study area were identified and were visited monthly by study personnel. All pregnancies occurring within the cohort were followed until at least six weeks after delivery to determine the outcome of birth.

The Projahnmo experience (Bangladesh)

The Projahnmo trial in, Sylhet district, Bangladesh, compared neonatal mortality rates in home-care, community-care and control arms of a cluster-randomised controlled trial (218). In the home-care arm, female community health workers made two antenatal and postnatal home visits to promote birth and newborn-care preparedness, to assess newborns and refer or treat sick neonates. In the community-care arm, female and male

community mobilisers held group sessions for birth-preparedness and newborn-care, and promotion of health-care seeking. There was no effect on neonatal mortality in the community-care arm (adjusted relative risk 0·95 (95% CI 0·69–1·31)), but a 34% reduction (0·66 (0·47–0·93)) was noted in the home-care group in the last 6 months of the programme.

These results are in contradiction with the Makwanpur findings, which showed strong effects of community mobilisation. Cause-specific mortality data is not available from either study to assess whether aetiological differences may explain the differing findings. Intervention differences may explain some of the discrepancy, as the community mobilisation components of the two interventions differed. Community mobilisation in Projahnmo was less intensive than in Makwanpur, with only one meeting every four months, and the communities were involved in a more passive role, rather than being involved with priority-setting and decision-making. This is not in line with the definition of community mobilisation given in the previous section. The investigators of the Projahnmo study also noted that "Availability of referral services and a strong supervisory system were crucial to this intervention and would be a necessary feature of scaling up the intervention."

The Shivgarh experience (India)

The Shivgarh study in Uttar Pradesh, India, investigated the effect of an intensive behaviour-change programme involving community meetings and home visits by a new cadre of paid, non-governmental community workers (217). Their cluster-randomised controlled trial showed a 54% reduction in neonatal mortality (relative risk 0·46, 95% CI 0·35–0·60) compared to control areas receiving usual care. They also showed changes in home-care practices related to birth-preparedness, hygiene and thermal care, but no real change in care-seeking behaviour.

This intervention was community-based and participatory in the sense that the community was the setting for change and community members were the targets of the intervention (251), but it did not involve community mobilisation, capacity building or empowerment. As such the community was not the agent and did not own the process, and this intervention once again was not in line with the definition of community mobilisation given in the previous section.

The Ekjut experience (India)

The Ekjut study from three districts in Jharkand and Orissa in northern India was an attempt to replicate the MIRA Makwanpur findings in a different setting. It was a cluster-randomised trial involving 36 clusters and an estimated population of 228,000. A similar women's group cycle to the one used in Nepal reduced neonatal mortality by 32% (adjusted odds ratio 0.68 (95% CI 0.59-0.78)) and had a large but non-significant effect on maternal mortality. There was an even larger (45%) reduction in neonatal mortality in the second and third years (0.55(0.46-0.66)) (25).

The PCP experience (Bangladesh)

Another recent attempt to replicate the Nepal findings in Bangladesh did not show such major changes (252). In this study 18 clusters from three rural districts were randomised to two interventions (women's groups and TBA resuscitation training) in a population of 500,000 After three years there was a non-significant difference between intervention and control areas of 7% (risk ratio 0.93, 95% CI 0.80-1.09). The authors suggest that this may have been due to limited coverage of community activities, with only one women's group per 1,414 of the population, and 9% of women of reproductive age attending.

Table 3.3: Design of studies using community-based women's groups to change behaviour and mobilise communities to reduce neonatal mortality

Study (primary author)	**Publication date**	**Study design**	**Setting**	**Population of study area**	**Total number of clusters**	**Coverage of women's groups**	**Number of live births**		**Number of neonatal deaths**		**Number of maternal deaths**	
							Intervention	Control	Intervention	Control	Intervention	Control
*O'Rourke	1998 (24)	Case-control studies before and after intervention	Rural Bolivia, Inquivisi	15,000	-	-	708	639	31	75	-	-
Manandhar	2004 (22)	Cluster randomised controlled trial	Rural Nepal, Makwanpur	170,000	24	- 1 group per 778 population - 37% pregnant women attended	2,899	3,226	76	119	2	11
Tripathy	2010 (25)	Cluster randomised controlled trial	Rural India, Jarkhand and Orissa	228,186	36	- 1 group per 468 population - 55% pregnant women attended (year 3)	9,388	8,819	397	518	49	60
Azad	2010 (252)	Cluster randomised controlled trial with factorial design	Rural Bangladesh, Bogra, Faridpur, and Moulavibazar	503,163	18	- 1 group per 1,414 population - 3% pregnant women attended	15,153	14,736	515	557	55	32

*Since this used a case-control before and after design, data are for post-intervention and pre-intervention, not intervention and control for this study. Outcomes are 'perinatal' deaths (from 28 weeks of pregnancy to 28 days after birth), not neonatal deaths.

Table 3.4: Results from studies using community-based women's groups to change behaviour and mobilise communities to reduce neonatal mortality

Study (primary author)	**Publication date**	**NMR**		**MMR**		**Adjusted odds ratio for impact on NMR** (95% CI)	**Adjusted odds ratio for impact on MMR** (95% CI)	**Antenatal care attendance**		**Institutional delivery**	
		Intervention	Control	Intervention	Control			Intervention	Control	Intervention	Control
*O'Rourke	1998 (24)	4.4	11.7	-	-	-	-	63%	48%	31%	34%
Manandhar	2004 (22)	26.2	36.9	69	341	0·70 (0·53–0·94)	0·22 (0·05–0·90)	55%	30%	7%	2%
Tripathy	2010 (25)	42.3	58.7	521.9	680.3	0·68 (0·59–0·78)	0·70 (0·46–1·07)	74%	75%	14%	20%
Azad	2010 (252)	33.9	36.5	388.9	189.1	0·90 (0·73–1·10)	1·74 (0·97–3·13)	59%	65%	15%	16%

*Since this used a case-control before and after design, data are for post-intervention and pre-intervention, not intervention and control for this study. Outcomes are 'perinatal' deaths (from 28 weeks of pregnancy to 28 days after birth), not neonatal deaths.

3.4 Complex evaluations of complex interventions in complex populations – the importance of effectiveness trials

Summarising the previous few sections, we can see that single interventions are not sufficient to deal with the complex problems faced in public health, and packages combining several interventions, delivered at high levels of coverage to whole populations or communities are likely to be more effective. Evidence for the impact of such strategies at population-level is essential, but is so far limited (60, 138, 142). In order to make appropriate decisions, policy-makers need evidence from studies of complex public health interventions in complex whole populations, and better understanding of the barriers to achieving universal coverage. Thus a process of moving from focusing on testing 'efficacy' (how interventions work in ideal trial situations) to testing 'effectiveness' (how interventions can be delivered in real world settings) is required (206).

Most of the estimates of intervention impact reviewed in earlier sections were efficacy studies and did not take into account the demand-side factors involved in assuring effectiveness at community level. It may not always be appropriate to use evidence for the efficacy of individual interventions in planning population-level strategies. An intervention that is effective for an individual might not be effective as a public health strategy (141). There is little reliable population data to inform these estimates that explores coverage, uptake and use of interventions as well as the related impact of these on mortality. The challenge then is to collect such community-effectiveness data and use it to improve our understanding of what the barriers are to achieving better coverage of existing interventions. Quantifying the evidence for the impact of community mobilisation approaches can be particularly challenging because they address a broad range of issues simultaneously (215), and use a multiplicity of definitions of community participation (246).

Evidence on the effectiveness of national public health strategies often relies on health information systems, and where these are weak, the available data are inadequate and unreliable. Knowledge on the benefits of many public health interventions currently in

use comes from observational studies, demographic surveillance and case studies, though cause-effect relationships are difficult to establish with these types of research.

Randomised controlled trials using communities as the unit of intervention can be used to evaluate the benefits of public health interventions in whole populations (253). They inherently take into account losses of effectiveness due to incomplete coverage or imperfect implementation and adherence, and provide data on population-level indicators of impact, such as mortality rates.

Context-specific evidence for the benefit of an intervention is also important, as contextual factors are often important in the success or failure of an intervention in different settings (57). In evaluating the success of interventions, randomised controlled trials are appropriate where the causal chains are simple, but in public health interventions the causal chains may be complex and results may be subject to effect modification (254). In cases such as clinical efficacy trials of single drug treatments, contextual factors make little difference, but with many public health interventions, the delivery of the intervention can have as much to do with its success as the actual clinical nature. Because it is impossible to perfectly replicate contextual delivery factors from one study to another it is difficult to compare studies that use reportedly the same intervention, but do not discuss in detail the possible contextual factors that contributed towards the success or failure of the intervention.

Randomised controlled trials of complex public health interventions are rarely sufficient by themselves (254). However, randomised controlled trials with integral process evaluations can generate more reliable results (255), and plausibility arguments (such as investigations of confounding and effect modifying factors, reasons for and effects of diversions from protocol, and biological and behavioural processes on the causal pathway) strengthen the findings of statistical analysis (254). Process evaluation can help to distinguish between interventions that are inherently faulty (failure of intervention concept or theory) and those that are badly delivered (implementation failure) (255). Information about cost and feasibility are also essential to policy-makers.

3.5 Rationale for the MaiMwana trial

In resource-limited settings such as Malawi, where the health service is under extreme pressure due to lack of qualified personnel and resources, community-based approaches may be an effective first step in reducing mortality while longer-term strategies are developed to address institutional weaknesses.

There is remarkably little research in rural Africa on the potential for sustainable community-based interventions to reduce maternal and neonatal mortality. A study of promotion of community-based IMCI activities in Ethiopia showed some impact on infant mortality and other behavioural outcomes, though neonatal outcomes were not reported, and results are difficult to interpret as background mortality increased over the course of observation and the study was only in one intervention and one control district (256). A community-based study in Kenya reported a substantial reduction in deaths amongst infants under six-weeks old following introduction of hygienic delivery packs (171), and a cluster-randomised trial of community-based treatment for malaria showed a significant reduction in under-five mortality (20). Though several large trials specifically targeting neonatal health have now been conducted in Asian countries (22, 25, 195, 217, 218, 252), no other randomised controlled trial of a community-based, participatory intervention in neonatal health in a rural African setting was found. Studies are currently under-way in Ghana and Guinea Bissau to evaluate the impact of community-based interventions on neonatal outcomes, but results from these are not yet available (257, 258).

This study was established in order to provide policy-relevant answers to key questions about strategies to improve mother and newborn health in Malawi and the region. Appropriate maternal and neonatal care for Malawi requires a holistic and integrated programme of interventions at various levels. Ideally, these interventions should not only include health-related measures that have a direct bearing on maternal and neonatal outcomes but other equally important indirect measures. These measures include poverty alleviation, improved opportunities for female education, and improvements in women's social status, empowerment and decision-making power. Family size and interpregnancy intervals are also critical factors in perinatal health.

Given that almost half of all births occur at home in Malawi (1), there is a large proportion of the population for whom health systems strengthening alone will provide no immediate benefit. There is a need to improve community perception and demand for health services and increase health service utilisation and coverage. Household and community care practices can also provide benefits, and a key question is whether behaviour-change activities at community-level can improve maternal and neonatal outcomes even without large investments in improving current health services.

Community-based interventions with health-worker home visits have rarely achieved adequate coverage, quality, or effectiveness when taken to scale, (259). In contrast, participatory community groups have the advantage of being able to achieve higher coverage, reach the poorest, are scalable at low cost, and produce potentially wide-ranging and long-lasting effects (25). As described in section 3.3, there is growing evidence that community mobilisation though women's groups is an effective strategy for improving maternal and neonatal health. Reductions in neonatal mortality were shown in two Asian settings and one in South America (22, 24, 25). Women's groups are community-based, and in the context of low service utilisation they have shown promise in increasing the demand for services. In addition to improving uptake of health services, the groups facilitate behaviour change in the home and community, particularly for preventive behaviours related to hygiene and nutrition. Through the use of a participatory approach for identifying and solving problems, the solutions identified are more sustainable than if they were introduced by external organisations. They do not rely on complicated technology or resources that are difficult to obtain, and they do not rely on the availability of highly trained health workers. Finally, the process of mobilising communities to take action for their own health is empowering, and can encompass the indirect measures of poverty reduction, female education and women's decision-making power (237).

It is on this basis that MaiMwana Project in Malawi was founded, in order to evaluate the impact of two community-based interventions on maternal and neonatal mortality. Both interventions have previously been tested in other countries and settings, but this is the first time that they have been tested in rural Africa. The first intervention uses community mobilisation to address maternal and neonatal health issues through

women's groups. The second intervention uses volunteers who make home visits and provide information and support about breastfeeding.

Women's groups were successfully used by Warmi Project to address mother and child health issues in a remote, hilly area of Bolivia. They achieved a 60% reduction in perinatal deaths over a period of three years (24). This project was not designed as a research study and did not have a comparison group or baseline socio-economic survey, however based on the activities described, it suggests that the intervention was successful in reaching illiterate women in remote areas. The MIRA Makwanpur project in Nepal replicated this project with a rigorous research design, and was able to demonstrate a 30% reduction in neonatal mortality and 78% reduction in maternal mortality over a two-year period (22). Cost-effectiveness analyses show that the intervention cost $0.75 per capita per year to run, and $111 per life-year saved. Although facility-based delivery only increased from 3% to 9% during the study period, significant reductions in mortality were achieved at community-level through improved hygiene practices at home deliveries, recognition of danger signs and early care-seeking. At the time of planning the MaiMwana trial in 2003 and 2004, data from the other studies reviewed in section 3.3 were not yet available.

Home-based infant feeding promotion has been tested in a number of different settings using different strategies. Randomised controlled trials in Mexico, Bangladesh and India demonstrated success in increasing rates of exclusive breastfeeding, using community-based strategies (21, 260, 261). In Mexico and Bangladesh individual home-based counselling visits were made, while in India counselling sessions were more opportunistic and could be made by several different cadres of health worker. The Mexico and Bangladesh studies focused on urban populations, but the study in India showed a high coverage and acceptance amongst the rural poor. This was the main model for the development of the volunteer infant feeding counselling intervention in this study (21).

MaiMwana will evaluate these interventions using a full population-level effectiveness design, using a cluster-randomised controlled trial, in order to evaluate the potential for their inclusion in future Malawi national health strategies. Integral process and economic evaluations will be conducted alongside the main impact evaluation to have a

more complete understanding of the strengths and weaknesses of the interventions and to explore the plausibility and validity of effects (254, 255). An added justification for a rigorously evaluated community-effectiveness trial is that there is a need to improve information on the magnitude and causes of maternal and neonatal mortality in Malawi and the southern African region. Data collected through this research will provide vital information for policy-makers.

Chapter 4 : Methods

4.1 Background to MaiMwana Project

MaiMwana Project was registered in Malawi as a charitable trust in October 2003 and is directed by Dr Charles Mwansambo, Dr Peter Kazembe and Professor Anthony Costello. Its main objective as outlined in the constitution is "to reduce maternal and newborn morbidity and mortality", through health facility and community-based interventions. The organisation is managed locally, with input and guidance from the Centre for International Health and Development (Institute of Child Health, London, UK). The emphasis is on local ownership, building links with local government and non-government stakeholders and maximising the participation of communities in decision-making processes. The main funders are Saving Newborn Lives (Save the Children US), Department for International Development (British Government) and Wellcome Trust (UK).

The project has a main office and a sub-office in the district administrative centre, and four nodal offices in smaller trading centres around the district. The senior MaiMwana Project field team was recruited between September and October 2003 and oriented to the main aims of the trial. Three weeks in-house staff training were carried out from 3rd to 21st November 2003 and the topics covered included: study design; qualitative and quantitative research skills; facilitation techniques; participatory interventions; skills for working in the community, skills for supervisors, team building, consent and ethics, safe motherhood and antenatal care and prevention of mother to child transmission of HIV.

4.2 Objectives

4.2.1 Objectives of MaiMwana Project

Goal

To improve the survival and health of mothers and infants in rural communities in Mchinji, Malawi.

Purpose

To test the effectiveness of two community-based health promotion interventions for improving mother and child health and reducing mortality.

Objectives

To test the impact of an intervention using community mobilisation through women's groups on:

a) Care practices and health care seeking behaviour for mothers and infants.

b) Maternal and neonatal morbidity.

c) Maternal, infant, neonatal and perinatal mortality.

To document and evaluate the process and costs of implementing the intervention for potential replicability and sustainability.

To test the impact of an intervention delivering health education through volunteer peer counsellors on:

a) Exclusive breastfeeding rates, other care practices and health care seeking behaviour.

b) Neonatal and infant morbidity.

c) Infant mortality.

To document and evaluate the process and costs of implementing the intervention for potential replicability and sustainability.

Outcomes

The women's group and peer counselling interventions are described in section 4.4.3, and the primary and secondary study outcomes are summarised in Table 4.1.

Table 4.1: Study outcomes

	Women's groups	Volunteer infant feeding and care counsellors
Primary outcomes	▪ Maternal mortality ▪ Perinatal mortality ▪ Neonatal mortality ▪ Infant mortality	▪ Rates of exclusive breastfeeding (EBF) in the first six months ▪ Infant mortality
Secondary outcomes	▪ Changes in caretaker practices: hygiene behaviours, use of insecticide treated nets (ITNs), early and exclusive breastfeeding and decreased use of pre-lacteal feeds ▪ Changes in care-seeking behaviour: antenatal care (use of malaria prophylaxis in pregnancy, tetanus toxoid), delivery (facility-based, skilled attendant, use of safe delivery kit), uptake of PMTCT, postnatal care (check-ups for mother and baby, infant vaccinations). ▪ Maternal and infant morbidity (breast problems, fever, diarrhoea, etc.)	▪ Changes in caretaker practices: EBF (duration of EBF, time to first feed, use of pre-lacteals, time to weaning), management and treatment of breast problems, family planning (including use of condoms) ▪ Changes in care-seeking behaviour: uptake of PMTCT (awareness, VCT, expressing breastmilk), uptake of vaccination services (3 doses pentavalent and 4 doses polio by 6 months • Neonatal mortality • Maternal and infant morbidity (breast problems, fever, diarrhoea, growth etc.)

4.2.2 Specific objectives of this PhD

The MaiMwana Project study is a large and complex one, with many impact and process outcomes. The scope of the research in this PhD was confined to looking at the impact of the women's group intervention only, as well evaluating the methods of surveillance and analysis. The primary research question for this thesis is:

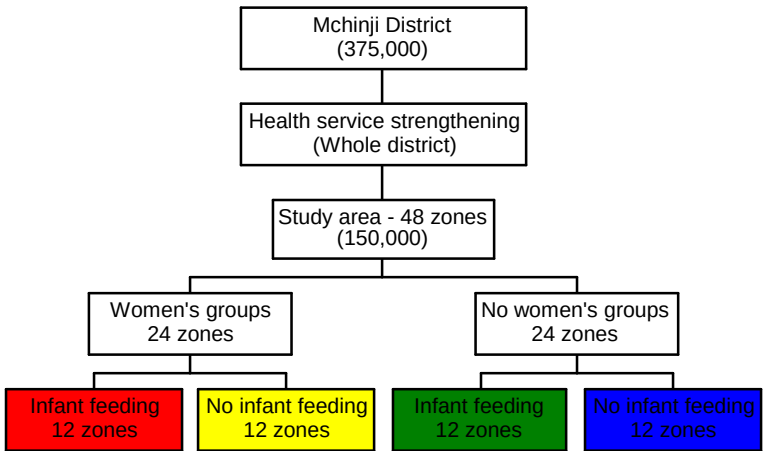
Will community mobilisation through women's groups reduce perinatal, neonatal, infant and maternal mortality rates through changes in care practices and health-seeking behaviour?

This Chapter will focus on aspects of methodology and study design that are relevant to this question, and will not go into the details of other areas.

4.3 Study design

This research is part of an ongoing study run by MaiMwana Project in Mchinji District, Malawi (262). The MaiMwana study is using a cluster-randomised controlled trial design to evaluate the impact of two community-based interventions in reducing maternal and neonatal mortality. The first intervention uses women's groups to address maternal and neonatal health issues through participatory health education and community mobilisation (263). The second intervention uses female, community-based volunteers who make home visits and provide information and support about breastfeeding (264). A cluster-randomised design was chosen because the allocation and loci of delivery of the interventions (community clusters) are groups rather than individuals, and it is the gold-standard for evaluating the effectiveness of public health interventions (253). 48 study clusters were defined and randomly allocated to one of four possible intervention combinations using a two-by-two factorial design (Figure 4.1) (265). The whole district population benefited from basic health service strengthening activities for mother and child heath at all health facilities.

Figure 4.1: Study design – showing two-by-two factorial design and zone allocation



For the purposes of this thesis, the impact only of the women's group intervention will be evaluated. The final impact analysis of the MaiMwana study as a whole, requires complete data on both interventions, so this evaluation will focus on the details of the implementation and impact of the women's group intervention only. The primary outcomes for this intervention are maternal, perinatal, neonatal and infant mortality

rates and the secondary outcomes are morbidity rates and health behaviours such as use of health services and home care practices (Table 4.1).

The focus of the women's group intervention activities is on maternal and newborn care, and maternal and neonatal mortality are primary outcomes of the study. As early neonatal deaths are sometimes difficult to distinguish from stillborn infants that died during labour (34), perinatal mortality has also been included as a primary outcome. Furthermore, as neonatal deaths make up a large proportion of infant deaths (5), this was the main focus of the intervention, but intervention activities go beyond the newborn period and some impact on post-neonatal mortality may be seen. As such, infant mortality is another important primary outcome. Secondary outcomes were chosen as measures of behaviour change that might lead to impact on mortality rates (58, 60, 142). These were home care behaviours such as hygiene, malaria prevention and breastfeeding, as well as health-care seeking behaviours such as uptake of antenatal, delivery and postnatal services and seeking treatment in the case of illness. Outcomes will be compared between intervention and control areas in order to evaluate the impact of the interventions.

The time-line for the main phases of data collection and activities have been outlined in Appendix 2 – Background and Orientation, Phase I, Phase II and Phase III. The Background and Orientation phase included an in-house training workshop, community entry and consent, orientation to Mchinji, a participatory census, piloting for mapping and enumeration, zone demarcation and cluster definition. Phase I included formative qualitative research, mapping and enumeration of study clusters and population, and random allocation of clusters to interventions. Phase II was the design and implementation of a prospective surveillance system, including development of the research tools, recruitment and training, and coordination and management of data collection. Phase III was a re-census of all households in the study areas, and involved piloting, training and data collection and management. These phases will be described in detail in the following sections.

4.3.1 Primary research question

Will community mobilisation through women's groups reduce maternal, perinatal, neonatal and infant mortality rates through changes in care practices and health-seeking behaviour?

4.3.2 Hypothesis

Community mobilisation through women's groups will lead to: reductions in maternal, perinatal, neonatal and infant mortality, reductions in maternal and infant morbidity, and increases in recognition of high-risk symptoms, increased health-care seeking behaviour and changes in care-taker practices.

4.3.3 Study endpoints and outcomes

The study endpoints are shown in Table 4.1. The interventions were planned to run for two years from the date when they were hypothesised to start having an effect. We hypothesised that benefits of the intervention would start to be seen nine months after the start of intervention activities, such that newly pregnant mothers would have had the benefit of exposure to interventions throughout their entire pregnancy.

4.4 Methods

4.4.1 Setting

Mchinji district is one of nine administrative districts in the Central Region of Malawi (Figure 4.2). Topographically, the Central Region of Malawi is mainly a plateau, over 1000m high, and is the country's main agricultural area. Mchinji district lies to the west of Lilongwe and has international borders with Zambia and Mozambique. It covers an area of 3356 sq km and had a population of approximately 375,000 in 2004 and 457,000 in 2008 with a growth rate of 2.4 percent per annum (according to projections from 1998 census data) (61, 266). The district administrative centre is Mchinji Boma, the site of the MaiMwana Project office, but about 90% of the population of Mchinji live in rural areas and make a living through subsistence farming. The main crops cultivated

are maize, tobacco and groundnuts, though periods of drought in previous years have led to episodes of acute food shortage.

The geo-political organisation of Mchinji District is outlined in Figure 4.3. As of October 2004 the district has 7 Traditional Authorities (TA) and 2 Sub-Traditional Authorities (STA). Of the 9 TAs and STAs, 3 are Ngoni and 6 are Chewa. Within each TA or STA there are several Village Development Committees (VDCs), each governed by a Group Village Headman (GVH). 61 VDCs are officially registered with the District Commissioner. Each GVH is responsible for overseeing several villages. 447 villages are officially registered with the DC. Each village is led by a Village Headman.

The main ethnic group in Mchinji are the Chewa (90%). Other tribes found in smaller numbers are Ngoni (7%), Senga (2%) and Yao (2%). The national language used throughout Malawi is Chichewa, and this is the main language spoken in Mchinji. The predominant religion in Mchinji is Christianity (92%), but there are a smaller number of Muslims (3%) and followers of other religions (3%), mainly based in trading centres, and a small number who follow no religion (2%) (61).

Maternal and perinatal health care is provided by personnel from one government district hospital (a first referral and secondary health facility), four rural community hospitals (one government and three mission hospitals), one maternity unit, six health centres providing maternity care, and two dispensaries and two private clinics offering antenatal care. In 2004, Mchinji District Hospital was recognised as a Baby Friendly Hospital, and in January 2005, it benefited from the Global Fund expanded access to ARV programme. Services for Prevention of Mother to Child Transmission of HIV (PMTCT), including Voluntary Counselling and Testing (VCT) and Nevirapine (NVP), were introduced from 2005 and by 2008 basic PMTCT services had been expanded to all health facilities. Quality of the health service in Mchinji is compromised by a severe shortage of personnel, low morale, and irregular drug supplies (94). Traditional Birth Attendants (TBAs) are available and were used in all localities during the trial (although in 2009 the government banned TBA attended deliveries). At the start of this project, data from the 1995 Malawi Social Indicators survey suggested that 95% of women in Mchinji attended antenatal care at least once during their pregnancy, but less than 40% of women delivered at a health facility (267).

Figure 4.2: Map of Malawi showing Mchinji District

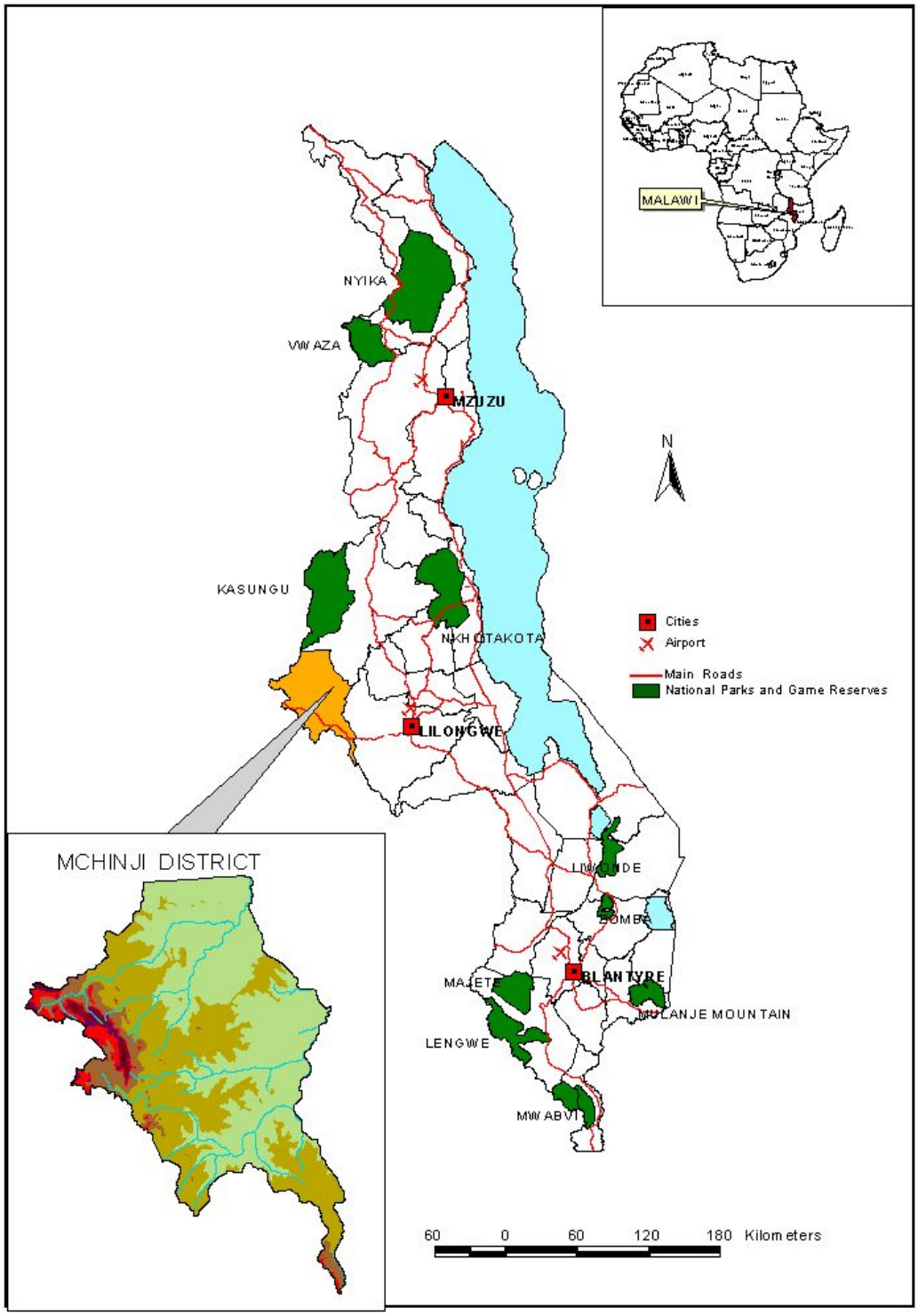


Figure 4.3: Geo-political organisation of Mchinji District

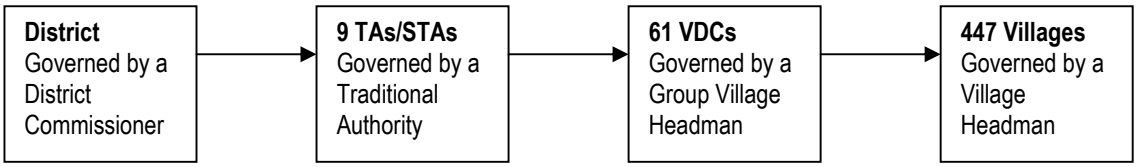


Table 4.2 shows how the population in Mchinji compares to the rest of Malawi on a number of key indicators.

Table 4.2: Socioeconomic and health indicators in Mchinji and Malawi

	Mchinji	**Malawi**
Poverty		
Human Development Index (out of 182 countries)	-	160
GNP per capita (US$)	-	690
Percent below $2 per day	-	90%
Education		
Female literacy (over 5 years of age)	46%	51%
Educational attainment – primary	60%	59%
– secondary	5%	8%
Health		
Access to improved water source	46%	45%
Access to sanitation	66%	53%
Total fertility rate (births per woman)	7.6	6.5
Crude birth rate (per 1,000 population)	55	50
Maternal mortality ratio (per 100,000 live births)	-	807
Infant mortality rate (per 1,000 live births)	65	72
Neonatal mortality rate (per 1,000 live births)	24	33

Sources: Malawi Population and Housing Census, 1998, Malawi DHS, 2004, World Bank 2006, State of the World's Newborns report 2001, UNDP 2009, MICS 2006

4.4.2 Target group and eligibility criteria

The target population for this study were rural communities with the least access to health services, who might benefit most from community-based interventions to improve maternal and child health. The district administrative centre was excluded because it is more urbanised than the rest of the district and therefore not comparable to other clusters. The target group for participation in both of the interventions was women of childbearing age (WCBA), between the ages of 15 and 49 years, and particularly pregnant mothers. Girls aged between 10 and 15 years were also monitored and encouraged to participate in interventions in order to identify and support early teenage mothers. Older women who were no longer childbearing were also encouraged to attend, as they influence decision-making around pregnancy, childbirth and childcare, and have valuable experiences to share (268).

All women aged 10 to 49 years (inclusive) who agreed to take part, were enrolled into the study, regardless of whether they were married or not. Women who had no

possibility of conceiving during the study period were enumerated but did not appear in the final sample, as they did not become pregnant (for example women who had hysterectomies or terminal family planning procedures). Participation in intervention activities was voluntary, and women's groups were free to establish their own membership criteria.

A cohort of 44,000 women aged between 10 and 49 years was defined during the baseline phase of the study, and each was visited monthly by study personnel. From the beginning of the study period all pregnancies, births and deaths occurring within the cohort of WCBA were identified, with follow-up until at least one year after delivery. The cohort members were listed in a master document to which new names could be added: the cohort is open and new participants were enrolled during the study period if they moved into the study area, or if they reached 15 years of age.

4.4.3 Intervention activities

The main activities and elements of the interventions are summarised in Table 4.3. Further details of the peer infant feeding counselling intervention are available in Appendix 3.

Table 4.3: Summary of activities in women's group and infant feeding and care counselling interventions

Women's groups	**Volunteer infant feeding and care counsellors**
Specific objectives	
Follow a participatory community mobilisation process to improve maternal and perinatal care	Make individual home visits to promote exclusive breastfeeding
Elements of the interventions	
The activities of 24 Zonal Facilitators (ZFs) are the key to this intervention. Each facilitator works within one zone, covering an average population of 3,000. She facilitates the activities of women's groups within the zone as they address the issues of pregnancy, childbirth, newborn and infant 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 activities of 72 Volunteer MaiMwana Counsellors (VMCs) are the key to this intervention. Three VMCs work within one zone, covering an average population of 1,000 each. Each VMC visits all pregnant mothers in her area 5 times – once before birth and four times after birth – to discuss the importance of exclusive breastfeeding, and to give support and advice on mother and child health. She also helps to identify any breastfeeding problems and refers them to a health facility.

The women's group intervention

The women's group intervention seeks to build the capacities of communities to take control of the mother and child health issues that affect them (263). The intervention is community based in that it defines the community as the agent of change (251). To achieve this, 24 local female facilitators (ZFs), one per cluster, were recruited and trained. The facilitators formed between six and 12 groups in their clusters and invited all women of childbearing age to attend. They guided the groups of women through a four-phase community mobilisation action cycle developed to be appropriate, accessible and feasible for the Malawian context from similar models in Bolivia and Nepal (Figure 4.4) (140, 269). In the first phase, consisting of eight meetings, the groups identified and prioritised the mother and child health problems they felt were most important and discussed what may contribute to these problems and how they might be prevented and managed. In the last meeting of this phase they shared their discussions with men in the community. In the second phase, consisting of four meetings, the groups planned locally feasible strategies to address the problems they had prioritised. In the last meeting of this phase they shared their discussions with the whole community. In the third phase, consisting of four meetings, the membership of the groups expanded to include all community members, including men, working together to implement the strategies that had been identified. In the fourth phase, four meetings, the groups evaluated what they had done and planned for the future. The facilitators received minimal health training but used participatory rural appraisal tools and picture cards to facilitate discussions and enable groups to access their collective knowledge and capacities. With these capacities the groups took increasing control of the intervention over the course of the cycle and did not receive any resources from MaiMwana Project except the guidance of the facilitator supported by four trained supervisors and a senior supervisor, employed by MaiMwana project.

A film called '*Umodzi*' (Together) was made in 2009, in which women and other community members in Mchinji explain the women's groups in their own words. A CD with a copy of this film has been included in the jacket of this thesis.

Figure 4.4: Women's group community mobilisation action cycle

Health service strengthening

This component was not evaluated through the RCT design described above as it was considered a requirement for all facilities in the District and not only those in intervention areas. Furthermore, as both interventions sought to increase demand for health services the supply of these services needed to be at an adequate level in order to have an overall improvement in health (175). Therefore strengthening of health service delivery was applied across the whole district and as a result is being evaluated separately through repeated health service audits. Health service strengthening was implemented in collaboration with the District Health Office. Health workers have been trained in Safe Motherhood, Essential Newborn Care and PMTCT by project staff and national facilitators, and a PMTCT programme was established at Mchinji District Hospital in 2004. From 2005, PMTCT services were extended to Kapiri, Mkanda,

Kochilira and Nkhwazi health facilities. By 2008, the services were also extended to the remaining health facilities at Guillime, Kapanga, Tembwe, Ludzi, Kaigwazanga, Mikundi and Chiwosha as well as ITES private clinic. Community-based volunteers will also be trained by national and district trainers to provide pre-test counselling with funding from the National AIDS Commission.

4.4.4 Sample size

The sample size for the cluster randomised controlled trial was arrived at by comparing statistical power for different estimates of population parameters related to primary outcomes. Parameters estimated included baseline mortality rates, the projected size of the reduction in maternal, neonatal and infant mortality and increase in exclusive breastfeeding rates due to the interventions, the number of births in each cluster over the trial period; the number of clusters in the intervention and control groups, the statistical power of the study, and the inter-cluster coefficient of variation (a measure accounting for the fact that people from within a cluster may be more similar to each other than people picked at random from across the study area) (253). Realistic values of some of these parameters were difficult to estimate, as few population-level mortality data were available at the start of the study, especially at district and sub-district level. The sources of data and values for these estimates are summarised in Table 4.4. We aimed to achieve the smallest sample size that would allow adequate power to detect an impact within a reasonable time-frame and would be logistically feasible to implement.

Initial sample size estimates were made using national estimates of crude birth rates from the Malawi DHS for 2000, subsequently revised after the results for the 2004 DHS survey were released (1, 2). Estimates were made with 80% power, a two-sided 5% significance level and an inter-cluster coefficient of variation (k) of between 0.15 and 0.30, using the methodology laid out by Hayes *et al* (Equation 1) (270) (271-273). An estimate of k=0.25 came from work on interventions to reduce HIV incidence rates (274), and later from work in Makwanpur, Nepal (22). We assumed that variability in neonatal, infant and maternal mortality between clusters would be less in rural Malawi, due to fairly uniform exposure to risk factors such as poor hygiene and poor quality or absent delivery care and endemic malaria. In addition, we reduced potential heterogeneity by excluding the main district administrative centre, as it was felt to be

socio-economically and demographically different from rural villages. In recognition of the lack of certainty for this estimate, sample sizes were calculated for a range of values of k.

Equation 1: $$c = 1 + (z_{\alpha/2} + z_{\beta})^2 [\pi_0(1-\pi_0)/n + \pi_1(1-\pi_1)/n + k^2(\pi_0{}^2 + \pi_1{}^2)] / (\pi_0 - \pi_1)^2$$

(Where c is the number of clusters required, $Z_{\alpha/2}$ and Z_{β} are standard normal distribution values corresponding to upper tail probabilities of $\alpha/2$ and β respectively, and π_1 and π_0 are the true (population) proportions in the presence and absence of the intervention, respectively.)

Using available estimates of crude birth rates and mortality rates, it was initially estimated that a sample size of 72 clusters with 150 births per cluster over two years (assuming a crude birth rate of 50 per 1000 population), would allow us to detect a 28-31% reduction in PMR, a 26-30% reduction in NMR, and an 18-24% reduction in IMR. On the basis of a reduction in NMR of 30% in a study in Nepal (22), this was felt to be a reasonable effect size for this study. However, in May 2004, after completing some background research into community size and organisation, it was decided to use 48 larger clusters rather than 72 smaller ones. The original plan had been to use VDCs as the unit of randomisation, but there were only 61 in the district, and they were of differing sizes. For logistical convenience and statistical efficiency, 48 equal-sized clusters were chosen instead (253). On this basis, the sample size calculations were revised, and maternal mortality was included as a primary outcome as evidence of the potential impact of women's groups on maternal outcomes was emerging (22). After starting the trial, sample size calculations were reviewed again in 2006, when the Malawi DHS report for 2004 containing new mortality estimates was released. (Revised parameter estimates and effect sizes are shown in Table 4.4.)

Table 4.4: Parameters used to estimate sample size, and the estimated effect sizes that would be detectable

Parameter	**Source of estimate**	**Original proposal** (2002)	**Revised design** (2004)	**Revised parameter estimates** (2006)
Number of clusters	Geopolitical subdivisions and logistical efficiency	72	48	48
Population per cluster	(Calculated)	1,500	3,000	3,000
Crude birth rate (per 1000 population)	National data from MDHS*	50	50	42
Time frame (years)	Funding period	2	2	2
Births per cluster within study period	(Calculated)	150	300	252
Inter-cluster coefficient of variation (k)	Hayes 1995	0.15-0.3	0.15-0.3	0.15-0.3
Statistical power of the study	Probability of Type I error Probability of Type II error	0.05 0.2	0.05 0.2	0.05 0.2
Perinatal mortality rate (per 1000 births)	National data from MDHS*	46	46	34
Size of reduction detectable	(Calculated)	28-31%	26-31%	29-34%
Neonatal mortality rate (per 1000 live births)	National data from MDHS*	42	42	27
Size of reduction detectable	(Calculated)	26-30%	24-30%	31-36%
Maternal mortality ratio (per 100,000 live births)	National data from MDHS*	-	1,120	984
Size of reduction detectable	(Calculated)	-	42-45%	47-50%
Infant mortality rate (per 1000 live births)	National data from MDHS*	104	104	76
Size of reduction detectable	(Calculated)	18-24%	18-26%	21-28%

* Malawi DHS (1) data used is the national estimate, as data were not disaggregated for Mchinji District

Interactions between the women's group and volunteer infant feeding and care counselling intervention

Through the two-by-two design, it will be possible to assess the interaction between the two interventions, though the study is not powered to evaluate the combined impact of the interventions on mortality compared to single interventions alone, as this would have required an unfeasibly large sample. We will explore qualitatively and quantitatively whether or not there is a synergistic relationship between the two interventions, resulting in an effect greater in magnitude than either intervention alone. We might expect that women in an enabling environment (provided by women's groups) would find it easier to discuss health issues and make health-seeking decisions for themselves and their babies than women in control areas where social barriers to care-seeking have not been addressed. More specifically, women in areas receiving both interventions might be more likely to use the Volunteer MaiMwana Counsellor and recognise the importance of her advice. More of these women may have decided to use

PMTCT services than those not receiving facilitation, and will therefore be in a better position to make informed choices about infant feeding and family planning based on knowledge of their HIV status. Conversely, individual visits made by volunteers to women in their homes may serve to reinforce messages and issues arising from women's group discussions.

4.4.5 Background and orientation

Community entry

Before beginning any work in the community, it was necessary to sensitize the relevant stakeholders at all levels to the aims and objectives of MaiMwana. The project team did three levels of sensitization starting with the Mchinji District Executive committee and Mchinji District Assembly, and followed by Area Development Committees and Village Development Committees. The main community entry activities took place during October 2003.

Mchinji District Executive Committee Sensitization Meeting

People from different government sectors and other non-governmental organisations working in Mchinji District were present at the meeting. The MaiMwana Team was led by Dr Charles Mwansambo, one of the project directors. The MaiMwana project study was presented in detail. At the end of this meeting the project was accepted into the district, and the District Commissioner signed a consent form to document this.

Mchinji District Assembly Committee Sensitization Meeting

The people present during this meeting were from different government sectors, chiefs, politicians, non-governmental organisations and other interested parties/ members working in the study district. At this meeting the MaiMwana study was also presented in detail. At the end of this meeting the project was accepted by the assembly and the Chairman of Mchinji District Assembly signed a consent form to document this.

Mchinji District Area and Village Development Committee Sensitization Meetings

The ADC and VDC sensitization meetings were done simultaneously, so that whenever there was a meeting for an ADC, members of the local VDCs were also present. People

from different community sectors, government sectors, political parties, and other NGOs within the TA's catchment area were also present. After each meeting a consent form was signed by the TA or STA, and also by each of the GVHs in attendance. Hence the project was accepted into all the communities of the district.

Cluster definition

Combinations of the interventions were to be delivered to whole communities rather than individuals, with the aim of evaluating their impact on maternal and neonatal mortality rates and other health indicators. Clusters needed to represent some kind of natural geo-political division and also be as similar in size as possible. The first in order to have a cohesive community in which the interventions could work well and potential communication of information to the surrounding non-study villages would be minimised, and the second to minimise the coefficient of variation of cluster size and maximise statistical power (275). In order to define such clusters it was necessary to collect sub-district level population data. However, data on district population broken down by geo-political units such as Traditional Authority (TA), Village Development Committee (VDC) or village was not available from the District Commissioner, and data from a preliminary MaiMwana participatory census (in which community leaders were asked to provide village household lists), proved to be inaccurate. Finally, it was decided that extrapolation from NSO census data might provide the most accurate area-based population estimates.

A list of villages used for the 1998 census was obtained from the National Statistics Office (NSO). However, this list of villages did not correspond well to the list of villages kept by the District Commissioner (DC), and in trying to locate these villages on the ground it was discovered that many of the villages on both the DC's list and NSO list were either no longer in existence, had changed names, had merged with other villages, or were newly formed (often split from bigger villages) so were not on the lists. This made it difficult to allocate population information to any particular geographical area, so instead of using the village-level population data, population data for the Enumeration Areas (EAs) was used. (Only 9 TA areas exist in Mchinji, so TAs could not be used as the geo-political unit of randomisation.) Together with a cartographic NSO map showing TA and EA boundaries, geographical features, roads and some of the larger villages, 48 areas were demarcated, roughly following the

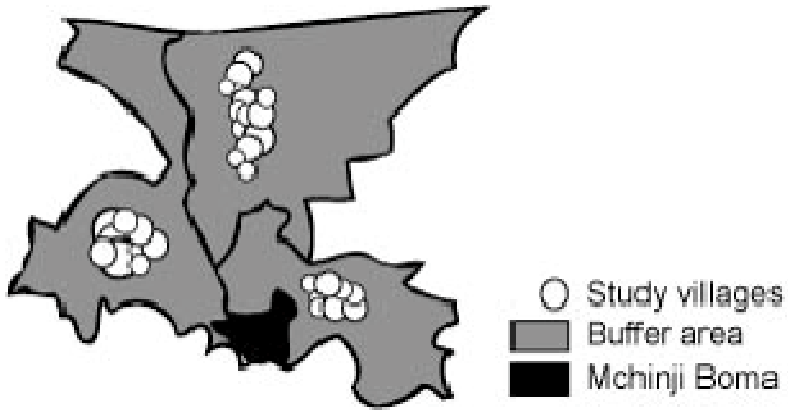
boundaries of currently existing VDC areas (equivalent to Group Village Headman (GVH) areas whose component villages are recorded with the DC).

The total population for the district in 1998 was 324,876 covering 302 EAs and was estimated to have grown to 376,757 by 2004 (after 1998 population figures had been adjusted for an estimated population growth of 2.5% per annum (61)). The average population for an EA was 1,076 in 1998 and was estimated to be 1,248 in 2004. A population of 13,305 (2004 estimate) from 9 EAs was excluded because they were in the district administrative centre, which was felt to be socio-economically and culturally different from the rest of the district. The remaining 293 EAs were then allocated to 48 'zones' on the basis of contiguity with other EAs in the zone and the presence of villages in the EA known to belong to the same VDC as other villages in the zone. Each of these zones comprised about 6 EAs and covered a population of approximately 7,600 (2004 estimate). Figure 4.5 shows the EAs for Mchinji (thin lines) and the study zones that were demarcated (thick lines).

After demarcating the zones the next stage was to identify a population of 3,000 in each zone to make up the study 'clusters'. Rather than selecting villages at random from each zone it was decided that a 'buffer area' surrounding the perimeter of the zone would be maintained and only villages at the centre of the zonal area would be eligible for inclusion in surveillance and intervention activities (Figure 4.6). This was intended to reduce contamination between study clusters due to interactions between people in neighbouring villages. Selection of central cluster villages was done by identifying a village in the centre of the area that appeared both on the NSO map and the DC's list of villages, then enumerating the households and population in that village, then going to the neighbouring village and enumerating it and then continuing to add and enumerate villages in a spiral around the first village until a total population of approximately 3,000 had been reached. Selection criteria for picking the villages were: proximity to previously mapped village (as reported by members of the community); falls within the perimeter of the zone; belongs to the same GVH as the first village. This process left buffer zones of roughly 4,600 population around each cluster.

Figure 4.5: Map of Mchinji District showing enumeration areas and demarcation of 48 study clusters

Figure 4.6: Study villages and buffer areas in three clusters near Mchinji Boma



4.4.6 Phase I – Formative research, mapping and enumeration of study clusters and random allocation to interventions

Formative qualitative research

Formative qualitative data were collected through semi-structured interviews and focus groups. These data were collected with the specific purpose of: a) exploring current care practices to help to develop the structured questionnaires and interviews; and b) exploring the aims, setting, target population, methods and resources of the interventions to assist in their development.

Mapping and enumeration

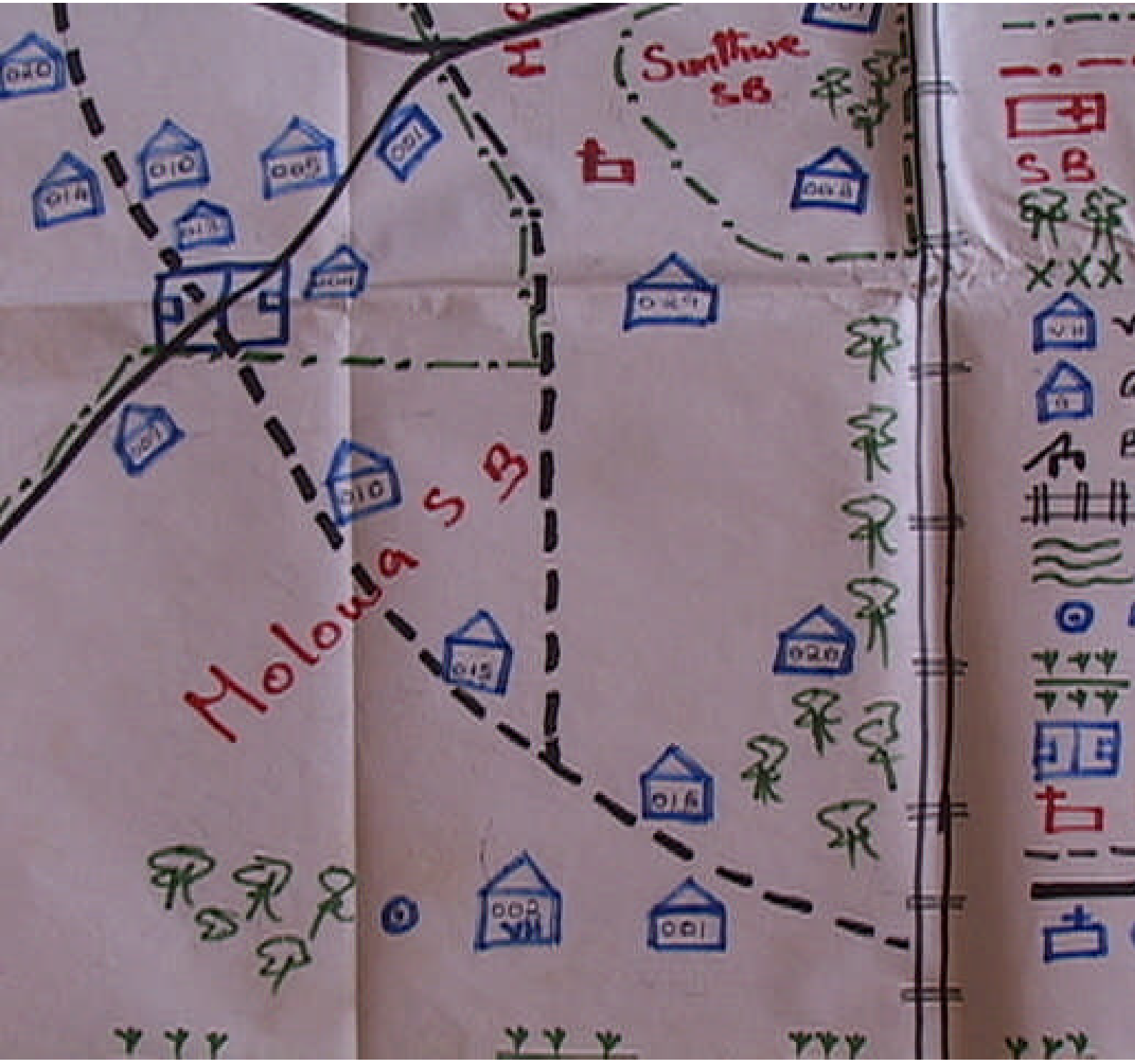
During Phase I (the baseline phase), a baseline census and survey was conducted before the interventions began in order to define the study population and to make comparisons between clusters. This also enabled the generation of a list of all women of childbearing age living in the study areas for use in the prospective pregnancy and birth surveillance. Enumeration involved mapping the village, numbering each household and then administering a short questionnaire to identify the total number of household members and women of childbearing age.

80 Field Interviewers (FIs) were recruited and trained in mapping and enumeration. The training took place in two groups, with each group attending a residential training workshop at a rural training centre for two weeks. Interviewers were trained in

interviewer skills, methods of data collection, mapping, negotiation skills and team building. In addition to classroom sessions, all interviewers were taken to nearby (non-study) villages to practice their mapping and interviewing skills. These practical sessions were observed by a supervisor and technical advisor, and suggestions were made during feedback sessions afterwards. Questionnaires were also modified to ensure clarity of questions.

A team of 3 or 4 FIs was allocated to each zone, and supervised by a Monitoring and Evaluation Officer, based in one of four nodal offices. Each zone was given a number from 01 to 48 and each village in each zone was given a number from 01 to 34 (depending on how many villages were in the zone). The team of FIs visited each village, meeting with the village chief and his or her advisors to seek permission to map the village. A group of between seven and ten villagers was gathered, including members from different sectors of the village, representing men, women and people of different age groups. The FIs and villagers drew a sketch map of the village using participatory rural appraisal techniques and marking major roads, minor roads, footpaths, rivers, health facilities, schools, bore holes and wells, the chief's house and other important features. Boundary features such as rivers or neighbouring villages were named. The FIs and village members then walked the boundaries of the village together, and community members acted as guides, helping in the identification of households. Large villages were divided into sections using footpaths, roads, rivers and gardens as markers. Each house was assigned an ID number (from 001 to 999, depending on how many households were in the village), which was marked on the door with chalk. No objections were made to houses being marked with chalk. The first and last house in a section and every tenth household was indicated on the map (see map section in Figure 4.7). One FI concentrated on drawing the map, while two other members of the team followed the mappers through the village and visited each household to collect basic data on household socio-economic status and household occupants (see Appendix 4 for an example of the Woman Enumeration Form). This data was then entered into a study database and used to generate a complete list of all of the women of childbearing age living in the study clusters.

Figure 4.7: A detail from a village map drawn during the baseline census



Problems faced during the mapping an enumeration included boundary disputes between chiefs, transport and allowance arrangements for FIs, fear of witchcraft and traditional ‘nyau’ secret society members, respondents adding extra household members (especially females) who were not resident (e.g. moved out and married elsewhere),

enumerating ‘gowelos’ (boys hostels) twice as if they were two separate households and using several different names. These issues all led to the possibility of an inflated or inaccurate number of households and household members.

During the baseline phase some geographic coordinate data was also collected for each village by the field supervisors, using hand-held global positioning system (GPS) units. And in addition to the quantitative data, qualitative data was also collected through focus group discussions and key informant interviews in order to learn more about existing care practices and community understanding of neonatal care, and to inform development of the interventions and the structured interview tools. Semi-structured interviews and focus group discussions were conducted, and some Participatory Rural Appraisal methods were used to facilitate discussion. Key informant interviews were held with health workers, TBAs, traditional healers, chiefs, and other NGOs operating in the district.

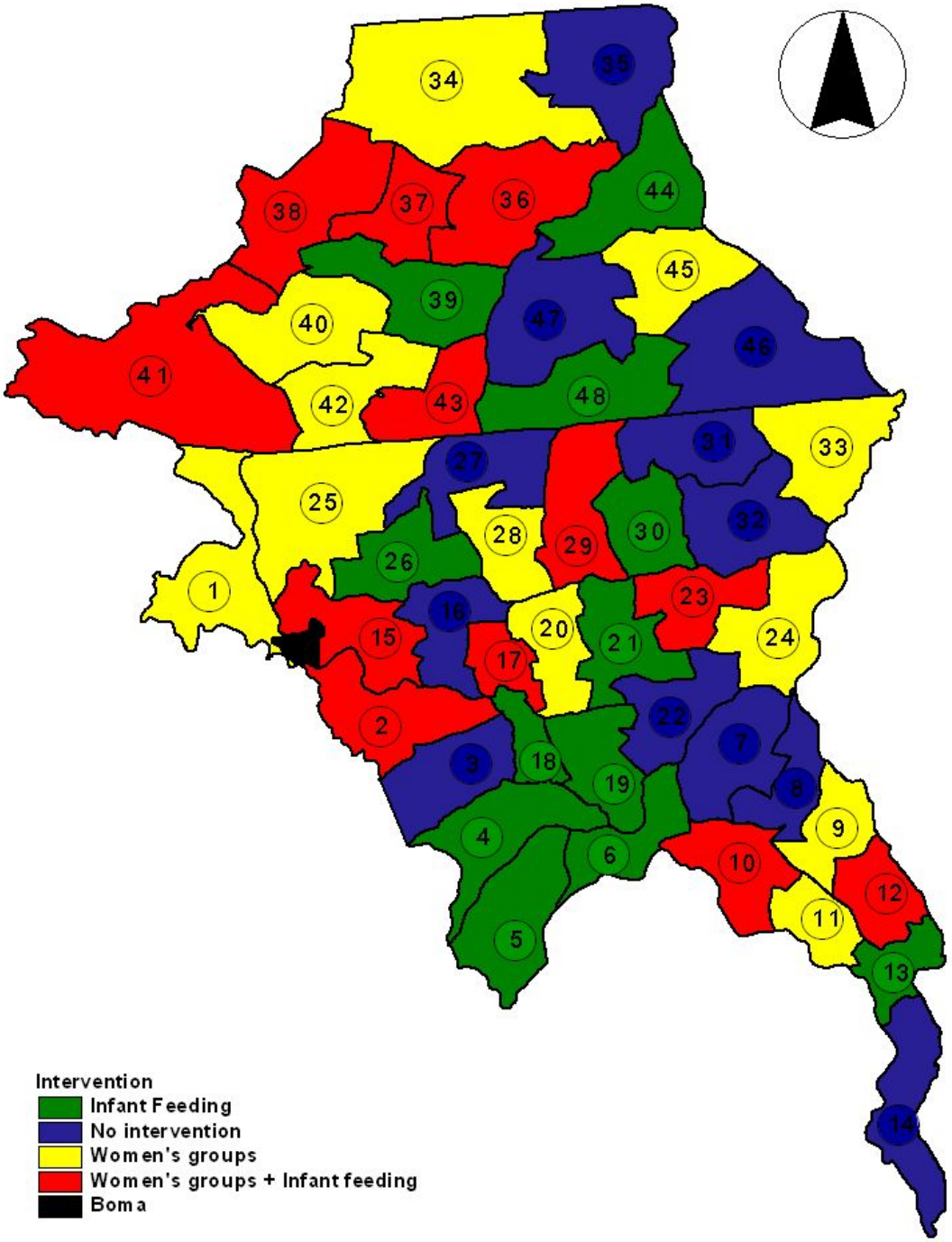
Randomisation and allocation

After dividing the district into 48 zones and mapping and enumerating them, these zones were then randomly allocated to one of four groups; 12 zones receiving infant feeding counselling and women’s groups, 12 zones receiving women’s groups only, 12 zones receiving infant feeding counselling only, and 12 zones receiving neither intervention (Figure 4.1). Figure 4.8 shows the geographical pattern of random allocation according to the 48 zone demarcations. In this way, each intervention was stratified according to the presence or absence of the other one, in order to balance any effects of one intervention on outcomes of interest in the other. Random number generation was done in STATA 7.0. All women aged between 10 and 49 years residing within the clusters were eligible for inclusion in the interventions and follow-up of maternal and child health outcomes. Records of a woman’s migrations within and outside of the study area are recorded in order to allow for standard ‘intention to treat’ analysis (women who were allocated to the intervention), as well as ‘per protocol’ analysis (women who actually received the intervention) and other levels of exposure (157, 255).

Due to the nature of the interventions, blinding of study participants to their allocation was not possible (276), though analysts and trial monitors were blinded to the study

allocation until the definitive analysis was performed. Data was collected independently from intervention implementation, and no results were fed back to inform the interventions.

Figure 4.8: Random allocation of zones to four different combinations of intervention



4.4.7 Phase II – Prospective surveillance

Data on the main primary and secondary outcomes were collected prospectively in order to reduce the possibility of recall errors and biases affecting the results. Phase II prospective surveillance data collection started in December 2004 and is still ongoing. In Phase II, two main types of data are being collected; vital events data and structured interview data about pregnancy, birth and child care practices. The WCBA list from the baseline enumeration is used to make monthly 'registers' listing all women in each cluster by village. 48 women enumerators (WEs) were recruited (one WE per cluster), and trained in the process of identifying and recording any pregnancies occurring within their cluster. WEs visit each woman of childbearing age (WCBA) in her area once per month and ask about the menstrual status of each female member of the household and record it in her register. She also asks about births, deaths and in- and out-migrations. A weekly summary is submitted to the field interviewer (FI) for that zone for verification, and a monthly summary is submitted to the nodal supervisor.

Structured interview data is collected from mothers at one month and six months after delivery. The general content of each questionnaire is outlined in the section below on Data Collection Tools. The qualitative information collected during the background and baseline phases was used to develop these structured questionnaires, and questionnaires were initially piloted by the monitoring and evaluation supervisors, and then piloted further during the training and orientation of a new group of 48 FIs (one per cluster). FIs visit each woman at one month and six months after giving birth. They ask a series of questions relating to antenatal care, delivery care, postnatal care, care of the baby, breastfeeding practices, sexual health and relationships, and any maternal or neonatal problems encountered. In the case of a maternal, perinatal or neonatal death, a verbal autopsy interview is conducted by the monitoring and evaluation supervisors, who were trained to probe carefully for the details, timing and duration of all signs and symptoms of illness that led to the death. This data is then sent to a team of physician reviewers to establish the probable cause of death. (See Appendix 4 for an example of the one-month questionnaire and perinatal verbal autopsy. Specific data from the maternal verbal autopsy was not used for this research, apart from date of death.)

For the purposes of trial follow-up, data was first frozen for review after two years of intervention - at the end of July 2007 for the infant feeding intervention and the end of February 2008 for the women's group intervention.

A summary of the main study procedures is outlined in Table 4.5.

Data collection tools

All data collection tools were extensively researched, and were developed using tools and experiences from similar studies in Nepal and Malawi (1, 22, 267, 277). Questionnaires were piloted and modified until data collectors and supervisors were comfortable with the format, content and flow of questions. Questionnaires were written in Chichewa, but were back-translated to English by independent staff members to ensure validity. The first period of questionnaire development and piloting took about three months. Decisions about when and what to ask affected development of questionnaires. For example, an interview to expectant mothers at 7-months of pregnancy was abandoned because it was felt that most of the questions could be asked at the time of a scheduled 1-month interview, and this would consequently reduce the number of contacts with participants, and hence the burden on their time. A comprehensive retrospective survey to collect baseline indicators of mortality and behaviour was also abandoned because it was not felt necessary given the randomised design of the study, and the inclusion of a birth history section in the prospective tools.

Prospective data relevant to the evaluation of the women's group intervention presented in this thesis were collected in two ways:

1. Neonatal and maternal mortality surveillance

To assess the impact of the interventions on mortality, all women of childbearing age (WCBA) were visited monthly to identify pregnancies, births, stillbirths and neonatal and maternal deaths. WCBA were visited by trained women enumerators (WE) once a month and events were recorded in a register holding an up-to-date list of all women of childbearing age in the cluster (generated from the baseline survey, plus new residents) (Table 4.6). One enumerator visited all WCBA in one cluster.

Table 4.5: Study procedures and time-line

Time	Procedure		
October 2003	1. *Community consent obtained* by senior staff members who explained the purpose, procedures, risks and benefits of the proposed study at district and sub-district level meetings		
July 2004	2. *Baseline census and survey* to enumerate all households and WCBA in the study areas and obtain basic demographic and socioeconomic information was conducted between July and September 2004		
November 2004	3. *Random allocation of zones* to "women's group" or "no women's group" and "infant feeding" or "no infant feeding" was done in November 2004		
December 2004 and ongoing	4. *New women* moving to study area or reaching 10 years of age[1] are prospectively enlisted	5. *Monthly pregnancy surveillance* is carried out by local Woman Enumerators, who detect and notify of new pregnancies (defined by two consecutive missed menses and two other reported signs of pregnancy).	6. *Birth notification* is typically within 1-week of birth to the Field Interviewers and within 1-month of birth to the supervisors
January 2005 and ongoing	7. *One-month post-partum interviews* are carried out with consenting women by a trained Field Interviewer, if the mother and infant both survive until 1-month postpartum, to obtain data on demographic details, reported health behaviours, health-care seeking and morbidity and other risk factor data on mothers and their infants	If mother or baby dies: 8. *Maternal and stillbirth/neonatal verbal autopsy interviews* are conducted with consenting women or relatives by trained M&E supervisors, if a mother has died during pregnancy or within 6-weeks of delivery or an infant is stillborn or dies within 4 weeks of birth, to elicit information that can aid in discerning causes of death. Two physician reviewers independently assign primary and contributory causes of death, and discuss any cases where they have disagreed until a consensus is reached	
	9. *Volunteer MaiMwana Counsellors* visit all pregnant women in their zones once before birth and four times after birth to give advice and support on family planning, PMTCT and birth preparedness, and also offer support regarding breastfeeding problems		
May 2005 and ongoing	10. *Women's groups meet* once per month (or less often depending on season) and discuss maternal and neonatal problems, contributing factors, strategies and actions		
June 2005 and ongoing	11. *Six month post-partum interviews* are carried out with consenting women by a trained Field Interviewer, if the infant survives until 6-months postpartum, to obtain information about infant morbidity, feeding practices and health-care seeking and other risk factor data on mothers and their infants		
May/June 2008	12. *Re-census of households in study areas* to re-enumerate all households and WCBA and collect information on in- and out-migration and births and deaths of women and children.		
April/June 2009	13. *Infant follow-ups* were carried out for all children born from 1st January 2005 in order to verify their status and collect basic details for children who have died or moved out. This data will be used for estimates of infant mortality.		

[1] Surveillance of girls is started from 10-years old as it is an open cohort and new participants can be enrolled as they reach 15-years of age and also so that early teenage pregnancies can be captured.

All deaths of women and infants were followed up by a monitoring and evaluation supervisor (MEO), who verified whether they were stillbirths, neonatal, infant or maternal deaths or not through a structured verbal autopsy interview conducted between two and six weeks after the death. This interview sought to elicit the causes and contributing factors of the deaths (86). There are five supervisors each based at a nodal office.

Table 4.6: Surveillance tools and content

Tool	Administered by	Content
Register	WE	An up-to-date list of all WCBAs in the cluster with space for WE to write an event code. Events include: pregnancy, birth, death, transfer out of area, etc
Maternal verbal autopsy	MEO	Questions from 1-month questionnaire (see below) plus: questions on details of illness, open history and optional health worker module
Neonatal verbal autopsy	MEO	Questions from 1-month questionnaire (see below) plus: questions on details of illness, open history and optional health worker module

2. Morbidity, care practices and behaviours

To assess the impact of the interventions on morbidity, care practices and behaviours, women who were identified as pregnant were followed up until 6 months after birth by trained field interviewers (FIs). Interviewers administered one-month and six-month post-partum interviews to collect detailed information about demographic characteristics, maternity history, health-seeking behaviours, care behaviours and maternal and infant morbidity (Table 4.7).

Table 4.7: Health care seeking and health behaviour data collection tools and content

Tool	Administered by	Content
1-month questionnaire	FI	Mother: Mother and father's demographic information, birth history, antenatal care, uptake of PMTCT, delivery details, maternal illness during pregnancy, delivery and post-partum, health seeking behaviour, family planning and relationship history, exposure to interventions Infant: Birth details, newborn care practices, feeding history, infant illness, health seeking behaviour
6-month questionnaire	FI	Mother: Use of ITN, uptake of VCT, maternal illness and breast problems, health seeking behaviour, family planning and relationships, exposure to interventions Infant: Vaccinations, feeding history including details of weaning, infant illness, health seeking behaviour

4.4.8 – Phase III – Re-census

In order to triangulate and verify prospective mortality data, and collect more complete information on infant and under-five outcomes, a re-census of all households was conducted in May and June 2008. An additional 96 FIs were recruited and trained, giving a total of 144 (3 FIs per zone). Lists of all enumerated households in the study areas were produced and FIs enumerated any additional households that had been missed during the previous census and continuing prospective enrolment. They visited each household and collected information about any members who had migrated into or out of the household since the last census. Details of ownership of a new set of household assets were also collected to cover a more comprehensive range than during the first survey. FIs then generated a list of all female household members, and elicited further details of any deaths or migrations. Birth histories of all women-of-childbearing age were collected in order to calculate child mortality rates, and retrospective maternal mortality data was collected using sisterhood methods (39, 278) in order to compare rates produced using different methodologies.

4.4.9 Data management, quality control and trial monitoring

Data management

All quantitative data collected was delivered to the main office for data entry in a relational database management system in Microsoft Access run on a dedicated server and workstations. Each WCBA was given a unique ID number generated from the cluster, village and household she comes from. All quantitative data from the mortality surveillance, morbidity, care practice and behaviour questionnaires was linked to the WCBAs through this unique ID. After checking and entry, all questionnaires were archived in a locked room for future reference.

Quality control

One enumerator per cluster identified births and deaths, and each event was crosschecked by one interviewer. Supervisors made regular field visits to check the quality of work done by enumerators and interviewers and observe some interviews. Each supervisor is responsible for between six and ten clusters. Interviewers meet with

enumerators weekly in order to check on their work and receive updates on births and deaths in their area. Supervisors meet with interviewers and enumerators fortnightly to check on their work, discuss problems and provide quality control feedback. A sample of 200 one-month and six-month interviews was selected to be independently re-done by the supervisor, in order to be able to estimate recall and interviewer error rates.

Quantitative data was checked in three stages. The first check was performed after completion of the questionnaire, by the supervisor and a nodal data checker based at one of the five nodal offices. The second check was done by a team of two data checkers based at the main office. The last stage of data checking was done at the point of data entry by the four data entry clerks. Further checks were carried out internally within the electronic data-handling environment, and measures to ensure the quality of data entered were taken. Due to the complex nature of the database and practicalities of handling such a large volume of data, it was not possible to do double-entry of all questionnaires to check for data entry and key-stroke errors. However, extensive data cleaning exercises have been done in order to check key variables such as ID numbers and dates of birth and death. This has mainly involved consistency checks and manual comparison of records with the original paper questionnaires. Data entered into the study databases were regularly reviewed for inconsistencies and missing information. Lists of women interviewed and key fields to be verified were produced, such as ID numbers, dates of birth, and reported pregnancies, births or deaths that had received no further follow-up. In the event of errors, omissions or discrepancies in data, a log was made of the nature of the error and the form was sent back to the data collection person responsible for verification and correction.

Data is regularly reviewed to check for more general problems. These reviews include: identification of reported pregnancies, births or deaths that had no further follow-up with no reason given; identification of infants visited at one-month post-partum but not visited again at six-months; comparisons of birth rates across all 48 zones to check for under- or over-reporting by particular field-workers; comparisons of maternal and neonatal deaths (not rates) across all 48 zones to check for over- or under-reporting by particular supervisors; comparisons of birth rates and deaths across all villages to make sure all villages are being visited by field workers; monitoring reporting trends in each zone over time to check for consistency of reporting; identification of births and deaths

that received an interview, but had not been reported through the surveillance (to look for problem areas in surveillance and reporting); average time delays between birth and interview for each interviewer or death and interview for each supervisor.

Dealing with loss to follow-up

Minimising loss to follow-up is an important aspect of trial conduct. Certain features of this location and population dynamic needed special attention for outcome tracking: a) Residents of Mchinji move seasonally to maximise their access to fertile land during the farming season, both within the district and across international borders into Zambia and Mozambique; b) Residents of Mchinji may go home for delivery and some time after birth (to other villages within Mchinji or to other districts); c) Non-residents may come into Mchinji from other districts for delivery and some time after birth; d) Families may move after a woman's death, making it difficult to find respondents who know the details of what happened; e) High population turnover in trading centres and commercial farm estates; f) Women being busy working in their gardens, or at community gatherings such as funerals and chieftainship ceremonies, making them unavailable for interview; g) Weather conditions making roads impassable and conducting interviews difficult.

For residents or respondents who are temporarily unavailable, the main strategy is to keep following up until an outcome is ascertained. All women who have ever lived in the study areas are maintained in the database, and appear every month in the register. Any events (such as pregnancy or birth) that are reported but no further details are known, are selected and lists produced to remind field-workers of the need for follow-up. In most cases this causes delays in getting complete data, though basic data for estimating mortality rates are still available. In recognition of the fact that certain data collected after a long delay will no longer be valid, sections in the questionnaire (such as infant feeding recall) are skipped.

For residents or respondents who are permanently unavailable, basic information about dates and timings of events is sought from other community members such as friends or neighbours.

Reducing contamination

Contamination may occur when people from one cluster have contact with people from another. In the rural villages of Mchinji, there are many opportunities for social mixing. Friends, relatives or neighbours may mix socially, or contact may be made through travel or migration between intervention and control clusters. There might be direct participation of residents from control areas in intervention activities, or more likely, informal discussion of ideas arising from intervention activities – control area residents may gain some benefit from hearing health messages received by intervention participants. The usual effect of this kind of contamination would be 'dilution' of the differences between treatment arms (253).

In order to reduce the possibility of contamination, we opted to use clusters of villages rather than individual villages as the unit of randomisation, thus reducing rates of travel across cluster boundaries (253). Furthermore, each zone had a defined 'buffer area' around the perimeter (Figure 4.6). A population of 3000 in each zone was required to achieve the desired sample size, but rather than selecting villages at random from each zone, only villages at the centre of the zonal area were eligible for inclusion in surveillance and intervention activities. This reduced the possibility of communication between neighbouring study villages in intervention and control areas.

Women's group facilitators and volunteer counsellors are residents of the zone in which they work. This reduces the possibility that they might transfer intervention benefits to neighbouring communities. For the women's group trial, whilst health messages are discussed in group meetings, it is unlikely that neighbouring control communities would spontaneously mobilise themselves without the presence of a facilitator. So the hypothesised benefits of community empowerment and social capital are unlikely to spread beyond intervention areas.

Trial monitoring

An independent Data Safety and Monitoring Board (DSMB) met four times during the trial to review progress and advise on the conduct of the trial according to the DAMOCLES statement (Box 1) (279). They first met in June 2007 and assessed compliance with the protocol, data quality and completeness, recruitment figures, sample size assumptions and ethical considerations. The DSMB met again in October

2008, and the panel recommended extending the women's group trial by an extra year (to 31st January 2009) in order to allow for completion of intervention activities which had faced unexpected delays, and re-census data processing. The final review of trial data was held in March 2010.

Box 1: Aims of Data Safety and Monitoring Board meetings

To independently:

- assess data quality, including completeness
- monitor recruitment figures and losses to follow-up
- monitor compliance with the protocol by participants and investigators
- monitor trial conduct – organisation and implementation of trial protocol
- suggest additional data analyses
- advise on protocol modifications suggested by investigators (e.g. to inclusion criteria, trial endpoints, or sample size)
- monitor planned sample size assumptions and review the plan for analysis of primary and secondary outcomes
- advise on safety issues
- consider the ethical implications of any recommendations made
- assess the impact and relevance of external evidence

4.4.10 Statistical analysis

Interim analyses and stopping rules

Interim DSMB meetings did not include analysis of outcome data by intervention allocation until completion of the trial because the study interventions did not involve medications and no significant safety issues were implicated, and because unplanned interim analyses would have reduced the power of the study. Baseline data were reviewed to evaluate how well balanced the clusters were after randomisation and suggestions were made for any adjustments that may needed to be made. We did not foresee any adverse effects of community mobilisation or peer counselling, so we did not apply stopping rules.

The trial was planned for 3 years, and was powered for a 2-year analysis of birth outcomes, after allowing a period for the intervention to be established. Analysis was by intention to treat at cluster and participant levels, and the significance of the intervention effect on primary and secondary outcomes was tested on the basis of previously agreed hypotheses.

Sample

Surveillance began in December 2004 and is ongoing. The infant feeding intervention started in January 2005 and the women's group intervention started in May 2005, but the effects of both interventions are not expected to have been apparent immediately. For the women's group intervention only births to women who had been exposed to the intervention for the whole of their pregnancy will be included in the final analysis, hence, the first months of surveillance are considered as a prospective baseline phase. Trial end-points for the women's group and infant feeding interventions are 31st January 2009 and 30th June 2008 respectively.

For the purpose of this thesis, data for all women who were pregnant and gave birth between January 2005 and February 2009 will be used. For analysis of the impact of the women's group intervention, data for births between 1st February 2006 and 31st January 2009 will be included.

Inclusion criteria

All women enrolled in the MaiMwana surveillance system who had pregnancies ending (with a live birth, stillbirth, neonatal death, infant death or maternal death) between 1st January 2005 and 31st January 2009 and who agreed to take part in the study.

Exclusion criteria

Women not enrolled in the MaiMwana surveillance system, women who had pregnancies ending before January 2005 or after January 2009, and women who had pregnancies ending in miscarriage (but the mother survived). Mothers or infants for whom month and year of birth and/or death were not known were excluded from analysis, and mothers or infants who died for whom classification according to the categories stillbirth, neonatal death, infant death or maternal death was not possible due to missing details in verbal autopsy were excluded from analysis of specific mortality outcomes. Infants were not classified according to exclusive breastfeeding status if data were collected more than 2-weeks after the scheduled time, as feeding recall data were considered unreliable.

Datasets used

Several datasets were used for the purposes of the analyses in this thesis. They are described in Table 4.8 below. Data collected for the first six months of the surveillance system, before the intervention started, was used to provide baseline estimates of mortality and other behavioural characteristics. This dataset, collected between 1st January 2005 and 30th June 2005 is known as the 'prospective baseline'.

Table 4.8: Datasets used for analyses presented in this thesis

Dataset	Use for PhD	Source	Data collection phase
Baseline household census	To explore variability in demographic and socioeconomic characteristics between zones before the interventions started in order to evaluate success of randomisation	Baseline survey	July to September 2004
Newly enumerated households	To explore variability in demographic and socioeconomic characteristics between zones before the interventions started in order to evaluate success of randomisation	Prospectively enrolled households	1st January 2005 to present
Prospective baseline data	To explore variability in primary and secondary outcomes between zones before the interventions started in order to evaluate the success of randomisation	Prospective surveillance system	1st January 2005 to 30th June 2005
Trial period mortality data	To evaluate impact of the intervention on maternal, perinatal and neonatal mortality	Prospective surveillance system	1st February 2006 to 31st January 2009
Trial period secondary outcome data (1-month outcomes)	To evaluate impact of the intervention on secondary process and behavioural outcomes at 1-month postpartum	Prospective surveillance system	1st February 2006 to 31st January 2009
Trial period secondary outcome data (6-month outcomes)	To evaluate impact of the intervention on secondary process and behavioural outcomes at 6-months postpartum	Prospective surveillance system	1st February 2006 to 31st January 2009
Re-census data	To evaluate impact of the intervention on infant mortality	Retrospective re-census survey	May to June 2008
Cluster-level characteristics	To adjust for cluster-level characteristics and imbalances	Survey of field workers and cluster-level medians, means or proportions derived from other datasets	1st January 2005 to present

Baseline comparisons

Descriptive statistics were used to present baseline demographic and socioeconomic characteristics of the study population. Principal components analysis (PCA) of household asset data was done for the dataset containing all households enrolled in the

study, and each household was given a socioeconomic score which was then used to divide the sample into quintiles (280).

The prospective baseline dataset was used make crude comparisons between intervention and control areas on several key socioeconomic and demographic characteristics, baseline mortality rates and baseline behavioural and process outcomes. Numbers, rates and proportions were derived, but statistical tests of significance were not performed as the null hypothesis must be true at baseline, and any differences are either due to chance or flawed randomisation (52). This was done in order to describe the characteristics of the trial participants to assess generalisability of the results, to check that the randomisation had led to balanced groups and to identify variables that might be strongly related to the outcomes.

Maternal and stillbirth/neonatal verbal autopsies were reviewed independently by two paediatricians. They assigned a cause of death, as well as any indirect or underlying causes of death using classification systems adapted from the Neonatal and Intrauterine death Classification according to Etiology (NICE) and Wigglesworth (for perinatal and neonatal deaths) and WHO (maternal deaths) (28, 281-284). They indicated whether or not the death could have been prevented, and named any 'avoidable' factors. Available data on causes and timing of death was explored, although cause-specific data was not available for maternal deaths. Exposure to the women's group intervention and factors related to participation were also explored.

Intervention impact

Primary and secondary outcomes were defined prior to analysis by intervention allocation. These are outlined in Table 4.1 and definitions are given in Appendix 1. All analyses were conducted in Stata (version 11.0 for Mac), MLwiN (version 2.18) and SPSS (version 18.0 for Mac), and impact was measured using odds ratios with 95% CIs.

Descriptive analysis

After data cleaning, range checks, consistency checks and removal of severe outliers, data collected during the trial period were explored through descriptive analyses looking at distributions of exposure and outcome variables, and trends in means and standard deviations. Univariate analyses were carried out in order to examine the

relationship between the primary mortality outcomes and each exposure of interest. This was done using simple two-by-two tables, and cross-tabulation (52). Univariate logistic regression with random effects (to adjust for clustering of data by zones) on individual-level data was done to explore the association between exposures and outcomes. In particular, relationships between primary mortality outcomes and maternal age, education, marital status and socioeconomic quintile were explored.

Unadjusted analysis

The association between the main exposure (allocation to women's group intervention or not), was explored through univariate logistic regression with random effects on individual-level data, adjusting only for clustering and stratification by the infant feeding intervention) (253, 265, 285). Analysis was done by intention-to-treat at cluster and individual levels, where a woman's exposure group was assigned according to the allocated intervention in the place of residence at the time of delivery.

Adjusted analysis

Multivariable logistic regression with random effects was used to estimate the impact of women's groups after adjusting for potential confounding variables. Confounding variables were selected on the basis of previous evidence of their association with study outcomes, and their inclusion in the model was explored to investigate their effects in this population (52). Exploratory analyses considered the effects of including individual and cluster-level socioeconomic variables, distance from health facility, maternal age, education, literacy, parity, tribe, religion and occupation (5, 25, 73, 94). The effects of including baseline values were also explored to adjust for any imbalance between study arms at baseline (253). Factors that were on the causal pathway, (e.g. health behaviours such as health facility delivery) were not adjusted for (52). Analysis of outcomes only in years 2 and 3 was also conducted in order to make the potential impact more concentrated by excluding data from the first year when the intervention was just being rolled out, although this was not an *a priori* analysis plan. The number of individuals differed slightly for each analysis because of missing data for particular variables.

Sub-group analysis

The women's group intervention may have had a greater or lesser impact in certain sub-groups, particularly those who were simultaneously exposed to the infant feeding intervention at the same time. It was also possible that there might have been a dose-response effect, with greater impact in those women who were more exposed to the intervention (i.e. attended a greater number of women's group meetings). Anecdotal evidence during the implementation of the intervention, suggested that certain groups of women might have benefitted more from the intervention. Thus, effect-modification of intervention group, exposure level, and socioeconomic quintile was explored (52, 285). P-values for the inclusion of the term rather than individual sub-groups are presented.

It is recommended that sub-group analyses are conducted with caution, as a small p-value in one subgroup may arise due to a larger number of observations in the group even if it has an identical treatment effect as in another group with smaller numbers (52). Analyses by intervention group and exposure level were planned, but analysis by socioeconomic quintile can be seen as an exploratory (*post hoc)* analysis to generate hypotheses for future testing, rather than to provide definitive results in this study.

4.4.11 Ethical issues

Approvals

Ethical permission for this study was granted by the Malawi National Health Sciences Research Committee in January 2003 (Ref: MED/4/36/I/167) (Appendix 5), and the ethics committee of the UCL Institute of Child Health and Great Ormond Street Hospital. It is registered with ISRCTN06477126.

Community consultation

Verbal and written consent was received from community leaders after full consultation and discussions. The regional, district and village leaders, and local health and development professionals had ongoing access to the research programme and will be the first to be briefed on study findings and outcomes through written and verbal reports.

Individual consent

Before each instance of data collection, the process and advantages and disadvantages of taking part were explained to all participants. Verbal consent was obtained, and participants informed that they could stop taking part at any time. Participation in intervention activities was voluntary, and women could choose to start or stop as they wished.

Benefits to the control communities

The study is designed to test the community effectiveness of two community-level initiatives to reduce maternal, perinatal, neonatal and infant mortality in rural Malawi. Encouraging community action for maternal and newborn care alone will not grant success. For health promotion interventions to work, the supply side of health care services must reach a minimum standard. The study team considered it unethical to strengthen services only in intervention and not control areas. Control communities benefitted from low-cost improvements in equipment, supplies and training at all primary level facilities in the district in intervention and control areas.

Treatment of illness in participating communities

When the study workers identified minor or chronic illness in mothers or infants in either intervention or control areas they encouraged referral to the appropriate health facility.

Confidentiality of information

All information will remain confidential. Access to information is limited to interviewers and their supervisors at sites of collection, to auditors and data feeders at the collation point and thence to the senior data management officers and principal investigators. No analyses or reports will include the names of participants. Paper files are kept in locked rooms and electronic data is kept in password-protected files.

4.4.12 Role of the investigator

This thesis is based on prospective data collected as part of MaiMwana Project between 1st January 2005 and 31st January 2009, as well as background and baseline information collected before that. This project is the result of efforts by a large multidisciplinary team, involving many people, who made different contributions according to their skills and knowledge. Most activities could not have been implemented by one person alone, and benefitted from inputs from a wide range of people. As an epidemiologist and technical advisor to this project since its inception I have been based in Malawi from 2003 to 2009 and have been involved in all aspects of the study. The main academic areas of work that I coordinated were: designing the study and developing the study protocol; random allocation of study clusters; sample size calculation and monitoring of sample size requirements; coordinating mapping, enumeration and census of the study area; designing, translating and piloting the data collection tools; recruiting and training the Monitoring and Evaluation team; managing the data collection, checking and entry processes; developing the study databases; cleaning and checking data and statistical analysis and presentation of the data. In addition, I helped to develop the original grant proposal to Saving Newborn Lives and was a principal investigator on the application for a second phase of the same funding. I coordinated the qualitative data collection during the baseline phase of the study that was used for tool development and intervention design, and was involved in discussions about the continued development of both of the interventions. I have co-authored several papers and conference presentations both nationally and internationally using findings from the study (262-264, 286).

Chapter 5 : Results

5.1 Participation in baseline census and prospective data collection

5.1.1 Baseline census and prospective enumeration

Between 1st July and 30th September 2004 28,339 households were visited for mapping and census, agreed to be included in the study and were interviewed. This represented a total population of 146,623, of which 43,719 were women aged between 10 and 49 years. Over the following months and years up to 31st January 2009, 8,965 additional households with 11,576 women aged between 10 and 49 years were enrolled, giving a total population of 182,944 from 36,321 households, of whom 55,295 are women aged 10-49. Over the study period 3,830 women and families moved out of the study areas, 61 refused to participate and 1,290 died. All households and women interviewed were included in the datasets looking at socioeconomic and demographic composition, as they were eligible for inclusion at some time during the study. These details are shown in Table 5.1.

Table 5.1: Composition of baseline and prospectively enumerated population sample

	Households	**Women aged 10-49 years**	**Total population**
Total enumerated	37,304	55,295 11,875 (10-14 years) 43,247 (15-49 years) 6 (over 49 years) 167 (age unknown)	182,944
Interviewed during baseline	28,339	43,719 10,763 (10-14 years) 32,956 (15-49 years)	146,623
Added prospectively	8,965	11,576	36,321
Died	-	1,290	-
Refused enumeration	-	61	-
Moved out	-	3,830	-

5.1.2 Prospective trial enrolment

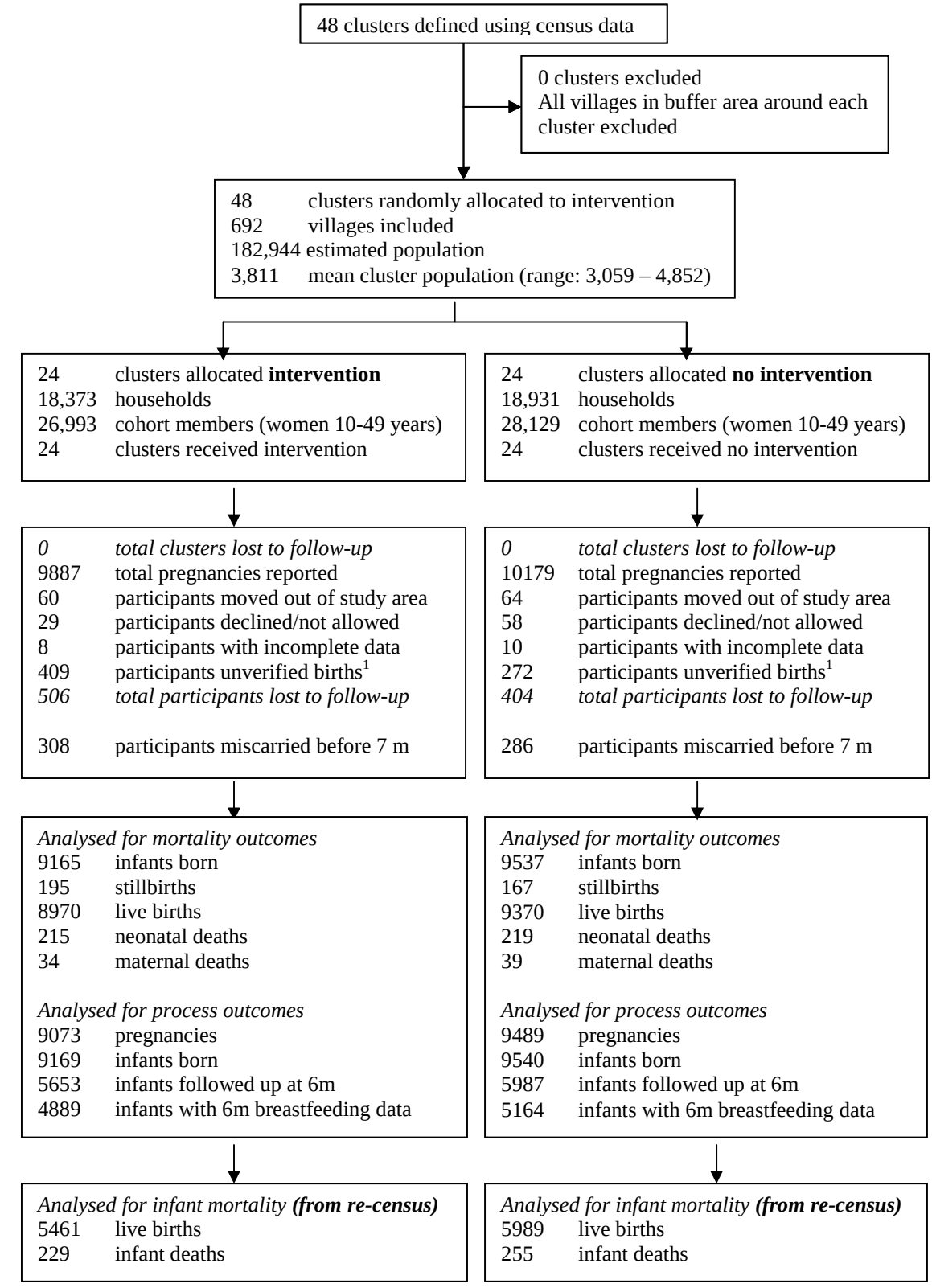
The women's group intervention trial period ran from 1st February 2006 to 31st January 2009. The database was formally frozen on 31st January 2009, and the trial profile (using CONSORT guidelines (287)) in Figure 5.1 shows progress on study accrual from 1st February 2006 to 31st January 2009. Pregnancies are only included in this dataset if they have had their outcomes (i.e. pregnancy completed due to miscarriage, stillbirth or

live birth) by the 31st January 2009. No zone or village refused to participate and only 87 (0.4%) of pregnant women refused or were not allowed to participate in interviews. Though numbers were small, there were twice as many refusals in control areas as in intervention areas, and there were almost twice as many reported but unverified births in intervention areas.

Between February 2006 and January 2009 20,066 pregnancies were reported, resulting in 18,340 live births, 362 stillbirths, 434 neonatal deaths and 73 maternal deaths. 594 women miscarried before seven completed months, and 910 pregnant women were lost to follow-up due to moving out of the study area, declining to take part, having incomplete data or the data not having been fully verified. Retrospectively collected data included 11,450 live births, and 484 infant deaths. Overall mortality rates for this sample were 398 maternal deaths per 100,000 live births, 19.4 stillbirths per 1,000 births, 23.7 neonatal deaths and 42.3 infant deaths per 1,000 live births. Of the infants that died during the neonatal period, 310 died within the first seven days, giving a perinatal mortality rate of 35.9 per 1,000 births.

Of the questionnaires received at the office, all were included in datasets estimating process outcomes. Seven verbal autopsy questionnaires were not included in the dataset enumerating the numbers of births and deaths by zone and by intervention because the exact timing of death was not known, so it was not possible to categorise (e.g. whether an infant was stillborn or born alive but died soon after).

Figure 5.1: Trial profile (CONSORT diagram)



1 Pregnancies reported in monthly registers but not followed up with an interview could include women who moved out permanently, declined, were temporarily out, reporting errors as well as some missed interviews. Some may be pregnancies that resulted in miscarriage, but the miscarriage was not reported.

5.2 Characteristics of the study population and participants

5.2.1 Socioeconomic and demographic characteristics of the whole study population

The socioeconomic and demographic characteristics of all enumerated households and women of childbearing age are described in Table 5.2 and Table 5.3. Most families lived in dwellings with a mud floor, a grass roof, a well for drinking water and a traditional pit latrine. Very few households have electricity or own a motorcycle, car or oxcart, but most did own a paraffin lamp and over half owned a radio or a bicycle. The mean age of women in the study population was 23.3 years and the median was 21.0 years. Most women were married, from the Chewa tribe and Christian. Most had been to primary school, but many had no education. The majority made their living through farming.

Table 5.2: Basic information about households in the study areas

Basic information about households	**N**	**%**
	37,304	
Type of flooring	37,107	
Dirt/sand/dung	33,660	90.7
Cement	3,314	8.9
Wood/plank/tiles/other	133	0.4
Type of roofing	37,110	
Natural	32,360	87.2
Iron sheets	4,569	12.3
Other	181	0.5
Use of agricultural land	37,071	
Own or family land	33,470	90.3
Rented or someone else's land	2,993	8.1
No agricultural work	608	1.6
Source of drinking water	37,099	
Piped water (house)	171	0.5
Piped water (yard)	61	0.2
Piped water (public)	2,201	5.9
Protected well/borehole	17,810	48.0
Traditional well	15,701	42.3
River/canal/surface water	1,155	3.1
Toilet	37,099	
Flush	184	0.5
Traditional pit latrine	29,571	79.7
VIP pit latrine	596	1.6
Bush/field	6,604	17.8
Other	144	0.4
Household members (average per household)	182,944	4.9
Sleeping rooms (average per household)	72,731	1.9
Household density (i.e. members per sleeping room) (average per household)	2.5	2.8
Assets	37,304	
Electricity	225	0.6
Radio	23,512	63.0
Bicycle	18,918	50.7
Motorcycle	232	0.6
Car	159	0.4
Paraffin lamp	34,715	93.1
Oxcart	1,545	4.1
Domestic worker	1,266	3.4

Data are number (%), unless otherwise specified.

Table 5.3: Basic information about women living in the study areas

Basic information about women aged 10 to 49 years	**N**	**%**
Women aged 10-49 years	55,122	-
10-14 years	11,875	24.6
15-49 years	43,247	75.3
Mean age (SD)	23.3	9.8
Median age (range)	21.0	10-49
Marital status	55,063	
Married	32,034	58.2
Never married	19,702	35.8
Divorced	1,205	2.2
Separated	1,257	2.3
Widowed	865	1.6
Tribe	55,055	
Chewa	48,923	88.9
Ngoni	3,351	6.1
Senga	1,175	2.1
Yao	831	1.5
Tumbuka	288	0.5
Lomwe	339	0.6
Other	148	0.3
Religion	55,049	
Christian (catholic)	25,923	47.1
Christian (other)	27,234	49.5
Moslem	928	1.7
Aaron	60	0.1
Pagan	233	0.4
Other	671	1.2
Education	55,055	
None	12,702	23.1
Primary	38,674	70.2
Secondary	3,584	6.5
Tertiary	95	0.2
Occupation	55,047	
Farming	32,773	59.5
Casual worker	572	1.0
Salaried worker	563	1.0
Small business	2,205	4.0
Rural artisan	62	0.1
Student	15,738	28.6
No work	3,134	5.7

Data are number (%), unless otherwise specified.

5.2.2 Principal Components Analysis for socioeconomic status

Principal components analysis of household assets was used to generate socioeconomic scores for each household in the study area. The distribution of these scores is shown in Figure 5.2. As can be seen in the figure, most values were clustered together in the lower range of scores. Cluster analysis showed that 80% of households fell within the cluster for the lowest socioeconomic group, and the first principal component accounted for 15% of the total variation. This ‘truncation’ makes it difficult to differentiate

between the poor and the very poor in this sample. Most households in rural Mchinji do not own durable assets, are built of the same materials and have similar levels of access to utilities. Such skewed distributions, with short tails to the left (poorer end) and long tails to the right (wealthier end), are often found for variables measuring concepts such as income and wealth (288).

Further exploration of socioeconomic scores by zone showed that households with the highest socioeconomic scores tended to be clustered in several zones, which had much higher mean and median scores than other zones. Mean and median socioeconomic scores were calculated for each cluster, and Figure 5.3 shows box-plots for the distribution of cluster-level scores by intervention allocation. Zone 17 (Kamwendo trading centre) in particular was far wealthier than any of the other zones, and is represented by the biggest outlier in Figure 5.3. It is interesting that the variability in terms of cluster-level socioeconomic scores is bigger in intervention areas, with both high and low outliers (beyond the whiskers of length 1.5 times the interquartile range from the box edge (289)), and a wider box (representing the 25^{th} and 75^{th} percentiles).

Figure 5.2: Frequency distribution of household socioeconomic scores

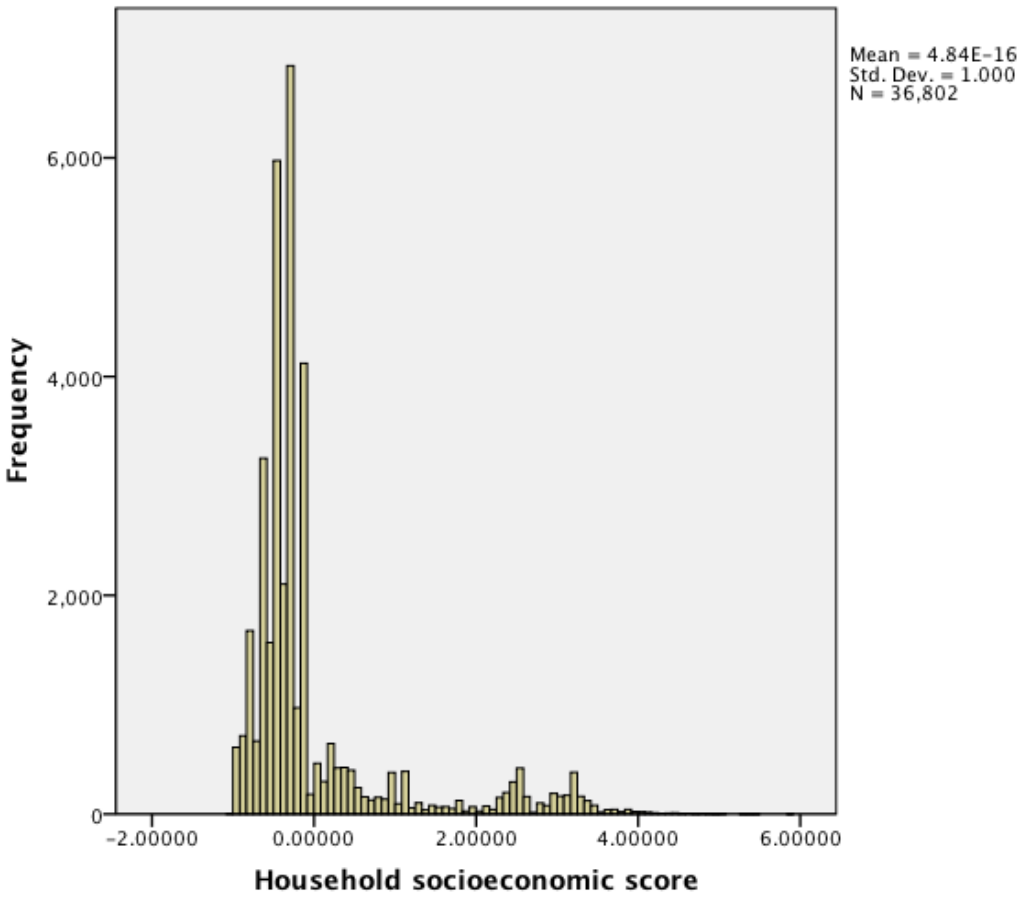
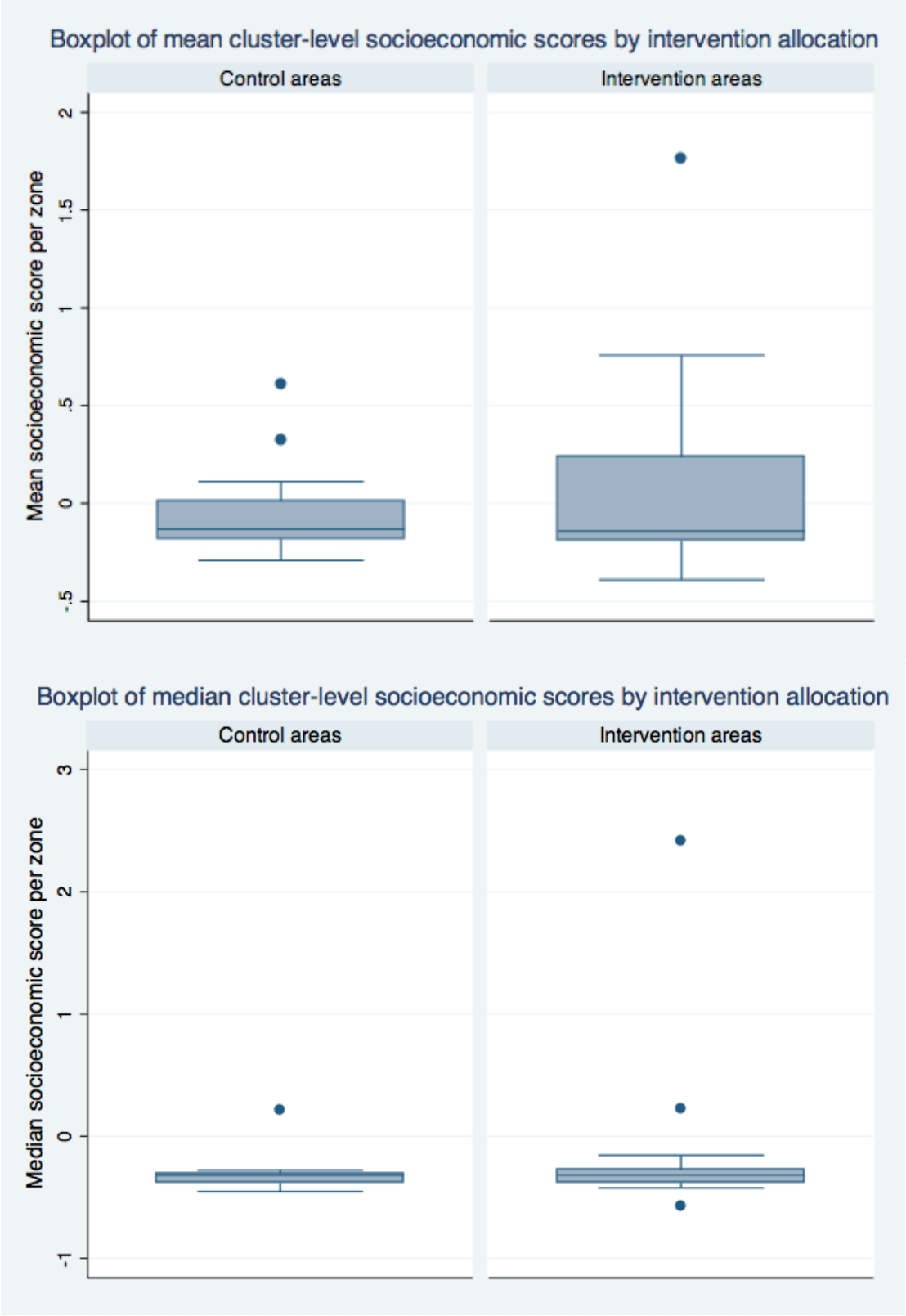


Figure 5.3: Box-plots showing distribution of cluster-level mean and median socioeconomic scores



5.2.3 Socioeconomic and demographic characteristics of pregnant women during prospective baseline

Comparisons of socioeconomic and demographic characteristics by intervention allocation are described in Table 5.4, using 'prospective baseline' data (collected between January and June 2005). This gives a picture of the characteristics of pregnant women in this population before the intervention started. Little difference was apparent between intervention and control areas at baseline. The mean household socioeconomic score was slightly higher in women's group compared to control areas, though the medians were almost identical. In both groups, the median was a lot lower than the mean, reflecting the skewed nature of the data described earlier (Figure 5.2). Looking at the quintiles of socioeconomic scores, there were a slightly higher proportion of households in both the poorest and the least poor quintiles in women's group areas, reflecting the presence of large trading centres as well as the most remote areas in the women's group zones.

Characteristics such as age, education, occupation, marital status and parity were very similar. The main differences seemed to be related to the distribution of different tribal groups between intervention and control areas, with more Ngoni, Senga and other tribes falling in intervention areas and a larger proportion of Chewa in control areas. The distribution of more Ngoni and Senga in the intervention areas is as a result of many those zones lying along the border with Zambia where these tribes are concentrated. There are also fewer Catholics, but more other Christian denominations and Muslims in the intervention group. Religious affiliation is partly a result of the denomination of the nearest church, though more diversity may reflect the presence of more trading centres in intervention areas. Overall, the intervention and control groups are very comparable on baseline socioeconomic and demographic characteristics.

Table 5.4: Comparison of socioeconomic and demographic characteristics by intervention allocation for women who became pregnant during the prospective baseline phase

		Prospective baseline January – June 2005	
		Women's group n (%)	**Control** n (%)
Household characteristics		1465	1537
Socioeconomic score	mean (±SE)	-0.040 (±0.025)	-0.087 (±0.022)
	median	-0.32	-0.31
Socioeconomic quintile	1 = poorest	304 (21.1)	304 (20.1)
	2	275 (19.1)	282 (18.7)
	3	307 (21.3)	346 (22.9)
	4	272 (18.9)	330 (21.9)
	5 = least poor	283 (19.6)	248 (16.4)
Woman characteristics		1465	1537
Age	mean (±SE)	26.3 (±0.17)	26.1 (±0.16)
	median	25.00	25.00
Tribe	Chewa	1235 (85.2)	1425 (93.3)
	Ngoni	124 (8.6)	66 (4.3)
	Senga	48 (3.3)	8 (0.5)
	Other	43 (3.0)	28 (1.8)
Religion	Catholic	585 (40.3)	782 (51.2)
	Other Christian	807 (55.7)	709 (46.4)
	Muslim	32 (2.2)	15 (1.0)
	Traditional	2 (0.1)	3 (0.2)
	Other	24 (1.7)	18 (1.2)
Education	None	294 (20.1)	337 (22.0)
	Primary	1065 (72.9)	1076 (70.1)
	Secondary or higher	122 (7.1)	122 (8.0)
Occupation	Farmer	1217 (83.9)	1260 (82.5)
	Ganyu	18 (1.2)	12 (0.8)
	Salaried	11 (0.8)	18 (1.2)
	Business	79 (5.5)	99 (6.5)
	Student	54 (3.7)	59 (3.9)
	No work	71 (4.9)	79 (5.2)
Marital status	Married	1365 (94.2)	1292 (93.8)
	Never married	32 (2.2)	108 (2.0)
	Divorced/Widowed	52 (3.6)	49 (4.2)
Parity	Ever previously pregnant	1213 (82.9)	1248 (80.8)
	Never previously pregnant	251 (17.1)	297 (19.2)

5.2.4 Primary (mortality) outcomes for mothers and infants during prospective baseline

Prospectively collected surveillance data, using registers documenting monthly visits to women of childbearing age (section 4.4.7), was used to calculate mortality rates in areas allocated to women's group and control at baseline, before the women's group intervention had started. The comparisons and combined mortality rates are shown in Table 5.5 below. Large differences were found between intervention and control areas, with infant, neonatal and perinatal mortality 62%, 42% and 64% higher respectively in intervention than control areas during this baseline phase. The number of maternal deaths during the six-month period was small, with only 14 deaths, but the maternal mortality ratio was also slightly higher in intervention areas (6%).

Table 5.5: Prospective baseline mortality rates by intervention allocation

	Prospective baseline January – June 2005		
Births and deaths	**Women's groups**	**Control**	**Total**
Births	1488	1564	3052
Live births	1445	1538	2983
Stillbirths (FSB and MSB)	43	26	69
Neonatal deaths	46	34	80
Early (0-6 days)	32	22	54
Late (7-28 days)	14	12	26
Infant deaths*	82	61	143
(retrospective live births)	(1307)	(1576)	(2883)
Maternal deaths	7	7	14
Mortality rates			
Stillbirth rate per 1000 births	28.9	16.6	22.6
Perinatal mortality rate per 1000 births	50.4	30.7	40.3
Early neonatal mortality rate per 1000 live births	22.1	14.3	18.1
Late neonatal mortality rate per 1000 live births	9.7	7.8	8.7
Neonatal mortality rate per 1000 live births	30.9	21.7	26.2
Infant mortality rate* per 1000 live births	62.7	38.7	49.6
Maternal mortality ratio per 100,000 live births	484	455	469

*Using retrospectively collected birth and death data for the same period, from the re-census conducted in June 2008

5.2.5 Secondary (behavioural and process) outcomes for mothers and infants during prospective baseline

Prospectively collected data from one- and six-month postpartum interviews during the six-month baseline phase before the women's group intervention had started, was used to calculate the prevalence of certain key health behaviours in areas allocated to women's group and control. The comparisons are shown in Table 5.6 below.

Table 5.6: Prospective baseline secondary outcomes by intervention allocation

	Prospective baseline January – June 2005	
	Women's group n (%)	**Control** n (%)
Pregnancies	1465	1537
Any antenatal care at a health facility	1336 (91.2)	1410 (91.7)
Four or more antenatal care visits	417 (30.0)	517 (35.2)
Any iron and folic acid	1199 (87.9)	1334 (92.0)
More that 90 days iron/folate	232 (17.0)	360 (24.8)
Any tetanus toxoid immunisation	1174 (86.1)	1189 (82.2)
Adequate tetanus toixoid[1]	822 (61.2)	885 (61.9)
Any sulphadine-pyrimethamine (SP)	1261 (91.6)	1375 (93.4)
Two or more doses of SP	564 (44.8)	559 (41.1)
Bednet use night before interview	625 (42.6)	688 (44.5)
Bednet used every night in pregnancy	686 (48.0)	751 (50.4)
Any HIV testing at antenatal care visit	164 (11.8)	201 (14.0)
Any perceived antenatal, delivery or postnatal maternal problem	822 (56.4)	750 (48.8)
Births	1488	1564
Institutional deliveries	536 (36.1)	682 (43.7)
Birth attended by skilled provider	535 (35.9)	663 (42.4)
Birth attended by a TBA	611 (41.0)	586 (37.5)
Attendant washed hands/wore gloves	1163 (91.7)	1266 (91.7)
Live births	1445	1538
Baby wrapped within 30 min	1330 (93.4)	1355 (88.7)
Baby bathed after 24hrs	454 (32.0)	553 (36.5)
Postnatal care at a health facility	344 (25.0)	454 (31.5)
Infant received BCG	641 (44.6)	643 (41.9)
Infant received polio immunisation	532 (37.1)	570 (37.3)
Any perceived infant problem (cough, fever or diarrhoea)	597 (45.3)	637 (45.8)
Infants with follow-up data at 6m	830	934
Infant received BCG by 6-months	799 (96.3)	891 (95.4)
Infant received any polio vaccine doses by 6-months	803 (96.8)	890 (95.4)
Infant received 4 polio vaccine doses by 6-months	50 (6.0)	164 (17.6)
Infant received any pentavalent vaccine dose by 6-months	752 (90.7)	878 (94.1)
Infant received 3 pentavalent vaccine doses by 6-months	456 (55.0)	537 (57.6)
Infants with 6m of breastfeeding data	778	844
Infant exclusively breastfed to 6m	137 (17.6)	91 (10.8)
Initiated breastfeeding within 1 hr	604 (79.5)	621 (75.3)
Use of prelacteals	111 (14.3)	186 (22.0)
Any breastfeeding problem	20 (2.6)	31 (3.7)

1 Adequate tetanus toxoid immunisation is 2 doses in pregnancy, or having completed the whole course of 5 doses over preceding years

Differences were seen between women's group and control areas, with many health indicators being worse in intervention areas. There were fewer health facility deliveries and fewer postnatal care visits in women's group areas, and more maternal antenatal, delivery and postnatal problems were reported. Combined with the fact that all primary mortality outcomes were worse in intervention areas (Table 5.5), there is some evidence that women and children in women's group areas had poorer health than those in control areas at baseline, suggesting that randomisation did not create balanced groups, and baseline values would have to be adjusted for in analysis of intervention impact (253).

5.2.6 Main cause and time of death

Data on cause and time of death are from all those records with available data, and do not exactly represent the study period. Less than 10 physician reviews assigning causes of maternal deaths were available at the time of writing, and will not be discussed here. Physician reviews of perinatal and neonatal deaths were also not complete at the time of writing, but data for 194 (53%) neonatal deaths and stillbirths out of 367 collected during the course of the baseline and inception phases of the study before the evaluation period started were available. There may have been differences between those included and not included, but cause-specific mortality was not a main focus of this research, and available data are presented here in order to provide a picture of the aetiology.

There were 17 macerated stillbirths, 62 fresh stillbirths, 17 undifferentiated stillbirths, and 98 neonatal deaths. Table 5.7 summarises the causes of all perinatal and neonatal deaths, and Figure 5.4 shows the distribution of causes of neonatal deaths. The most common cause of neonatal death was severe infection, accounting for more than half of all neonatal deaths. This is a much higher proportion than the WHO regional estimates for Africa shown for comparison in Figure 5.5, where severe infection accounts for just over one quarter of neonatal deaths (53). Birth asphyxia accounted for almost one third of deaths in both cases, but prematurity and tetanus were much more common in the WHO estimate.

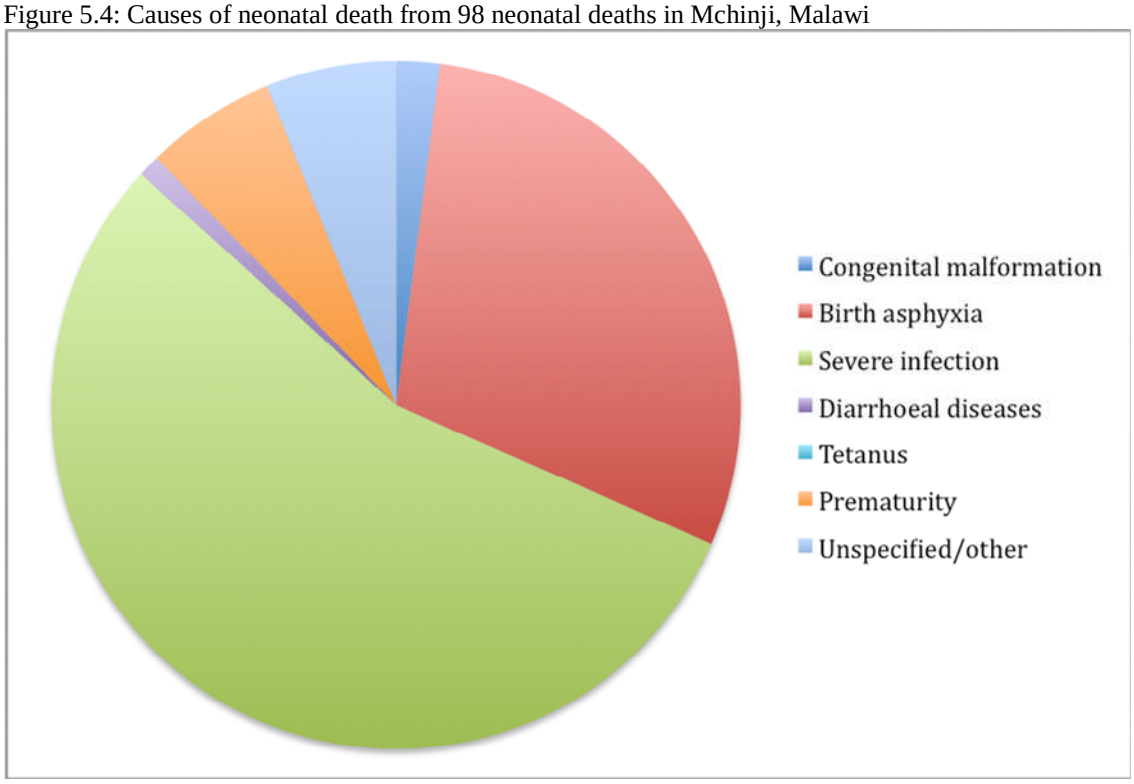
Table 5.7: Causes of neonatal death and stillbirth

Cause	N	%
Stillbirths	96	49.5
Macerated stillbirth	17	17.7
Fresh stillbirth	62	64.6
Undifferentiated stillbirth	17	17.7
Neonatal deaths	98	50.5
Congenital malformation	2	2.0
Birth asphyxia	29	29.6
Infectious causes	55	56.1
Sepsis and meningitis	41	41.8
Tetanus	0	0
Diarrhoea	1	1.0
Pneumonia	13	13.3
Prematurity	6	6.1
Hypoglycaemia/hypothermia	2	2.0
Sudden infant death	2	2.0
Unspecified	2	2.0

Of 640 neonatal deaths for whom data on dates of birth and death were available (for the whole study period including baseline), 253 (39.5%) happened on the first day, and 455 (71.1%) were within the first week of life. Figure 5.6 shows the distribution of day of death for neonatal deaths.

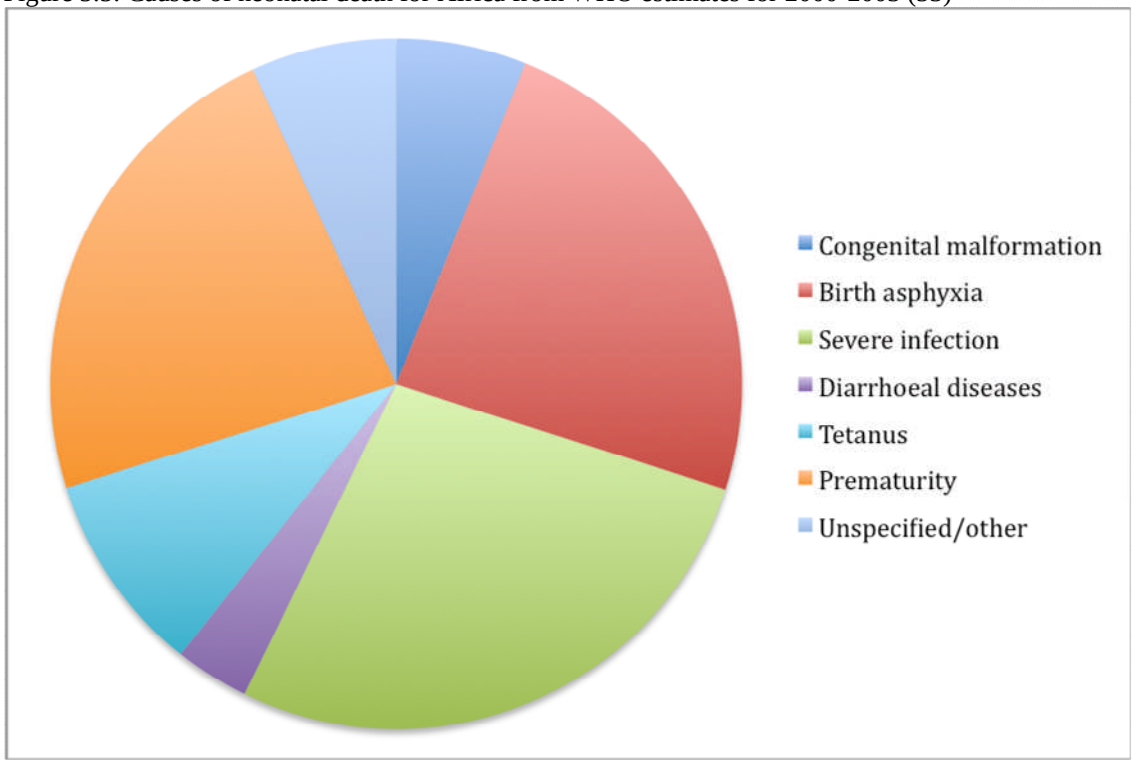
Of 82 maternal deaths for whom data on stage of pregnancy was available, 10 (12.2%) happened before seven completed months of pregnancy, 22 (26.8%) happened after seven completed months but before the onset of labour, and 50 (61.0%) happened during or after delivery. Of those that happened during or after delivery, 16 (32%) were on the first day, and 29 (58%) were within the first week. Figure 5.7 shows the distribution of maternal deaths.

Figure 5.4: Causes of neonatal death from 98 neonatal deaths in Mchinji, Malawi



(98 neonatal deaths from baseline and year 1)
Severe infection includes the sepsis and meningitis, and pneumonia categories

Figure 5.5: Causes of neonatal death for Africa from WHO estimates for 2000-2003 (53)



Severe infection includes pneumonia, meningitis, sepsis/septicaemia

Figure 5.6: Day of death for 640 neonatal deaths

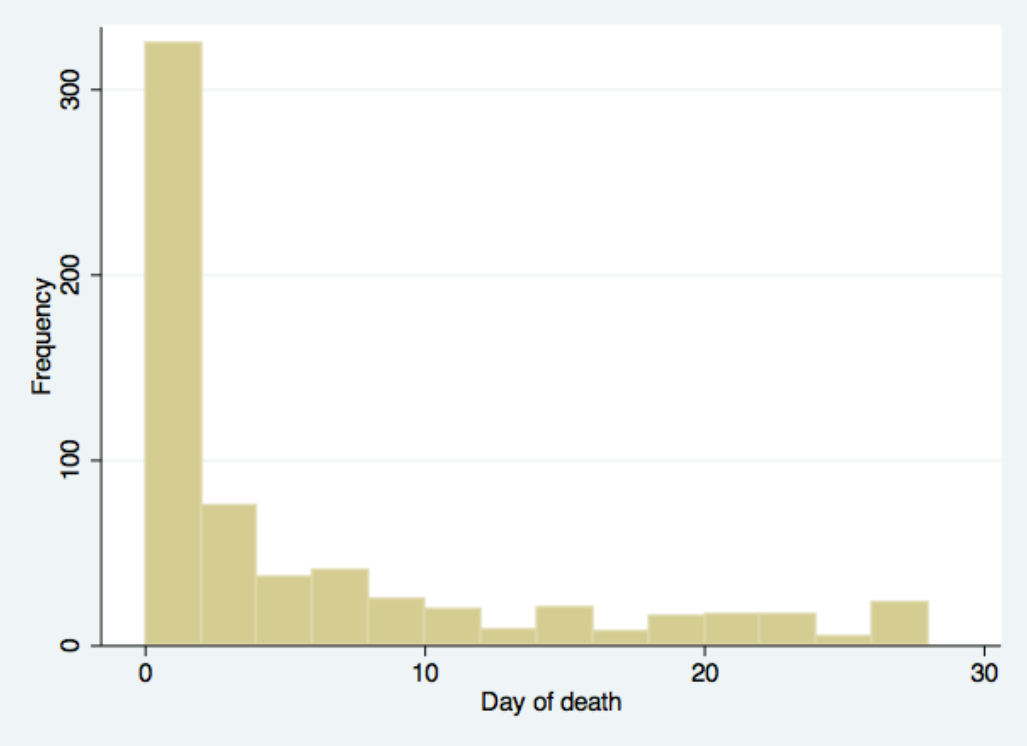
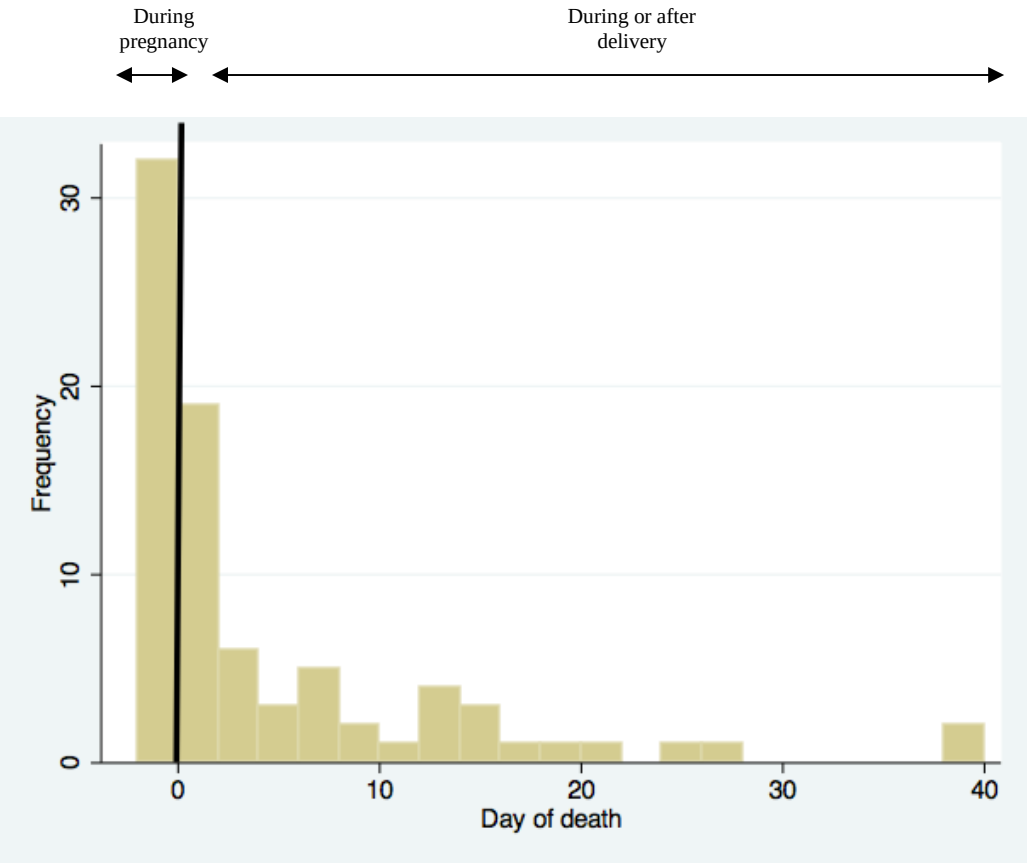


Figure 5.7: Day of death for 82 maternal deaths



NB: Deaths during pregnancy, before the onset of labour, are included as those less than day 0. Deaths during delivery are counted as day 1.

5.2.7 Socioeconomic and demographic characteristics related to primary and secondary outcomes

Section 2.2 describes some of the socioeconomic and demographic characteristics known to be related to maternal and neonatal mortality and coverage of health-care interventions. The relationship between risk factors and adverse health outcomes was explored in this study population. Mortality rates and health-care seeking differed according to maternal age, education and socioeconomic status, as well as maternal parity and marital status. Given the collinearity between some of these variables, the independent effects of each will not be described fully here. This section presents data showing primary mortality outcomes and three key secondary outcomes by maternal age, educational level, marital status and socioeconomic group.

Maternal age

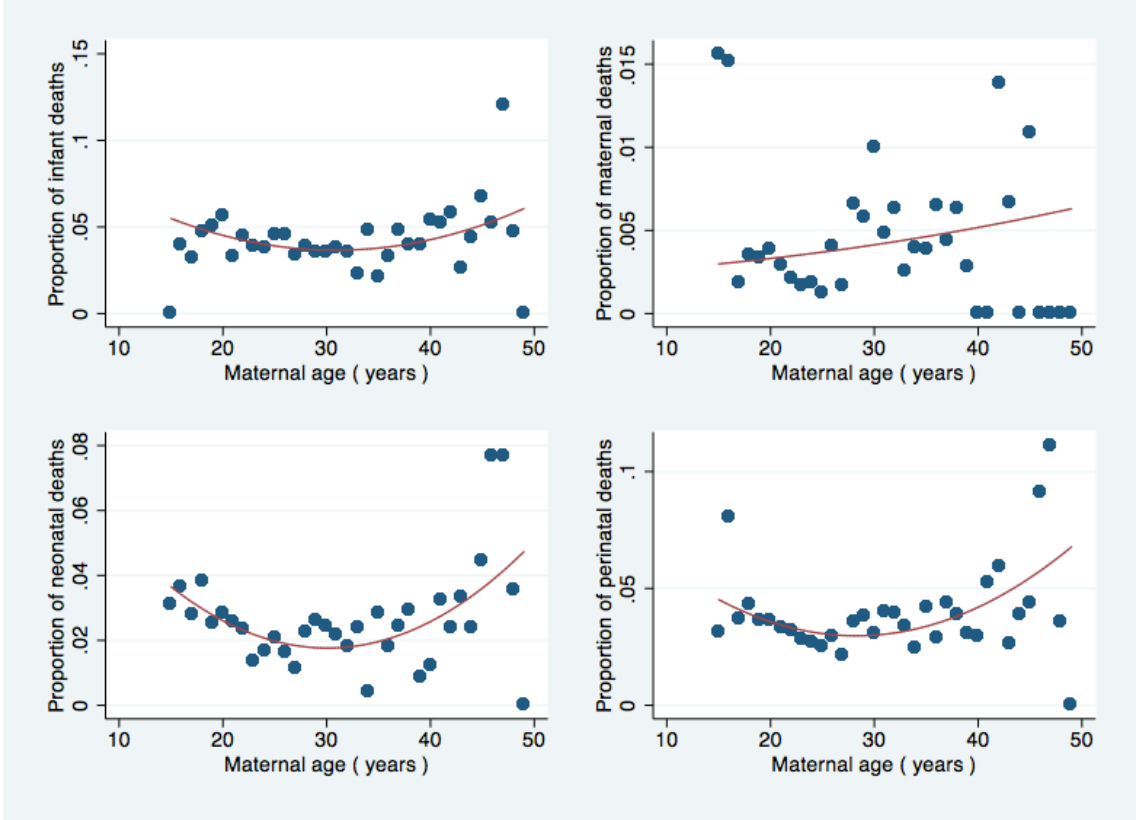
Figure 5.8 shows the proportion of births resulting in infant, maternal, neonatal and perinatal deaths for different maternal ages. Mortality was higher amongst the youngest and oldest groups of mothers. For neonatal and perinatal deaths, the relationship is clearly not linear, and is better represented by a quadratic, curved line. The relationship between infant death and maternal age is less curved, but still clearly quadratic. We would expect to see a similar quadratic relationship between maternal age and maternal death because first pregnancies at young ages and late pregnancies are known to have higher risks associated with them (290, 291), but this pattern is less obvious in this dataset, though is still best described statistically by a curve than a straight line.

Age reporting is inaccurate, as many women do not know their age or date of birth, and ages for women in the older age groups particularly, may be misclassified. However, the outlying points for the youngest and oldest ages represent only a small number of women, so for the bulk of the dataset (for the purposes of statistical modelling) we can consider age as quadratic for mortality outcomes.

As coefficients and odds ratios from quadratic terms in models are difficult to interpret, further exploration of differential effects of the intervention by age was done using four age groups. Table 5.8 shows how mortality rates and key health-care seeking indicators vary by age-group, confirming the clear pattern of higher mortality in the youngest and

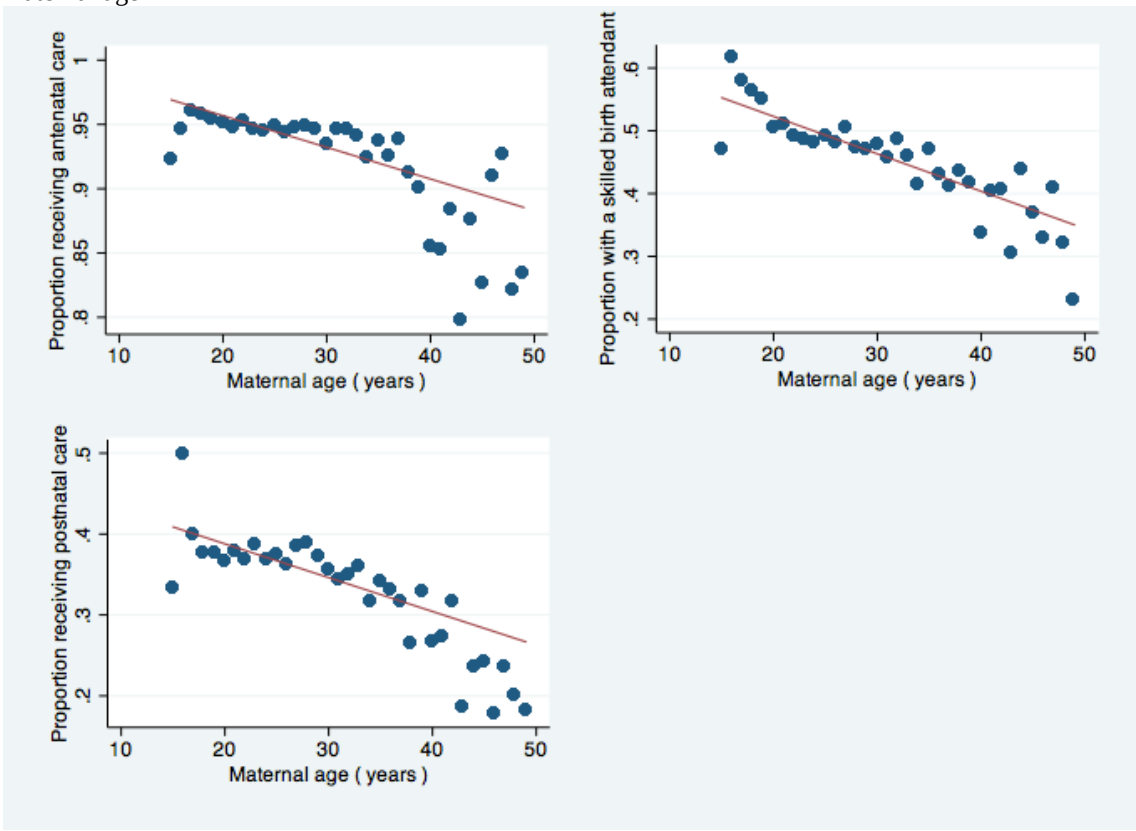
oldest age groups for perinatal and neonatal mortality, and a less clear pattern for infant and maternal mortality.

Figure 5.8: Proportion of births resulting in infant, maternal, neonatal and perinatal death by maternal age



Process outcomes, such as antenatal care, skilled birth attendance and postnatal care did not follow a quadratic relationship (Figure 5.9). For most health-care seeking variables, older women were less likely to seek care than younger women. Thus for secondary outcomes, a linear age term was included in regression models. Table 5.8 again shows significantly lower health-care seeking in the older age groups.

Figure 5.9: Proportion of mothers receiving antenatal care, skilled birth attendance and postnatal care by maternal age



Educational level

There appears to be a pattern of reduced risk of maternal death with higher level of maternal education (Table 5.8), but the pattern is less clear for perinatal and neonatal mortality. There is a significantly higher risk of perinatal death amongst women with primary education compared to those with no education, and women with primary education are also at highest risk of neonatal death.

The pattern of health-care seeking with maternal education is much clearer. Antenatal care, skilled birth attendance and postnatal care are significantly higher amongst women with primary education, and higher still amongst women with secondary education, compared to women with no education.

Marital status

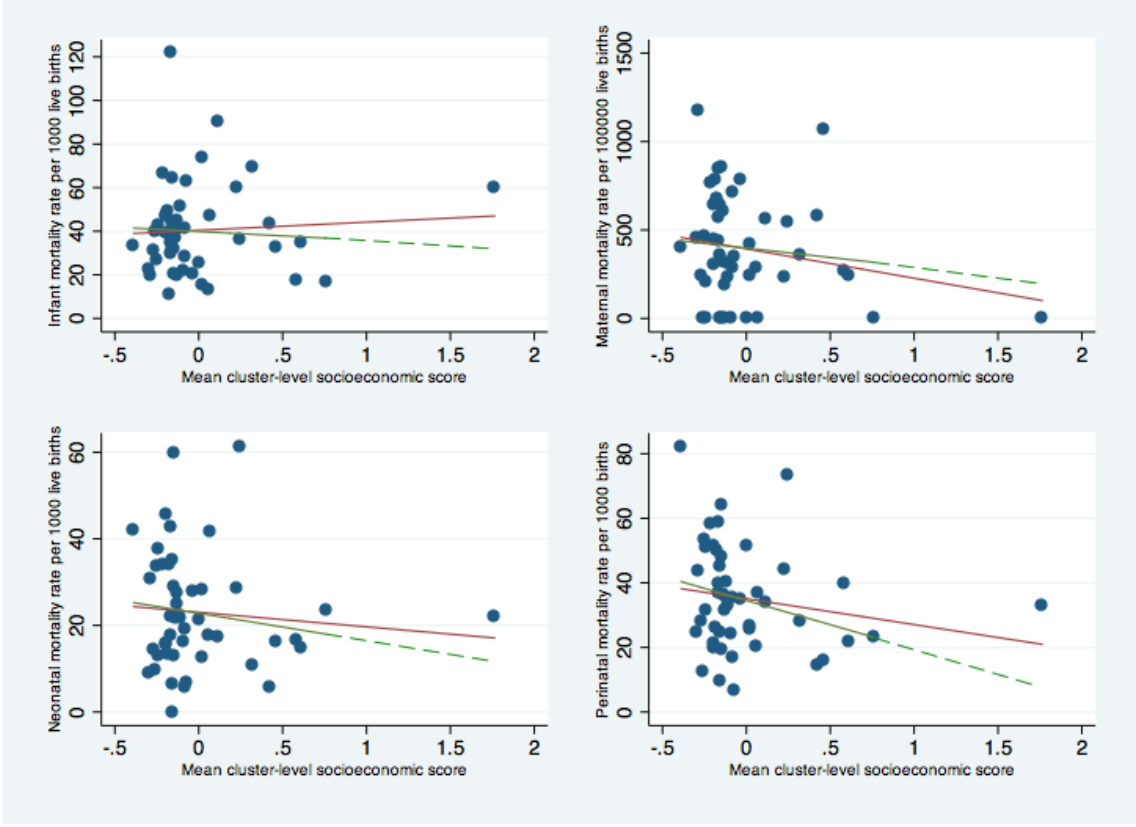
Marital status is closely related to age, with most of the never married women being found in the youngest age group. Women who have never been married (corresponding to the youngest age group), are at significantly higher risk of perinatal, neonatal and maternal death when they become pregnant, than women who are currently married

(Table 5.9). Divorced or widowed women are also at significantly higher risk of perinatal and neonatal death, and they also have significantly lower uptake of antenatal care, skilled birth assistance and postnatal care. Antenatal care is significantly lower amongst never married women, perhaps because of fear of the stigma associated with being a young, unmarried mother, but skilled birth attendance is significantly higher amongst unmarried women.

Socioeconomic status

Poverty is a well-documented determinant of poor health as described in section 2.2, and it was important to explore the magnitude of health inequalities in this study population. Figure 5.10 shows that mortality rates tend to decrease with increasing socioeconomic status. The relationship is not as strong for infant mortality, and in fact mortality increases with increasing socioeconomic status when zone 17 (a socioeconomic outlier described in section 5.2.2 and Figure 5.3) is included.

Figure 5.10: Infant, maternal, neonatal and perinatal mortality rates by cluster-level socioeconomic score



Scatter of cluster-level mortality rates against mean cluster-level socioeconomic score
Line of best fit to all points
Line of best fit to all points excluding zone 17 (outlier with mean socioeconomic score above 1.0)

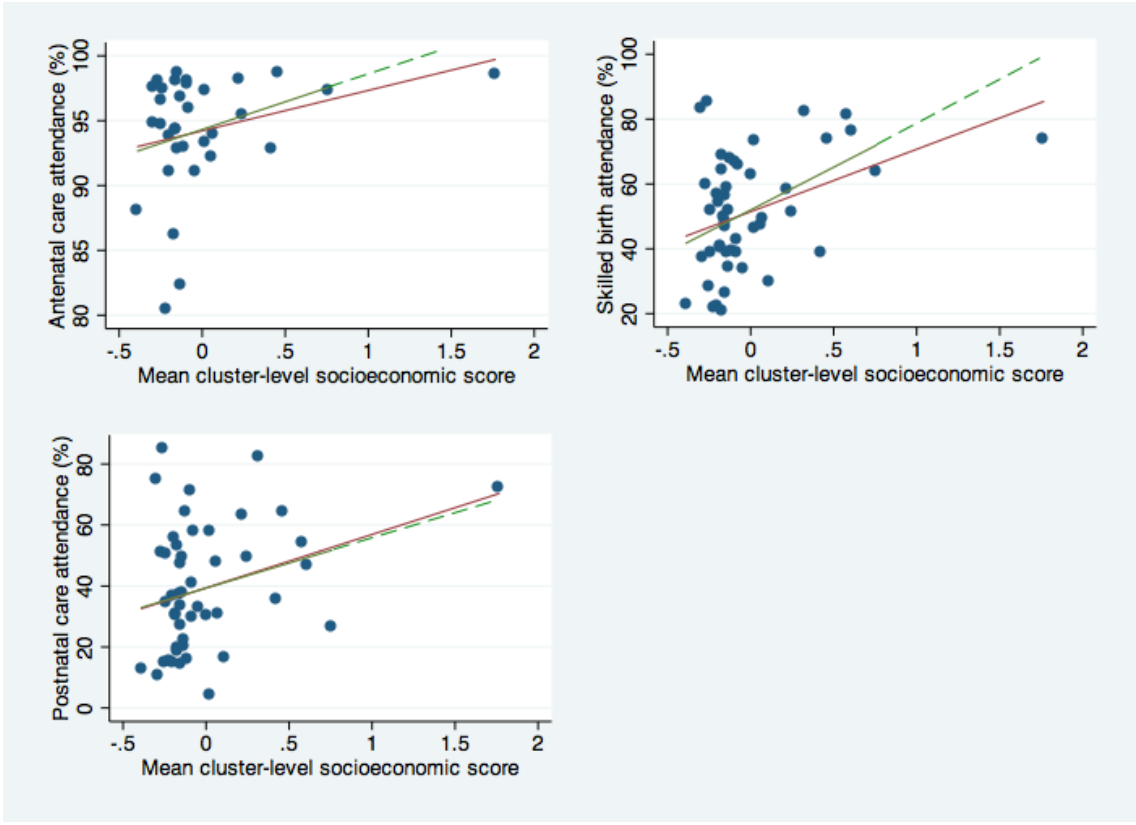
The non-normal distribution of household socioeconomic scores (Figure 5.2) makes its coefficient difficult to interpret in regression models, and without a suitable transformation it was more informative to create a categorical variable by dividing individual household scores into quintiles (292). The magnitude of the difference in mortality between the poorest and the least poor quintiles is greatest for peinatal and neonatal mortality, which is more than 30% higher in the poorest quintile compared to the least poor. For maternal mortality this difference is less than 10% (Table 5.9). For maternal, perinatal and neonatal mortality, the highest mortality rates are found in the lowest quintile, but the lowest mortality rates are not found in the highest quintile. Instead the lowest mortality is found in the fourth quintile for perinatal and neonatal, and the third quintile for maternal mortality. For maternal mortality in Malawi, as described in section 2.2.3, this flattening of the socioeconomic gradient, as well as the loss of the 'urban advantage' has previously been attributed to HIV (77, 85).

Odds ratios show that there is a significant relationship between perinatal mortality and socioeconomic group, with the highest mortality amongst the poorest women (reference group). For neonatal and maternal mortality, the relationship is not significant, but is similar, and appears to be greater in all other socioeconomic groups compared to the poorest quintile.

For infant mortality, the pattern is quite different. Infant mortality is just over 20% higher in the poorest compared to the least poor quintile, but the highest mortality rate is in the third quintile, the lowest is in the least poor quintile, and the second lowest in the poorest quintile.

The relationship between health-care seeking rates and socioeconomic status is much clearer and more consistent (Figure 5.11), and coverage rates for antenatal care, skilled birth attendance and postnatal care increase with socioeconomic status. The relationship between socioeconomic quintile and health-care seeking is highly significant (Table 5.9). Similar patterns are seen with most other secondary outcome variables.

Figure 5.11: Percentage of mothers receiving antenatal care, skilled birth attendance and postnatal care by cluster-level socioeconomic score



Scatter of cluster-level mortality rates against mean cluster-level socioeconomic score
Line of best fit to all points
Line of best fit to all points excluding zone 17 (outlier with mean socioeconomic score above 1.0)

Table 5.8: Primary mortality outcomes and selected secondary outcomes by age group and educational level

	Age group				Educational level			
		Rate by group N/total (rate)	**Odds ratio** Years 1-3*	**p value** (Wald)		**Rate by group** N/total (rate)	**Odds ratio** Years 1-3*	**p value** (Wald)
Primary outcomes								
Perinatal mortality rate (per 1000 births)	10-19 years	93/2317 (40.1)	-	0.012	None	111/3669 (30.3)	-	0.08
	20-29 years	320/10431 (30.7)	0.76 (0.60-0.96)		Primary	495/13364 (37.0)	1.26 (1.02-1.56)	
	30-39 years	174/4913 (35.4)	0.87 (0.67-1.13)		Secondary or higher	50/1594 (31.4)	1.12 (0.80-1.58)	
	40 years and over	41/847 (48.4)	1.20 (0.83-1.76)					
Neonatal mortality rate (per 1000 live births)	10-19 years	68/2275 (29.9)	-	0.042	None	79/3669 (21.5)	-	0.25
	20-29 years	212/10260 (20.7)	0.69 (0.52-0.91)		Primary	320/13364 (23.9)	1.13 (0.88-1.46)	
	30-39 years	106/4812 (22.0)	0.72 (0.53-0.98)		Secondary or higher	27/1594 (16.9)	0.84 (0.54-1.32)	
	40 years and over	23/822 (28.0)	0.94 (0.58-1.52)					
Infant mortality rate (per 1000 live births)	10-19 years	23/562 (40.9)	-	0.26	None	NA	NA	NA
	20-29 years	268/6289 (42.6)	1.06 (0.69-1.65)		Primary			
	30-39 years	131/3463 (37.8)	0.95 (0.60-1.50)		Secondary or higher			
	40 years and over	42/787 (53.4)	1.37 (0.81-2.31)					
Maternal mortality rate (per 1000 live births)	10-19 years	11/2315 (475)	-	0.009	None	16/3627 (441)	-	0.61
	20-29 years	24/10343 (232)	0.49 (0.24-1.00)		Primary	52/13267 (392)	0.89 (0.51-1.56)	
	30-39 years	27/4856 (556)	1.17 (0.58-2.36)		Secondary or higher	4/1577 (254)	0.58 (0.19-1.72)	
	40 years and over	1/836 (120)	0.25 (0.03-1.95)					
Secondary outcomes								
Any antenatal care (%)	10-19 years	2240/2313 (96.8)	-	<0.0001	None	3256/3620 (89.9)	-	<0.0001
	20-29 years	9878/10328 (95.6)	0.75 (0.58-0.97)		Primary	12724/13253 (96.0)	2.37 (2.05-2.74)	
	30-39 years	4574/4851 (94.3)	0.57 (0.44-0.75)		Secondary or higher	1552/1577 (98.4)	5.70 (3.76-8.63)	
	40 years and over	737/836 (88.2)	0.27 (0.20-0.39					
Skilled birth attendance (%)	10-19 years	1376/2318 (59.4)	-	<0.0001	None	1342/3671 (36.6)	-	<0.0001
	20-29 years	5342/10437 (51.2)	0.72 (0.66-0.80)		Primary	6897/13373 (51.6)	1.74 (1.61-1.89)	
	30-39 years	2345/4916 (47.7)	0.65 (0.59-0.73)		Secondary or higher	1180/1594 (74.0)	4.34 (3.78-4.99)	
	40 years and over	343/847 (40.5)	0.49 (0.42-0.59)					
Postnatal care attendance (%)	10-19 years	825/1965 (42.0)	-	<0.0001	None	817/3116 (26.2)	-	<0.0001
	20-29 years	3528/8783 (40.2)	0.98 (0.88-1.10)		Primary	4447/11232 (39.6)	1.65 (1.50-1.82)	
	30-39 years	1507/4176 (36.1)	0.84 (0.75-0.95)		Secondary or higher	804/1379 (58.3)	3.35 (2.89-3.88)	
	40 years and over	196/706 (27.8)	0.57 (0.46-0.70)					

* Adjusted for clustering and stratification only.

NA: Maternal education data were not available with the retrospective infant outcome dataset.

P-values have not been adjusted for multiple testing as these are exploratory analysis rather than hypothesis testing

Table 5.9: Primary mortality outcomes and selected secondary outcomes by marital status and socioeconomic quintile

	Marital status				Socioeconomic quintile			
		Rate by group N/total (rate)	**Odds ratio** Years 1-3*	**p value** (Wald)		**Rate by group** N/total (rate)	**Odds ratio** Years 1-3*	**p value** (Wald)
Primary outcomes								
Perinatal mortality rate (per 1000 births)	Married Never married Divorced/widowed/other	585/17411 (33.6) 21/395 (53.2) 44/648 (67.9)	- 1.71 (1.09-2.69) 2.05 (1.49-2.83)	<0.0001	1 – Poorest 2 3 4 5 – Least poor	169/3694 (45.7) 122/3531 (34.6) 140/3977 (35.2) 109/3915 (27.8) 104/3057 (34.0)	- 0.77 (0.61-0.98) 0.80 (0.63-1.01) 0.63 (0.49-0.81) 0.80 (0.61-1.03)	0.009
Neonatal mortality rate (per 1000 live births)	Married Never married Divorced/widowed/other	372/17093 (21.8) 18/386 (46.6) 31/625 (49.6)	- 2.41 (1.48-3.93) 2.24 (1.53-3.27)	<0.0001	1 – Poorest 2 3 4 5 – Least poor	105/3600 (29.2) 80/3468 (23.1) 86/3904 (22.0) 82/3857 (21.3) 66/2999 (22.0)	- 0.81 (0.60-1.09) 0.77 (0.58-1.04) 0.75 (0.56-1.02) 0.78 (0.57-1.08)	0.32
Infant mortality rate (per 1000 live births)	Married Never married Divorced/widowed/other	NA	NA	NA	1 – Poorest 2 3 4 5 – Least poor	95/2370 (40.1) 107/2318 (46.2) 117/2514 (46.5) 106/2347 (45.2) 59/1790 (33.0)	- 1.12 (0.84-1.49) 1.12 (0.84-1.48) 1.08 (0.81-1.45) 0.77 (0.55-1.08)	0.17
Maternal mortality rate (per 1000 live births)	Married Never married Divorced/widowed/other	65/17263 (377) 6/396 (1515) 1/641 (156)	- 4.07 (1.75-9.45) 0.41 (0.06-2.98)	0.003	1 – Poorest 2 3 4 5 – Least poor	17/3658 (465) 12/3502 (343) 10/3930 (286) 15/3889 (386) 13/3036 (428)	- 0.74 (0.35-1.54) 0.55 (0.25-1.19) 0.83 (0.41-1.66) 0.92 (0.45-1.90)	0.62
Secondary outcomes								
Any antenatal care (%)	Married Never married Divorced/widowed/other	16424/17245 (95.2) 363/396 (91.7) 587/639 (91.9)	- 0.46 (0.31-0.67) 0.55 (0.41-0.74)	<0.0001	1 – Poorest 2 3 4 5 – Least poor	3368/3649 (92.3) 3287/3493 (94.1) 3740/3928 (95.2) 3741/3881 (96.4) 2940/3028 (97.1)	- 1.21 (1.00-1.47) 1.46 (1.20-1.78) 1.90 (1.53-2.36) 2.44 (1.89-3.14)	<0.0001
Skilled birth attendance (%)	Married Never married Divorced/widowed/other	8813/17421 (50.6) 244/396 (61.6) 289/648 (44.6)	- 1.28 (1.02-1.59) 0.77 (0.65-0.92)	0.001	1 – Poorest 2 3 4 5 – Least poor	1435/3695 (38.8) 1675/3532 (47.4) 1942/3977 (48.8) 2080/3916 (53.1) 2020/3059 (66.0)	- 1.23 (1.11-1.36) 1.36 (1.24-1.51) 1.61 (1.46-1.78) 2.63 (2.36-2.93)	<0.0001
Postnatal care attendance (%)	Married Never married Divorced/widowed/other	5731/14838 (38.6) 149/340 (43.8) 171/509 (33.6)	- 0.95 (0.75-1.21) 0.80 (065-0.98)	0.09	1 – Poorest 2 3 4 5 – Least poor	934/3111 (30.0) 1108/2986 (37.1) 1278/3365 (38.0) 1312/3283 (40.0) 1256/2612 (48.1)	- 1.17 (1.04-1.32) 1.31 (1.17-1.47) 1.41 (1.25-1.58) 2.05 (1.82-2.32)	<0.0001

* Adjusted for clustering and stratification only.
NA: Marital status data were not available with the retrospective infant outcome dataset.
P-values have not been adjusted for multiple testing as these are exploratory analyses rather than hypothesis testing.

5.2.8 Exposure to the intervention

Of the 7,705 women in intervention areas interviewed at one-month post-partum during the three-year period covered by this analysis, and who had data available on women's group attendance, 4120 (53%) had ever attended a women's group. Of those who attended, 1179 (29%) had only been once or twice, 919 (22%) had been three or four times, and 2022 (49%) had been five or more times (Figure 5.12). The coverage of women's groups per zone (defined as the percentage of women who had ever attended) ranged from 33% to 82% (Figure 5.13), and the cluster mean was 49% (95% CI 40-58). 78 women (1%) of women in control areas reported ever having been to a women's group meeting. The proportion of women per zone in control areas who had ever attended ranged from 0% to 5%.

Figure 5.12: Distribution of the number of women's group meetings attended by those who had ever attended at least once

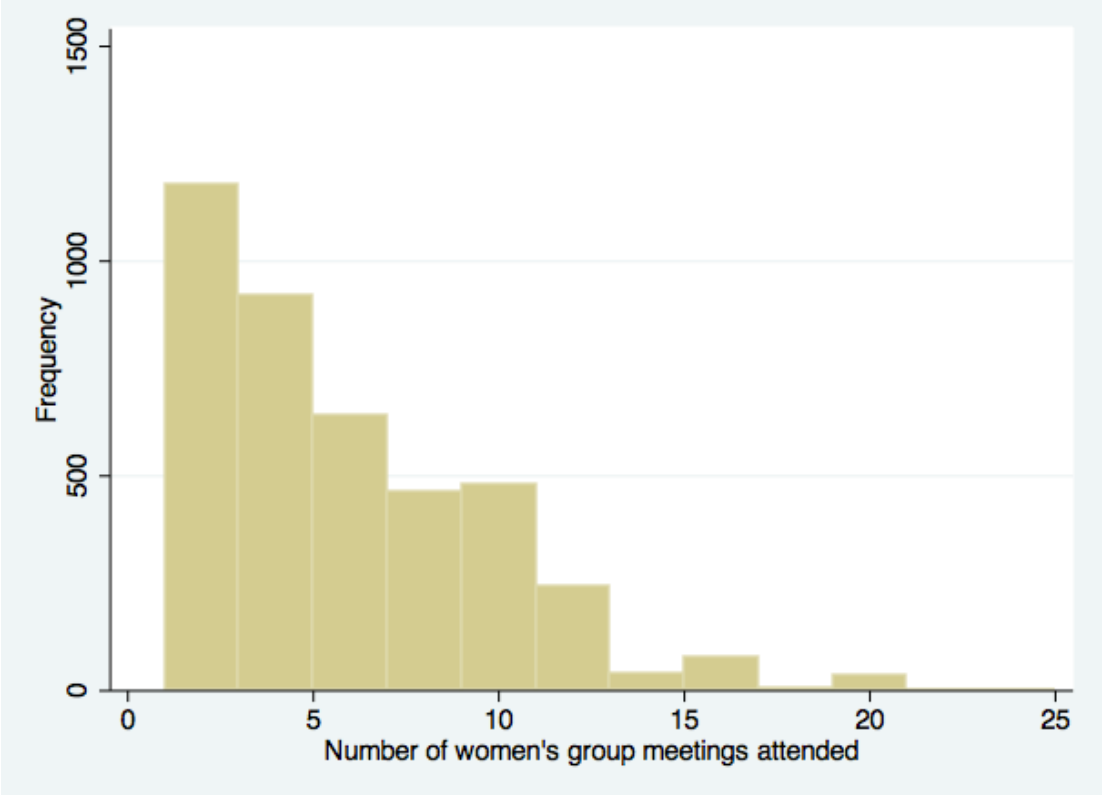
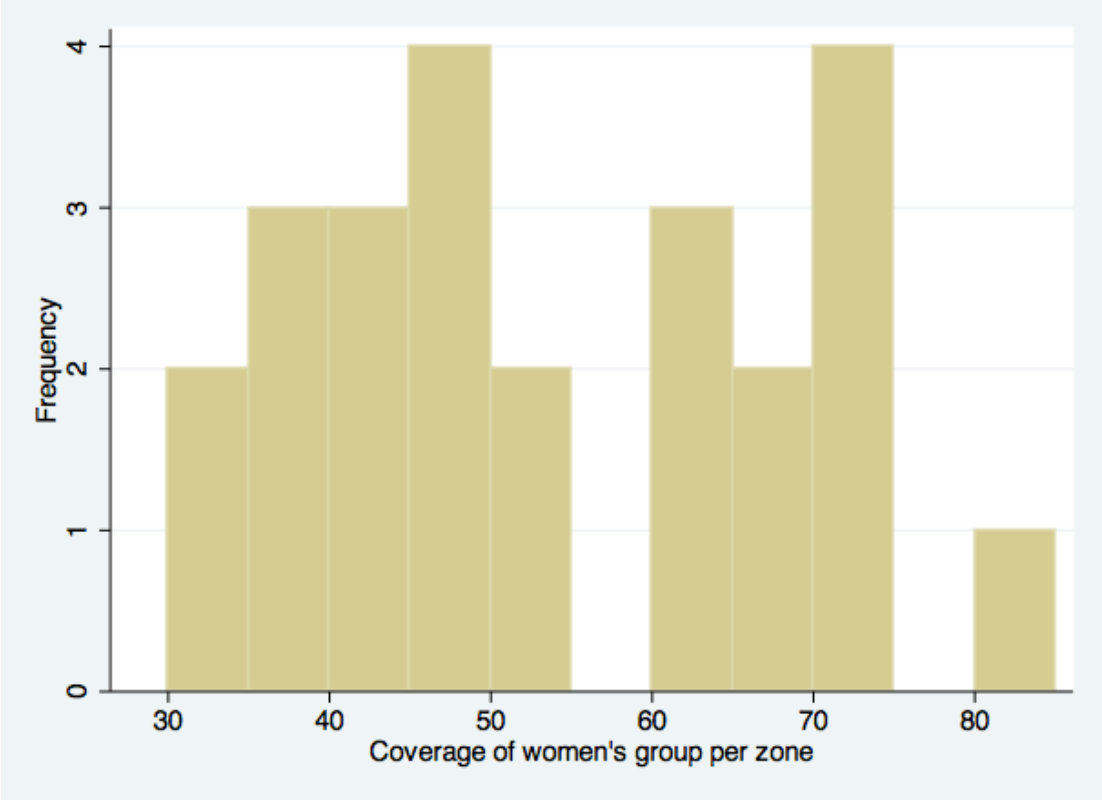


Figure 5.13: Distribution of percentage coverage of women's groups in intervention zones



5.2.9 Socioeconomic and demographic characteristics related to exposure to the intervention

Table 5.10 presents data for exposure to the women's group intervention (defined as reporting ever having attended a group) in different sub-groups of the study population in women's group intervention areas. Looking at exposure by age-group, there was an increasing trend with age in the proportion of women who had ever attended a women's group (also see Figure 5.14). Similarly, exposure increased with parity, with only 28% of women who had no previous pregnancy ever attending a group, and 56-63% of women with one or more previous pregnancies attending. Exposure by socioeconomic quintile was similar across the first four quintiles (54-58%), but in the least poor quintile attendance was lower (44%). Perhaps reflecting a similar underlying phenomenon, a smaller proportion of women with secondary education or higher attended groups (44%) compared to those with primary or no education (54-57%).

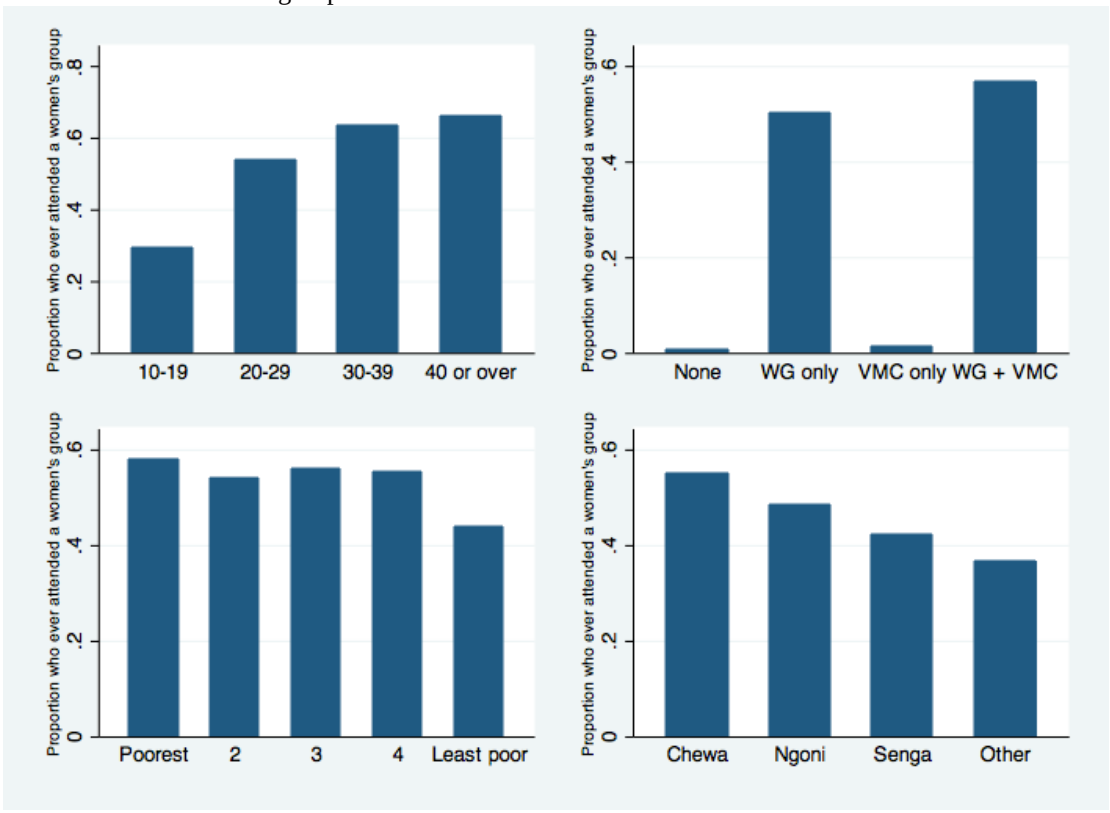
Table 5.10: Exposure to women's group intervention by sub-group

	Population in this group N (%)	**Proportion attending women's groups** %
Age group		
10-19 years	2315 (13)	30
20-29 years	10343 (56)	54
30-39 years	4856 (26)	63
40 and over	836 (5)	66
Socioeconomic quintile		
Poorest	3658 (20)	58
2	3502 (19)	54
3	3930 (22)	56
4	3889 (22)	55
Least poor	3036 (17)	44
Allocation to peer counselling		
Women's groups + peer	4461 (24)	57
counselling	4612 (25)	50
Women's groups alone	4566 (25)	1
Peer counselling alone	4903 (26)	1
No intervention		
Tribe		
Chewa	16386 (90)	55
Ngoni	1026 (6)	49
Senga	379 (2)	42
Other	408 (2)	37
Married		
Married	17263 (94)	55
Never married	396 (2)	21
Divorced, widowed, other	641 (4)	41
Education		
None	3627 (20)	57
Primary	13267 (72)	54
Secondary or higher	1577 (9)	44
Study year		
1	6280 (34)	51
2	6061 (33)	54
3	6201 (33)	55
Parity		
No previous pregnancy	3367 (18)	28
1 or 2	6658 (36)	56
3 or 4	4259 (23)	59
5 or more pregnancies	3987 (22)	63

Attendance varied by tribe, with Chewa having the highest proportion attending (55%), and 'other tribes' having the smallest proportion (37%). However, other tribes were in a minority, only reflecting 2% of the overall population, and are likely to be from highly mobile groups such as traders and estate workers. The presence of peer-counsellors in the same area seemed to have a small effect on women's group attendance, with slightly higher attendance in areas where both women's groups and peer-counsellors were operating (57%) compared to areas with women's groups alone (50%). But interestingly, there was more evidence that women's groups increased counsellor coverage, with a greater proportion of women in areas with both peer-counsellors and

women's groups being counselled by a volunteer (65%) than in areas with counsellors only (47%).

Figure 5.14: Proportion of women who ever attended a women's group by age, intervention, socioeconomic and tribal groups

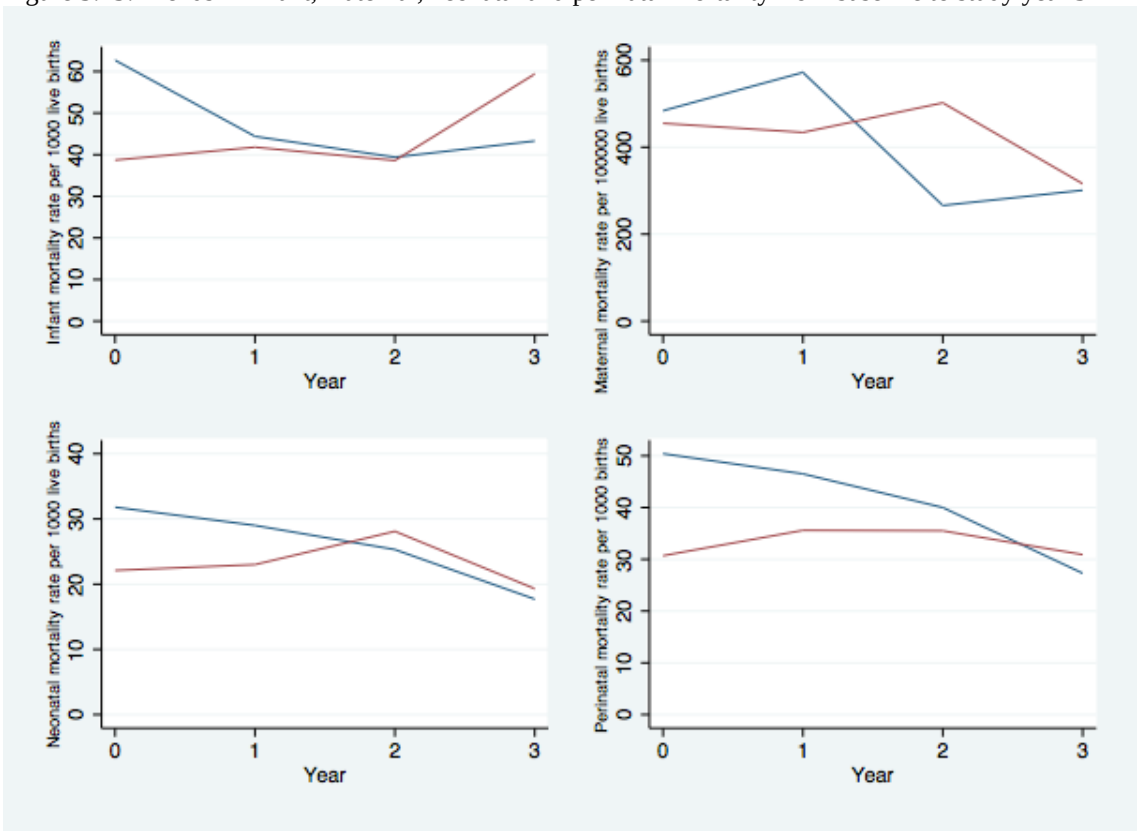


5.3 Intervention impact

5.3.1 Impact on primary (mortality) outcomes

As shown in Table 5.5, all mortality rates were higher in intervention areas at baseline. Figure 5.15 and Table 5.11 show trends for decreasing mortality rates in women's group areas, and no consistent trend in control areas. Similarly, although overall perinatal and neonatal mortality rates for the three-year study period were slightly higher in intervention than control areas, percentage change scores from baseline show consistent, large reductions in all mortality outcomes of over 20%, whereas no consistent patterns are seen in control areas, and some mortality rates are higher than they were at baseline (Table 5.12). Unadjusted odds ratios for each of the mortality rates, and odds ratios adjusted for baseline values and socioeconomic and demographic factors are shown in Table 5.12. Baseline skilled birth attendance was used to adjust for initial imbalance rather than baseline mortality, because in univariate and descriptive analyses it correlated better with all mortality outcomes except infant mortality, and had a much stronger effect in regression models. In years 1-3, both adjusted and unadjusted odds ratios show no difference between women's group and control areas in terms of mortality. *Post hoc* analysis comparing the odds in years 2-3 only shows evidence of a pattern of reduced mortality in women's group areas, but none of these reductions has yet reached a level of statistical significance.

Figure 5.15: Trends in infant, maternal, neonatal and perinatal mortality from baseline to study year 3



— Women's group areas
— Control areas

(NB: Year 3 data for infant mortality using re-census data is only for five-months, from 1/2/08 to 30/6/08)

Table 5.11: Births, deaths and mortality rates in intervention and control clusters at baseline and during trial

	Baseline			Year 1		Year 2		Year 3		Years 1-3		
	Intervention	**Control**	**All**	**Intervention**	**Control**	**Intervention**	**Control**	**Intervention**	**Control**	**Intervention**	**Control**	**All**
Births and deaths												
Births	1488	1564	3052	3053	3289	3073	3039	3039	3209	9165	9537	18702
Live births	1445	1538	2983	2970	3224	3006	2986	2994	3160	8970	9370	18340
Stillbirths	43	26	69	83	65	67	53	45	49	195	167	362
Neonatal deaths	46	34	80	86	74	76	84	53	61	215	219	434
Early (0-6 days)	32	22	54	59	52	56	55	38	50	153	157	310
Late (7-28 days)	14	12	26	27	22	20	29	13	11	60	62	122
Infant deaths	82	61	143	97	102	101	107	31	46	229	255	484
(retrospective births)*	(1307)	(1576)	(2883)	(2181)	(2443)	(2565)	(2772)	(715)[1]	(774)[1]	(5461)	(5989)	(11450)
Maternal deaths	7	7	14	17	14	8	15	9	10	34	39	73
Mortality rates												
Stillbirth rate per 1000 births	28.9	16.6	22.6	27.2	19.8	21.8	17.4	14.8	15.3	21.3	17.5	19.4
Perinatal mortality rate per 1000 births	50.4	30.7	40.3	46.5	35.6	40.0	35.5	27.3	30.9	38.0	34.0	35.9
Early neonatal mortality rate per 1000 live births	22.1	14.3	18.1	19.9	16.1	18.6	18.4	12.7	15.8	17.1	16.8	16.9
Late neonatal mortality rate Per 1000 live births	9.7	7.8	8.7	9.1	6.8	6.7	9.7	4.3	3.5	6.7	6.6	6.7
Neonatal mortality rate per 1000 live births	30.9	21.7	26.2	29.0	23.0	25.3	28.1	17.7	19.3	24.0	23.4	23.7
Infant mortality rate per 1000 live births	62.7	38.7	49.6	44.4	41.8	39.4	38.6	43.3	59.4	41.9	42.6	42.3
Maternal mortality ratio per 100,000 live births	484	455	469	572	434	266	502	301	316	379	416	398

*Using retrospectively collected birth and death data from the re-census in June 2008

[1] Year 3 data for infant mortality is only for five-months, from 1/2/08 to 30/6/08

Table 5.12: Women's group impact on mortality rates

	Intervention N (rate)	% change from baseline	Control N (rate)	% change from baseline	Years 1-3*	p value	Years 1-3†	p value	Years 2 and 3†	p value
Stillbirth rate per 1000 births	195/9165 (21.3)	-26.3	167/9537 (17.5)	+5.4	1.20 (0.94-1.53)	0.14	1.07 (0.85-1.34)	0.56	0.90 (0.67-1.21)	0.50
Perinatal mortality rate per 1000 births	348/9165 (38.0)	-22.6	324/9537 (34.0)	+10.7	1.09 (0.84-1.42)	0.50	0.98 (0.79-1.22)	0.87	0.85 (0.64-1.13)	0.27
Early neonatal mortality rate per 1000 live births	153/8970 (17.1)	-22.6	157/9370 (16.8)	+17.5	1.01 (0.67-1.52)	0.97	0.90 (0.62-1.32)	0.60	0.78 (0.48-1.29)	0.33
Late neonatal mortality rate per 1000 live births	60/8970 (6.7)	-30.9	62/9370 (6.6)	-15.4	1.02 (0.68-1.54)	0.91	0.99 (0.66-1.49)	0.98	0.84 (0.51-1.36)	0.47
Neonatal mortality rate per 1000 live births	215/8970 (24.0)	-22.3	219/9370 (23.4)	+7.8	1.05 (0.76-1.46)	0.76	0.95 (0.71-1.28)	0.95	0.82 (0.55-1.22)	0.33
Infant mortality rate per 1000 live births	229/5461 (41.9)	-33.2	255/5989 (42.6)	+10.1	1.03 (0.76-1.40)	0.84	‡ 0.88 (0.65-1.20)	0.43	‡ 0.86 (0.58-1.27)	0.45
Maternal mortality ratio per 100,000 live births	34/8970 (379)	-21.7	39/9370 (416)	-8.6	0.91 (0.57-1.44)	0.68	0.94 (0.56-1.61)	0.84	0.68 (0.33-1.41)	0.30

Data are odds ratio (95% CI). *Adjusted for stratification (by other factorial intervention) and clustering only. † Adjusted for stratification, clustering, cluster-level baseline skilled birth attendance, socioeconomic quintile, maternal age (quadratic term), and education. ‡ Adjusted for stratification, clustering, cluster-level baseline infant mortality, socioeconomic quintile and age (quadratic term). Education data was not available with the retrospective infant outcome dataset.
Adjustments for multiple testing have not been made because none of the p-values were close to significance.

Due to the social processes involved, the full impact of women's groups may take time to achieve, and the inclusion of data for year 1 may have diluted the effect seen. The apparent increase in effect size for all mortality outcomes when looking at years 2 and 3 only, prompted further *post hoc* exploration into the impact in year 3 alone. There were a relatively small number of observations in this dataset, and regression for maternal outcomes could not be run. For perinatal and neonatal outcomes, little difference was seen between year 3 alone and years 2 and 3 together. However, for infant mortality, the effect in year 3 alone was more pronounced, though not statistically significant (adjusted odds ratio 0.53 (95% CI 0.21-1.35). The lack of statistical significance is not surprising given that data for only the first 5-months of year 3 were available, but it suggests that the magnitude of mortality reduction may increase with time.

Zone 17 was an extreme outlier for cluster-level socioeconomic score and its effect on the results was considered here (Figure 5.3 and Figure 5.10). Analyses were repeated excluding zone 17, but this did not make a large difference on any variable. The largest effect was for infant mortality (adjusted odds ratio for years 1-3 0.85 (95% CI 0.62-1.15)), but this was still not significant.

Baseline mortality rates were not highly correlated with mortality outcomes (with the exception of infant mortality), and their inclusion in the models in order to adjust for baseline imbalances was not significant. However, baseline skilled birth attendance was highly correlated with all mortality outcomes (with the exception of infant mortality), and was included instead to adjust for baseline differences. The possible reasons for the lack of correlation between baseline and study mortality rates might be that the period of data collection for baseline was short and produced highly variable mortality estimates. Furthermore, the surveillance system was newly established during this phase and may have been more prone to error. Infant mortality would not be expected to be so highly correlated with skilled birth attendance given the high burden of post-neonatal illness in this setting.

5.3.2 Impact on secondary (behavioural and process) outcomes

Data were collected prospectively from one-month postpartum interviews and were used to calculate the prevalence of certain key health behaviours in women's group and control areas. The comparisons are shown in Table 5.13 below. Many secondary outcomes improved in both intervention and control areas. Odds ratios for any antenatal care, births attended by TBAs, and four polio doses by 6-months of age, adjusted for baseline values, socioeconomic quintile, maternal age and education, show significant improvements in women's group areas compared to control areas. The unadjusted odds ratio for exclusive breastfeeding shows a significant 79% improvement in women's group areas, and there is still and increase after adjusting for socioeconomic and demographic factors, but this is no longer significant. The adjusted odds ratio for three pentavalent vaccine doses suggested a detrimental effect of women's groups, but given the large number of tests performed here, the validity of these significant results needs to be interpreted with caution, as some may have occurred just by chance.

Many adjusted odds ratios showed non-significant improvements in intervention areas compared to control areas, but there were improvements for increased health-care seeking and reduced maternal and infant morbidity in control arms as well. This could be due to secular trends, or possibly the effects of the infant feeding intervention, which was present in half of zones in both women's group and control areas, and had similar outcomes (especially uptake of antenatal HIV-testing, childhood immunisations and exclusive breastfeeding). In recognition of the fact that there were some imbalances between intervention and control areas at baseline, percentage change from baseline scores have been calculated (Table 5.13). Larger improvements in health-care seeking were seen in women's group areas compared to control areas for uptake of HIV-testing, skilled attendance at delivery, delayed infant bathing, post-natal care and complete infant polio immunisation. Greater reductions were also seen in reported maternal problems (especially antenatal problems) and deliveries attended by TBAs.

Coverage of some of the secondary outcome indicators was already very high at baseline: antenatal care, use of any SP, clean delivery (washing hands with soap or wearing gloves), early wrapping and any BCG, polio and pentavalent immunisation

were all over 90%. This may have left relatively little room for improvement, making it unlikely that the study would detect large, significant effects on these outcomes.

In most cases, the effect of adjusting for baseline values was to increase the effect size, however for many of the secondary outcome variables (two or more doses of SP, bednet used the night before interview and dipped, birth attendant washed hands or wore gloves, baby wrapped within 30 minutes, any infant diarrhoea, any BCG vaccination by 6-months (years 2 and 3), any polio dose, initiated breastfeeding within 1 hour, use of prelacteals, and any breastfeeding problem), the cluster-level baseline values did not predict the outcome well, so may be part of the reason why adjusting for baseline values made no difference.

The effect of adjusting for baseline values may have had special implications for exclusive breastfeeding outcomes. The infant feeding intervention, which promoted exclusive breastfeeding, may have had some early effects during the baseline phase, as it had already started during this period. Adjusting for baseline breastfeeding outcomes may remove some of the effect of the infant feeding intervention, since it was not a true baseline measure (in the absence of any intervention) for this outcome. Adjusting for socioeconomic and demographic variables but not baseline exclusive breastfeeding rates shows a significant increase of around 82% in women's group areas compared to control areas (adjusted odds ratio 1.82 (95% CI 1.07-3.08)).

As was done with the mortality outcomes, the effect of excluding zone 17 from these analyses because of its atypical socioeconomic score was explored, but it made little difference.

Table 5.13: Women's group impact on process indicators and secondary outcomes

	Intervention N (%)	% change from baseline	Control N (%)	% change from baseline	Odds ratio (95% CI) for years 1-3*	Odds ratio (95% CI) for years 1-3†	Odds ratio (95% CI) for years 2 and 3†
Pregnancies	9073		9469				
Any antenatal care at a health facility	8657 (95.7)	+4.9	8926 (94.4)	+2.9	1.44 (0.89-2.34)	1.46 (1.00-2.13)	1.33 (0.89-1.98)
Four or more antenatal care visits	2564 (29.3)	-2.3	2703 (29.7)	-15.6	0.91 (0.63-1.34)	1.03 (0.73-1.44)	0.96 (0.66-1.40)
Any iron and folic acid	7692 (88.9)	+1.1	8160 (90.3)	-1.8	0.93 (0.57-1.52)	1.11 (0.72-1.69)	1.13 (0.66-1.94)
More than 90 days iron/folate	1587 (18.3)	+7.6	1362 (15.1)	-39.1	1.26 (0.67-2.38)	1.67 (0.99-2.82)	1.89 (1.07-3.34)
Any tetanus toxiod immunisation	7600 (87.8)	+2.0	7504 (83.3)	+1.3	1.40 (0.94-2.09)	1.20 (0.83-1.75)	1.16 (0.80-1.70)
Adequate tetanus toxoid[1]	5831 (68.2)	+11.4	6298 (71.1)	+14.9	0.83 (0.57-1.20)	0.83 (0.63-1.09)	0.80 (0.61-1.06)
Any sulphadine-pyrimethamine (SP)	8288 (92.7)	+1.2	8664 (92.7)	-0.7	1.05 (0.72-1.54)	1.17 (0.89-1.54)	1.16 (0.87-1.55)
Two or more doses of SP	4031 (48.8)	+8.9	4398 (50.8)	+23.6	0.80 (0.42-1.50)	0.75 (0.40-1.39)	0.76 (0.39-1.49)
Bednet use night before interview	4978 (54.9)	+28.9	5363 (56.6)	+27.2	0.91 (0.66-1.27)	0.97 (0.74-1.26)	0.98 (0.72-1.35)
Bednet used every night in pregnancy	4964 (55.1)	+14.8	5090 (54.1)	+7.3	1.02 (0.69-1.51)	1.07 (0.76-1.51)	1.14 (0.76-1.72)
Any HIV-testing at antenatal care	4522 (50.4)	+427.1	4989 (53.2)	+380.0	0.79 (0.42-1.48)	0.87 (0.52-1.45)	0.77 (0.38-1.55)
Any perceived antenatal, delivery or postnatal maternal problem	4345 (48.1)	-14.7	4255 (45.1)	-7.6	1.02 (0.59-1.78)	0.79 (0.54-1.18)	0.80 (0.52-1.24)
Infants with 1m follow-up data	9169		9540				
Institutional deliveries	4599 (50.3)	+39.3	4734 (49.7)	+13.7	0.99 (0.63-1.56)	1.24 (0.92-1.68)	1.22 (0.86-1.72)
Birth attended by skilled provider	4670 (50.9)	+41.8	4792 (50.2)	+18.4	1.00 (0.64-1.55)	1.20 (0.89-1.62)	1.16 (0.82-1.64)
Birth attended by a TBA	2700 (29.4)	-28.3	3267 (34.2)	-8.8	0.78 (0.48-1.27)	0.71 (0.51-0.97)	0.69 (0.48-0.99)
Attendant washed hands/wore gloves	6864 (90.1)	-1.7	8137 (92.9)	+1.3	0.70 (0.39-1.24)	0.67 (0.38-1.16)	0.54 (0.30-0.97)
Baby wrapped within 30 min	8635 (97.9)	+4.8	9093 (98.3)	+10.8	1.04 (0.53-2.07)	1.01 (0.50-2.06)	0.92 (0.45-1.88)
Baby bathed after 24hrs	4925 (56.2)	+75.6	5334 (58.0)	+58.9	0.95 (0.34-2.65)	1.20 (0.54-2.66)	1.32 (0.55-3.21)
Postnatal care at a health facility	2933 (37.9)	+51.6	5132 (39.3)	+24.8	0.85 (0.49-1.48)	1.11 (0.76-1.61)	1.24 (0.81-1.89)
Infant received BCG	4660 (60.1)	+34.8	4823 (55.9)	+33.4	1.20 (0.70-2.07)	1.14 (0.77-1.68)	1.22 (0.76-1.96)
Infant received polio immunisation	4143 (52.3)	+41.0	4608 (51.8)	+38.9	1.03 (0.59-1.77)	1.05 (0.66-1.67)	1.00 (0.55-1.85)
Any perceived infant problem (cough, fever or diarrhoea)	2794 (37.5)	-17.2	2868 (37.3)	-18.6	1.04 (0.67-1.62)	1.04 (0.72-1.48)	1.15 (0.76-1.73)
Infants with follow-up data on vaccinations received by 6m	5653		5987				
Any BCG	5421 (96.5)	+0.2	5752 (97.0)	+1.7	0.67 (0.31-1.47)	0.61 (0.29-1.28)	0.67 (0.25-1.78)
Any polio dose	5468 (97.4)	+0.6	5764 (97.2)	+1.9	0.86 (0.39-1.92)	0.81 (0.38-1.72)	1.17 (0.51-2.67)
4 polio doses	433 (7.7)	+28.3	817 (13.8)	-21.6	0.86 (0.39-1.92)	2.52 (1.07-5.96)	2.62 (0.89-7.69)
Any pentavalent dose	5065 (90.2)	-0.6	5681 (95.9)	+1.9	-	0.85 (0.45-1.61)	1.03 (0.50-2.10)
3 pentavalent doses	2940 (52.4)	-4.7	3780 (63.8)	+10.8	0.60 (0.26-1.39)	0.60 (0.33-1.10)	0.45 (0.21-0.96)
Infants with 6m of breastfeeding data	4889		5164				
Infant exclusively breastfed to 6m	902 (18.4)	+4.5	591 (11.4)	+5.6	1.79 (1.05-3.05)	1.29 (0.84-1.98)	1.27 (0.79-2.04)
Initiated breastfeeding within 1 hr	4081 (84.2)	+5.9	4056 (79.3)	+5.3	1.32 (0.48-3.60)	1.26 (0.50-3.16)	1.10 (0.39-3.08)
Use of prelacteals	332 (6.8)	-52.4	496 (9.6)	-56.4	0.76 (0.48-1.20)	0.84 (0.53-1.33)	0.91 (0.58-1.43)
Any breastfeeding problem	76 (1.6)	-38.5	58 (1.1)	-70.3	1.34 (0.68-2.64)	1.33 (0.66-2.68)	1.30 (0.58-2.94)

Data are N (%) and odds ratio (95% CI), unless otherwise indicated. *Adjusted for stratification (by other factorial intervention) and clustering only. † Adjusted for stratification, clustering, baseline values, socioeconomic quintile, maternal age and education.

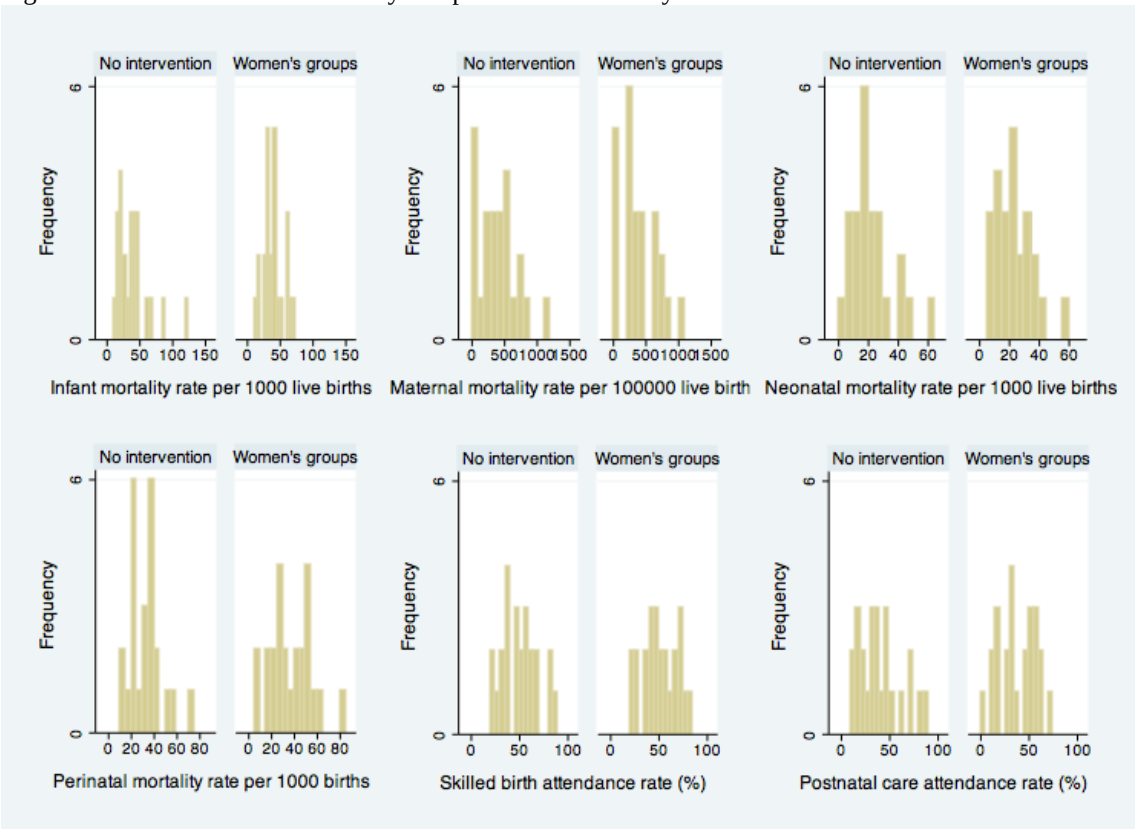
1 Adequate tetanus toxoid immunisation is 2 doses in pregnancy, or having completed the whole course of 5 doses over preceding years.

NB: Denominators for calculating percentages do not include missing data, which differs for each variable, so percentages presented are not directly calculable from the table.

5.3.3 Variation in exposures and outcomes between clusters by study arm

Outcomes of interest and exposure to risk factors or protective factors were not uniformly distributed across zones within study arms (between cluster variability), and individuals within clusters tend to be more similar to each other than individuals selected at random across a population (within cluster variability), and this reduces the variability of responses in a sample. When the ratio of between-cluster variability to within-cluster variability increases (as measured by the intracluster correlation coefficient (ICC)), the power to detect statistical differences between study arms is reduced. Figure 5.3 and Figure 5.13 illustrate the between-cluster variability for cluster-level summary scores of socioeconomic index and the proportion of women attending women's groups. Figure 5.16 further shows how infant, maternal, neonatal and perinatal mortality and skilled birth attendance and postnatal care attendance vary by zone and intervention arm.

Figure 5.16: Distribution of mortality and process outcomes by intervention allocation



Despite restricting the study areas by excluding the main urban centre in Mchinji, there is still considerable variability. Primary mortality outcomes tended to follow a slightly

skewed distribution, with a longer positive tail, caused by a few clusters having very high mortality rates. Secondary outcomes tended to be more normally distributed. As Taljaard (2008) and Campbell (2005) point out, ICCs for process measures (such as number of antenatal visits) tend to be larger than for outcome measures (in their case measures such as number of births or birthweight). A similar pattern can be seen here, with ICCs for all 48 clusters for mortality outcomes ranging from <0.00001 to 0.0096, and those for process outcomes ranging from 0.037 to 0.17 (Table 5.14) (ICC estimates for more outcomes are provided in Appendix 6). This effect may also be partly explained by the fact that ICCs tend to increase with higher prevalences (Taljaard 2008). However, the most likely explanation is the fact that ICC is dependent on the scale of the variable. Intercluster coefficients of variation (k) are not dependent on scale, and these show similar ranges: from <0.05 to 0.47 for mortality outcomes and from 0.04 to 0.52 for process outcomes.

Table 5.14: Intracluster correlation coefficients and intercluster coefficients of variation for primary and key secondary outcomes

	Intra-cluster correlation coefficient (±SE)			**Intercluster coefficient of variation (±SE)**		
	All clusters (48)	Control clusters (24)	True control clusters (12)	All clusters (48)	Control clusters (24)	True control clusters (12)
Perinatal mortality rate per 1000 births	0.0050 (±0.0016)	0.0031 (±0.0017)	0.00076 (±0.0014)	0.368	0.297	0.140
Neonatal mortality rate per 1000 live births	0.0049 (±0.0016)	0.0058 (±0.0025)	0.0027 (±0.0022)	0.449	0.491	0.309
Infant mortality rate per 1000 live births	0.0096 (±0.0029)	0.015 (±0.0056)	0.022 (±0.011)	0.467	0.581	0.656
Maternal mortality ratio per 100,000 live births	<0.00001 (±0.00054)	<0.00001 (±0.00075)	0.00060 (±0.0013)	<0.05	<0.05	0.349
Antenatal care attendance (%)	0.037 (±0.0079)	0.032 (±0.0099)	0.019 (±0.0065)	0.044	0.043	0.056
Skilled birth attendance (%)	0.12 (±0.02)	0.13 (±0.03)	0.16 (±0.06)	0.348	0.352	0.449
Postnatal care attendance (%)	0.17 (±0.03)	0.19 (±0.05)	0.24 (±0.08)	0.520	0.544	0.691
Ever attending women's group (%)	0.41 (±0.051)	0.09 (±0.025)*	0.07 (±0.030)**	1.048	0.281	0.265

*Women's group areas and women's group plus infant feeding areas
**Women's group only areas

ICCs are presented for all clusters (48), control clusters for the women's group trial (24 clusters having no women's groups), and true control clusters (12 clusters having no intervention at all). With interventions impacting on the outcomes and increasing difference between intervention and control areas, you might expect that ICCs for all clusters combined would be larger (more between-cluster variability) than for women's group control or true control clusters, and this is the case for perinatal mortality and antenatal care attendance. However, this is not the case for most other variables, ICCs for infant mortality, skilled birth attendance and postnatal care increase as the number

of clusters gets smaller. There may be different effects on overall variability, depending on whether the intervention reduces the variability of outcomes in women's group areas (thus reducing the overall variability), as well as increasing or reducing the overall proportion or rate. This effect may differ depending on the outcome in question. For example, the effect on mortality may be greater in zones with higher baseline mortality, and thus reduce the variability in mortality rates in intervention areas (i.e. it brings the positive tail in).

5.4 Sub-group analysis and effect modification

5.4.1 Impact according to intervention group

As both women's groups and infant feeding counsellors work to improve mother and child health, the presence of both interventions in an area has the potential to create a synergistic or even antagonistic effect, resulting in greater or smaller effects respectively than either intervention alone. The interaction between the women's group (WG) and infant feeding (VMC) interventions was explored descriptively, and also by inclusion of an interaction term (WG*VMC) in regression models. This was an *a priori* planned analysis. Interaction plots of primary mortality outcomes against intervention allocation showed that there did appear to be interaction between women's groups and infant feeding counselling for perinatal, neonatal and maternal mortality outcomes, but not for infant mortality (Appendix 7). The significance of adding an interaction term to the regression model was evaluated using likelihood ratio tests, but was non-significant for any models, except exclusive breastfeeding. However, given the limited power of this analysis, it is not surprising that interactions were not significant, and non-significant results do not rule out the possibility that there was some interaction between the two interventions (265, 293). Adding the interaction term affected the model so that the effects for WG and VMC interventions alone changed in magnitude and sometimes direction, making the impact of the WG intervention alone stronger (less than 1.00). The odds ratios for the WG*VMC variable were close to 1.00 for perinatal, neonatal and maternal mortality, suggesting that there was no difference in mortality rates between control areas (with neither intervention) and areas with both WG and VMC.

This further supports the idea that there may have been an interaction between the two interventions, but that there is insufficient power for this to reach statistical significance. A null or possibly slightly negative effect of both interventions together was unexpected, and highlighted the importance of understanding how the two interventions work together and separately. Further exploration was made into the impact in each of the four arms of the study. This data is presented in Table 5.15.

For maternal, perinatal and neonatal mortality, analysing outcomes according to the four intervention groups revealed an effect size in women's group only areas that was more pronounced than in the earlier analysis (Table 5.12), but close to 1 (no effect) in women's group and infant feeding areas combined (WG+VMC). Thus the apparent lack of effect in the earlier analysis that compare 24 women's group areas (WG and WG+VMC) with 24 control areas (VMC and no intervention), may have arisen because the impact in areas with women's groups alone is obscured by the lack of impact in areas with both interventions. For infant mortality the picture was different; the effect again became more pronounced in women's group only areas when including all four intervention groups in the model, but was even larger in areas with both interventions.

For infant, neonatal and perinatal mortality, the lowest mortality rates are in areas with infant feeding intervention only, and unadjusted odds ratios show larger effects in this group. For maternal mortality, the lowest mortality rate (and corresponding unadjusted odds ratio) is in areas with only women's group intervention. After adjusting for baseline differences and other covariates, the biggest reduction in maternal mortality is still seen in women's group only areas, followed by infant feeding alone. And after adjustment, the biggest effects in perinatal and neonatal mortality are now seen in areas with women's groups only, highlighting the confounding of the relationship between intervention allocation and mortality, and this was mostly due to baseline imbalances. In women's group only areas in *post hoc* exploratory analysis of year 2 and 3 data, the effect on perinatal mortality is significant, and the effect on neonatal mortality is close to significant (reflecting 36% and 41% reductions respectively). Very little effect on perinatal, neonatal or maternal mortality is seen in areas with both interventions in analysis for years 1-3 and in years 2 and 3 only. The exception to this is an apparent large effect on maternal mortality in years 2 and 3. After adjustment, there were

borderline effects for infant mortality in women's group plus infant feeding and infant feeding only areas in years 1-3.

Figure 5.17 shows trends in unadjusted mortality rates over the study period by intervention group. Mortality rate estimates broken down both by year and by intervention group are likely to be imprecise due to the small numbers in each group, and the bounds of uncertainty are wide. However, for all four mortality outcomes shown, rates are lower in year 3 than they were at baseline for women's group and women's group plus infant feeding areas, but this is not the case for infant feeding alone and control areas.

Consistent with the mortality outcomes, the adjusted effects on antenatal care, tetanus immunisation, taking SP, maternal antenatal problems, skilled birth attendance and postnatal care attendance were all highest is women's group only and women's group plus counselling areas, though these were also not statistically significant (Table 5.15). Little effect on antenatal care and postnatal care was seen in infant feeding only areas, but a stronger effect on reported infant illnesses was seen. Maternal morbidity was reduced by 33% in areas with both interventions, while little effect was seen in areas with either intervention alone. When broken down by the four intervention groups, the effects on exclusive breastfeeding are much higher in women's group plus infant feeding areas, and after adjusting for covariates, there is very little effect in areas with women's group alone or infant feeding alone.

It is important to remember that many comparisons have been made here, and significant effects should be interpreted with caution. It was not felt necessary to adjust p-values for multiple testing given the overall lack of significance seen for all primary outcomes, and tests for years 2 and 3 were *post hoc* and should be considered as exploratory. Part of the reason for the lack of significant effect may be the lower power to detect differences by four intervention groups rather than just two. In summary, it is difficult to draw firm conclusions about the effects of the interaction between the women's group and peer counselling interventions, though patterns of effects suggest that a qualitative interaction does exist (265).

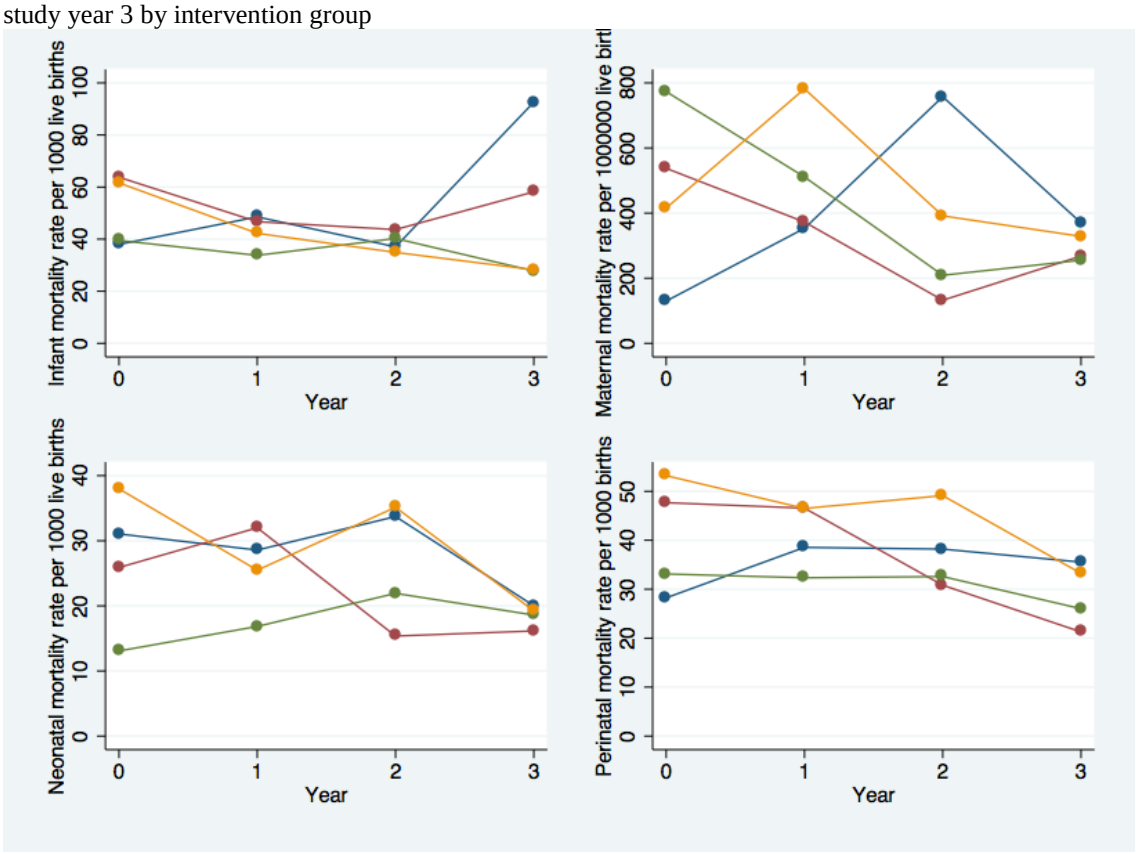
Table 5.15: Comparison of primary and secondary outcomes by four intervention groups

	Rate by intervention group N/total (rate)	**Years 1-3***	**p value** (Wald)	**Years 1-3†**	**p value** (Wald)	**Years 2 and 3†**	**p value** (Wald)
Primary outcomes							
Perinatal mortality rate (per 1000 births)							
No intervention	185/4941 (37.4)	-		-		-	
Women's groups only	155/4661 (33.3)	0.84 (0.59-1.21)		0.84 (0.62-1.13)		0.64 (0.44-0.94)	
Infant feeding only	139/4595 (30.3)	0.78 (0.54-1.12)	0.20	0.89 (0.65-1.21)	0.47	0.88 (0.60-1.29)	0.09
Women's groups + infant feeding	193/4500 (42.9)	1.12 (0.79-1.59)		1.04 (0.78-1.38)		1.00 (0.70-1.43)	
Neonatal mortality rate (per 1000 live births)							
No intervention	133/4851 (27.4)	-		-		-	
Women's groups only	98/4577 (21.4)	0.77 (0.49-1.19)		0.77 (0.52-1.15)		0.59 (0.34-1.03)	
Infant feeding only	86/4518 (19.0)	0.67 (0.43-1.05)	0.23	0.78 (0.52-1.19)	0.50	0.89 (0.51-1.54)	0.22
Women's groups + infant feeding	117/4390 (26.7)	0.98 (0.64-1.51)		0.94 (0.64-1.39)		1.00 (0.60-1.68)	
Infant mortality rate (per 1000 live births)							
No intervention	152/3127 (48.6)	-		-		-	
Women's groups only	129/2758 (46.8)	0.96 (0.64-1.47)		‡ 0.79 (0.52-1.20)		‡ 0.84 (0.50-1.41)	
Infant feeding only	103/2862 (36.0)	0.69 (0.45-1.06)	0.26	‡ 0.67 (0.45-1.00)	0.16	‡ 0.73 (0.44-1.22)	0.41
Women's groups + infant feeding	100/2703 (37.0)	0.77 (0.50-1.17)		‡ 0.67 (0.44-1.01)		‡ 0.65 (0.38-1.11)	
Maternal mortality rate (per 100000 live births)							
No intervention	24/4903 (489)	-		-		-	
Women's groups only	12/4612 (260)	0.53 (0.26-1.06)	0.19	0.60 (0.28-1.31)	0.42	0.51 (0.19-1.36)	0.39
Infant feeding only	15/4566 (329)	0.67 (0.35-1.28)		0.71 (0.33-1.54)		0.52 (0.18-1.51)	
Women's groups + infant feeding	22/4461 (493)	1.01 (0.56-1.80)		1.07 (0.56-2.07)		0.54 (0.22-1.37)	
Secondary outcomes							
Any antenatal care (%)							
No intervention	4576/4896 (93.5)	-		-		-	
Women's groups only	4371/4601 (95.0)	1.32 (0.67-2.60)	0.35	1.38 (0.81-2.35)	0.26	1.43 (0.82-2.49)	0.55
Infant feeding only	4350/4558 (95.4)	1.16 (0.59-2.27)		0.94 (0.56-1.60)		1.05 (0.61-1.83)	
Women's groups + infant feeding	4286/4448 (96.4)	1.84 (0.93-3.64)		1.47 (0.85-2.53)		1.30 (0.74-2.29)	
Mother received any Tetanus Toxoid Vaccine (%)							
No intervention	3756/4657 (80.7)	-		-		-	
Women's groups only	3828/4385 (87.3)	1.73 (0.99-3.03)	0.13	1.41 (0.84-2.36)	0.64	1.33 (0.79-2.24)	0.74
Infant feeding only	3748/4354 (86.1)	1.63 (0.93-2.85)		1.19 (0.70-2.02)		1.23 (0.72-2.10)	
Women's groups + infant feeding	3772/4267 (88.4)	1.84 (1.05-3.21)		1.23 (0.71-2.14)		1.24 (0.71-2.17)	
Mother received any SP (%)							
No intervention	4429/4831 (91.7)	-		-		-	
Women's groups only	4182/4542 (92.1)	1.08 (0.63-1.85)	0.70	1.13 (0.78-1.63)	0.45	1.00 (0.68-1.47)	0.23
Infant feeding only	4235/4512 (93.9)	1.29 (0.75-2.21)		1.11 (0.77-1.62)		1.05 (0.71-1.56)	
Women's groups + infant feeding	4106/4397 (93.4)	1.31 (0.77-2.25)		1.37 (0.94-1.99)		1.45 (0.97-2.16)	

	Rate by intervention group N/total (rate)	Years 1-3*	p value (Wald)	Years 1-3†	p value (Wald)	Years 2 and 3†	p value (Wald)
Always used bednet during pregnancy (%)		-	0.44	-	0.32	-	0.59
No intervention	2480/4884 (50.8)	1.06 (0.61-1.84)		0.89 (0.55-1.45)		0.94 (0.52-1.68)	
Women's groups only	2434/4580 (53.1)	1.44 (0.82-2.50)		1.07 (0.65-1.76)		0.95 (0.52-1.73)	
Infant feeding only	2610/4532 (57.6)	1.41 (0.81-2.46)		1.40 (0.86-2.26)		1.35 (0.76-2.40)	
Women's groups + infant feeding	2530/4426 (57.2)						
Maternal morbidity (antenatal, delivery or postnatal problem) (%)							
No intervention	2194/4891 (44.9)	-		-		-	
Women's groups only	2460/4596 (53.5)	1.46 (0.67-3.15)	0.44	0.93 (0.54-1.62)	0.43	1.00 (0.54-1.85)	0.48
Infant feeding only	2061/4555 (45.3)	1.07 (0.49-2.31)		0.98 (0.57-1.69)		1.07 (0.59-1.95)	
Women's groups + infant feeding	1885/4442 (42.4)	0.77 (0.35-1.66)		0.67 (0.39-1.15)		0.69 (0.38-1.26)	
Skilled birth attendance (%)							
No intervention	2184/4943 (44.2)	-		-		-	
Women's groups only	2404/4664 (51.5)	1.21 (0.65-2.25)	0.60	1.23 (0.81-1.88)	0.60	1.24 (0.77-2.01)	0.78
Infant feeding only	2608/4597 (56.7)	1.53 (0.83-2.84)		1.14 (0.74-1.74)		1.16 (0.71-1.89)	
Women's groups + infant feeding	2266/4505 (50.3)	1.26 (0.68-2.34)		1.32 (0.87-2.02)		1.25 (0.77-2.02)	
Postnatal care attendance (%)							
No intervention	1419/4213 (33.7)	-		-		-	
Women's groups only	1394/3911 (35.6)	0.92 (0.42-2.00)	0.49	1.08 (0.64-1.80)	0.95	1.23 (0.68-2.21)	0.79
Infant feeding only	1733/3815 (45.4)	1.60 (0.73-3.49)		0.97 (0.57-1.65)		0.93 (0.51-1.70)	
Women's groups + infant feeding	1539/3835 (40.1)	1.27 (0.58-2.78)		1.12 (0.67-1.87)		1.17 (0.65-2.10)	
Infant morbidity (cough, fever or diarrhoea) (%)							
No intervention	1749/4009 (43.6)	-		-		-	
Women's groups only	1501/3768 (39.8)	0.92 (0.49-1.72)	0.12	0.94 (0.57-1.55)	0.33	0.96 (0.54-1.71)	0.39
Infant feeding only	1119/3686 (30.4)	0.52 (0.28-0.97)		0.65 (0.39-1.09)		0.62 (0.35-1.12)	
Women's groups + infant feeding	1293/3675 (35.2)	0.61 (0.32-1.14)		0.75 (0.45-1.25)		0.85 (0.47-1.53)	
Exclusive breastfeeding rate (%)							
No intervention	258/2641 (9.8)	-		-		-	
Women's groups only	231/2606 (8.9)	0.86 (0.43-1.74)	<0.001	0.81 (0.46-1.44)	0.04	0.93 (0.49-1.76)	0.28
Infant feeding only	333/2521 (13.2)	1.03 (0.51-2.09)		0.86 (0.48-1.53)		0.94 (0.49-1.82)	
Women's groups + infant feeding	671/2282 (29.4)	3.78 (1.89-7.57)		1.82 (0.98-3.39)		1.69 (0.84-3.42)	

Data are odds ratio (95% CI). *Adjusted for stratification clustering only. † Adjusted for clustering, cluster-level baseline values, socioeconomic quintile, maternal age (quadratic term) and education. ‡ Adjusted for clustering, cluster-level baseline values, socioeconomic quintile and maternal age (quadratic term). Education data was not available with the retrospective infant outcome dataset.
Adjustments for multiple testing have not been made because none of the p-values for primary outcomes were close to significance.

Figure 5.17: Trends in unadjusted infant, maternal, neonatal and perinatal mortality from baseline to study year 3 by intervention group



5.4.2 Impact according to level of exposure

The main analysis was performed by intention-to-treat, with all women, regardless of whether they attended groups or not, being classified as exposed to the intervention according to the zone they were allocated to (Table 5.12). Coverage of women's groups was just over 50% in intervention areas, so 50% of women allocated as exposed to women's groups may in fact not have been exposed at all. The nature of the intervention as a community mobilisation approach means that even if women did not attend groups, they may have benefited from changes in their community and discussions they had with women who did attend groups, however, we might still expect that women who attended groups would have better outcomes than those who did not. Indeed, in a crude comparison of mortality rates according to whether women had ever attended a group, it was found that neonatal mortality rates were higher amongst women who had never attended a group but lived in a women's group area (28.7 per 1000 live births), compared to those who had ever attended (23.3).

Furthermore, one of Bradford Hill's criteria for assessing the evidence of a causal association is 'biological gradient', or 'dose-response', meaning that greater exposure to a causative factor should generally lead to a larger effect (294). Thus outcome effects were explored according to level of exposure to the intervention in a 'per protocol analysis' (according to who got the intervention) as an addition to the main intention-to-treat analysis. This analysis is presented in Table 5.16 below.

Individual data on attendance of women's groups was not available for infant mortality data using the retrospective re-census dataset. It was also not possible to analyse maternal mortality in this way, as many respondents were not able to provide information about women's group attendance for their deceased wife or relative, so there was a lot of missing data. However, data from other prospective datasets did show significant trends for lower neonatal and perinatal mortality as group attendance increased. Women who never attended women's groups, but lived in women's group areas had the highest mortality rates (higher than in control areas), and this was used as the reference group. Odds ratios and adjusted odds ratios for perinatal and neonatal mortality showed significantly decreasing risk of mortality with increasing number of times women's groups were attended.

For all health-care seeking variables (except tetanus toxoid immuisation), coverage rates significantly increased with women's group 'dose' level, and women's group dose effects on exclusive breastfeeding were also significant. Reported maternal antenatal and delivery problems decreased with increasing women's group 'dose', though not significantly. Reporting of maternal problems did not have a clear dose-response effect, but infant morbidity appeared to increase with women's group 'dose' level, and women who attended groups 11 or more times reported significantly more infant problems. It is not clear whether this is due to higher incidence of problems, or higher reporting.

Table 5.16: Comparison of primary and secondary outcomes by exposure level

	Rate by exposure group N/total (rate)	**Years 1-3***	**p value** (Wald) ‡	**Years 1-3†**	**p value** (Wald) ‡	**Years 2 and 3†**	**p value** (Wald) ‡
Primary outcomes							
Perinatal mortality rate (per 1000 births)							
Control areas	304/7759 (39.2)	0.72 (0.52-0.99)		0.76 (0.56-1.01)		0.77 (0.52-1.14)	
WG area never attended	178/3619 (49.2)	1.00	0.0001	1.00	0.0001	1.00	<0.0001
Attended 1-5 times	103/2537 (40.6)	0.72 (0.56-0.94)		0.69 (0.53-0.90)		0.53 (0.36-0.77)	
Attended 6-10 times	36/1269 (28.4)	0.51 (0.35-0.74)		0.48 (0.33-0.71)		0.38 (0.22-0.63)	
Attended 11 or more times	6/409 (14.7)	0.26 (0.11-0.59)		0.21 (0.09-0.53)		0.18 (0.06-0.51)	
Neonatal mortality rate (per 1000 live births)							
Control areas	204/7602 (26.8)	0.81 (0.54-1.21)		0.88 (0.60-1.29)		0.92 (0.55-1.55)	
WG area never attended	104/3523 (29.5)	1.00		1.00		1.00	
Attended 1-5 times	70/2479 (28.2)	0.84 (0.54-1.21)	0.02	0.86 (0.62-1.19)	0.04	0.73 (0.47-1.15)	0.02
Attended 6-10 times	25/1250 (20.0)	0.59 (0.37-0.93)		0.59 (0.37-0.95)		0.46 (0.25-0.84)	
Attended 11 or more times	2/403 (5.0)	0.15 (0.04-0.62)		0.16 (0.04-0.66)		0.08 (0.01-0.58)	
Infant mortality rate (per 1000 live births)	NA	NA	NA	NA	NA	NA	NA
Maternal mortality rate (per 1000 live births)	(Not enough values in some groups even after collapsing last 2 groups)						
Secondary outcomes							
Any antenatal care (%)							
Control areas	7236/7684 (94.2)	0.83 (0.51-1.36)		0.87 (0.58-1.30)		1.10 (0.70-1.74)	
WG area never attended	3411/3584 (95.2)	1.00	0.09	1.00	0.01	1.00	0.005
Attended 1-5 times	2398/2500 (95.9)	1.32 (1.01-1.72)		1.42 (1.08-1.87)		1.87 (1.28-2.73)	
Attended 6-10 times	1207/1256 (96.1)	1.27 (0.90-1.80)		1.35 (0.95-1.92)		1.57 (1.00-2.48)	
Attended 11 or more times	394/405 (97.3)	1.66 (0.88-3.16)		2.24 (1.11-4.54)		2.67 (1.17-6.11)	
Mother received any Tetanus Toxoid Vaccine (%)							
Control areas	6061/7356 (82.4)	0.61 (0.43-0.87)		0.73 (0.51-1.02)		0.76 (0.53-1.10)	
WG area never attended	3051/3425 (89.1)	1.00	0.005	1.00	0.27	1.00	0.27
Attended 1-5 times	2071/2389 (86.7)	0.80 (0.68-0.95)		0.90 (0.75-1.07)		0.98 (0.78-1.23)	
Attended 6-10 times	1058/1212 (87.3)	0.86 (0.70-1.07)		1.01 (0.81-1.26)		1.05 (0.80-1.37)	
Attended 11 or more times	327/391 (83.6)	0.65 (0.48-0.89)		0.84 (0.62-1.16)		0.74 (0.52-1.07)	
Mother received any SP (%)							
Control areas	7010/7603 (92.2)	1.14 (0.79-1.63)		1.07 (0.82-1.40)		1.07 (0.77-1.48)	
WG area never attended	3226/3540 (91.1)	1.00	0.0001	1.00	<0.0001	1.00	0.003
Attended 1-5 times	2297/2466 (93.2)	1.47 (1.20-1.81)		1.56 (1.26-1.81)		1.66 (1.23-2.25)	
Attended 6-10 times	1168/1243 (94.0)	1.49 (1.13-1.96)		1.57 (1.19-2.08)		1.46 (1.01-2.11)	
Attended 11 or more times	386/401 (96.3)	2.32 (1.35-3.99)		2.62 (1.49-4.62)		2.20 (1.14-4.26)	
Always used bednet during pregnancy (%)							
Control areas	4069/7656 (53.2)	1.01 (0.74-1.36)		1.01 (0.76-1.36)		0.74 (0.51-1.09)	
WG area never attended	1884/3569 (52.8)	1.00	<0.0001	1.00	0.0004	1.00	0.002
Attended 1-5 times	1375/2484 (55.4)	1.27 (0.92-1.73)		1.23 (1.09-1.38)		1.22 (1.05-1.41)	
Attended 6-10 times	732/1256 (58.3)	1.28 (0.92-1.73)		1.23 (1.06-1.42)		1.21 (1.01-1.45)	
Attended 11 or more times	264/403 (65.5)	1.49 (1.02-2.19)		1.48 (1.16-1.88)		1.45 (1.09-1.91)	

	Rate by exposure group N/total (rate)	Years 1-3*	p value (Wald) ‡	Years 1-3†	p value (Wald) ‡	Years 2 and 3†	p value (Wald) ‡
Maternal morbidity (antenatal, delivery or postnatal problem) (%)			0.23		0.32		0.59
Control areas	3465/7680 (45.1)	1.23 (0.83-1.83)		1.48 (0.85-2.58)		1.04 (0.48-2.26)	
WG area never attended	1732/3580 (48.4)	1.00		1.00		1.00	
Attended 1-5 times	1256/2499 (50.3)	1.11 (0.99-1.25)		1.09 (0.97-1.22)		1.11 (0.96-1.29)	
Attended 6-10 times	540/1252 (43.1)	1.04 (0.90-1.21)		1.00 (0.86-1.17)		1.03 (0.86-1.24)	
Attended 11 or more times	171/403 (42.4)	1.22 (0.97-1.54)		1.17 (0.92-1.50)		1.19 (0.90-1.56)	
Skilled birth attendance (%)							
Control areas	3841/7762 (49.5)	0.91 (0.65-1.28)		0.87 (0.67-1.15)		0.90 (0.65-1.24)	
WG area never attended	1901/3621 (52.5)	1.00	0.03	1.00	0.002	1.00	0.09
Attended 1-5 times	1203/2538 (47.4)	0.92 (0.83-1.03)		0.99 (0.88-1.11)		1.05 (0.90-1.22)	
Attended 6-10 times	638/1270 (50.2)	1.05 (0.91-1.21)		1.19 (1.03-1.39)		1.21 (1.01-1.46)	
Attended 11 or more times	250/409 (61.1)	1.33 (1.06-1.68)		1.47 (1.16-1.87)		1.32 (1.01-1.75)	
Postnatal care attendance (%)							
Control areas	2920/7564 (38.6)	1.18 (0.80-1.75)		1.08 (0.78-1.48)		0.93 (0.64-1.37)	
WG area never attended	1337/3490 (38.3)	1.00	0.47	1.00	0.03	1.00	0.25
Attended 1-5 times	909/2455 (37.0)	1.05 (0.94-1.19)		1.13 (1.00-1.28)		1.14 (0.98-1.34)	
Attended 6-10 times	428/1242 (34.5)	1.08 (0.92-1.26)		1.21 (1.03-1.42)		1.17 (0.96-1.41)	
Attended 11 or more times	177/394 (44.9)	1.22 (0.96-1.55)		1.37 (1.07-1.76)		1.23 (0.93-1.63)	
Infant morbidity (cough, fever or diarrhoea) (%)							
Control areas	2734/7317 (37.4)	0.87 (0.61-1.24)		0.73 (0.42-1.25)		0.58 (0.28-1.21)	
WG area never attended	1271/3368 (37.7)	1.00	0.22	1.00	0.09	1.00	0.005
Attended 1-5 times	897/2368 (35.1)	1.01 (0.90-1.14)		1.05 (0.93-1.19)		1.18 (1.01-1.38)	
Attended 6-10 times	423/1204 (35.1)	0.95 (0.82-1.11)		1.02 (0.87-1.19)		1.03 (0.84-1.24)	
Attended 11 or more times	151/389 (38.8)	1.28 (1.01-1.24)		1.35 (1.06-1.73)		1.53 (1.15-2.02)	
Exclusive breastfeeding rate (%)							
Control areas	538/4957 (10.9)	0.59 (0.37-0.93)		0.75 (0.50-1.13)		0.87 (0.55-1.38)	
WG area never attended	352/2201 (16.0)	1.00	0.002	1.00	0.03	1.00	0.01
Attended 1-5 times	387/1542 (18.6)	1.00 (0.82-1.21)		1.00 (0.82-1.22)		0.93 (0.72-1.20)	
Attended 6-10 times	189/841 (22.5)	1.31 (1.04-1.65)		1.28 (1.01-1.62)		1.45 (1.09-1.92)	
Attended 11 or more times	72/263 (27.4)	1.48 (1.06-2.06)		1.39 (0.50-1.13)		1.35 (0.92-1.98)	

Data are odds ratio (95% CI)., and all models , use women in intervention areas who never attended groups as the reference category. *Adjusted for stratification clustering and stratification only. † Adjusted for clustering, stratification, cluster-level baseline values, socioeconomic quintile, age (quadratic for mortality outcomes, linear for process outcomes) and education. Education data was not available with the retrospective infant outcome dataset.

‡ Unadjusted p-values are presented, but after adjustment for multiple testing using the Holm correction (295), p-values for primary outcomes are still significant at the 5% level.

NA – Data not available on women's group attendance for infant mortality using retrospective dataset

5.4.3 Impact according to socioeconomic status

The purpose of the analysis presented in this section was to explore whether or not there were differential effects of the intervention in different socioeconomic groups. This was a *post hoc* analysis, and was done to see whether low effects in some sub-groups may have masked larger effects in other groups. For example, it has been reported that many public heath interventions disproportionately benefit the better off (138), so if poorer women represented a larger proportion of women's group attenders (Table 5.10) but received less of the benefits of the intervention, the effects in other groups may not be apparent.

Table 5.17 shows rates and odds ratios exploring the effects of the interaction between the women's group intervention and socioeconomic status on primary and secondary outcomes. Regression models exploring the interaction between women's group and socioeconomic quintile were built, and women in the lowest quintile in control areas were used as the reference group. No significant interaction effects for primary mortality outcomes were found, though the study was not powered to look at these interactions. However, there are patterns that are suggestive of some degree of interaction. Odds ratios for the 2nd, 3rd, 4th and 5th quintiles all showed greater reductions in neonatal mortality when compared to the poorest quintile, suggesting that the women's group intervention may have had most impact amongst the least poor women and less impact amongst the poorest women. However, the opposite is true for perinatal, infant and maternal mortality, and the effect of women's groups on reducing the risk of adverse outcome is lower in the wealthier quintiles when compared to the poorest.

For health-care seeking outcomes, most showed lower effects of women's groups in the wealthier quintiles (2nd to 5th) compared to the poorest quintile, though they were not large or significant effects. Bednet use showed the least effect amongst the poorest group. A large, significant effect of women's groups on increasing rates of exclusive breastfeeding was seen in the 2nd quintile, and the smallest effect was seen in the least poor quintile. The effects on maternal and infant morbidity are not significant, though women reported significantly more maternal problems in the 3rd and 4th quintiles compared to the 1st.

Due to the number of tests carried out and the low of power to detect statistical differences between sub-groups, it is difficult to draw any firm conclusions about whether women's group effects were stronger in different socioeconomic groups. Overall, it seems that there may have been stronger effects of women's groups amongst the poorest women for infant and maternal mortality and health-care seeking outcomes, suggesting that the intervention did not disproportionately benefit better off women.

Table 5.17: Effects of interaction between women's group intervention and socioeconomic quintile on primary and secondary outcomes

	Rate by intervention group N/total (rate)	**Years 1-3***	**p value** (Wald)	**Years 1-3†**	**p value** (Wald)	**Years 2 and 3†**	**p value** (Wald)
Primary outcomes							
Perinatal mortality rate (per 1000 births)							
1 – poorest	169/3694 (45.7)	-		-		-	
2	122/3531 (34.6)	1.20 (0.74-1.94)	0.73	1.23 (0.74-2.04)	0.79	1.09 (0.58-2.06)	0.97
3	140/3977 (35.2)	0.98 (0.61-1.55)		0.95 (0.59-1.54)		1.25 (0.67-2.35)	
4	109/3915 (27.8)	1.29 (0.78-2.13)		1.25 (0.75-2.09)		1.18 (0.61-2.30)	
5 – least poor	104/3057 (34.0)	0.97 (0.58-1.62)		1.06 (0.63-1.79)		1.11 (0.57-2.18)	
Neonatal mortality rate (per 1000 live births)							
1 – poorest	105/3600 (29.2)	-		-		-	
2	80/3468 (23.1)	0.74 (0.40-1.35)	0.12	0.88 (0.47-1.65)	0.26	0.40 (0.17-0.96)	0.23
3	86/3904 (22.0)	0.70 (0.38-1.26)		0.69 (0.38-1.27)		0.67 (0.30-1.49)	
4	82/3857 (21.3)	0.84 (0.46-1.54)		0.95 (0.51-1.75)		0.68 (0.31-1.50)	
5 – least poor	66/2999 (22.0)	0.42 (0.21-0.80)		0.50 (0.26-0.98)		0.45 (0.19-1.06)	
Infant mortality rate (per 1000 live births)							
1 – poorest	95/2370 (40.1)	-		-		-	
2	107/2318 (46.2)	‡1.62 (0.91-2.88)	0.39	‡1.64 (0.90-2.98)	0.42	‡1.53 (0.70-3.32)	0.73
3	117/2514 (46.5)	‡1.71 (0.97-3.02)		‡1.67 (0.93-3.00)		‡1.49 (0.67-3.30)	
4	106/2347 (45.2)	‡1.42 (0.79-2.54)		‡1.40 (0.77-2.55)		‡1.44 (0.65-3.18)	
5 – least poor	59/1790 (33.0)	‡1.57 (0.79-3.09)		‡1.64 (0.82-3.28)		‡1.86 (0.74-4.67)	
Maternal mortality rate (per 1000 live births)							
1 – poorest	17/3658 (465)	-		-		-	
2	12/3502 (343)	3.79 (0.80-17.93)	0.27	5.12 (0.91-28.93)	0.34	5.62 (0.67-47.44)	0.51
3	10/3930 (286)	4.08 (0.79-21.10)		3.70 (0.62-22.27)		1.76 (0.10-31.21)	
4	15/3889 (386)	3.67 (0.85-15.76)		2.80 (0.62-12.59)		4.74 (0.58-38.74)	
5 – least poor	13/3036 (428)	1.56 (0.34-7.24)		1.53 (0.29-8.12)		1.94 (0.11-34.40)	
Secondary outcomes							
Any antenatal care (%)							
1 – poorest	3368/3649 (92.3)	-		-		-	
2	3287/3493 (94.1)	0.80 (0.54-1.18)	0.83	0.80 (0.54-1.20)	0.79	1.19 (0.70-2.02)	0.93
3	3740/3928 (95.2)	0.97 (0.65-1.44)		1.02 (0.68-1.54)		1.22 (0.70-2.13)	
4	3741/3881 (96.4)	0.87 (0.56-1.35)		0.89 (0.57-1.39)		1.14 (0.63-2.07)	
5 – least poor	2940/3028 (97.1)	0.88 (0.53-1.49)		0.99 (0.58-1.67)		1.33 (0.62-2.87)	
Mother received any Tetanus Toxoid Vaccine (%)							
1 – poorest	2882/3414 (84.4)	-		-		-	
2	2856/3310 (86.3)	0.76 (0.58-1.01)	0.16	0.77 (0.57-1.02)	0.23	0.77 (0.54-1.12)	0.31
3	3198/3750 (85.3)	0.79 (0.60-1.03)		0.80 (0.61-1.06)		0.86 (0.61-1.23)	
4	3243/3756 (86.3)	0.97 (0.73-1.29)		0.98 (0.73-1.30)		1.14 (0.79-1.65)	
5 – least poor	2458/2923 (84.1)	0.97 (0.73-1.30)		0.96 (0.71-1.29)		0.95 (0.65-1.39)	
Mother received any SP (%)			0.67		0.49		0.89
1 – poorest	3223/3589 (89.8)	-		-		-	
2	3165/3447 (91.8)	0.91 (0.65-1.27)		0.84 (0.60-1.19)		0.95 (0.60-1.50)	
3	3604/3892 (92.6)	1.06 (0.76-1.47)		1.03 (0.74-1.45)		1.00 (0.62-1.63)	
4	3634/3843 (94.6)	0.84 (0.58-1.21)		0.81 (0.56-1.18)		1.00 (0.60-1.68)	
5 – least poor	2842/3006 (94.5)	1.10 (0.74-1.64)		1.10 (0.74-1.66)		1.28 (0.73-2.26)	

	Rate by intervention group N/total (rate)	Years 1-3*	p value (Wald)	Years 1-3†	p value (Wald)	Years 2 and 3†	p value (Wald)
Always used bednet during pregnancy (%)							
1 – poorest	1669/3627 (46.0)	-		-		-	
2	1740/3482 (50.0)	1.15 (0.95-1.40)	0.50	1.16 (0.95-1.42)	0.50	1.05 (0.82-1.35)	0.83
3	2159/3911 (55.2)	1.14 (0.94-1.38)		1.14 (0.94-1.38)		1.10 (0.86-1.41)	
4	2284/3869 (59.0)	1.18 (0.97-1.44)		1.18 (0.97-1.44)		1.10 (0.86-1.41)	
5 – least poor	1917/3016 (63.6)	1.12 (0.91-1.39)		1.14 (0.92-1.42)		0.97 (0.73-1.27)	
Maternal morbidity (antenatal, delivery or postnatal problem) (%)							
1 – poorest	1652/3644 (45.3)	-		-		-	
2	1618/3490 (46.4)	1.11 (0.91-1.37)	0.05	1.12 (0.91-1.38)	0.07	1.31 (1.01-1.69)	0.05
3	1893/3920 (48.3)	1.24 (1.02-1.52)		1.25 (1.02-1.53)		1.29 (1.00-1.66)	
4	1800/3880 (46.4)	1.31 (1.07-1.61)		1.31 (1.07-1.61)		1.43 (1.11-1.85)	
5 – least poor	1363/3025 (45.1)	1.06 (0.85-1.32)		1.08 (0.87-1.35)		1.13 (0.85-1.49)	
Skilled birth attendance (%)							
1 – poorest	1435/3695 (38.8)	-		-		-	
2	1675/3532 (47.4)	1.12 (0.91-1.37)	0.10	1.10 (0.89-1.35)	0.21	1.10 (0.86-1.35)	0.23
3	1942/3977 (48.8)	0.94 (0.77-1.15)		0.93 (0.76-1.14)		0.89 (0.70-1.15)	
4	2080/3916 (53.1)	0.99 (0.81-1.20)		0.99 (0.81-1.20)		0.89 (0.70-1.15)	
5 – least poor	2020/3059 (66.0)	0.83 (0.67-1.03)		0.85 (0.68-1.06)		0.82 (0.62-1.09)	
Postnatal care attendance (%)							
1 – poorest	934/3111 (30.0)	-		-		-	
2	1108/2986 (37.1)	0.90 (0.71-1.14)	0.37	0.89 (0.70-1.14)	0.41	1.05 (0.78-1.40)	0.21
3	1278/3365 (38.0)	0.86 (0.68-1.08)		0.86 (0.68-1.09)		0.85 (0.64-1.13)	
4	1312/3283 (40.0)	0.88 (0.70-1.11)		0.88 (0.69-1.11)		0.94 (0.70-1.25)	
5 – least poor	1256/2612 (48.1)	0.78 (0.61-0.99)		0.78 (0.61-1.00)		0.75 (0.55-1.02)	
Infant morbidity (cough, fever or diarrhoea) (%)							
1 – poorest	1101/2965 (37.1)	-		-		-	
2	1074/2877 (37.3)	1.07 (0.85-1.34)	0.34	1.11 (0.88-1.40)	0.31	1.12 (0.84-1.49)	0.72
3	1231/3241 (38.0)	1.01 (0.81-1.26)		1.03 (0.82-1.28)		1.05 (0.79-1.39)	
4	1188/3157 (37.6)	0.89 (0.71-1.11)		0.91 (0.72-1.14)		0.92 (0.69-1.23)	
5 – least poor	908/2512 (36.2)	1.12 (0.88-1.43)		1.15 (0.90-1.47)		0.98 (0.72-1.34)	
Exclusive breastfeeding rate (%)							
1 – poorest	280/1949 (14.4)	-		-		-	
2	283/1883 (15.0)	1.48 (0.99-2.19)	0.07	1.49 (1.00-2.22)	0.04	1.45 (0.89-2.36)	0.23
3	324/2197 (14.8)	0.98 (0.67-1.44)		0.96 (0.66-1.40)		0.90 (0.57-1.44)	
4	325/2166 (15.0)	1.01 (0.69-1.48)		0.98 (0.67-1.44)		1.02 (0.63-1.63)	
5 – least poor	277/1729 (16.0)	0.83 (0.55-1.24)		0.79 (0.53-1.18)		0.83 (0.50-1.38)	

Data are odds ratio (95% CI). *Adjusted for stratification clustering and stratification only. † Adjusted for clustering, stratification, cluster-level baseline values, age and education. ‡ Adjusted for clustering, cluster-level baseline values, socioeconomic quintile and age. Education data was not available with the retrospective infant outcome dataset.
P-values have not been adjusted for multiple testing as these are exploratory analyses rather than hypothesis testing, and none of the p-values for primary outcomes were close to significance.

Chapter 6 : Discussion – impact of the women's group intervention

The fundamental question addressed in this thesis is whether women's groups had an impact on perinatal, newborn, infant and maternal mortality rates and health-care seeking outcomes, and whether the groups were primarily responsible for any differences observed between intervention and control areas, or whether other factors may have caused variability between clusters and study arms. This chapter will review the evidence for the first possibility, as well as exploring other explanatory factors.

6.1 Key findings

6.1.1 Summary of findings

The MaiMwana trial results demonstrated that the women's group intervention led to significant improvement in antenatal care attendance, reduced the number of births attended by TBAs (accompanied by a non-significant increase in skilled birth attendance), and improved complete infant polio immunisation (four doses by six-months). There was no significant impact on pre-specified mortality outcomes or other process indicators after three years of the intervention being in place.

Other studies have shown a significant impact of women's groups on neonatal mortality (22, 24, 25), but while potentially important in improving individual women's and community empowerment, community mobilisation through women's groups may not have been sufficient to reduce mortality among mothers and infants over this time-scale and in this setting. However, there is some evidence that implementation and methodological factors may have obscured the results, and these will be discussed further in below.

6.1.2 Mortality

The intervention did not show a significant impact on any of the primary mortality outcomes, though the adjusted odds of mortality showed consistently lower risk in women's group areas than control areas, particularly in years 2 and 3. Adjusted odds ratios (and 95% CIs) for perinatal, neonatal, infant and maternal mortality for years 2 and 3 were 0.85 (0.64-1.13), 0.82 (0.55-1.22), 0.86 (0.58-1.27) and 0.68 (0.33-1.41) respectively (Table 5.12). Mortality rates were much higher in intervention areas at baseline, and from these high starting values, Figure 5.15 shows that all of the mortality rates in women's group areas have now crossed below those in control areas, and Table 5.12 shows reductions in women's group areas of over 20% for all mortality outcomes between baseline and the study period, and smaller reductions or increases in mortality in control areas. It will be interesting to see how this trend continues after more time, and when complete infant mortality data is available for year 3.

In general, mortality rates were lower than the most recent national estimates from DHS and MICS surveys discussed in section 2.2.1 (Table 2.7 and Table 2.8) (1, 63). The overall maternal mortality rate during the study was 398 per 100,000 live births, which is less than half of that estimated in the DHS and MICS surveys (984 and 807 per 100,000 live births respectively), and decreased from a baseline rate of 469 per 100,000 live births. This is still much lower than DHS and MICS estimates, but closer to other reported estimates, particularly those using prospective methods (Table 2.2). It is also closer to recent WHO model estimates for 2008, which give an estimate of 510 per 100,000 live births for Malawi (37). The maternal mortality ratio was slightly higher in intervention areas at baseline, and slightly lower at the end of the study period, but the number of maternal deaths was relatively small, with only 73 deaths, and with wide confidence intervals this makes accurate comparison between groups and over time difficult. Infant mortality estimates were also lower than other reported estimates (DHS 76 and MICS 72 per 1000 live births), with 49.6 per 1000 live births at baseline, and 42.3 during the study period. The overall neonatal mortality rate at baseline (26.2 per 1000 live births), was similar to recent DHS and MICS estimates (27 and 33 per 1000 live births respectively), but decreased below this level to 23.7.

There could be several reasons for the lower mortality rates in this study, such as: a general, secular trend towards reduced mortality rates, with these estimates reflecting a more recent period (mid-point 2007) than those in DHS and MICS surveys that are centred on a point three years before the survey (DHS mid-point 2002, MICS mid-point 2004); differences in the methodology and definitions used (especially the inclusion of all pregnancy-related deaths in DHS and MICS – see Section 2.1); impact of the MaiMwana interventions; and impact of the surveillance system itself. Mchinji may also have lower mortality rates than the national average. The MICS survey shows lower maternal mortality in rural than in urban areas, and in the northern and central regions (Table 2.8), so perhaps this rural, central region population is at lower risk than the national average. Indeed, they do report that neonatal and infant mortality is lower in Mchinji compared to other districts and to the national average (Table 2.8) (63).

6.1.3 Behaviour

The intervention showed some impact on secondary behavioural and process outcomes (Table 5.13). The proportion of women attending antenatal care and infants immunised with four polio doses by 6-months of age significantly increased (adjusted odds ratio 1.46 (95% CI 1.00-2.13) and 2.52 (1.07-5.96) respectively), and the proportion of women delivering at a TBA significantly decreased (0.71 (0.51-0.97)). Although they did not reach statistical significance, improvements were also seen in iron folate, tetanus toxoid vaccination and SP in pregnancy, institutional deliveries, delayed infant bathing, post-natal care visits and exclusive breastfeeding rates compared to control areas (increases of 67%, 20%, 17%, 24%, 20%, 11%, and 29% respectively). And there were a reduced proportion of women reporting any maternal antenatal, delivery or postnatal problems (21% reduction). The lack of significant effects detected may in part be due to the fact that coverage of many secondary outcome indicators was already very high at baseline, and this may have left relatively little room for improvement.

Antenatal care and skilled delivery care coverage at the end of the trial were similar to national estimates reported in DHS and MICS surveys (Table 2.7 and Table 2.8) (1, 63). The proportion of women reporting any postnatal care visits was slightly higher than national estimates in this study, but similar to estimates for Mchinji in the MICS survey. Both skilled delivery and postnatal care attendance rates were much lower than the

national average at baseline, and rose in both women's group and control areas, though by a greater amount in women's group areas (skilled delivery increased by 39% and postnatal care by 51% (Table 5.13)). Many health-care seeking indicators improved in control areas during the course of the study, but generally less than in women's group areas. The reasons for increased uptake of health services could be secular trends, partly as a result of national campaigns and increased donor funding in the wake of international calls for action (221) and national priority-setting following the large increase in maternal mortality between 1992 and 2000 DHS estimates (1, 296). There may also be some effects of the peer counselling intervention, which was present in half of the control areas, and also encouraged use of antenatal, delivery and postnatal health services.

The reporting of maternal and infant problems decreased in both intervention and control areas between baseline and the study period, but reported maternal problems decreased by a much larger amount in women's group areas and this was largely due to a reduction in reported antenatal problems. It is difficult to interpret the effects of the intervention on morbidity. The interventions may prevent some types of problems from occurring (e.g. postpartum and neonatal sepsis, anaemia), but cannot prevent others (e.g. obstructed labour, postpartum haemorrhage). We might actually expect higher reporting of some sorts of problems, because with raised awareness they may have been better identified (140). To fully understand the impact of the intervention on maternal morbidity it would be necessary to explore more about what the problems reported actually were. Health-care seeking rates in the event of a problem, might be a more useful indicator of intervention impact.

6.1.4 Sub-group analysis

A number of sub-group analyses were carried out in order to explore any differential intervention effects within specific groups of the study population. It appears that the intervention may have had more impact in areas with only the women's group intervention than in areas with both interventions, on women who were more exposed to the intervention (i.e. attended more groups), and among poorer women. The sub-group effects on health-care seeking were clearer than for mortality outcomes, but the overall patterns were similar.

Interaction between the two interventions and analysis by four intervention groups

The interaction between the women's group and infant feeding intervention was not statistically significant for primary outcomes, but it did appear that there was some interaction such that the effects of each intervention were affected by the presence of the other intervention – a 'qualitative' interaction. This qualitative interaction may have complicated the interpretation of the analysis of main effects, and in this case the sub-group effects may provide less misleading results (265).

Looking at the four intervention groups (no intervention, women's group alone, peer counselling alone, both interventions), adjusted odds ratios for women's groups alone compared to no intervention at all (12 clusters versus 12 clusters) showed much larger effects (MMR 0.60, PMR 0.84, NMR 0.77, IMR 0.79) than for the comparison of women's groups alone and both interventions with infant feeding alone and no intervention (24 clusters versus 24 clusters) that was presented in the main analysis (MMR 0.94, PMR 0.98, NMR 0.95, IMR 0.88) (Table 5.15 and Table 5.12). Intervention effects on maternal, perinatal and neonatal mortality were most pronounced in women's group areas alone, and little effect was seen in areas with both interventions, but the effect on infant mortality appeared to be slightly larger in areas with both interventions.

Overall, the less pronounced effect of the women's group intervention seen in the main comparison in Table 5.12 compared to the sub-group comparison in Table 5.15 may have been due to several factors, including mortality reduction as a result of peer counselling in half of the comparison areas in the main analysis, and lack of effect in the areas with both interventions. Thus, looking at the magnitude of differences between main analysis and sub-group analysis, it appears that observed effects of the women's group may have been diluted by between 10 and 36% due to the inclusion of the peer counselling intervention in the design and analysis.

Mortality reduction in control areas as a result of peer counselling cannot adequately explain the lack of effect in the main comparison, as there was little or no observed reduction in overall mortality rates in control communities over the same period (Figure 5.15, Table 5.11 and Table 5.12). The lack of effect on maternal, perinatal and neonatal mortality in areas with both interventions is surprising, and based on accruing evidence

from the process evaluation it seems more likely to be due to cluster characteristics or implementation factors rather than an antagonistic effect of the two interventions (297). The slight increase in coverage of each intervention in the presence of the other (section 5.2.9 and Table 5.10) is not consistent with an antagonistic interaction, such as community members tiring of the commitment to two simultaneous interventions.

The interaction between the women's group and peer counselling interventions was not significant for any secondary outcomes except for exclusive breastfeeding. Exclusive breastfeeding rates were much higher in areas with both women's groups and peer counselling, which corresponds with the reduced infant mortality in those areas, but is different to the pattern seen for other mortality outcomes.

Dose-response effect and analysis by different levels of exposure

A dose-response relationship is one of the Bradford-Hill criteria for evidence of causation (294). The results showed an apparent 'dose-response' effect for perinatal and neonatal mortality, with odds ratios decreasing significantly with higher numbers of women's group meetings attended (adjusted odds ratios and 95% CIs for NMR in women attending 1-5 times, 6-10 times and 11 or more times were 0.86 (0.62-1.19), 0.59 (0.37-0.95), 0.16 (0.04-0.66)) (Table 5.16). Mortality rates and odds ratios were highest for women in women's group areas who did not attend groups, and lowest for women who attended 11 or more times. Similarly, there was a strong dose-response effect on health-care seeking, with antenatal (ANC), delivery (SBA) and postnatal (PNC) care attendance all increasing significantly with number of meetings attended (adjusted odds ratios and 95% CIs for ANC, SBA and PNC in women attending 11 or more times were 2.24 (1.11-4.54), 1.47 (1.16-1.87), 1.37 (1.07-1.76)). About half of women who had ever attended a women's group attended five or more meetings (section 5.2.8), and this suggests that larger effects might have been achieved if more women had attended a higher number of meetings.

Although this dose-response effect is interesting, it may not be causal. Better outcomes amongst women who attended more groups might result from the self-selecting effect of healthier women attending more groups rather than attending more groups causing women to be healthier. For example, women with better health and more interest in being involved in community activities may choose to attend groups more frequently (a

healthy volunteer effect (298, 299)). Furthermore, being a more frequent group attender might affect the way women answered behaviour questions, as their knowledge about what the 'right' answers were increased. Some self-reported morbidity outcomes seem to get worse with the number of groups attended, particularly maternal postnatal problems and infant morbidity, but again this could be because women are more aware of and more able to identify and report important illnesses the more they attend groups. Since mortality rates decreased with exposure level, it doesn't make sense that morbidity would increase. Exploration of the specific morbidities reported would be needed in order to understand better whether there is a pattern of increasing serious problems such as postpartum haemorrhage, or greater reporting of minor illnesses. Also, problems such as anaemia may not be identified unless a woman went to a health facility, so if skilled birth attendance increases with women's group 'dose' level, the likelihood of a problem being identified would have increased.

Socioeconomic inequality and analysis by socioeconomic quintiles

Assessing the 'focus' and 'coverage' of the intervention is an important way of understanding how much inequality there might be between socioeconomic groups, and whether the intervention is reaching the most disadvantaged women (230). Higher attendance of women's groups amongst the poorest women (Table 5.10) suggests that there was no inequality in terms of coverage or intervention reach (230). Looking at the proportion of benefits of the intervention in each socioeconomic group tells us about the focus or 'benefit-incidence', and this was explored by looking at the interaction between the intervention and socioeconomic quintile.

No significant interactions between impact of the women's group intervention and socioeconomic quintile were seen for primary mortality outcomes, although there were some patterns suggesting differential effects, with poorer women disproportionately benefitting from reductions in maternal and infant mortality (adjusted odds ratios and 95% CIs for least poor compared to poorest were 1.53 (0.29-8.12) and 1.64 (0.82-3.28) respectively) (Table 5.17). The only secondary outcome with a significant interaction between intervention and socioeconomic quintile was exclusive breastfeeding, which had the strongest effect in the 2nd quintile and the weakest effect in the 5th quintile when compared to the poorest quintile. Effects on health-care seeking outcomes tended to be stronger in the poorest quintile, though these were not large or statistically significant.

Low power limited the scope of this analysis to detect statistically significant interaction effects. If a larger impact of the intervention is seen after it has been running for longer, it may be important to re-visit this analysis in future and explore how equitably the impact has been distributed.

6.2 Did the study address the research hypothesis?

The primary hypothesis of the study was that women's groups would lead to behaviour changes including uptake of health services, and these would in turn lead to reductions in maternal, perinatal, neonatal and infant mortality. Through the measurement of mortality rates in trial communities, this study was able to compare rates in communities with and without women's groups. In addition, this study measured the impact of women's groups on other secondary and process outcomes, such as use of routine antenatal, delivery and postnatal health services and maternal and infant morbidity.

It was hypothesised that women's groups would empower women and communities to take actions to improve their own health. The processes involved in running women's groups and the 'how' and 'why' of their success or failure have been investigated in a parallel process evaluation, but this has not been presented here. In-depth understanding of reasons for intervention success or failure is beyond the scope of this thesis, though some possible explanations will be explored.

6.3 Strengths and limitations of the study design and methods

6.3.1 Strengths

The study design had a number of strengths. A randomised controlled trial is the gold standard for evaluating the impact of health interventions (253), and using community clusters as the unit of randomisation allowed the effectiveness of this intervention to be evaluated at population level. The factorial design of the MaiMwana study allowed the effects of two interventions to be evaluated simultaneously, thus reducing the cost of running two separate studies and increasing logistical efficiency (265). The use of a control group to compare mortality rates with, rather than making comparisons in the same population over time, means that secular trends would affect both groups equally and could not be the cause of any effects seen. The random allocation of clusters to intervention groups should have meant that potential confounding factors were evenly distributed between groups, and any significant differences between intervention and control arms would be likely to be due to intervention effects. 'Buffer areas' around study villages reduced the possibility of contamination of control areas with benefits of the intervention (253). A particular strength of the design was that primary outcomes were objective mortality outcomes rather than only subjectively reported health behaviour and morbidity outcomes, which are more prone to measurement bias.

Data on the main study outcomes was collected prospectively to further reduce the possibility of recall errors and biases (Table 2.1). In addition, the inclusion of a 6-month baseline period before the intervention started, and the repeat cross-sectional census survey towards the end, allowed estimation of outcomes for comparison at baseline and endline, as well as the main comparison between intervention and control groups. Baseline values could also be used to adjust for imbalances between clusters after randomisation. The repeat census provided the opportunity to triangulate data and verify the accuracy of prospective mortality data from each cluster. Robust data on infant outcomes had not been collected from the outset with the prospective surveillance system, so retrospective census data provided more complete data for the estimation of infant outcomes in the analysis in this thesis.

6.3.2 Limitations

Cluster-randomised trials are being increasingly used to evaluate health interventions, but there are considerable challenges in their implementation, and issues of internal and external validity must be properly addressed (57, 300, 301). Internal validity may be affected by sample selection, bias and appropriateness of analytical approaches. External validity refers to the extent to which results can be generalised to other individuals and settings. This section will discuss some of the limitations to data collection and analysis affecting the validity of this study.

Sample selection

The sampling frame for the study was the whole of Mchinji District, which was divided into 48 roughly equal sized clusters, with the exclusion of the district administrative centre at Mchinji Boma. As this was a population-based study, all births and deaths in the study areas were eligible for inclusion, and thus strictly speaking sampling error does not arise. However, there is still inherent uncertainty and variability in the estimates due to random fluctuations over time, and the observed outcomes in the study population can be considered to be 'one realisation of events sampled by nature'.

Although the study was population-based, selection forces may have acted at any of four main stages; selection of villages, selection and enumeration of households and women of childbearing age, identification of pregnancies, and loss to follow-up of study outcome. Some different selection forces may also have acted during the retrospective re-census. At any of these stages, a systematic exclusion of a particular type of participant could have produced a biased or unrepresentative sample (302).

The first stage of selection was selection of villages for inclusion within the defined clusters. Villages were sampled from the centre of each cluster, and could have introduced selection bias if central villages differed systematically from those on the edges of cluster areas. Systematic difference is unlikely, as cluster boundaries used NSO census enumeration area boundaries rather than roads or geographic features, so villages in the centre were not further away from health facilities or transport routes than those on the edges.

The second stage of selection was enumeration of households for enrolment in the study cohort. Research participants were initially identified through a house-to-house census, which was a good way of identifying stable residents of the study communities. It is unknown how many households refused to take part or were missed, and no information is available on the characteristics of 'non-responders'. Interviewers were instructed to re-visit households three times if respondents were not available on the first visit, but some households were still missed. The baseline household census was conducted in the months of June to September, which is not a busy farming time, but respondents who were not available for interview may have been more likely to be seasonal workers (e.g. on commercial farms and tobacco estates), small business traders or have other mobile professions. During continued enumeration of in-migrants to study areas, people with mobile professions or those who only stayed for a short time (especially in trading centres or estates), may have been missed.

The third stage of selection was identification of pregnancies to be followed up, which involved monthly visits to all women of childbearing age by field-workers. It is unknown how many pregnancies were not reported, or the characteristics of these women. It is likely that unreported pregnancies included those ending in early miscarriage or termination, and those arising during a period of absence such as farming or school. In some cases, distance from the field-worker's home may have been a factor related to how frequently she visited households, and more distant villages may have been visited less. It is not clear what effect this might have had, but exploration of birth rates by village may help to identify areas where this happened. The fourth stage of selection, losses to follow-up of study outcomes, is discussed further in the next section.

Any selection biases introduced through village selection or household selection are unlikely to have differed between intervention and control areas because these were done before random allocation to study arms, and the main effect would be related to reduced generalisability of the findings. There is a possibility that pregnancy identification could have been affected by intervention allocation, such that pregnancies were easier to identify in intervention areas, where the presence of women's groups or peer counsellors sensitised communities to pregnancy-related issues. Interaction between the intervention and data collection is discussed further below.

Losses to follow-up of study outcome and attrition

There are considerable challenges of longitudinal population follow-up in resource-poor settings with no vital registration infrastructure (302). This study was successful in identifying and following up 18,709 infants to one-month post-partum, though there were some losses to follow-up that may have affected the findings.

Once pregnancies were identified, coverage of data for primary outcomes and most secondary process outcomes was very high. Only 681 (3%) of pregnancy outcomes were not verified (Figure 5.1). Six-month follow-up data and data on exclusive breastfeeding were less complete. Of 18,275 infants with data available and alive at one-month, only 11,640 (64%) also had data available at six-months, and only 10,053 (55%) had breastfeeding data (Table 5.13). Thus loss to follow-up of primary outcome was very low and unlikely to have caused substantial selection bias, though losses to follow-up of some secondary outcomes (such as exclusive breastfeeding and immunisation) were higher and characteristics of those followed and not followed should be explored further in future analysis. Losses to follow-up among infants alive at one-month were 35% in both intervention and control areas, and would have affected generalisability rather than biasing the results.

The sample of live births from the retrospective sample (11,450 live births) was 38% lower than the prospectively collected data (18,340 live births) (Table 5.11). It is important to remember that the retrospective sample represents a period of two years and five months, while the prospective sample represents three years. After adjusting for this time difference (assuming recapture rates remain the same), the retrospective sample is still 22% smaller than the prospective sample. This is likely to be due to a combination of recall error in the retrospective survey, as well as missing data on dates of birth and death, which resulted in exclusion of data from the sample. It is unlikely that under-reporting of births and deaths differed systematically between intervention and control areas, because the proportion of live births identified retrospectively is similar in each arm (61% intervention areas, 64% control areas), but under-reporting may have systematically differed between live and dead infants. There is some evidence from other surveys in Malawi that respondents tend to under-report dead infants, and they are also more likely not to remember their dates of birth (1). This appears to have been the case in this study, as perinatal and neonatal mortality rates estimated from the

retrospective sample (31.9 per 1000 births and 17.9 per 1000 live births respectively) were lower than prospectively estimated rates for years 1 to 3 (35.9 per 1000 births and 23.7 per 1000 live births). Retrospective neonatal mortality estimates were similarly 27% lower than prospective estimates in a population-based study in Nepal (303, 304).

Other reasons for losses to follow-up at six-months or during the retrospective survey might include permanent or seasonal internal migration, out-migration, changing of names, or changing household living arrangements. Migration within the district is usually from villages to larger trading centres, although there is also seasonal migration between villages and farming areas during cultivation periods, and movements from one village to another following marriage, divorce or widowhood. Such migration may have the effect of increasing loss-to-follow-up at one-month, six-month and retrospective survey visits, if mothers were out of their usual village at the scheduled time. Permanent or temporary migration across international borders also occurs frequently in Mchinji, for business, family visits and farming, and it was not possible to trace these participants. 3,830 women (7% of women enumerated) moved out of the study area permanently during the follow-up period, and 124 of them were pregnant (1% of pregnancies identified).

Another particularly challenging aspect of follow-up was the lack of any identifying documents such as passports or driving licenses, the lack of a street address, and the use of several different names by study participants. Women may be known by different names to different people and at different times. They often have a Chichewa name as well as an English name, a husband's first name or surname may be used as a surname, or a father's name may be used, and clan names and nicknames are also used frequently. The names used for tracing women were the first name, surname and alternative names listed at the time the household was enumerated (either during the baseline survey or prospectively). Most women did not know their exact dates of birth, but rough ages, and names and dates of birth of children were also used in an effort to trace the correct woman. Women whose details changed were the most difficult to follow up. No information was available to assess how these women might have differed from those who were easier to trace, but proportions of pregnant women lost-to-follow-up due to unverified births in intervention and control arms were similar (4% and 3% respectively).

Losses to follow-up arose due to recall error or under-reporting, in- and out-migration and inability to trace the correct respondent. These did not appear to differ systematically between intervention and control areas, and are unlikely to have biased analysis comparing intervention and control areas. However, the effects of in- and out-migration may be that the proportion of women exposed to women's groups amongst those followed up (particularly during the retrospective census) is lower than the proportion of the population who actually attended.

Generalisability

In order to take the lessons learned from this study and apply them to other settings, it is important to know if and how the study population may have differed from other rural populations in Malawi and sub-Saharan Africa.

Mchinji District is close in proximity to the capital, Lilongwe, and this may give it infrastructural and economic advantages compared to other more remote districts. Many districts in Malawi have international borders with Zambia, Mozambique or Tanzania, and Mchinji is not unusual in having international borders with Zambia and Mozambique. However, one of the major road transport routes to Zambia passes through the district, and this may create a special socioeconomic environment along its course. Another feature that is not unique to Mchinji, but perhaps more developed compared to other districts, is the presence of many commercial tobacco estates, especially in the northern part of the district. Cross-border trade, estate work and truck driving are all occupations associated with a high prevalence of HIV in Malawi, and though Mchinji is not a particularly high prevalence district overall, certain areas such as roadside trading centres and estates may have higher levels of HIV (95).

Due to the exclusion of the main trading centre in Mchinji, the selected study area reflects a mainly rural population that is reliant on subsistence farming. This population may not be representative of the Malawian population as a whole, although at a national level 85% of the population lives in rural areas (305). Mortality rates in rural areas tend to be higher than in urban areas (apart from maternal mortality), and it is surprising that the mortality rates found in this study (particularly maternal and infant mortality) were

so low compared to DHS and MICS national estimates for rural areas (Table 2.7 and Table 2.8) (1, 63).

The selection forces and losses to follow-up described above may also have acted to create a study population that differed from the general population in certain ways. In particular, mobile women may have been under-represented, and they may be at higher or lower risk of adverse outcomes than the general population of pregnant and postpartum women from which they came. This might limit the ability to extrapolate the findings of this study to other settings in Malawi. Although overall, socioeconomic, demographic and behavioural characteristics (such as health-care seeking rates) derived from this study population were similar to national estimates (1, 63), and sample selection doesn't seem to have affected generalisability too greatly.

Imbalance after randomisation

Randomisation should eliminate selection bias (301), and data on socioeconomic and demographic characteristics of the study population at baseline suggest that study arms were relatively well balanced in terms of socioeconomic status, age, education, occupation, marital status and parity after randomisation (Table 5.4). Tribe and religion were not so evenly balanced, with fewer Chewa and Catholic women than in control areas. In spite of the apparent overall balance, data on mortality rates and process outcomes were not well balanced (Table 5.5 and Table 5.6). Perinatal, neonatal, infant and maternal mortality rates at baseline were 54%, 47%, 62% and 6% higher in women's group areas respectively, compared to control areas. Skilled attendance at delivery was 14% lower and postnatal care attendance was 20% lower in women's group areas compared to control areas, though antenatal care attendance was identical.

It is unclear what the cause of these imbalances in primary and secondary outcomes could be, given the relative balance of socioeconomic and demographic factors. Such large imbalances are unlikely to be due to the tribal and religious differences observed, and must be due to some other unmeasured confounding factors. Perhaps the imbalances can be explained by a randomisation pattern that resulted in a combination of both the poorest and the least poor communities in women's group areas, such that the overall average is similar to control areas, but there is more variability between women's group zones. This is reflected by the wider distribution of cluster-level

socioeconomic scores in women's group areas shown in Figure 5.3. The five zones furthest from a health facility, with a walking time of three hours or more, were all women's group areas. Conversely, the three largest trading centres were all in women's group areas. Data show that mortality rates are higher in both the poorest and the least poor quintiles for perinatal, neonatal and maternal mortality (Table 5.17). Lower access to health services may be largely responsible for higher mortality in the poorest quintile, while factors such as high HIV prevalence and unregulated private health service providers might contribute to higher mortality in the least poor quintile (74, 82, 85). Thus average socioeconomic characteristics were similar in intervention and control areas, but mortality risks may have been higher in intervention areas due to more areas at the extremes of the socioeconomic distribution.

Although cluster-level baseline values were included in adjusted regression models, adjustment for baseline differences may have been insufficient and still resulted in dilution of the effects. Analysis of cluster-level percentage change scores would be less statistically efficient, but may be more robust under these conditions (253).

Sources of measurement error and bias in measures of exposure to the intervention

Error or bias in measuring or assigning exposure status may result in incorrect or inaccurate conclusions about the relationship between exposure and outcome. Error or bias in measures of actual exposure to the women's group intervention may have arisen in several ways: dilution through inclusion of new in-migrants to study cohort, dilution through not following out-migrants beyond study areas, 'contamination' of control areas through internal migration, and variability in intensity of exposure between individuals, communities and over time.

In the main impact analysis, intervention exposure was assigned by 'intention-to-treat', such that any women living and enumerated in clusters allocated to the women's group intervention at the time of the birth of their infant and subsequent interviews were said to be exposed to this intervention, even if they did not attend any women's group meetings. In drug trials, the intention-to-treat approach has the advantage that it allows for any effects of selective withdrawal from the intervention after allocation that may be related to the outcome of interest. However, in this community-randomised trial, selective withdrawal due to intervention exposure is unlikely. More likely is that not all

women assigned to the intervention would be able to access it. It was not feasible for every woman of childbearing age to attend all of the women's group meetings, and less than 100% coverage was expected from the outset. Women who migrated seasonally and were absent from the village for long periods, also had less opportunity to attend meetings, though the number of women who migrated seasonally is unknown. The nature of the intervention being one that mobilises community-wide social capital means that even without attending groups, women may still have experienced some benefits, but we might expect these to be less than for those who attended more frequently. Indeed, analysis by level of exposure to the intervention suggests that there were greater benefits with greater attendance (Table 5.16).

The fact that the study population was an 'open cohort' (enumerating new community members as they moved into the area), may have accentuated the diluting effect of the intention-to-treat analysis in this study. In-migrants were included in the study cohort, even though they may have had little time to be exposed to the intervention. Due to logistical constraints, out-migrants who moved out of the study areas while pregnant were not followed, even though they may have been exposed to the intervention. High levels of in- and out-migration may have been a problem particularly in areas with a high population turnover, such as trading centres and tobacco estates. But although there were more trading centres and tobacco estates in intervention areas, the cohort grew by similar amounts in both study arms (25% increase in intervention areas and 27% in control areas). Migration may also have been a particular problem for infant mortality estimates derived from retrospective data, as infants born in the three year period preceding the survey, as identified through birth histories, were included even if they were born before their mother had moved into the area and could not have attended groups at that time. Although migration data has been collected, it was not available for the analysis presented here. In future, an analysis confined only to women who were resident in study areas at baseline may reduce some of the diluting effects of this problem.

Population movements resulting in 'contamination' of control areas with intervention messages may also have occurred, resulting in further dilution of study effects. Contamination appears to have been low, as only 78 women (1%) of women in control areas interviewed at one-month postpartum reported ever having attended a women's

group. To reduce the potential for contamination, communities in the study were separated from each other by 'buffer zones', and this appears to have been effective.

Community interventions like the women's groups may take time to achieve their full potential as they follow a slow process of building social capital and changing behaviours. Intensity of exposure to the intervention elements most potent in changing behaviours changed over the course of the study. For example, the impact of the women's groups in the first year of the intervention is unlikely to have been at its highest level, as this was a phase of discussion and planning. Implementation of chosen strategies did not happen until later in the second and third years of the trial. Thus inclusion of all three years of follow-up data may have diluted the full potential effects of women's groups. Looking only at the impact in years 2 and 3 shows more consistent and pronounced effects on all mortality outcomes than when year 1 data is also included (Table 5.12).

Variability in intensity of exposure between communities may also have arisen due to implementation factors. Intention-to-treat analysis can lead to false conclusions about intervention impact if, for example, there was poor delivery of the intervention (255) (255, 306). Limitations of intervention implementation will be discussed further in section 6.4.2.

Overall, assignment of exposure status according to allocation to women's group intervention area was a crude measure of exposure. In fact there was considerable variation in exposure, coverage and delivery of the intervention between individuals and clusters. Assigning exposure by intention-to-treat meant that many women were assigned as exposed when in fact they may have received very little or no benefit from the intervention. The main effect was to overestimate exposure levels, which may have led to false conclusions about the impact of the intervention, in particular an underestimation of its effects. Although evaluation of public health interventions through effectiveness trials should not try to reproduce coverage levels only attainable in ideal study situations (254).

Sources of measurement error and bias in measures of exposure to other risk factors

In order to be able to adequately control for potential confounding factors or effect modification, accurate data on these is required. The main additional explanatory factors included in the model were cluster-level baseline values, household socioeconomic quintile, maternal age and education, and these will be considered in turn.

First, as discussed in the section above on imbalance after randomisation, there were important differences between intervention and control areas at baseline that needed to be adjusted for in the analysis. Cluster-level baseline values were generated from data collected during the prospective baseline period (1st January to 30th June 2005). Baseline values for secondary outcomes were highly correlated with outcomes during the study period. However, apart from infant mortality, baseline mortality rates were not highly correlated with mortality during the study period. This may have been because the period of prospective baseline data collection was only six-months, and mortality rates estimated were likely to be imprecise. This was also the time when the surveillance system was newly established, and may have been more prone to error. Instead of baseline mortality rates therefore, baseline skilled birth attendance rates were used to adjust for baseline imbalances in mortality (for all mortality outcomes except infant mortality), and these correlated well. This may not have adequately adjusted for the confounding effects.

A second important factor adjusted for in the analysis was household socioeconomic status. Socioeconomic scores produced by principal components analysis were highly skewed with a long positive tail, but the majority of scores being clustered at the lowest end of the range (Figure 5.2 and Figure 5.3). Such truncation may reflect the fact that most rural households are homogenously poor. In this analysis, socioeconomic quintile groups were used rather than continuous scores, in order to avoid problems associated with non-normal data. However, inaccurate conclusions about associations may still be drawn if the principal components do not predict socioeconomic status well (i.e. no internal coherence) (307). In future analysis, new lists of household assets collected during the re-census in 2008 could be used to better capture inequality between the poorest households and broaden the distribution (280). These included additional asset variables that may vary more between households, such as ownership of cellphones, mattresses, table and chairs, and sofa sets. Cellphone ownership in particular has

become much more common over the course of the study. Though data collected on assets is usually less prone to measurement error than income, consumption or expenditure data as a way of estimating household socioeconomic status, there was some evidence that respondents denied ownership of certain assets such as radios or bicycles because they had misunderstood the purpose of the project and thought they would receive one. Onwujekwe 2006 similarly found test-retest and inter-rater reliability not to be high resulting in differences of classification of households into different socioeconomic groups (307). Univariate relationships between socioeconomic quintile still showed the expected socioeconomic gradients, with poor health and lower health-care seeking amongst the poorest women (Figure 5.11), but these may have been attenuated due to imprecision estimating socioeconomic status.

Finally, the other factors adjusted for in the analysis were maternal age and education. One third of women did not know their year of birth, though most were able to give their age in years when probed about events that happened around the time they were born. Imprecise age data is likely to have resulted in some imprecision in estimating relationships between age and outcomes, widening the ranges of uncertainty, and may have caused some bias if older or less well-educated women were less likely to know their age. Educational attainment was more easily reported, and was only categorised into three groups: no education, primary education and secondary or higher education. Significant misclassification of educational level is unlikely.

Overall, misclassification of other risk factors is unlikely to have differed between intervention groups or to have caused bias or confounding, so the overall impact would be imprecision, and thus underestimation of their effect. Most importantly, inaccurate measurement of baseline outcome measures would reduce their strength in adjusting for baseline imbalances in the analysis.

Sources of measurement error and bias in outcome measures

The primary outcomes in this study were objective mortality outcomes, which are less prone to error and bias than subjective outcomes such as self-reported behaviour and morbidity. However, errors and biases could still have affected mortality rate estimates. The main sources of error and bias in this study were missing or unclear information on dates of birth and death or signs of life for infants immediately after birth, incomplete

identification and reporting of pregnancies, loss to follow-up with a questionnaire or verbal autopsy, misclassification of cause and timing of deaths, and interaction of the surveillance system with the intervention. These are described below.

In both prospective and retrospective datasets, records with missing data on date of birth were excluded because it was not possible to say whether or not they had been born during the baseline or study periods. This particularly affected retrospective data, with 1,417 (12%) records being discarded due to lack of date of birth data. Similarly, neonates, infants and mothers were excluded from analysis when missing date of death information made it impossible to say whether or not they had died within 28, 365 or 42 completed days respectively (i.e. within the defined neonatal, infant or maternal periods). Seven (1%) records without clear details of peripartum events were also excluded from analysis of stillbirth and neonatal outcomes because it was not possible to tell whether the infant had died during labour or soon after birth. Though these were still included in analysis of perinatal outcomes.

As described earlier, identification and reporting of pregnancies may not have been complete, and this may have led to errors or biases in estimating mortality rates. As described above in the section on losses to follow-up, the follow-up rate for reported pregnancies was very high, but it is impossible to know the number of pregnancies that were never reported at all. Incomplete reporting may have been a particular problem in areas with high population turnover, such as trading centres and commercial tobacco estates, or high seasonal migration. Furthermore, fieldworkers were not all equally diligent in visiting all households or villages, and some may have visited the remotest villages in their zone less frequently, thus under-reporting pregnancies there. The extent of this is not known at present, though further data quality checks will be made. It is unlikely that this would have differed between study arms.

Losses to follow-up with a one-month and six-month questionnaire have been described above, but loss to follow-up with verbal autopsy may also have occurred and caused error or bias. In order to avoid misclassification of miscarriages, stillbirths and early neonatal deaths, which have confusing and overlapping names in the local language, these were not classified by fieldworkers themselves, but through complete verbal autopsy by a supervisor. Though the requirement for verbal autopsy as the basis for

classification brought in its own source of bias, as supervisors were not equally diligent in following these up. Some were less willing to travel to the furthest zones, meaning that deaths may have been more under-reported in the remotest zones, making their mortality rates lower than expected. This may have led to overall underestimates of mortality rates. There may have been some imbalance in this effect between study arms as they were not evenly distributed between supervisors, but again, the extent of this is not known at present.

Definitions of miscarriage, stillbirth, neonatal, infant and maternal death occasionally caused confusion amongst fieldworkers, despite repeated training and monthly review meetings. There was also some evidence from management feedback that several fieldworkers may have over-classified stillbirths and under-classified neonatal deaths in an attempt to avoid the longer interview required for neonatal deaths, and this happened more in control areas. In the first three years of surveillance, maternal deaths were reported by fieldworkers and followed up with verbal autopsy by a supervisor. However, it was observed that fieldworkers might have been misclassifying maternal deaths that occurred several weeks after delivery because they did not consider these to be maternal, and reporting them as non-maternal. As a result of this, in October 2007, a list of all women of childbearing age reported to have died during the study was generated, and followed up with a short interview to the relatives about timing of the death in relation to pregnancy and description of events leading to the death. This process uncovered at least 10 (14%) maternal deaths that had originally been misclassified as non-maternal deaths among women of childbearing age, and this misclassification was slightly more common in control areas. Most were subsequently followed up, but where relatives had moved out of the area, follow-up with an interview was not possible.

Finally, there is some evidence that there may have been interaction between data collection through the surveillance system and the women's group intervention, potentially causing bias. Early findings from the process evaluation suggest that with heightened community awareness of mother and child health issues in women's group areas, pregnancies, births and deaths are easier to identify than in control areas (297). In some cases female interviewers and enumerators also attended women's groups. Fieldworkers in women's group areas reported that it was easier to interview women

about their pregnancy and birth experiences than in control areas, and there were twice as many refusals in control areas, though numbers were small (Figure 5.1). In addition, due to financial constraints, monitoring and evaluation supervisors shared a motorbike with women's group supervisors, and this may have made them more likely to follow up verbal autopsies in intervention than control areas. Anecdotal evidence from project management sources confirms this (128). The size of effect is not presently known, though this may mean that deaths were more under-reported in control areas, which may have reduced the magnitude of difference seen between intervention arms.

Secondary outcomes were more prone to error or bias as they were self-reported behaviour and morbidity. Recall of behaviours such as diet (e.g. infant feeding recall) or signs of illness may be particularly prone to error. In order to try and reduce recall error, data for classification of breastfeeding outcomes were not included if collected four weeks or more after the scheduled visit time. Accurate classification of exclusive breastfeeding was limited by the fact that data were only collected at two points in time (308, 309). The fact that neither women interviewed nor data collectors were blind to the study allocation meant that there was a possibility of 'best behaviour bias' or 'interviewer preference', where answers may have been influenced by knowledge of which study group the respondent was in. In order to reduce this, interviewers were instructed not to read out lists of possible answers, but wait for respondents to answer spontaneously. They also asked women to bring their health passports, if available, which contained information recorded by health workers at antenatal, delivery and postnatal visits, as well as visits for vaccinations or illness. Given the lack of significant impact on most of the secondary behaviour and morbidity outcomes, it seems unlikely that differential recall bias was a major problem.

As with the measurement of other risk factors discussed above, the question of whether the measures chosen adequately capture the underlying concept is important. Death is an objectively verifiable event, but the periods defined as neonatal, infant and maternal are somewhat arbitrary (see section 2.1.1), and it is possible that they did not capture the periods most affected by the intervention. For example, death rates amongst women continue to be higher than background mortality rates for several months after birth in Malawi (14). In light of this, in September 2006, the follow-up with verbal autopsy of maternal deaths was extended to one year after delivery (i.e. late maternal deaths), and

future analysis of this data will be interesting. However, since many of these late maternal deaths may be HIV-related, and women's groups did not put major focus on HIV-related problems (286), there may not have been large impact of the intervention on these. Women's groups focused largely on obstetric maternal problems, so analysis of data only on direct maternal deaths may show a bigger impact than including all maternal deaths. Evidence suggests that failure to differentiate between direct and indirect causes of maternal death may lead to misleading estimates of the success of failure of an intervention (78). For infant outcomes, the opposite applies, with women's groups focusing on problems arising within a broader time period but the outcome measure being linked to a shorter time period. Women's groups did not focus solely on health problems affecting neonates, but ranged into problems that affect older children more, such as malaria and diarrhoea (310). Focusing analysis only on neonates and infants may miss some important effects on older children. Future analysis of data on under-five mortality will be important.

In summary, non-differential errors or exclusions in classifying outcomes may have led to imprecision in estimating the impact of the intervention, and errors or exclusions that were more pronounced in intervention or control arms may have led to bias, and incorrect conclusions about the impact.

Data quality and internal validity

Data on most of the study outcomes were collected through face-to-face interviews and visits. Interpretation of the findings depends to what extent the data are valid, reliable and unbiased. There is inherent uncertainty in the measurement of human characteristics (292), and some sources of error and bias have been described in the previous sections.

In order to make data more reliable, supervisors were required to check completed questionnaires and make spot visits to study areas to observe interviews. Re-interviews were also done on a sub-sample of 100 one-month and 100 six-month questionnaires. This data is not yet available, but in future this may allow calculation of test-re-test and inter-rater reliability scores, which would help to understand the influence of measurement errors on the results seen.

There is natural variability in health-care seeking and mortality between zones, but some of the variability seen in the data may also be due to variability in data quality between zones. In large surveys there are inevitable differences between interviewers in their technique, in spite of rigorous and systematic training (302). There were some 'extreme' values in cluster-level summary data for secondary outcomes that seemed not to correspond with other variables for that cluster, raising questions about internal validity for some secondary outcome measures. A few cluster outliers due to poor data quality may not affect the overall direction of the relationship between exposure and outcome, and inaccuracies may be equally distributed between intervention and control areas, but it does suggest that some of the errors and biases discussed above may be influencing the results. During the re-census, to try and make the quality of the data less dependent on the individual assigned to each zone, two additional interviewers were recruited. Future investigations of the re-census data will allow interviewer effects on variability of data to be explored.

Statistical methods

Logistic regression with random effects to take account of between-cluster variation in outcomes is the recommended way to analyse individual-level data from cluster-randomised trials with more than 20 clusters (253). However, there are ways in which the statistical analysis was limited in this study due to design factors, such as lack of stratification for imbalances at baseline, imperfect statistical adjustment of baseline differences, and lack of power to explore interaction between the two interventions and other complications of the factorial design (265). Further elements of the analysis that could be improved would be to increase precision by including fewer additional explanatory variables, and more complete exploration of multilevel data structure and sources of variation.

Randomisation was performed after the baseline survey data was collected, but before data entry had been completed. This prevented exploration of potential imbalances between clusters that could have been used as a basis for stratification. Stratifying by cluster-level socioeconomic scores might have reduced baseline imbalances between intervention and control arms. Better still would have been to wait until after the prospective baseline phase, and use baseline mortality rate estimates to stratify or match clusters. Having said this, neither cluster-level socioeconomic scores nor baseline

mortality rates were strong predictors of primary outcomes, and stratification may have reduced the power of the study without providing great advantage (293).

Given that there was a large imbalance between clusters at baseline, adjustment for baseline values in the analysis was necessary. Adjusting mortality outcomes for baseline mortality rates, by including cluster-level baseline mortality variables in regression models, did not prove effective. Instead perinatal, neonatal and maternal mortality were adjusted for baseline imbalances by including cluster-level baseline skilled birth attendance rates as a variable in the model. This may still not adequately have accounted for imbalances at baseline, resulting in underestimation of the impact of the intervention. Adjustments for baseline imbalances were also made at cluster-level rather than individual-level, because individual-level baseline data on mortality is not possible, and this may not have been a sufficiently precise measure of the initial imbalance between study participants. Imprecision again resulting in underestimating the effect size. A future analysis of cluster-level changes in mortality would be less statistically efficient, but might be a better way of adjusting for differences at baseline (253)**.**

Cluster randomised trials are a robust means of evaluating the benefits of public health interventions, but logistical constraints often limit the number of clusters leading to limited statistical power (253). There was inadequate statistical power to provide definitive answers about the interaction between the women's group and peer counselling interventions. Exploratory analysis showed some evidence of interaction for perinatal, neonatal and maternal mortality outcomes, but not for infant mortality. Infant mortality and exclusive breastfeeding were the primary outcomes of the peer counselling intervention, and primary and secondary outcomes respectively of the women's group intervention. This means that activities to reduce infant mortality and increase exclusive breastfeeding were happening in half of the control areas included in the main analysis, and this may have masked some of the impact of the women's group intervention. The factorial design made it difficult to disentangle the separate effects of the two interventions in main effects analysis (Table 5.12), and though lacking power, sub-group analyses are important in the presence of a qualitative interaction (265).

Baseline values, household socioeconomic quintile, maternal age and education were all included as explanatory variables in adjusted analysis, as well as the presence of the

peer counselling intervention. The inclusion of so many additional variables may have resulted in some loss of precision in estimating effects, especially as there may have been some collinearity, such as between age and education, and between education and socioeconomic status. In linear and logistic regression without random effects to control for clustering, stepwise methods can be used to select variables for inclusion in regression models. This was not possible for random effects logistic regression, and explanatory variables were selected on the basis of their known association with the outcomes, as well as strength of association in bivariate analysis (52). Furthermore, a standard model was applied across all primary and secondary outcomes for ease of presentation, but in fact relationships with other explanatory variables may have been different for different outcomes. Records with missing values for covariates (such as socioeconomic score or maternal age) were excluded in adjusted analyses. For example 48 (11%) records for neonatal deaths and 996 (6%) for live infants were excluded in analysis of neonatal outcomes. Imputation of missing data may be important if records with missing data differ systematically from those without in ways related to other outcomes or risk factors (311).

Finally, the analysis presented in this thesis was limited to random effects or variability between clusters (i.e. a random intercept model), but did not allow the effect of the intervention in each cluster to vary (i.e. a random coefficient model). Further exploration of sources of variability might prove fruitful in understanding the nature of the relationship between the intervention and outcome. It might also allow for more detailed understanding of how intervention impact varies between clusters, and the influence of individual-level and cluster-level contextual factors in intervention success or failure (292).

6.4 Limitations of the intervention

One explanation for the lack of significant impact may have been weaknesses in the design or implementation of the intervention.

6.4.1 Intervention design

This was a well thought out intervention that was developed from similar interventions in Bolivia and Nepal that had showed beneficial effects. The adaptation of the intervention to the Malawian context was carefully considered after formative research to explore issues of accessibility, acceptability and feasibility (263). The intervention had a number of constraints due to the Malawian context, and the requirement that it should be sustainable, relatively low cost and easy to scale-up by government or other local partners. Some limitations of the intervention design may include the staffing and supervision structure, coverage and reach, lack of health information content as a basis for decision-making, promotion of health-care seeking without concomitant improvements in the health services, and narrow neonatal focus of materials.

Staffing and supervision structure

Consideration of cost-effectiveness and sustainability were the main limiting factors on the staffing and supervision of the intervention. There was one paid facilitator per cluster, and one paid supervisor for every six clusters. Each facilitator formed between eight and 10 groups, and due to demand, facilitators were running between four and 12 groups by the end of the trial. The distances between villages where groups were held were quite large in some cases, and limited the frequency with which meetings could be held. Similarly, distances covered by supervisors when visiting zones for supervision could be up to 20km, and the time and cost of fuel involved limited the number of supervisory visits that could be made.

In addition to human resource limitations, there were some limitations on capital equipment available. The fact that women's group and surveillance supervisors had to share motorbikes limited the frequency and intensity of supervision that each was able to provide, particularly to the most remote areas.

Coverage and reach

With one facilitator running an average of 9 groups per cluster, there were limitations to the coverage of the intervention. With a total population of between 3,100 and 4,900 per cluster, this means about one group per 350-550 people. There were an average of 900 women aged 15 to 49 years per cluster, meaning roughly one group per 100 women. Data show that 53% of women interviewed postpartum had ever attended a women's group, and this corresponds well to a successful women's group interventions in India (one group per 468 population and 55% attendance by pregnant women) (25), and is slightly higher than a successful intervention in Nepal (one group per 778 population and 37% attendance by pregnant women) (22). If all women of childbearing age had attended in this study, group sizes would have been unmanageable. But not all women of childbearing age did attend, and though no longer childbearing, a large number of older women attended. Through social networks, women's group messages may have reached beyond those who actually attended groups (238), though there is some evidence that women who attended more meetings themselves did have health advantages over those who did not (Table 5.16). In order to increase coverage in future, in a second phase of women's group activities starting in 2010, after the study period, chairwomen of existing groups were trained in facilitation skills and run the groups as volunteers. New groups have been established in villages that did not have their own group, and are facilitated by the original paid facilitators.

In terms of how equitable the coverage was, data showed good uptake amongst the poorest and least well-educated women (Table 5.10). Groups that were less well reached were young, unmarried women, with no previous pregnancies, as well as wealthier, more educated women. Groups were allowed to choose their own membership criteria, and young girls who had never been pregnant, or who were pregnant for the first time, were sometimes prevented from attending. 153 (74%) of groups specified pregnancy status as a criteria for group membership. During a mid-term review, concern was expressed at the lack of older grandmothers present at groups because of their important in influential role in decision-making around pregnancy, birth and child-care. In fact, no groups excluded older women, though some older women chose not to attend because they felt that the discussions were no longer of benefit to them.

Lack of health information content as a basis for decision-making

Facilitators were not trained in health education themselves, so were not able to provide specific information on diseases, and strategies to prevent and treat them. Instead communities were encouraged and empowered to seek health information and care from existing sources. As such they did successfully organise 369 health education talks with their local health extension workers (HSAs), and established five mobile antenatal, and 21 under-five clinics. A weekly mother and child health programme was also broadcast on local radio in a collaboration between the MaiMwana women's group team, the District Health Office and community-based listening groups. However, as these activities were all part of the implementation phase (phase 3), the new knowledge gained was not available to the groups at the time of problem identification, prioritisation and planning. Health education was the most commonly identified and implemented strategy and this shows how disadvantaged communities had initially felt in relation to health knowledge.

In Nepal and India, there was perhaps more implicit knowledge transfer in the groups about home care behaviour, hygienic delivery practices and being prepared for emergencies than was the case in Malawi, and significant reductions in both neonatal and maternal mortality were achieved without high levels of health facility deliveries in the intervention group (22, 25). The intervention was described as 'participatory learning and action' and facilitators were trained in 'participatory learning skills' in Nepal and India. In all cases, there was consideration of how to strike a balance between facilitators being supportive and being directive of group processes (140). In Malawi, the women's group intervention was developed with a conscious decision about the importance of community empowerment as a beneficial outcome in itself, and aimed for processes that were community driven for collective community action (237), while transfer of health information was not explicitly included in the process, unless the groups identified the need and planned it themselves. Heath education on hygienic home delivery practices was considered to be less important, given that a larger proportion of women delivered in facilities to begin with, and that government policy strongly discourages home delivery in Malawi. Furthermore, the picture card game adapted for use in Malawi was more of a planning tool than a learning tool, and picture cards were only shown after a problem had been identified and used to stimulate and

guide discussion, rather than for role-playing during the process of problem prioritisation.

It seems that overall, the women's group process in Malawi was more focused on capacity building to enable communities to take control of their own health issues (245, 247). The process did not suggest any pre-prepared solutions to the problems identified by the groups, and as such, some of the strategies chosen may not have been the most effective way of addressing the problems, and some were chosen to address broader underlying problems and may have an effect in the longer term. Direct comparison of the three trials is difficult given the differences in community context, health system factors and other disease determinants, but it seems likely that there were also differences in the concept and design of the intervention in the different settings that may have contributed to the impact observed. The main difference may have been in the way community participation was conceptualised and achieved (246), and the main effect of this may have been that the time-scale of the change process was longer in Malawi, because learning and action was driven more by communities identifying the need for it themselves.

Increasing demand for health services without improving quality

As stated in the section on ethics in 4.4.11, it was felt to be unethical to increase demand for health services without improving their quality. Therefore, simple, low-cost health service strengthening activities were undertaken, but it is not clear to what extent these were effective. Health facility audits in 2004 and 2007 found that communication systems and infection prevention had improved (Mchinji was awarded national Infection Prevention and Reproductive Health shields during this period), but drug supply systems were still inadequate, antenatal syphilis testing was unavailable, and most of the staff that were trained in essential newborn care had transferred out of the district (312).

In a maternal death review in Malawi, Kongnyuy 2009 shows that major avoidable factors in institutional maternal deaths are health-worker related and that provision of care in cases of maternal death was inadequate and delayed (6). Poor quality care may have limited the impact of strategies that increased uptake of health services. No refresher or replacement training was carried out, and continued MaiMwana support for

supervision systems and service provision were difficult to maintain, and did not happen for a large part of the study period. Renewed effort has been put into this more recently. Collaborative work on rolling out services for PMTCT was more successful. Coverage was improved greatly, from services being almost non-existent when the project started, to currently operating basic services (antenatal HIV testing, single-dose Nevirapine, referral for longer-term ART, and postnatal cotrimoxizole prophylaxis for exposed infants) in all health facilities. Further analysis by place and cause of death, and exploring avoidable factors might elucidate whether or not limited health service quality had played a significant role in lack of impact in this study.

A sense of fatalism and inevitability of adverse outcomes may impede health-care seeking (140), and without obvious improvements to the quality of services, these attitudes are unlikely to change. The concept that people possess equal rights to health, education and social services is key in increasing demand for services and for better allocation of resources, and this must be coupled with greater community participation in planning and decision-making processes to ensure services meet their own health care needs (238, 313). Many groups did engage in advocacy activities with their local health facility to address cases of poor quality care and advocate for better coverage of outreach services, and 67 groups (34%) successfully lobbied for community health workers to be stationed in their area rather than in a more distant trading centre. Constructive dialogue between communities and providers will increase demand for services that better meet the needs of the users, but this is likely to be effective over a longer period of time than that covered this study.

Narrow neonatal focus of materials

The women's group intervention and materials were developed using manuals and documents from Warmi, Bolivia, and MIRA, Nepal. As well as maternal outcomes, these focused on perinatal and neonatal outcomes because of the important contribution of these to child mortality in Asian and South American settings (314). However, in sub-Saharan Africa a smaller proportion of child and infant mortality is due to perinatal and neonatal complications. In sub-Saharan Africa post-neonatal mortality from malaria, pneumonia, diarrhoea and HIV is generally high. Though infant mortality was a primary outcome of the intervention, and all groups discussed infant health problems, women's group materials focused more on the neonatal period. Therefore the design of

the women's group intervention in Malawi may have been tailored towards an aspect of child survival with smaller and less immediate gains to be made than in the Asian and South American settings. It is difficult to gauge the contribution of HIV to maternal and child deaths in Malawi, but WHO estimates that 32% of maternal deaths in Malawi are HIV-related (37), and other authors have also highlighted the importance of tackling HIV in order to achieve reductions in maternal and infant mortality (14, 74, 76, 82).

6.4.2 Intervention implementation

Although implementation problems reflect real-world public heath challenges, it is still important to understand why the intervention may have had less impact than expected, and whether there were any contextual and implementation factors that could be addressed differently in order to achieve greater impact. Therefore, in evaluating the potential of the women's group intervention as a future public health strategy for mother and child health, it is important to ask whether the intervention was well-implemented in this study. Lack of significant impact may be a result of poor or incomplete implementation (255). A parallel process evaluation has been carried out to explore implementation factors in depth, and the findings from this will provide further important information for interpretation of the impact analysis. A number of factors may have led to sub-optimal implementation, including delays in implementation, particular implementation problems with certain meetings, and particular implementation problems in certain areas.

A further feature, which was both a benefit and a limitation of the way the intervention was designed and implemented, was the freedom of communities to choose their own strategies. Although this is likely to have resulted in increased social capital, empowerment and greater sense of ownership of the activities (313), the freedom to choose also resulted in groups finding it difficult to implement certain strategies, a diversity of strategies being chosen having diverse effects, and strategies being chosen to address broader underlying social problems but lacking maternal and infant focus (140).

Delays in implementation

Community interventions take time to implement, particularly while ensuring active participation at all stages. However, there were some disruptions to the implementation of intervention activities that caused additional delays, and may have caused delays in evidence of overall intervention impact. In June 2006, five of the senior personnel involved in coordinating the project, including the senior facilitation officer in charge of the intervention, were involved in a serious road traffic accident. Project activities in all departments were affected for at least 18 months after this. Lack of guidance at the top trickled down to fieldworkers, resulting in lower motivation and delays in holding scheduled meetings, and reduced frequency and intensity of supervision. An additional factor causing low morale during the same period was a significant delay of funds, meaning that many activities such as meetings and refresher trainings had to be postponed or cancelled. Secure funding was only re-established in mid-2007. The average timing of each meeting is shown in Figure 6.1, as well as the range of dates. As can be seen, there is some skew, with most groups holding the meeting around the expected time, but some lagging behind.

Annual seasonal delays also occurred during busy farming seasons as it became difficult to convene all group members. Similarly, delays occurred during the rainy season (December to March) because it was difficult to find a sheltered meeting location in some areas. Other reasons for unexpected delays were funerals, weddings and other community gatherings that required participation of the entire community.

As described below, some of the meetings caused delays, and some strategies chosen by communities to address the problems they identified were difficult to implement. After reviewing some process evaluation data in 2008, the Data Safety and Monitoring Board panel recommended extending the follow-up of the women's group intervention beyond the original two-year period to allow for complete implementation of the intervention and collection of more complete data, especially on infant mortality. Even by January 2009, the final end-date of the trial, although 176 (89%) of groups had completed the whole women's group cycle, some had not, and a small number had not managed to implement any strategies. The average time for the start of strategy implementation was July 2007, which is the mid-point of the study period. Although individual behaviour change may have occurred much earlier, some of the biggest effects of the intervention

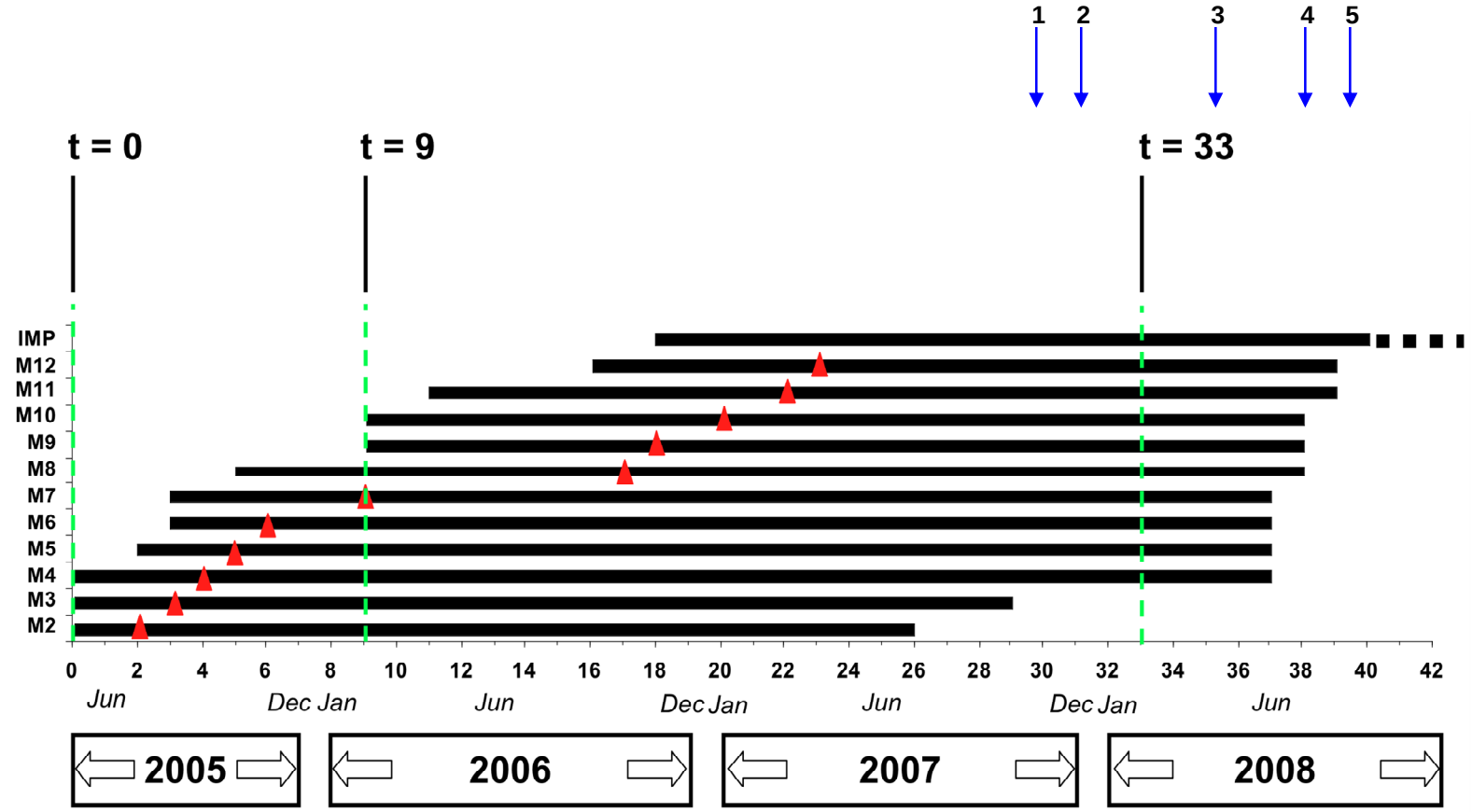
would not have started to be seen until half way through the evaluation period. Indeed, data from years 2 and 3 alone show greater impact than when year 1 is also included (adjusted odds ratios and 95% CIs for NMR were 0.82 (0.55-1.22) and 0.95 (0.71-1.28) respectively) (Table 5.12). Longer follow-up, into years 4 and 5, will allow continuing effects to be observed.

Implementation problems with certain meetings

Confusion and disagreement over the role of men in the women's group intervention process resulted in delays in holding meeting eight (where men were first invited). The average length of the delay between meeting seven and meeting eight was around eight months (Figure 6.1).

'Male championship' has become a fashionable catchphrase amongst development workers in Malawi and the international community (315), and male involvement was incorporated into MaiMwana PMTCT activities from the outset. However, male involvement in 'women's groups' was a more complicated issue, and there were many misunderstandings and disagreements about how and whether this should be done. Many groups took a long time to organise meeting eight because they thought that it was compulsory, so scheduled and re-scheduled the meeting until men attended, but in the process got de-motivated because men did not immediately attend (297). Arguably, part of the benefit of being a member of a women's group is the sense of individual empowerment and confidence gained by the women themselves through an increasing sense of decision-making power in relation to their health (316). When groups did become open to male membership this may have influenced the way in which women participated, and indeed it was observed that in the presence of men women did tend to talk less and take on more traditional deferential roles in relation to male members. And although there was always higher representation of women in decision-making roles, men also began to take on roles such as secretary or chairperson of the groups. On the other hand, many men were very involved in the implementation of the chosen strategies, and were particularly helpful in relation to resource mobilisation and advocacy (297).

Figure 6.1: Implementation of meetings 2 to 12 (M2 to M12) and the start of the implementation phase (IMP) – showing average and range of times, and timing of strategies



Average and range of time of holding meeting

t=0 is the time of the first group meetings, t=9 is nine months later when the intervention evaluation period began (i.e. from 1st February 2006), t=33 is the original end of the evaluation period after two years of intervention (i.e. to 31st January 2008)

1 = Bicycle ambulances donated, 2 = 400 ITN distributed & first clinics established, 3 = 100 ITN distributed, 4 = 300 ITN distributed, 5 = more clinics established

There was also a delay between the implementation phase and the start of the evaluation phase (between meetings 16 and 17). This was a planned delay because groups were encouraged to implement strategies for at least nine months before they started evaluation.

Implementation problems in certain areas

Implementation of women's groups in some types of communities raised particular problems. Trading centres and tobacco estates were particularly difficult. It was sometimes difficult for groups to find a quiet place to meet, but more importantly, many women were too busy with business or work commitments to be able to attend meetings. Individual or community attitudes about not spending time on intervention activities that did not provide 'hand-outs' such as farming inputs or loans were particularly common in these areas. They were both less likely to attend at all, as well as less regular in their attendance. This is reflected in the group attendance data (Table 5.10), which shows that wealthier and more educated women were less likely to have ever attended a group.

Remote areas also raised challenges. Facilitators and supervisors visited less frequently, and the groups had less access to resources than in areas closer to trading centres and health facilities. Difficulty accessing the necessary resources for implementing some strategies led to failure to implement strategies and consequently de-motivation. It was difficult to recruit and retain staff at the most remotely located nodal office, and there was a high staff turnover, with four different supervisors being recruited over the study period. Finally, in some specific areas, chieftainship conflicts also resulted in parts of communities being prevented from attending groups.

Diversity of strategies chosen, with diverse implementation problems

In phases 2 and 3 of the women's group cycle, groups chose and implemented strategies to address mother and child health problems (Figure 4.4), and 197 groups managed to implement strategies. Some of the strategies chosen by the groups were difficult to implement due to external factors. The most commonly identified strategy (by 96% of groups), was health education, and 134 groups (68%) managed to organise health talks in their community, though these were generally delivered by the lowest cadre of health-worker, with only 8-weeks of training. 120 (61%) groups also set up radio-

listening clubs and listened to weekly broadcast mother and child health education shows. The next most commonly identified strategy was bicycle ambulances (88% of groups), but due to the cost and difficulty in obtaining bicycle ambulances locally, only 40 were donated and had to be shared between 95 groups (48%) in neighbouring villages. The third most commonly identified strategy was TBA training (71% of groups). A government ban on TBA deliveries in 2009 meant that none of the groups who identified TBA training as a key strategy were successful in implementing it. 60% of groups identified the need for better access to insecticide-treated bednets (ITN), and collected funds to buy and distribute low-cost ITNs, but a change in government policy meant that they could no longer organise their own access to nets outside of government sources. When new government supplies finally arrived, an agreement was signed with the district hospital so that women's groups could be community-based distributors of nets to all women with children under five years old. 130 groups (66%) distributed a total of 247 ITNs. Lack of success with planned strategies led to frustration.

Having said this, groups went on to identify a wide range of other strategies that they successfully implemented. More groups who identified *dimba* vegetable gardens (identified by 61%, implemented by 69% of groups), mobile clinics (identified by 48%, implemented by 44%), small-scale income-generating activities (identified by 37%, implemented by 33%), distribution of oral rehydration solution (identified by 7%, implemented by 17%), and group funds (identified by 3%, implemented by 52%) were successful in implementing them. In addition, many groups implemented other strategies that were not originally identified in phases 1 and 2: 11 groups (6%) established literacy clubs, 96 groups (49%) dug pit latrines, 108 groups (55%) treated drinking water with chlorine, 12 groups (6%) lobbied for forestry training and inputs, and two groups (1%) established child care centres.

Figure 6.1 shows how strategies such as bicycle ambulances, ITN distribution and mobile clinics were implemented towards the end of the second year of the original evaluation period.

Diversity of strategies chosen, with diverse effects

The fact that groups were free to choose their own strategies, and that they all chose different strategies, means that the effects may also be heterogeneous. Different

strategies might affect maternal, perinatal, neonatal and infant mortality to greater or lesser extents, resulting in different effects in each cluster depending on what strategies had been implemented.

Strategy selection was not evidence-based, and some strategies chosen may not in fact have been very effective in reducing mortality in the short term. For example, use of an insecticide treated bednet during pregnancy is reported to be 23% effective in reducing low birth weight (Table 3.1), and 22% effective at reducing all-cause infant mortality (144, 317). The 22% reduction in mortality was achieved with a level of bednet use of 83%. In this study bednet use increased from 42.6% at baseline to 54.9% during the follow-up period (a 29% increase). Low birth weight is an underlying factor in approximately 30% of neonatal deaths, so the effectiveness of bednets as a strategy to reduce neonatal mortality (assuming similar conditions to the other studies) would be about 7% (0.3 x 0.23). So even with almost complete coverage with bednets, the maximum likely impact on neonatal and infant mortality would have been around 7% and 22% respectively. However, the benefits of 'co-coverage' with several interventions of low effectiveness can add up to a larger effect overall (60, 318).

Diversity of strategies chosen, with lack of maternal and infant focus

The process of community mobilisation has achieved a great deal in terms of solidarity, confidence and community problem solving capacities. Many of the most direct and obvious gains have been more closely related to general household livelihoods than to maternal and infant health. As described above, small businesses, group loans, *dimba* vegetable gardens, farming inputs and advice, water and sanitation projects were some of the most successfully implemented strategies. A smaller number of the successfully implemented strategies were directly related to maternal and infant health outcomes.

We can consider the MaiMwana women's group intervention according to the model of maternal and neonatal health strategies described in Figure 3.1, with a package of interventions, delivery mechanism and target population (106). In the development of this intervention, the means of distribution and target population were given considerable thought – the means of distribution was the women's group process facilitated by a trained facilitator, and the target population was women of childbearing age in rural areas. However, the single interventions in the package through which

mortality reductions would be achieved were not specified. This was left to the groups to decide for themselves, in line with the paradigm of community decision-making and empowerment followed (237, 238, 313).

As they were free to choose, communities may have incorrectly identified the most important causes of maternal and infant mortality, and/or incorrectly identified the most suitable interventions to address these problems, thus making the 'package of interventions' less powerful. Some important causes of maternal and infant deaths that were not directly identified or tackled were HIV, maternal sepsis and meningitis (286, 310). Birth asphyxia was also not highly prioritised. However, communities may also have taken a longer-term view to solving their health problems, and considered the underlying causes of poor health, such as poverty and illiteracy more than specific quick fixes. As described earlier, many communities did choose more general strategies related to poverty-reduction, nutrition and literacy. Whilst these strategies may also have beneficial effects on mother and child health, it is likely that their impact will be seen after a much longer period of time (313), further adding to the delay in seeing an impact of the intervention. A parallel evaluation looking at benefits of the intervention for household wealth and investment in the health and education of other children in the family is also being conducted, but analysis of this data is still in progress, and will be completed in 2011.

6.5 Alternative explanations for the results

In light of the methodological and intervention limitations, it is important to consider whether there may be other explanations for the observed effect that differences in primary mortality outcomes between intervention and control areas were not significant. The three main alternative explanations to consider are chance, bias and confounding.

6.5.1 Chance

Random errors affect intervention groups equally, and can result in chance findings. Imprecision in measuring the association between exposure and outcome makes it more likely to underestimate the strength of the relationship. The effects of random error can be reduced by and increasing sample size, but as with most community-based trials, the power of this study was limited by the relatively small number of clusters used as the unit of randomisation. With 48 clusters, the study was planned with adequate power to detect a reduction in neonatal, infant and maternal mortality of 31-36%, 21-28% and 47-50% respectively (Table 4.4**).** It was clear after estimating mortality rates during the prospective baseline period, that these were much lower than predicted, and the actual power of the study to detect an impact would be reduced.

Apart from the number of clusters, which was fixed once the study had started, other factors affecting the power of the study were size of clusters (number of births per cluster), baseline mortality rates and intercluster variability. The number of births per cluster was higher than expected, after following up for three years, but mortality rates were much lower, and intercluster variability was somewhat higher than expected, and this resulted in an overall loss of power. Using birth rates, mortality rates and intercluster coefficients calculated from the study data, the size of reduction in mortality that would have been detectable at 80% power at a 5% significance level was 34-42% for neonatal mortality, 40-49% for infant mortality, and around 60% for maternal mortality. Reductions in mortality of this magnitude were not achieved, even with data from years 2 and 3 alone. Even with mortality reductions of the magnitude seen in years 2 and 3, the study only had 22%, 22%, 14% and around 30% power, at the 5% significance level, to detect a significant effect on perinatal, neonatal, infant and maternal mortality respectively. Thus there is a high probability of making a ‘Type II

error', and failing to reject the null hypothesis, when it is in fact false (52). With the inclusion of other covariates and sub-groups in regression models, the power to detect statistically significant differences was even further reduced. Even a 41% reduction in neonatal mortality in women's group only areas in years 2 and 3 was only of borderline significance (adjusted odds ratio 0.59 (95% CI 0.34-1.03)).

As described earlier, in section 6.3.2, error and imprecision in measuring exposures and outcomes that did not systematically differ between intervention arms may have led to an underestimation of the impact of the intervention.

6.5.2 Bias

Systematic error is error that affects intervention groups unequally, and can lead to a false understanding about the differences between treatment groups, or an inaccurate estimate of the relationship. There may seem to be an effect where none exists, or no effect where one does exist. Possible sources of the two main types of bias – selection bias and measurement bias – have been described in section 6.3.2.

Losses to follow up may lead to selection bias in two ways. Firstly, if people followed up or data are not missing at random, but differ systematically from those who were followed up or have complete data, then the study sample may be different from the general population, and this may affect the generalisability of the findings. Secondly, if people not followed up or missing data differ systematically between intervention and control groups, then this may bias the observed association (301). In this study, people lost to follow-up at different stages of the study may have been more mobile than those not lost to follow-up, and these women may have been at higher or lower risk of adverse pregnancy outcomes. There may also have been some bias as a result of differential follow-up of women in intervention and control groups, with slightly more refusals in control areas. The overall impact of selection bias on the findings is likely to be minimal as follow-up was very high for most outcomes, and the number of births per woman of childbearing age in each arm was similar (Figure 5.1).

Measurement bias may have arisen through differential misclassification, such that exposure status affected the probability of a death being classified. For example, as

described in section 6.3.2, if communities were more sensitised about maternal and child health in intervention areas and supervisors visited them more frequently, deaths may have been more completely reported than in control areas. Or there may have been recall bias, or 'best behaviour bias', with unequal recollection of behaviour or disease between intervention groups, particularly as respondents were not blinded to intervention allocation. Finally, there is a possibility of observer bias, with interviewers perhaps tending to seek information or interpret it differently according to their knowledge of exposure status. Data handling and analyses were carried out blind to intervention allocation, and are unlikely to have affected the results.

The overall impact of measurement bias on the findings is difficult to tell. Raised community awareness accompanying intervention activities and shared transport between intervention and data collection staff may have resulted in more complete death reporting in intervention areas, and biased mortality rates upwards. However, recall and observer bias would tend to bias secondary outcome estimates in the opposite direction, making them better than control areas. Primary and secondary outcome data does not seem to reflect this scenario, with consistent non-significant improvements being seen in both (Table 5.12 and Table 5.13).

6.5.3 Confounding

Problems arise when a confounding factor (that is independently related to both the exposure and the outcome), is unequally distributed between intervention groups (52). This may lead to misunderstanding of the relationship between exposure and outcome if not taken into consideration. Randomisation should have prevented this from happening, as known and unknown confounding factors should be evenly distributed between intervention and control arms. However, trials randomised by clusters have small numbers and the potential for imbalance is greater. There does appear to have been some initial imbalance in the way the clusters were allocated to intervention groups in this study, and primary and secondary outcomes were worse in intervention areas at the start of the intervention (Table 5.5 and Table 5.6). Even with adjustment for baseline values, this imbalance may have masked some of the effects of the intervention. A few of the clusters were unlike the majority, having more, large, periurban trading centres or large commercial tobacco estates. Balanced distribution of

these clusters would not have been possible unless they were matched or stratified at the design stage. Thus, clusters were allocated to intervention areas in such a way that they had a combination of the most remote rural areas (where mortality was much higher to start with) plus the wealthiest trading centres (where women's groups didn't work as well, but HIV may have been higher), and this might have led to dilution of the effect.

Other factors known to be related to an increased risk of mortality include poverty, maternal age and parity and low education. There did not appear to be any imbalance in these risk factors between intervention arms (Table 5.4), but they were adjusted for in the statistical analyses anyway. It is unlikely that they have biased the results and masked any effects of the intervention. Other unknown confounding factors must be responsible for differences in mortality at baseline, and these factors have not been adjusted for. One possible unmeasured confounding variable might be HIV. Female cross-border traders and estate workers were found to be at higher than average risk of HIV infection in Malawi (95). Further exploration of imbalances between study arms in terms of such HIV-related risk factors would be useful.

Another possibility is that exposure to other health interventions in the district may not have been balanced between intervention arms resulting in bias or masking of effects. Data on presence of other interventions has been collected, but was not available for this analysis. Anecdotal data on other NGOs working in the district suggests that few of them were working specifically in the field of mother and child health, and their activities were either mainly in health facilities, or in only a small number of villages in one TA. Though not formally measured, access to television and newspapers are unlikely to differ between intervention arms. Data on ownership of radios show that 63% of households overall own a radio (Table 5.2), 62% in women's group areas and 64% in control areas. MaiMwana, in partnership with the District Health Office, started a community radio programme about pregnancy and child health in 2009, after the study end-point. Coverage of this programme was across the whole district, though introduction of radio listener groups in women's group areas may have meant that they had better access to these health messages.

Clusters with large trading centres and tobacco estates were more difficult to collect information in, more difficult to implement the intervention in, and likely to have higher

prevalences of HIV. Three of the most problematic zones (zones 15, 17 and 23) were allocated by chance to the arm with both women's group and infant feeding interventions. This could possibly partly explain why the arm with both interventions appears to have had the least impact on maternal, perinatal and neonatal mortality.

6.6 Evidence for a causal association between intervention and outcome

In investigating causal associations in epidemiology, Bradford Hill noted that a small association does not mean that there is not a causal effect, though the larger the association, the more likely that it is causal (294). Apart from the strength or magnitude of association, some of the other criteria that Bradford Hill suggested as a guideline for assessing causal relationships were: consistency with other findings, temporal relationship between exposure and effect, biological gradient, plausible mechanism, experimental evidence, and analogy with similar factors.

6.6.1 Consistency

The evidence reviewed in section 3.3.2 suggested that women's groups have the potential to reduce perinatal and neonatal mortality, and there is also some evidence for reduction in maternal mortality. The studies in Bolivia, Nepal and India all found large reductions in perinatal and neonatal mortality (Table 3.3) (22, 24, 25). In Nepal there was a large, significant reduction in maternal mortality, and in India a large, but non-significant reduction in maternal mortality. However, a similar study in Bangladesh found no effect of women's groups on perinatal, neonatal or maternal mortality (252). A possible reason cited for the lack of success of the Bangladesh study was low coverage of the intervention, especially among newly pregnant women.

The findings from all the women's group studies so far are not unequivocal, though suggestive of a beneficial effect overall. In this context, the new data from this trial in Malawi suggest a smaller impact of women's groups at this stage, but one that could increase further with time.

Part of the reason for the difference between studies may be contextual factors that facilitate or hinder the intervention. Such contextual factors may be environmental, socio-cultural or epidemiological. Measurement of observable environmental factors such as degree of urbanisation and distance from health facilities may be easier than for socio-cultural and epidemiological influences that might not be easy to identify. Obvious differences exist in epidemiological contexts between the Asian study settings and Malawi, such as much higher prevalence of malaria and HIV in Malawi. The ability of a community mobilisation intervention using women's groups to tackle these diseases may be limited, or require a longer time to be effective. If the attributable risk of HIV is high, maternal and infant mortality may not be substantially reduced without directly addressing HIV. In addition, health behaviours differ between the settings, with much higher usage of health services in Malawi than in other settings. As such, large reductions in mortality as a result of changes in pre-existing practices at community-level may have been less likely. Antenatal care, clean delivery (gloves or hand-washing with soap), early newborn care (early wrapping and early breastfeeding), and immunisation were all around 80-90% at baseline.

Though not statistically significant, most results were internally consistent. All primary outcomes showed trends in a positive direction, and key secondary outcomes, including antenatal care, skilled birth attendance and postnatal care, also showed positive trends.

6.6.2 Temporality

If a relationship is causal, the effect must occur after exposure to the intervention. Data show very clear declining mortality rates for perinatal, neonatal and infant mortality that start to occur after exposure to the intervention, when women's groups started (Figure 5.15). The trend in maternal mortality reduction is less clear, perhaps due to inaccuracy in estimating yearly rates with small numbers, but still shows an overall decline. Trends in mortality rates in control areas are not so clear, and some increased slightly during the course of the study Table 5.12. Health-seeking behaviours increased in both intervention and control areas over the course of the study, though improvements tended to be greater in intervention areas. Change over time cannot be seen as definitive proof that the women's group process caused the behaviour changes (294).

General improvements could be partly due to secular trends, especially with government initiatives and other NGOs being active in the area, and reducing maternal mortality currently being prominent on the national agenda. It might also be that women changed their behaviour just as a result of being monitored – the Hawthorne effect (319) – either reporting more desirable outcomes as they became more aware of what the 'right' answers were, or actually changing their behaviours. Changes in reporting are unlikely to explain the whole effect, as mortality rates were also reduced, and these could not be subject to the same kind of reporting bias. In an attempt to minimise the possibility that observation might itself change behaviour, interviews were conducted at the end of the neonatal period, after most outcomes would already be determined. Community awareness of mother and child issues is likely to have increased over time, even in control areas, through being part of a community-based study in which women were visited every month to identify pregnancies, local stakeholder meetings were held, and as many as 6 local people were employed in MaiMwana activities per zone.

Evidence of a temporal association must also be viewed in light of any expected delays between cause and effect, such that the effect should start to occur after the period of these delays. There is an inherent delay expected between exposure to community mobilisation through women's groups and an effect on mortality, as community empowerment approaches can take considerable time to show effects (313). Various additional delays in complete implementation of the intervention (see section 6.4.2), mean the full benefits may not yet have been seen, and we would expect these to emerge after continued exposure. The continuing downward trend from years 2 to 3, with no sign of levelling out, suggests that the intervention has not yet achieved its full potential.

On an individual level, it would be important to explore the timing of exposure to women's groups in relation to pregnancy and study outcomes. Complete data are not available to explore this further, though available data were collected at one-month postpartum, so for those that attended groups, it is known that attendance occurred before neonatal outcomes were measured. Many women stopped attending groups during the later stages of pregnancy and early postpartum period for practical reasons, but it is probable that attendance continued after the time of the one-month interview. Data on later group attendance has not been collected through the surveillance system,

but measurement at the time of the six-month postpartum interview would have given a better idea of complete exposure. Attendance figures for women beyond one-month postpartum may show higher coverage than when only considering this period.

6.6.3 Biological gradient

There does appear to be evidence of a 'dose-response' relationship, or biological gradient, such that greater exposure to women's groups (more meetings attended) results in lower mortality and higher rates of health-care seeking (Table 5.16). This was discussed in sections 5.4.2 and 6.1.4. It would also be interesting to explore this relationship at a cluster level, using women's group coverage as a measure of dose

6.6.4 Plausible mechanism

Data on changes in cause-specific mortality were not yet available for this study. Data from other studies of women's group interventions did not show evidence of changes in the proportion of neonatal deaths due to different causes (22, 25). As such, it is not clear what the biological mechanisms underlying reductions in mortality may be.

The effects in Nepal and India were achieved without large improvements in institutional deliveries (7% and 14% of births respectively in intervention communities). The most significant effects on process outcomes were related to hygienic home delivery practices. In India the proportion of institutional deliveries was slightly lower than control areas. It seems plausible that much of the impact on neonatal mortality observed in Nepal and India was due to more hygienic home delivery and neonatal care, although cause-specific early neonatal mortality data in India did not show differences in the proportion of septicaemia deaths between intervention and control areas. However, the Gadchiroli study in India provides compelling evidence for the benefits of community management of neonatal sepsis in reducing neonatal mortality, suggesting that infection prevention could have similar large effects (195). Since the intervention in Malawi emphasised institutional delivery, hygienic home delivery practices were not discussed in detail in groups, and unlike the Asian settings, clean home delivery kits were not used and have not been developed anywhere in Malawi. Given the Malawi government ban on TBA attended deliveries, it is unlikely

that clean home delivery kits will be introduced in future. Deliveries in which attendants washed their hands or wore gloves were high – around 90% in both intervention and control areas – and rates were similar at baseline. Data on hygienic cord care have not yet been coded, and may provide evidence of more hygienic practices in intervention areas. Early and exclusive breastfeeding, and better identification and care-seeking for problems might be other possible mechanisms, but require further investigation.

6.6.5 Experimental evidence

This is an experimental study design. Three of the women's group studies reviewed used cluster randomised controlled trial designs, the gold standard for providing evidence of causal associations, and two of these showed strong effects of women's groups on reducing neonatal mortality.

6.6.6 Analogy

It is difficult to know how to explore the effect of interventions similar to women's groups on maternal and infant outcomes, as data on similar interventions is limited. Interventions that build individual confidence and capacity to make choices have been widely applied in the field of HIV research, and some have shown beneficial effects on attitudes and behaviour, though effects on biological outcomes have been more difficult to prove (239-241). It has been argued that in addition to building the confidence and voice of disadvantaged individuals and groups, the promotion of receptive social environments for change may be important (207). The effects of some of the individual elements promoted by the intervention have been investigated and proven, such as insecticide-treated bednets, PMTCT, skilled birth attendance, breastfeeding and immunisations (Table 3.1). Evidence for the benefits of other elements, such as antenatal care, is less clear. In general, increasing coverage of known effective interventions would be expected to have an overall benefit.

As mentioned earlier, in section 6.4.2, apart from promotion of health service utilisation, the effectiveness of some of the strategies chosen by groups to reduce maternal and infant mortality is not known. Evidence suggests that improving social capital and reducing inequality improves health (136, 229, 313), but no study has been conducted that shows the effects of increasing social capital on mortality outcomes.

Chapter 7 : Conclusion

As described in Chapter 2, maternal and neonatal mortality rates are high in Malawi (1, 63). Some progress has been made in recent years in improving the survival of mothers and children, but greater efforts will need to be made to reach the Millennium Development Goal target of reducing maternal mortality by three quarters and under-five mortality by two thirds between 1990 and 2015. A greater proportion of children die in rural than urban areas in Malawi (Table 2.7 and Table 2.8), and a large proportion of deaths in children under five years old occur in the neonatal period (20%). Women's groups in rural areas, that mobilised communities to tackle maternal and neonatal health problems, were chosen as a means to tackle maternal and child health issues at the point of greatest potential impact.

Section 7.1 will summarise the results and discussion covered in the previous chapters, Section 7.2 will make recommendations for further research based on these findings, and Section 7.3 will discuss the implications of the findings for policy-makers.

7.1 Summary and interpretation of the main findings

The women's group intervention did not show significant impacts on any primary mortality outcomes, but was consistent in showing decreasing trends and non-significant effects, which were larger in years 2 and 3. If rates continue to decline we may see bigger, and possibly statistically significant, effects with follow-up into years 4 and 5. Significant increases in antenatal care uptake and polio immunisation were seen, and a significant reduction in the proportion of TBA attended deliveries was also seen. Non-significant improvements were seen in several elements of antenatal care, skilled assistance at delivery, postnatal care and exclusive breastfeeding.

There appears to have been some interaction between the two interventions, with attenuated effects in areas with both women's groups and peer counselling. However, it is not clear whether this is a true interaction, or a spurious effect caused by imbalance of confounding factors after randomisation. Some evidence of a dose-response relationship

adds weight to the idea that there may be a causal relationship between intervention and most primary and secondary outcomes, even though it is not yet strong enough to reach statistical significance.

Returning to the main question of the thesis, as to whether women's groups were responsible for reductions in perinatal, neonatal, infant and maternal mortality through changes in care practices and health-seeking behaviour, it is difficult to draw firm conclusions. Comparisons between study arms do not suggest reductions in mortality as a result of the intervention, but comparisons over time show much greater reduction in women's group areas. The intervention and study design were complex, and careful consideration of process and contextual factors is important when interpreting the results (255, 306). The lack of an overall significant effect may have been a true finding, demonstrating the ineffectiveness of the women's group intervention in this setting. But the lack of impact seen may also have been due to implementation factors that limited the intervention in this study, or due to methodological factors that reduced the ability to detect significant effects. These have been summarised in Table 7.1 and Table 7.2.

There were some limitations to the design and implementation of the intervention (Table 7.1). An intervention that is sustainable and feasible to deliver through existing community-development and health infrastructure was always likely to be delivered imperfectly and with variable quality (57, 255). The intervention was constrained by its staffing and supervision structure, coverage and reach, and availability of resources, which were kept low in order to try and make the intervention cost-effective and feasible to scale up. Coverage was similar to other successful women's group studies (22, 25), but uptake among young women was low and not all women attended all meetings, which may have limited the benefits. The intervention focused more on community empowerment than transfer of health knowledge, and this may have delayed some knowledge, attitude and behaviour changes compared to women's group studies in other settings (22, 25, 313). The success of an intervention that promotes uptake of health services may also have been limited by the quality of the services available.

Table 7.1: Factors that limited the effectiveness and impact of the intervention in this study

Factor	Type of effect	Likely magnitude and direction of effect
Design factors limiting effectiveness		
Coverage	Limited by costs of staff and equipment	Achieved similar levels of coverage as other successful interventions → Probably not a major limiting factor
	Significant dose-response effect on many primary and secondary outcomes	Not all eligible women attended all groups → May have reduced the potential to achieve greater impact
	Lower uptake amongst younger women	Low coverage amongst younger women, who are at higher risk of poor outcomes → May have reduced the potential to achieve greater impact
Design	Lack of health information content in the intervention	Women identified the need to know more about health issues, and organised health education sessions themselves. Community radio programme came after the study period. → May have resulted in less immediate behaviour change than in other studies
	Increasing demand without improving quality of health services	Women seek more health care but not have better outcomes → Ineffective mechanism through which to reduce mortality
	Focus on neonate	Post-neonatal contributions to infant mortality are higher in sub-Saharan Africa than Asian settings → Focusing discussions mainly on newborn care would have smaller impact on infant outcomes
	Community empowerment takes time	Empowerment and social change processes take time to work → Study time-frame may have been too short
Implementation factors limiting the impact seen in this study		
Delayed implementation	Unexpected programmatic delays and problems with specific meetings	Strategies implemented late in follow-up period meaning intervention has not yet reached its maximum capacity to impact health outcomes → May have reduced the size of effect seen in this study
Incomplete implementation	Problems in trading centres and tobacco estates	Women's groups were difficult to run in these areas, were fewer, had fewer members and met less frequently → May have limited the effectiveness of the intervention in these areas
	Difficulty implementing some chosen strategies due to external factors such as government policy	Strategies such as TBA training, bednet distribution and bicycle ambulances were difficult to implement → May have limited the effectiveness of the intervention for groups who chose these strategies
Choice of strategies	Diversity of effects not captured in single mortality and process outcomes	Many strategies chosen within and between groups having heterogeneous effects → Effects may be spread out between many pre-specified mortality and process outcomes
	Address broader underlying factors such as poverty, nutrition and illiteracy	Broader societal changes will take longer to achieve → May have limited the impact seen over this time scale
	Choice of strategies was not evidence-based	Strategies chosen and implemented may not have been the most effective ways to reduce mortality → Limited impact of the intervention
	Strategies may not have targeted areas of maternal and child health with highest population attributable risk	Groups did not address issues such as HIV that contribute to maternal and child mortality → Limited impact of the intervention

Table 7.2: Factors affecting ability to see significant effects

Factor	Type of effect	Likely magnitude and direction of effect on results
Study design and methods		
Interaction between women's group and peer counselling interventions	No interaction for IMR, possible non-significant interaction for PMR, NMR, MMR	Large effect in areas with women's groups only masked by little effect in areas with both interventions → Effect dilution in main analysis by 10-36%
Selection bias	Household selection Identification of pregnancies	Magnitude unknown, though likely small, and similar selection processes in intervention and control areas so unlikely to cause bias → May affect generalisability if different from those included
	Losses to follow-up for 1-month outcomes (due to permanent and temporary migration, lack of identifying documents)	Losses to follow-up similar in both arms (5% in intervention and 4% in control) so unlikely to cause bias → May affect generalisability if different from those followed up
	Losses to follow-up at 6-month and retrospective census interviews (due to recall errors and missing data, permanent and temporary migration, lack of identifying documents)	Losses to follow-up similar in both arms so unlikely to cause bias (both 35% at 6-months, and 39% and 36% for intervention and control areas respectively for retrospective) → May affect generalisability if different from those followed up
Measurement bias (exposure)	Inclusion of in-migrants to study cohort and not following out-migrants	Dilution of exposure (particularly in trading centres and tobacco estates, and for infant mortality estimates) → Effect dilution
	Contamination	Little exposure of women in control areas to the intervention → Negligible effect on results
	Variable intensity of exposure (over time and between areas)	→ Imprecision in estimating exposure levels → Effect dilution
Measurement bias (other risk factors)	Misclassification of risk level	Unlikely to have differed between study arms → Imprecise estimates of risks factors reduce their power to adjust for confounding (especially baseline disadvantage)

Factor	Type of effect	Likely magnitude and direction of effect on results
Measurement bias (outcomes)	Non-differential misclassification of outcome category (due to missing dates and details, misunderstanding of definitions and loss to follow-up)	Similar misclassification in both study arms (1% perinatal/neonatal, 14% maternal) → Imprecision → May result in random error making results less precise and wider confidence intervals
	Differential misclassification of outcome category (greater misclassification of NNDs as SBs in control areas, greater loss to follow-up of deaths in control areas)	Unknown magnitude, warrants further investigation
	Differential misclassification of outcome category (best behaviour bias and/or interviewer preference in intervention areas)	Doesn't seem to have produced any large or significant effects
Low statistical power	Imprecision in estimating effect	70-86% chance of failing to indentify an effect if one exists
Confounding	Due to imbalance in levels of disadvantage after randomisation	Mortality rates much higher (6-62%) and health-care seeking lower (14-20%) in intervention areas at baseline Large reductions in mortality rates seen in intervention areas, but baseline mortality rates not strongly correlated with outcomes in regression → Imperfect adjustment of baseline imbalance → Effect dilution
	Due to other demographic and socioeconomic factors	These were balanced between groups and unlikely to have confounded the results

Delays and problems in implementation of the intervention arose due to delays in funding, seasonal conditions, confusion about how to involve men, and high mobility and lack of group cohesion in trading centres and tobacco estates. The largest delay was seen in mid-2006 (about eight months), and may have prevented the intervention from achieving its maximum impact during the time-frame of the study. In addition, community empowerment and social change processes take time show to effects, and the length of follow-up may have been insufficient to see effects (313).

There were some limitations in study design and methodology that may have affected the results (Table 7.2). The factorial design led to an apparent interaction between women's group and peer counselling interventions that was difficult to disentangle, and may have masked the impact seen in areas with women's groups only. There was low loss-to-follow-up for most primary and secondary outcomes, but higher loss-to-follow-up for six-month and retrospective infant mortality data. This was largely due to seasonal migration, out-migration and missing date or birth and death data. Losses to follow-up of pregnancies and births were balanced between study arms, and may have affected generalisability, but are unlikely to have biased the results. There may have been some dilution of effect by including new in-migrants with little exposure to the intervention as 'intention-to-treat' in the study cohort, and not following out-migrants who were exposed to the intervention. Misclassification of other explanatory factors, such as baseline levels of mortality, may have reduced the strength of these variables to adjust for the large baseline imbalances. Misclassification of outcomes due to interaction between the surveillance system and the intervention may have biased mortality rates upwards in intervention areas, resulting in a further reason for attenuation of the observed impact on mortality outcomes.

Neither chance, bias nor confounding can be completely ruled out as possible alternative explanations for the findings. The study had much lower statistical power than expected to detect large reductions in mortality, and this combined with imprecision due to random error in measuring outcomes, may have resulted in an effect of smaller magnitude that did not reach statistical significance. There was also inadequate statistical power to explore the interaction between women's group and peer counselling interventions, and there is need for further investigation into why there seems to be a lack of effect on perinatal, neonatal and maternal mortality in areas with

both interventions. Selection biases and losses to follow-up did not differ between study arms, but the main bias that could potentially have affected the magnitude of the results seen was differential misclassification of mortality outcomes (measurement bias). The size of this problem is unknown, but further investigation would show whether it has made a substantial difference to the results.

Some uncontrolled confounding is likely, due to the large imbalance between study arms at baseline, which may not have been adequately adjusted for in the analysis by using baseline values. Further confounding may have resulted from imbalances between study arms in other unknown and unmeasured factors, such as HIV or other health programmes active in the area.

Although the effect of the intervention on primary outcomes was not significant, some of the Bradford Hill criteria still support the idea of a causal association. Other studies of women's groups have shown positive impacts (22, 24, 25), and this intervention shows a smaller effect in the same direction. By nature of the experimental design, it was possible to see that cause preceded effect, and there is a pattern of continuing reduction in mortality over time in intervention areas. There also seems to be a biological gradient, with effects increasing with higher exposure to women's group meetings. Evidence for the biological mechanism is unclear, but process evaluation data from this and other studies provides a plausible explanation of the social mechanism for the effects observed.

Non-significant trends in mortality reduction and increased health-care seeking suggest there may be some emerging benefits of the women's group intervention that have been obscured by implementation-related and methodological factors. However, it is also possible that women's groups did not have as large a benefit in this setting as in other settings due to 'impact-related' factors. In a multi-country review of the Integrated Management of Childhood Illness strategy (214), implementation-related and impact-related factors were identified that confounded the relationship between delivery of the intervention and its impact, and explained variability of impact between settings (57). Implementation-related factors included characteristics of delivery systems such as skills of implementers and availability of materials, and these approximate to factors in this study outlined in Table 7.1. Impact-related factors included baseline levels and

patterns of child mortality. Therefore, differences seen between the studies in Bolivia, Nepal, India and Malawi may also reflect differences in the underlying epidemiology and health system factors (22, 24, 25).

7.2 Recommendations for further research

7.2.1 Further analysis of existing data

The dataset collected during this study is large and complex, and the analysis presented here was restricted to the main impact of the women's group intervention. However, there are other ways that the data could have been analysed that will be explored further over time. Many of the areas of further research relate to investigating the limitations outlined in Table 7.1 and Table 7.2 more thoroughly, and understanding their contribution to the lack of significant effect seen on mortality rates and most secondary outcomes.

Exploratory analysis

One exploratory analysis that merits further attention is to investigate the relationship between uptake of the intervention and various demographic and socioeconomic characteristics. This would highlight possible barriers to attendance and suggest ways in which it could be better targeted to the most high risk women, like to the poorest women and young women experiencing their first pregnancy (320).

Another useful exploratory analysis would be to use the data to predict the probability of maternal, neonatal or infant death for 'ideal' or 'typical' individuals in this population – for example a woman who goes for antenatal care, gets adequate iron folate, tetanus toxoid immunisation and antimalarial treatment, sleeps under a bednet during pregnancy, delivers with a skilled birth attendant and goes for a postnatal check-up. The probability of death in different scenarios could be used to build predictive models to test the potential effects of different approaches to improving maternal and infant survival (176, 220). We could also identify the most potent points of intervention for future studies, and this information could be combined with research evidence to make 'intentional packages' of interventions (215).

Impact analysis

Due to the concerns raised earlier (section 6.3.2) about dilution of effects due to inclusion of new in-migrants, an important addition to the impact analysis presented here would be to re-analyse data excluding women who had moved into the area after randomisation. A more pure 'intention-to-treat' analysis may be achieved by not including women who were not allocated to the intervention at the start of the intervention in the study cohort. Kirkwood et al 2010 compare effects of vitamin A supplements on maternal mortality using several different intention-to-treat definitions, and a similar strategy could be followed here (157). We might also analyse data for all deaths reported, rather than only those with verbal autopsy, to reduce the possibility of differential loss to follow-up rates between study arms as discussed in section 6.3.2.

Future analysis should also include complete infant mortality data for year 3 to allow better assessment of the effects of women's groups on this outcome. Longer follow-up of all outcomes into years 4 and 5, would allow evaluation of longer term effects, especially in light of the delays in implementation described earlier (section 6.4.2).

Though not an *a priori* primary outcome, further exploration of the retrospective re-census survey data would permit the analysis of impact of women's groups on under-five mortality. Given the lack of distinction made by women's group participants between the arbitrary childhood categories of 'neonatal', 'infant' and 'under-five', and the subsequent diversity of strategies implemented, (many addressing broader health issues as well as underlying factors contributing to poor health), we might expect to see reductions in mortality amongst older children (321). Increased use of bednets, improvements in hygiene and sanitation, better immunisation coverage, and reduced poverty and illiteracy should all contribute to reductions in under-five mortality, and the benefits of the intervention may have been distributed across a larger age-group than focused in young infants alone. With a larger under-five mortality rate, this analysis would also have greater statistical power than for neonatal and infant mortality outcomes. Retrospective re-census data would allow analysis of the impact of women's groups at different stages of childhood. Infancy has already been broken down into early neonatal, neonatal and infant, but post-neonatal and child mortality could also be presented in order to look at the contribution of each to the overall effect. Furthermore, classification of all neonatal, infant and maternal verbal autopsies to assign cause of

death and estimate cause-specific mortality rates, would allow better understanding of the mechanism through which the intervention works. Distinction between impact of women's groups on direct and indirect maternal deaths would provide a more complete picture of intervention effectiveness. Avoidable factors could also be explored to give a practical understanding of where things are still going wrong, and where the best points of intervention would be in future.

Full exploration of intervention effects on maternal and infant morbidity would also contribute to better understanding of the mechanism of action. Coding of maternal morbidity data according to what the antenatal, delivery and postnatal problems were would be important. Conversely, infant morbidity data is already coded according to any reported episodes of cough, fever or diarrhoea, but could be combined into a single infant morbidity variable to look at the impact on overall morbidity.

To better understand reasons for variation between and within clusters, and explore variation in impact between clusters, a multilevel modelling approach should be used. More detailed exploration of the influence of contextual factors will be an important part of this. A village-level survey will be conducted in the next few months, and data from this will provide general contextual information to explore reasons for variability in mortality and other outcomes between areas, and will also provide information on limiting and facilitatory factors to intervention success in certain communities, such as local access to health services, local access to resources, other NGOs working in the area, community attitudes and leadership, and social capital. Exploration of effects by village and not only by cluster may be important, as not every village in a cluster had its own group, and it may be that villages without groups benefitted less as women had to attend groups in neighbouring villages and may have had less influence over decision-making processes in their own village than women whose village hosted the group and could draw in locally influential people to discussions. Exploration of whether the inclusion of group village headmen and traditional authority's own villages within a cluster influenced the ease with which groups were able to bring about change will also be interesting, and this will be possible using data from the village-level survey.

Multilevel modelling can be conducted to explore the causes of variation between and within clusters in terms of outcomes, as well as intervention impact, in order to

understand where and how effects may be occurring. Considering the influence of contextual factors is important in understanding why the intervention may have worked better or worse in some areas. Factors related to data quality may also be partly responsible for variability between clusters. Specific questions that could be explored with multilevel modelling include:

- Do the relationships between intervention, group attendance and exposure level vary across zones?
- Is the effect on mortality greater in zones where a larger proportion of women attend groups?
- Is the effect on mortality greater for women in the lowest socioeconomic group?
- Is the effect on mortality less in estates and trading centres than in rural villages?
- Is the effect on mortality less in zones that are furthest from a health facility?
- Is the effect on mortality greater in zones with higher baseline mortality?
- Is the effect on mortality greater in zones that implemented bednet distribution as a strategy?
- Is the effect on mortality more or less for second pregnancies in the study period?
- Is the effect more or less for infants born during the rainy season?
- Is zone X different from other zones in the sample in its effect?
- Is village X different from other villages in the zone in its effect?
- How has the intervention affected variability in mortality?
- Are intervention or control zones more or less variable in their mortality rates?
- Does the effect of women's groups reduce the variability in mortality rates as compared to baseline?

Some of these multilevel analyses may help to uncover reasons why effects on maternal, perinatal and neonatal mortality seem to be less in areas with both interventions. This, alongside data from the process evaluation, will help us better understand whether and how the two interventions might be interacting. However, multilevel analysis may have limited power and will be used for hypothesis generation rather than definitive tests of effect.

Analysis to explore data quality

Some sources of imprecision or inaccuracy in the data may have contributed towards attenuation of the observed intervention impact. Further analysis exploring issues related to data quality would help to better understand how this might have influenced the results. Exploring variability of outcomes and intervention effects by field-worker (enumerator, interviewer or supervisor) would be one way to do this. Another would be to link births and deaths from prospective and retrospective datasets and estimate recapture rates according to who collected the data. Performance of the zonal interviewers collecting prospective data could be compared with the two additional short-term interviewers per zone during the re-census. Exploration of birth rates by village, to see whether more remote villages have fewer reported births per capita, would be one way to investigate the potential for incomplete pregnancy reporting by enumerators.

More emphasis will also be placed on following up infant outcomes prospectively. This process is ongoing, and this data might provide more robust estimates of infant mortality, with lower attrition (303). With the current dataset, detailed exploration of the characteristics of women lost to follow-up at six-months or during the retrospective survey would show whether or not there was any selection bias introduced in this way. And analysis of the re-interview data collected from a sample of women at one-month and six-months would allow estimates of test-retest and inter-rater reliability on interview questions for secondary outcomes.

Different analysis approaches could also be compared to see how they affect the results, as different methods may give divergent results (285). Random effects logistic regression was used in this analysis, but generalised estimating equations could have been used, providing population-average estimates (253). Since most of the mortality distributions are slightly skewed, transformation could also be done, or non-parametric methods used on cluster-level data. Analysis of cluster-level data would also enable calculation of difference scores (between baseline and study) for each cluster, and though less efficient and flexible for exploring effects of covariates, these might better account for the imbalances seen at baseline between study arms (253).

7.2.2 Further data collection and processing from this study population

Alongside the main impact evaluation described in this thesis, a process evaluation and economic evaluation were carried out. Data from these has either not yet been completely collected or fully analysed, but will form an important basis for understanding the strengths and weaknesses of the intervention and understanding the 'how' and 'why' of intervention success and failure. Many factors that may have affected the findings have already been discussed, but systematic analysis of process evaluation data, including large qualitative datasets, is required to fully understand what worked, what did not work and why, and how contextual factors may have influenced the results.

The economic evaluation will assess the potential replicability and scalability of the intervention, and the potential for it to be adopted as a larger scale public health intervention in Malawi. The cost per maternal, infant, neonatal and perinatal death averted can be estimated, with appropriate sensitivity analyses to explore the implications of uncertainty of any assumptions. The cost of scaling up the interventions at national level can be estimated in order to explore cost-saving opportunities and to investigate issues of generalisability beyond the trial context and beyond domestic boundaries.

In addition, to the integral process and economic evaluations, a parallel study, conducted in collaboration with researchers from the Institute of Fiscal Studies in London, will explore the non-health benefits of the intervention to households, and how these further benefit older children and other family members.

During the re-census, sibling survival data was collected for all women of childbearing age in order to estimate maternal mortality ratios using the sisterhood method used in DHS surveys. This will enable comparison of estimates using different methodologies within the same population over the same time period, and provide a basis for making comparisons with sisterhood data collected in the DHS. Data on late maternal deaths and other women of childbearing age can be used to estimate background adult female mortality in this population, and understand how maternal mortality fits into the demographic patterns. Because women's groups may be more effective at reducing

direct maternal deaths, analysis excluding deaths due to indirect causes could reveal more effect (31, 78).

The peer counselling intervention promotes family planning, but there is anecdotal evidence to suggest that the women's group intervention, and even the surveillance system itself may have affected fertility rates. Women attending groups, and women visited monthly by an enumerator reported being more aware of the importance of child spacing for their own and their other children's health. Data on birth histories has been collected for all women who were interviewed postpartum during this study. It would be interesting to generate a variable for time since last birth in each case, and compare this between intervention and control areas, and over time. Process evaluation data may also allow exploration of how and why effects on fertility may have occurred, as well as giving better understanding of interactions between women's group and peer counselling interventions, and between interventions and surveillance.

Further use of collected but as yet unprocessed data could be made by coding of open-ended questions for inclusion in quantitative analysis. These include questions related to umbilical cord care, which may reveal important newborn care behaviour changes. Other questions are about barriers to desired behaviours. When a respondent answered "No" to a question such as "Did you attend antenatal care during this pregnancy?", this question is followed up by asking "Why not?". Analysis of this data would provide a picture of the relative importance of factors that prevent health-care seeking or intervention uptake, such as lack of money, lack of transport, needing permission and attitudes and beliefs. Comparison of perceived barriers could also be compared between women's group and control areas.

Household asset data collected in the 2008 re-census can be processed and analysed to see whether it provides a less truncated distribution of socioeconomic scores. Full analysis and comparison of data from health facility audits in 2004 and 2007 can also be done. This would enable better evaluation of the extent, reach and quality of health service strengthening activities that might have impacted on mortality, or limited intervention effectiveness.

Finally, in a new phase of the intervention, women's groups have begun a second cycle of community mobilisation, and new groups have been started in the same intervention areas in villages that previously did not have their own group. Exploration of future impact with this new, higher level of coverage, but facilitated by community volunteers, will perhaps address some of the limitations described in section 6.4, and be both more effective and more sustainable.

7.2.3 Further studies

An important study, after complete analysis and publication of the results from this study, will be to conduct a meta-analysis of data from all the women's group studies that have been conducted to date. Perhaps more powerful as an exploratory approach, would be multilevel modelling, including data on important contextual factors in each location. This would enable investigation into the possible reasons for the differences in impact seen in different settings.

7.3 Implications for policy-makers

Data from the process evaluation, non-health benefits evaluation and cost-effectiveness evaluation will provide important information for policy-makers about how useful and feasible it would be for the government or other partners to scale up the intervention. At this stage, without a large, significant impact, the cost of the intervention is less important than proving its effectiveness. If the intervention does prove to be effective after running for a longer period of time, it will be important to separate the set-up costs and running costs. With such a long lead-in phase before effects start to be evident, it may seem that the intervention could not be cost-effective. However, if well-established, women's groups can become a self-sustaining community structure that may eventually need little government input (313). In Mchinji, zonal committees, nodal committees and a district committee have already been established, representing women's group members from across the district. These structures provide a means of organising on a larger scale, which can have even more powerful effects and potential for collective action than disconnected groups in villages, as they are a form of

'bridging' social capital – that is they create social networks between heterogeneous groups that can be mutually beneficial (322-324). Microfinance projects have shown benefits for social capital and health in other settings (325), and the district women's group committee in this study has opened a bank account from which they can pay out loans to community groups, and into which they can receive donations and loan re-payments. This account was opened after the trial period for the analysis in this study, but has so far been used to give out small loans totalling MK1.2 million (£5000). The district committee also provides a stronger voice for advocacy to health providers in the district, as well as a forum for writing proposals to local organisations to apply for funds for activities such as building clinics.

Lessons learned from the implementation of this women's group intervention have already been used in developing women's group programmes in two other settings in Malawi, which started before this trial had been completed. They both use a lower cost system, that might be more sustainable by government and other partners, and feasible as a model for scale-up. One, in a population of 98,000 in Ntcheu District, uses government Health Surveillance Assistants to facilitate groups. They are paid an additional allowance by the programme for the meetings they hold, rather than a monthly salary, and the intervention is more closely integrated into the district health infrastructure. The other, in a population of 312,000 in Lilongwe, Salima and Kasungu districts, uses local volunteers to facilitate groups. They are also unpaid, but receive allowances for meetings held. The Lilongwe, Salima, Kasungu programme is using a version of the women's group manual and cycle that has been shortened to try and reduce the implementation period.

In anticipation of positive findings, and in light of the broader non-health and social benefits, plans are being developed for scale-up of MaiMwana women's groups. The first element of scale-up has been to introduce groups in villages in existing intervention areas that did not previously have their own group. The original groups have started a second cycle of the women's group process, and to keep the costs low, this is facilitated by trained volunteers. With benefit of experience, this second cycle has been shortened, and explicit discussion of under-five and infant health problems has been included. Should this model prove attractive to donors, the next phase would be to introduce groups to control areas, and then into non-study, buffer areas in Mchinji.

Even though specific effects of women's groups on maternal and neonatal mortality rates have been difficult to show, findings from the evaluation of the non-health benefits of the intervention may show beneficial effects. In considering the ultimate usefulness of this intervention as a pubic health strategy, the whole range of benefits will need to be taken into account.

Geographic and cultural diversity between regions, different epidemiology, different health system capacities and different usage patterns should be taken into consideration in adapting interventions to different settings (215), and may partly explain the differing results between studies (22, 25, 252). The women's group intervention could be better tailored to the Malawian context by more consciously including elements that address HIV and malaria, as well as the fact that uptake of health services is higher than in many Asian settings and can be built upon.

7.4 Concluding remarks

In conclusion, it is disappointing that a significant impact of a women's group intervention on perinatal, neonatal, infant and maternal mortality has not been observed in this study by the time this dataset was analysed. However, there were promising signs of sustained mortality reduction and increased health-care seeking over the course of the intervention. The results of longer-term follow up studies will be important, as well as studies of the non-health benefits of the intervention, such as household livelihood and community empowerment. Fuller contextual information will also be required in making a final assessment of the impact and broader benefit of women's groups as a strategy for consideration by policy-makers in Malawi to achieve Millennium Development Goals for maternal and child health.

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Appendices

Appendix 1 – Glossary of terms and definitions of outcomes

1.1 Primary outcomes

Live birth

The complete expulsion or extraction from its mother of a product of conception, irrespective of the duration of the pregnancy, which after such separation, breathes or shows any other evidence of life, such as beating of the heart, pulsation of the umbilical cord, or definite movement of voluntary muscles, whether or not the umbilical cord has been cut or the placenta is attached; each product of such a birth is considered a live-born. (ICD-10) (28)

Stillbirth

The death prior to the complete expulsion or extraction from its mother of a product of conception, after 28 completed weeks of pregnancy; the death is indicated by the fact that after such separation the foetus does not breathe or show any other evidence of life, such as beating of the heart, pulsation of the umbilical cord or definite movement of voluntary muscles. (ICD-10) (28)

Macerated stillbirth

A stillborn baby who may have died some time before labour started and whose body and skin appeared pulpy/puffy/mushy/swollen.

Fresh stillbirth

A stillborn baby who died immediately before or during delivery and whose body and skin did not appear pulpy/puffy/mushy/swollen.

Early neonatal death

A neonatal death occurring during the first seven completed days of life (0-6 days).

Perinatal death

A stillbirth or early neonatal death.

Late neonatal death

A neonatal death occurring after the seventh day but before the completion of the 28th day of life (7-28 days).

Post-neonatal death

A death arising after the 28th day but before completion of the first year of life.

Infant death

A death arising within the first year of life.

Maternal death

The death of a woman while pregnant or within 42 days of termination of pregnancy, irrespective of the duration and site of the pregnancy, from any cause related to or aggravated by the pregnancy or its management but not from accidental or incidental causes. (ICD-10) (28)

Late maternal death

The death of a woman from direct or indirect obstetric causes more than 42 days but less than one year after termination of pregnancy. (ICD-10) (28)

Pregnancy-related death

The death of a woman while pregnant or within 42 days of termination of pregnancy, irrespective of the cause of death. (ICD-10) (28)

1.2 Secondary outcomes

Outcome	Definition
1. Any antenatal care at a health facility	Answered 'yes' to the question "Did you go for an antenatal check-up during this pregnancy?", and gave the name of a health facility or outreach clinic to the question "Where did you go?"
2. Four or more antenatal care visits	Answered 'yes' to the question in 1, and a number greater than 3 to the question "How many times did you go altogether during this pregnancy"
3. Any iron and folic acid	Answered 'yes' to the question "During this pregnancy were you given, or did you buy any iron tablets or iron syrup?"
4. More than 90 days iron/folate	Answered 'yes' to the question in 3, and a number of days greater than 90 to the question "During the whole pregnancy, for how many days did you drink the tablets or syrup?"
5. Any tetanus toxiod immunisation	Answered 'yes' to the question "Did you have a Tetanus Toxoid Vaccine (TTV) injection in the arm during this pregnancy?"
6. Adequate tetanus toxoid	Either answered 'yes' to the question in 5 and '2' or '3' to the question "During this pregnancy, how many times did you get this injection?", or answered 'yes' to the question "Have you received all the five injections?"
7. Any sulphadine-pyrimethamine (SP)	Answered 'SP/Fansidar/Novidar' to the question "During this pregnancy did you take any drugs in order to prevent you from getting malaria?"
8. Two or more doses of SP	Answered '2' or '3' to the question "During this pregnancy did you take any drugs in order to prevent you from getting malaria?" (in which they were also asked to specify how many times each type of medicine was taken)
9. Bednet use night before interview	Answered 'self' to the question "Did anyone sleep under a mosquito net last night? If yes, who?"
10. Bednet used night before and dipped	Answered 'self' to the question in 9, 'yes' to the question "Since you got the mosquito net, was it ever soaked or dipped in chemicals to repel mosquitoes or insects?", and a number between 1 and 6 to the question "When was the last time the net was soaked or dipped in these chemicals?"
11. Bednet used every night in pregnancy	Answered 'every night' to the question "During this pregnancy, how often did you sleep under the mosquito net?"
12. Any HIV-testing at antenatal care	Answered 'yes' to the question "I do not want to know the result, but have you ever been for VCT?", and 'yes' to the question "Did you collect your results?"
13. Any reported antenatal problem	Answered 'yes' to the question "Were you sick or did you have any serious problems during the recent pregnancy?"
14. Any reported delivery problem	Answered 'yes' to the question "Were you sick or did you have any serious problems during this delivery?"
15. Any reported postnatal problem	Answered 'yes' to the question "Were you sick or did you have any serious problems after this delivery, including problems related to breastfeeding?"
16. Institutional deliveries	Answered with the name of a health facility to the question "Where was (NAME) born?"
17. Birth attended by skilled provider	Answered 'doctor/nurse/clinical officer/midwife' to the question "Who helped with the delivery?"
18. Birth attended by a TBA	Answered 'TBA' to the question "Who helped with the delivery?"
19. Attendant washed hands/wore gloves	Answered 'yes' to the question "Did the person who helped wash his/her hands with soap before the delivery?", or 'yes' to the question "Did the person who helped wear gloves during the delivery?"
20. Baby wrapped within 30 min	Answered with a time between 1 and 30 minutes to the question "How long after birth was (NAME) wrapped up?"
21. Baby bathed after 24hrs	Answered with a time greater than 24 hours to the question "How long after birth was (NAME) bathed?"

22. Postnatal care at a health facility	Answered 'yes' to the question "After the baby was born, did a health professional or a traditional birth attendant check on your or your baby's health?", and gave the name of a health facility or outreach clinic to the question "Where did this check first take place?"
23. Infant received BCG (by one-month)	Answered 'yes' to the question "Has (NAME) had a BCG immunisation (injection on left arm)?"
24. Infant received polio immunisation (by one-month)	Answered 'yes' to the question "Has (NAME) received a polio immunisation?"
25. Any infant cough	Answered 'yes' to the question "Has the bay had a cough?"
26. Any infant fever	Answered 'yes' to the question "Has the baby had a high fever?"
27. Any infant diarrhoea	Answered 'yes' to the question "Has the baby had diarrhoea more than 3 times a day?"
28. Any BCG (by six months)	Answered 'yes' to the question "Has (NAME) had a BCG immunisation (injection on left arm)?"
29. Any polio dose (by six months)	Answered 'yes' to the question "Has (NAME) ever received a polio immunisation?"
30. 4 polio doses (by six months)	Answered with the number '4' to the question "How many times did (NAME) receive polio immunisation after they were born?"
31. Any pentavalent dose (by six months)	Answered 'yes' to the question "Has (NAME) ever received a tetanus (5-in-1) immunisation in the leg?"
32. 3 pentavalent doses (by six months)	Answered '3' to the question "How many times did (NAME) receive tetanus (5-in-1) immunisation after they were born?"
33. Infant exclusively breastfed to 6m	Defined as exclusively breastfed to 6-months if the first food swallowed was breastmilk, no prelacteal feeds or water was given, no other liquids or foods were given according to 24-hour recall and 7-day recall for the first week, and age of introducing porridge was 6-months or more.
34. Initiated breastfeeding within 1 hr	Answered with a time of 60 minutes or less to the question "How long after birth did you first breastfeed the baby/put (NAME) to the breast?"
35. Mean time to first breastfeed	Cluster-level mean time to first breastfeed
36. Use of prelacteals	Defined as not given prelacteal feeds if the first food swallowed was breastmilk, and no other liquids or foods were given before initiating breastfeeding.
37. Mean age of starting porridge	Cluster-level mean time to starting to give porridge
38. Any breastfeeding problem	Answered 'yes' to the question "Have you had any problems with breastfeeding?"
39. Seeking help for breast problem	Answered 'yes' to the question in 38, and 'went without referral' or 'was referred' to the question "Did you go, or were you refrred to a health facility because of these problems?"

1.3 Mortality rates and ratios

Stillbirth rate

The number of stillbirths during a given time period per 1000 births during the same period.

Perinatal mortality rate

The number of perinatal deaths during a given time period per 1000 births during the same period.

Neonatal mortality rate

The number of neonatal deaths during a given time period per 1000 live births during the same period.

Infant mortality rate

The number of infant deaths during a given time period per 1000 live births during the same period.

Maternal mortality ratio

The number of maternal deaths during a given time period per 100 000 live births during the same time-period.

Maternal mortality rate

The number of maternal deaths in a given period per 100 000 women of reproductive age during the same time-period. It is also sometimes given as the number of maternal deaths per 1000 person-years of exposure (29).

Lifetime risk of maternal death

The probability of dying from a maternal cause during a woman's reproductive lifespan. Lifetime risk of maternal death = $(1-(1-\text{maternal mortality rate})^{35})$ (35).

Adult lifetime risk

The probability that a 15-year old female will die eventually from a maternal cause. Adult lifetime risk of maternal mortality = $(T15 - T50 / l\ 15) \times$ maternal mortality rate

(Where l 15, T15 and T50 are quantities from a life table for the female population during the period in question (l 15 equals the probability of survival from birth until age 15, and (T15 – T50)/l15 equals the average number of years lived between ages 15 and 50 – up to a maximum of 35 years – among survivors to age 15). (36)

Appendix 2 – Time-line of activities and achievements to date

Activities from October 2003 – September 2004

ACTIVITY	MONTH											
	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	June	July	Aug	Sept
BACKGROUND AND ORIENTATION												
In-house training workshop	■											
Community entry and consent	■	■										
Mchinji orientation and TA visits		■	■	■	■	■	■					
Zone definition				■	■	■	■	■	■			
Participatory census							■	■				
Participatory census data entry								■	■			
Mapping and enumeration piloting						■	■	■				
Chapter 8												
PHASE I – baseline survey												
Formative qualitative research				■	■	■	■	■	■	■	■	■
FI recruitment and training								■	■			
Mapping and enumeration – first 24 zones										■	■	
Mapping and enumeration – second 24 zones											■	■
Randomisation												■
Refinement of baseline database												■
PHASE II – prospective surveillance												
1-month questionnaire design											■	■

Activities from October 2004 – September 2005

ACTIVITY	MONTH											
	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	June	July	Aug	Sept
PHASE I – baseline survey												
Formative qualitative research												
Data entry of basic baseline data												
Refinement of baseline database												
Data entry of remaining baseline data												
Data cleaning												
Preliminary analysis of baseline data												
PHASE II – prospective surveillance												
1-month questionnaire design												
1-month questionnaire piloting												
FI recruitment and training												
WE recruitment and orientation												
Pregnancy and birth surveillance												
1-month questionnaires in use												
Maternal Verbal Autopsies in use												
Perinatal Verbal Autopsies in use												
Data checking and feedback												
Development of 1-month questionnaire database												
6-month questionnaire design												
6-month questionnaire piloting												
FI refresher training												
6-month questionnaire in use												
Entry of register data												

Activities from October 2005 – September 2006

ACTIVITY	MONTH											
	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	June	July	Aug	Sept
PHASE II – prospective surveillance												
Pregnancy and birth surveillance												
1-month questionnaires in use												
6-month questionnaires in use												
Maternal Verbal Autopsies in use												
Perinatal Verbal Autopsies in use												
Data checking and feedback												
Entry of WCBA register data												
Development of 1-month questionnaire database												
Entry of 1-month questionnaire data												
Development of maternal verbnal autopsy database												
Development of perinatal verbal autopsy database												
Development of 6-month questionnaire database												
Entry of verbal autopsy data												

Activities from October 2006 – September 2007

ACTIVITY	MONTH											
	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	June	July	Aug	Sept
PHASE II – prospective surveillance												
Pregnancy and birth surveillance												
1-month questionnaires in use												
6-month questionnaires in use												
Maternal Verbal Autopsies in use												
Perinatal Verbal Autopsies in use												
Data checking and feedback												
Entry of WCBA register data												
Development of 1-month questionnaire database												
Entry of 1-month questionnaire data												
Development of maternal verbnal autopsy database												
Development of perinatal verbal autopsy database												
Development of 6-month questionnaire database												
Entry of verbal autopsy data												
Data preparation for DSMB meeting												
DSMB meeting												

Activities from October 2007 – September 2008

ACTIVITY	MONTH											
	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	June	July	Aug	Sept
PHASE II – prospective surveillance												
Pregnancy and birth surveillance												
1-month questionnaires in use												
6-month questionnaires in use												
Maternal Verbal Autopsies in use												
Perinatal Verbal Autopsies in use												
Data checking and feedback												
Entry of WCBA register data												
Development of 1-month questionnaire database												
Entry of 1-month questionnaire data												
Development of maternal verbnal autopsy database												
Development of perinatal verbal autopsy database												
Development of 6-month questionnaire database												
Entry of verbal autopsy data												
Data preparation for DSMB meeting												
PHASE III – re-census												
Re-census development, piloting and training												
Re-census data collection												
Re-census database development and pilot entry												

Activities from October 2008 – September 2009

ACTIVITY	MONTH											
	Oct	**Nov**	**Dec**	**Jan**	**Feb**	**Mar**	**Apr**	**May**	**June**	**July**	**Aug**	**Sept**
PHASE II – prospective surveillance												
Pregnancy and birth surveillance												
1-month questionnaires in use												
6-month questionnaires in use												
Maternal Verbal Autopsies in use												
Perinatal Verbal Autopsies in use												
Data checking and feedback												
Entry of WCBA register data												
Development of 1-month questionnaire database												
Entry of 1-month questionnaire data												
Development of maternal verbnal autopsy database												
Development of perinatal verbal autopsy database												
Development of 6-month questionnaire database												
Entry of verbal autopsy data												
Data preparation for DSMB meeting												
DSMB meeting												
PHASE III – re-census												
Re-census data entry												
Infant outcome verification												

Appendix 3 – Details of the infant feeding and care counselling intervention

Primary research question

Will volunteer infant feeding and care counselling for pregnant and breastfeeding mothers in their homes reduce infant mortality through changes in knowledge and practices regarding exclusive breastfeeding, family planning and other care practices and health-seeking behaviours?

Hypothesis

Infant feeding and care peer counselling sessions will lead to: reductions in neonatal and infant mortality, reductions in maternal and infant morbidity, increases in exclusive breastfeeding rates in the first six months, increases in health-care seeking behaviour, and changes in care-taker practices.

The infant care and feeding intervention is based on studies in Mexico, Bangladesh and India (21, 260, 261) and uses training materials and manuals adapted and developed from WHO manuals and national guidelines. The volunteer counselling intervention seeks to change the behaviour of individuals in relation to care and care-seeking for mothers and children (264). The intervention is community based in that it defines the community as the target of change (251). In particular, the intervention seeks to provide health education to raise the awareness, change the attitudes and build the self-efficacy of mothers in relation to exclusive breastfeeding. To achieve this, 72 volunteer counsellors were identified by local communities and trained in nutrition and breastfeeding counselling. The volunteer counsellors identify pregnant women and visit them at home at five key times in pregnancy and after birth (see table). They provide support and advice on breastfeeding, family planning, PMTCT and birth-preparedness, and also support women when they have problems with breastfeeding. Women are also supported and counselled about when to start complementary feeding, and which foods are most nutritious. The volunteer counsellors received minimal health training but used a picture book to facilitate learning. The volunteer counsellors were supervised by 24

government Health Surveillance Assistants and the intervention was coordinated by one supervisor employed by MaiMwana project.

Infant feeding and care counselling intervention visit guide

Visit 1	**Visit 2**	**Visit 3**	**Visit 4**	**Visit 5**
Pregnancy	After birth			
3rd trimester	**1st week**	**1 month**	**3 months**	**5 months**
*Introduction *Early BF *Exclusive BF *PMTCT *Birth-preparedness *Family planning and condoms	*Attachment & positioning *Exclusive BF *Vaccinations *Warmth *Hygiene *Danger signs *Family planning and condoms *Advice on BF problems	*Attachment & positioning *Exclusive BF *Vaccinations *Warmth *Hygiene *Danger signs *Discuss weaning at 6m *Advice on BF problems	*Attachment & positioning *Exclusive BF *Vaccinations *Warmth *Hygiene *Danger signs *Discuss weaning at 6m *Advice on BF problems	*Attachment & positioning *Exclusive BF *Vaccinations *Warmth *Hygiene *Danger signs *Discuss weaning at 6m *Discuss weaning foods *Advice on BF problems

Appendix 4 – Example data collection forms

1. Woman enumeration form – for collection of household socio-economic data and demographic data for all female household members

2. One-month questionnaire – for collection of information during interview at one-month post-partum about:

- demographic characteristics
- antenatal care
- use of bednets
- use of HIV counselling and testing services
- problems during antenatal, delivery and post-partum periods
- care-seeking for those problems
- family planning and sexual relationships
- exposure to interventions
- birth details
- newborn care
- breastfeeding and feeding recall
- infant illness and care-seeking

3. Perinatal verbal autopsy – for collection of information during interview at least two weeks after the termination of a pregnancy or the death of a newborn infant. The section of the one-month questionnaire relating to maternal behaviour is administered (Sections A to F – Questions 1.1 to 10.11), and additional information is collected in the perinatal verbal autopsy about:

- birth details
- a description of what happened in the respondent's own words
- signs and symptoms of illness
- newborn care
- breastfeeding
- feeding recall
- infant illness and care-seeking

TA ID ☐ Zone ID ☐☐

Village name …… Village ID ☐☐ Household ID ☐☐☐

Interviewer ID ☐☐ Interview date ☐☐/☐☐/☐☐

Data checker ID ☐☐ Data checking date ☐☐ ☐☐ ☐☐

Data entry ID ☐☐ Data entry date ☐☐ ☐☐ ☐☐

Original village: (Village/GVH/TA/District) ……
……
……

Identified: 1 = New woman come into previously enumerated house? → Q2.1
2 = New woman came into a house not previously enumerated?
3 = The woman has stayed in the village for a long time, the door has been numbered, but the house isn't in the register?

Name of head of household …… Name of respondent ……..

Look at the house…		Ask the resident…					
1.1	1.2	1.3	1.4	1.5	1.6	1.7	1.8
What is the main type of flooring? ☐	What is the main type of roofing? ☐	Do you or members of your HH work on agricultural land? ☐	What is the main HH source of drinking water? ☐	What is the main type of toilet facility used by members of your HH? ☐	Number of members of the HH ☐☐	Number of sleeping rooms ☐	In your HH is there… (Y/N)
1 = Dirt, sand or dung 2 = Wood or plank 3 = Cement 4 = Tiles 5 = Other	1 = Natural material (e.g. grass) 2 = Iron sheets 3 = Iron and tiles 4 = Asbestos 5 = Cement 6 = Other	1 = Mainly on own or family's land 2 = Mainly on rented or someone else's land 3 = Do not do agricultural work	1 = Piped water inside house 2 = Piped water into yard or plot 3 = Public tap (piped) 4 = Protected well/borehole 5 = Traditional public well 6 = River, canal or surface water	1 = Own flush toilet 2 = Shared flush toilet 3 = Traditional pit toilet 4 = VIP pit latrine 5 = Bush or field 6 = Other	(including those sleeping in boys + girls hostels)	(including boys + girls hostels)	Electricity? ___ A radio? ___ A bicycle? ___ A motorcycle? ___ A car? ___ A paraffin lamp? ___ An oxcart? ___ A domestic worker not related to the head of the HH? ___

Please complete the following table for all females who usually live in the household (include those attending school or doing short-term business away from the village):

2.1	2.2	2.3	2.4	2.5	2.6	2.7	2.8	2.9	2.10	2.11
First name	Surname	Alternative names	a. Age in years b. Year of birth c. Age group	Marital Status	Tribe	Religion	Education	Main Occupation (apart from housework)	Has she ever been pregnant before? (Y/N)	Is she pregnant now? (Y/N)
			a b c							
			a b c							
			a b c							
			a b c							
			a b c							
			a b c							
			a b c							
			a b c							
			a b c							
			c. Age group 1 = Less than 15 yrs 2 = 15 to 49 yrs 3 = Above 49 yrs	1 = Married 2 = Never married 3 = Divorced 4 = Separated 5 = Widowed	1 = Chewa 2 = Ngoni 3 = Senga 4 = Yao 5 = Tumbuka 6 = Lomwe 7 = Other	1 = Catholic 2 = Christian 3 = Moslem 4 = Aaron 5 = Pagan 6 = Other	1 = None 2 = Primary 3 = Secondary 4 = Tertiary	1 = Farming 2 = Casual worker 3 = Salaried worker 4 = Small business 5 = Rural artisan 6 = Student 7 = No work		

MAIMWANA PROJECT – ONE MONTH QUESTIONNAIRE

BEFORE STARTING OFF FOR THE INTERVIEW – COMPLETE THIS SECTION USING THE INFORMATION FROM THE WCBA REGISTER. IF THE WOMAN YOU ARE GOING TO INTERVIEW DOES NOT APPEAR IN THE WCBA REGISTER AND DOES NOT HAVE A WCBA_ID NUMBER, PLEASE COMPLETE A HOUSEHOLD ENUMERATION FORM WHEN YOU ARRIVE, BEFORE STARTING THE ONE-MONTH INTERVIEW AND LEAVE THIS SECTION BLANK.

WCBA names from register:			
WCBA ID from register: |__|__|-|__|__|-|__|__|__|-|__|			

PLEASE TICK AS APPROPRIATE:
WCBA ALREADY APPEARS ON REGISTER |__|
HOUSEHOLD ENUMERATION FORM COMPLETED |__|

ON ARRIVING AT THE RESPONDENT'S HOUSE – GREET THE RESPONDENT. ASK FOR A PRIVATE PLACE TO SIT AND CHAT, AWAY FROM OTHER PEOPLE. ASK THE RESPONDENT TO BRING HER HEALTH PASSPORT AND TTV CARD, IF SHE HAS ONE. CHAT A LITTLE BIT, TO HELP THE RESPONDENT TO FEEL RELAXED.

ASK FOR CONSENT – My name is _____. I am working with MaiMwana Project. MaiMwana is trying to improve the health of mothers and babies in Mchinji. We are doing a survey of women who have recently given birth, in order to learn about their experiences.

We assure you that everything you tell us will be kept confidential, and will only be used for study purposes. You do not have to take part in this research if you do not want to. If you do not wish to take part, this will not affect your right to take part in other MaiMwana activities in the future. If there are any questions that you do not want to answer, you do not have to answer them. There are no wrong answers to these questions. We just want to know about the experiences of pregnant women. If you do not understand a question, please ask me to explain it again.

This interview will take about one hour. Do you agree to take part?

Yes |__|

No |__|

AFTER GAINING CONSENT – COMPLETE A HOUSEHOLD ENUMERATION FORM IF NECESSARY, THEN FILL IN THE DETAILS BELOW. IF THE RESPONDENT APPEARS ON THE WCBA REGISTER, BUT SHE LIVES IN A DIFFERENT ZONE, VILLAGE OR HOUSE FROM THE ONE IN THE WCBA REGISTER, OR USES ANY DIFFERENT NAMES, PLEASE WRITE THESE DETAILS BELOW.

Zone ID: |__|__|	Village ID: |__|__|	Village name:	Household ID: |__|__|__|
WHERE DID THE RESPONDENT LIVE BEFORE THIS/WHICH VILLAGE DID THEY COME FROM?			
Zone ID: |__|__|	Village ID: |__|__|	Village name:	Household ID: |__|__|__|
District/country:		TA name:	VDC/GVH name:
Names used by WCBA that are not on the register:		First name	Surname

Interviewer ID: |__|__|	Date of interview: |__|__|/|__|__|/|__|__|	Time started interview: __ __ : __ __

FOR OFFICE USE ONLY

Supervisor's signature:		Date received in nodal office: |__|__|/|__|__|/|__|__|
Data Checker ID: |__|__|	Date checked: |__|__|/|__|__|/|__|__|	
Data Entry ID: |__|__|	Date entered: |__|__|/|__|__|/|__|__|	

Part A: Personal Details of Mother and Father

First I would like you to tell me about yourself and the father of your baby			
Mother			
1.1	How old are you?	Age (years) |__|__| Day/Month/Year |__|__|/|__|__|/|__|__|	
1.2	What is the highest level of school you attended? FOR PRIMARY AND SECONDARY ALSO PUT HIGHEST STANDARD OR FORM REACHED	1 = None 2 = Primary |__| 3 = Secondary |__| → 4 = Tertiary	 Q1.5
1.3	Have you ever participated in a literacy programme or any other programme that involves learning to read or write (not including primary school)?	1 = Yes 2 = No	
1.4	Can you read this sentence?	1 = Reading with ease 2 = Reading with difficulty 3 = Cannot read	
Father			
1.5	What is the age of the man who fathered this pregnancy? IF THE RESPONDENT DOESN'T KNOW THE EXACT AGE, CIRCLE THE CORRECT AGE GROUP	Age (years) |__|__| 1 = <20 years 2 = 20-29 years 3 = 30-39 years 4 = 40-49 years 5 = >49 years	
1.6	What is your relationship to him?	1 = Married 2 = Boyfriend/fiancé 3 = Casual acquaintance → 4 = Relative 5 = Divorced/separated → 6 = Widowed → 7 = Other (specify)	 Q2.1 Q2.1 Q2.1
1.7	Which of the following best describes your living arrangements with this man? READ OUT THE LIST OF STATEMENTS	1 = Live together all of the time 2 = Live together but occasionally apart for work reasons 3 = Live together but separated for a period every year for work reasons (i.e. seasonal/ganyu work) 4 = Live apart but regular/frequent cohabitation (i.e. return visits) 5 = Live apart, infrequent cohabitation 6 = Never live together	
1.8	What is the highest level of school he attended? FOR PRIMARY AND SECONDARY ALSO PUT HIGHEST STANDARD OR FORM REACHED	1 = None 2 = Primary |__| 3 = Secondary |__| → 4 = Tertiary	 Q1.10
1.9	Has he ever participated in a literacy programme or any other programme that involves learning to read or write (not including primary school)?	1 = Yes 2 = No	
1.10	What is his main occupation? PROBE FOR THE ONE WHICH HE SPENDS MOST TIME DOING	1 = Farming 2 = Casual worker/ganyu 3 = Salaried worker 4 = Small business/artisan 5 = Student 6 = No work 7 = Other (specify _____)	
1.11	Does he do any other type of work, apart from that mentioned in Q1.10? If yes, what type?	1 = No other work 2 = Farming 3 = Casual worker/ganyu 4 = Salaried worker 5 = Small business/artisan 6 = Student 7 = Other (specify _____)	

Part B: Birth History

2.1	Have you ever had a pregnancy before this child, even if it ended early or the baby was a stillbirth?					1 = Yes 2 = No ---------- (→ Q2.9)	
	Now I am going to ask you some questions about all of the pregnancies you have had during your life before this one. Starting from your first pregnancy, can you tell me about ALL your pregnancies, even if the pregnancy only lasted a few months, if the baby was born dead, or if it died soon after birth?						
	2.2 On what day, month and year was the baby born? PROBE: "What is his/her birthday?" CHECK HEALTH PASSPORT IF AVAILABLE	2.3 Was this pregnancy single or multiple? *RECORD TWINS AND TRIPLETS ON SEPARATE LINES*	2.4 Did this pregnancy end in a miscarriage, a stillbirth or a live birth? FOR STILLBIRTHS, PROBE FOR SIGNS OF LIFE AT BIRTH IF MISCARRIAGE OR STILLBIRTH, GO TO NEXT PREGNANCY	2.5 Is (NAME) a boy or a girl?	2.6 Is (NAME) still alive?	2.7 How old was (NAME) at his/her last birthday? RECORD AGE IN COMPLETED YEARS GO TO NEXT PREGNANCY	2.8 How old was (NAME) when he/she died? PROBE TO MAKE SURE YOU GET THE RIGHT AGE CATEGORY
01	Day/ Month/ Year __ __/__ __/__ __	|__|	|__|	|__|	Yes No (→ 2.8)	|__|__| years	|__|
02	Day/ Month/ Year __ __/__ __/__ __	|__|	|__|	|__|	Yes No (→ 2.8)	|__|__| years	|__|
03	Day/ Month/ Year __ __/__ __/__ __	|__|	|__|	|__|	Yes No (→ 2.8)	|__|__| years	|__|
04	Day/ Month/ Year __ __/__ __/__ __	|__|	|__|	|__|	Yes No (→ 2.8)	|__|__| years	|__|
05	Day/ Month/ Year __ __/__ __/__ __	|__|	|__|	|__|	Yes No (→ 2.8)	|__|__| years	|__|
06	Day/ Month/ Year __ __/__ __/__ __	|__|	|__|	|__|	Yes No (→ 2.8)	|__|__| years	|__|
07	Day/ Month/ Year __ __/__ __/__ __	|__|	|__|	|__|	Yes No (→ 2.8)	|__|__| years	|__|
08	Day/ Month/ Year __ __/__ __/__ __	|__|	|__|	|__|	Yes No (→ 2.8)	|__|__| years	|__|
09	Day/ Month/ Year __ __/__ __/__ __	|__|	|__|	|__|	Yes No (→ 2.8)	|__|__| years	|__|
10	Day/ Month/ Year __ __/__ __/__ __	|__|	|__|	|__|	Yes No (→ 2.8)	|__|__| years	|__|
11	Day/ Month/ Year __ __/__ __/__ __	|__|	|__|	|__|	Yes No (→ 2.8)	|__|__| years	|__|
12	Day/ Month/ Year __ __/__ __/__ __	|__|	|__|	|__|	Yes No (→ 2.8)	|__|__| years	|__|
		1 = Single 2 = Multiple	1 = Live birth 2 = Stillbirth 3 = Miscarriage	1 = Girl 2 = Boy			1 = 0-7 days 2 = 8-28 days 3 = 29 days -1yr 4 = >1yr 5 = >2yrs 6 = >3yrs 7 = >4yrs 8 = >5yrs

REMEMBER:
- A **MISCARRIAGE** IS A PREGNANCY THAT ENDS BEFORE 7 COMPLETED MONTHS
- A **STILLBIRTH** IS A PREGNANCY THAT ENDS AFTER 7 COMPLETED MONTHS, BUT THE BABY IS BORN DEAD
- A **LIVE BIRTH** IS A PREGNANCY THAT ENDS WITH A LIVE BABY, EVEN IF THAT BABY ONLY SURVIVES FOR A FEW MOMENTS

- PROBE BY ASKING "APART FROM THE PREGNANCIES YOU HAVE MENTIONED, HAVE YOU HAD ANY OTHERS THAT ENDED BEFORE 7 MONTHS, OR THAT ENDED AFTER 7 MONTHS BUT WERE BORN DEAD?"
- FOR ANY STILLBIRTHS REPORTED, MAKE SURE YOU ASK "DID THE BABY CRY OR SHOW SIGNS OF LIFE? DID IT MOVE AN ARM OR A LEG, OR BREATHE FOR A MOMENT?"

2.9	Have you ever had a pregnancy that ended before 7 completed months? IF YES, MAKE SURE THESE DETAILS ARE RECORDED IN TABLE 2	1 = Yes 2 = No	
2.10	Have you ever had a pregnancy that ended with a dead baby?	1 = Yes 2 = No →	Q2.12
2.11	Did the baby show any signs of life after it was born? Did it cry or breathe or move an arm or a leg? IF YES, RECORD THE BABY AS A LIVEBIRTH IN TABLE 2 IF NO, RECORD THE BABY AS A STILLBIRTH IN TABLE 2	1 = Yes 2 = No	
2.12	Have you ever had any children that died at any time after being born? IF YES, MAKE SURE THESE CHILDREN ARE RECORDED IN TABLE 2	1 = Yes 2 = No	

Part C: Details About the Recent Pregnancy

Now I would like to ask you about the details of your recent pregnancy			
ANC			
3.1	Did you go for an antenatal check-up during this pregnancy?	1 = Yes → 2 = No	Q3.3
3.2	Why did you not go to ANC?	Go to →	Q3.12
3.3	Where did you go? PROBE FOR MORE CIRCLE ALL THAT APPLY FOR OUTREACH SPECIFY WHERE THE OUTREACH WAS, NOT THE HEALTH FACILITY THAT IT CAME FROM	1 = Mchinji District Hospital 2 = Kapiri 3 = Kaigwazanga 4 = Kochilira 5 = Mkanda 6 = Guillime 7 = Nkhwazi 8 = Chipumi 9 = Chiwosha 10 = Ludzi 11 = Mikundi 12 = Kapanga 13 = Tembwe 14 = St Gabriel's 15 = TBA 16 = Outreach (specify _____) 17 = Other (specify _____)	
3.4	How many months pregnant were you when you first went?	|__| months	
3.5	How many times did you go altogether during this pregnancy?	|__|__| times	
3.6	During any of your antenatal visits, did the provider do any of the following at least once? EMPHASISE THAT THIS DOES NOT INCLUDE ANY VISITS ONCE THE LABOUR HAS STARTED Weigh you? Measure your height? Make you lie down and examine your belly? Measure your BP with a cuff? Take a sample of your urine? Take a sample of your blood for tests? Do a syphilis test? Perform a vaginal examination? Give information about VCT/PMTCT services? Give information on breastfeeding? Give information on contraception? Give information on postnatal check? Give information on danger signs?	 1 = Yes 2 = No 1 = Yes 2 = No 1 = Yes 2 = No 1 = Yes 2 = No 1 = Yes 2 = No 1 = Yes 2 = No 1 = Yes 2 = No 1 = Yes 2 = No 1 = Yes 2 = No 1 = Yes 2 = No 1 = Yes 2 = No 1 = Yes 2 = No 1 = Yes 2 = No	
3.7	Did you have a Tetanus Toxoid Vaccine (TTV) injection in the arm during this pregnancy?	1 = Yes 2 = No →	Q3.9

3.8	During this pregnancy, how many times did you get this injection?	|__| times	
3.9	Have you received all the five injections? CHECK TTV CARD OR HEALTH PASSPORT	1 = Yes 2 = No	
3.10	During this pregnancy were you given, or did you buy any iron tablets or iron syrup? SHOW TABLETS	1 = Yes 2 = No →	Q3.12
3.11	During the whole pregnancy, for how many days did you drink the tablets or syrup? IF ANSWER IS NOT NUMERIC, PROBE FOR APPROXIMATE NUMBER OF DAYS	|__|__|__| days	
3.12	Did you go to anyone else for advice during your pregnancy?	1 = Yes 2 = No →	Q3.14
3.13	Who did you go to?	1 = TBA 2 = Sing'anga 3 = Grandmother 4 = Other (specify _____)	
3.14	During this pregnancy, did you take any drugs in order to prevent you from getting malaria? NOT CONSIDERED HERE ARE INSTANCES WHEN YOU TOOK THE DRUG BECAUSE YOU HAD MALARIA	1 = Yes 2 = No →	Q3.17
3.15	Which medicines did you take to prevent malaria? RECORD ALL MENTIONED. AND ASK FOR EACH DRUG CIRCLED HOW MANY TIMES IT WAS TAKEN DURING THE PREGNANCY	1 = SP/Fansidar/Novidar |__|__| 2 = Other (specify _____) |__|__|	
3.16	Did you get the medicine during an antenatal visit, during another visit to a health facility or from some other source?	1 = Antenatal visit 2 = Another facility visit 3 = Other source (specify _____)	
3.17	Does your household have any mosquito nets that can be used while sleeping?	1 = Yes 2 = No →	Q3.24
3.18	How many mosquito nets does your household have?	|__|	
3.19	Since you got the mosquito net, was it ever soaked or dipped in chemicals to repel mosquitoes or insects?	1 = Yes 2 = No → 3 = Not sure →	Q3.22 Q3.22
3.20	When was the last time the net was soaked or dipped in these chemicals?	|__|__| months ago	
3.21	Did anyone sleep under a mosquito net last night? If yes, who? CIRCLE ALL THAT APPLY IF THE NUMBER OF NETS SEEMS LOW FOR THE NUMBER OF PEOPLE THAT SLEPT IN IT, PROBE TO MAKE SURE THE ANSWER IS CORRECT	1 = Nobody 2 = Self 3 = Husband 4 = New baby 5 = All other children 6 = Some other children 7 = Other (specify _____)	
3.22	During this pregnancy, how often did you sleep under the mosquito net?	1 = Every night → 2 = Some nights 3 = Never	Q3.24
3.23	Why did you not sleep under the mosquito net every night?		
3.24	Have you ever talked with your husband/partner about ways to prevent HIV?	1 = Yes 2 = No	
3.25	What methods have you ever tried to prevent HIV? LIST ALL MENTIONED		
3.26	Do you know a place that you can go to for HIV testing and counselling? If yes, name all the ones you know. CIRCLE EACH NAME MENTIONED PROBE FOR OTHERS	1 = No → 2 = Mchinji District Hospital 3 = Kapiri 4 = Mkanda 5 = St Gabriel's 6 = Banja La Mtsogolo 7 = MACRO	Q4.1

		8 = Other (specify _____)	
3.27	I do not want to know the result, but have you ever been for VCT?	1 = Yes → 2 = No	Q3.28
3.28	Why did you not go?	Go to →	Q4.1
3.28	When did you go for VCT? READ OUT THE LIST OF RESPONSES	1 = During ANC visit 2 = A separate visit during this pregnancy 3 = Before you were pregnant 4 = After this pregnancy 5 = Don't know	
3.29	Where did you go?	1 = Mchinji District Hospital 2 = Kapiri 3 = Mkanda 4 = St Gabriel's 5 = Other (specify _____)	
3.30	Did you go for testing together with your partner?	1 = Yes 2 = No	
3.31	Did you collect your results?	1 = Yes → 2 = No	Q4.1
3.32	Why did you not collect your results?		
Delivery			
4.1	How long did the labour last?	1 = 0 – 6 hours 2 = 7 – 12 hours 3 = 13 – 18 hours 4 = 19 – 24 hours 5 = >24 hours	
4.2	How many hours before the baby was born did the waters break?	1 = <24 hours 2 = >24 hours 3 = Don't know	
4.3	How did the waters smell and look?	1 = No odour/normal odour and clear 2 = Foul smell and green 3 = Don't know	
4.4	How long after the baby's birth did the placenta come out? IF THE BABY WAS BORN BY C-SECTION, CIRCLE "<1 hour"	1 = <1 hour 2 = >1 hour	
4.5	Did you drink 'mwana mphepo' medicine to assist labour?	1 = Yes 2 = No →	Q5.1
4.6	How many spoonfuls did you drink?	|__| spoonfuls	

Part D: Problems, Healthcare-seeking and Treatment – Mother

Antenatal problems									
5.1 Were you sick or did you have any serious problems during the recent pregnancy?							1 = Yes 2 = No ---------- (→ Q6.1)		
Now I would like to ask you about ALL the problems you had while you were pregnant this time									
5.2 What was the first/next problem you had? PROBE FOR MORE PROBLEMS	5.3 Did you consult anybody?	5.4 If NO, why not? SKIP TO NEXT PROBLEM AT Q5.2	5.5 If YES, who was the first/next person you consulted?	5.6 What did the person you consulted do? WRITE ALL THAT APPLY	5.7 Did you have to ask permission from anyone before you could go there? If YES, who?	5.8 How long was it from the start of your illness until you received treatment?	5.9 Did you go to anyone else for help? If YES, were you referred or did you go of your own accord?	5.10 Did you go?	5.11 If NO, why not?
1	|__|		|__|		|__|	|__|__| days |__|__| hours	|__|	|__|	
2	|__|		|__|		|__|	|__|__| days |__|__| hours	|__|	|__|	
3	|__|		|__|		|__|	|__|__| days |__|__| hours	|__|	|__|	
4	|__|		|__|		|__|	|__|__| days |__|__| hours	|__|	|__|	
5	|__|		|__|		|__|	|__|__| days |__|__| hours	|__|	|__|	
6	|__|		|__|		|__|	|__|__| days |__|__| hours	|__|	|__|	
	1 = Yes → 5.5 2 = No → 5.2 (SKIP TO NEXT PROBLEM)		1 = Sing'anga 2 = TBA 3 = HSA 4 = Health worker in Mchinji 5 = Health worker outside Mchinji 6 = Grandmother 7 = Other relative 8 = Other (specify)		1 = No 2 = Husband 3 = Mother 4 = Father 5 = Mother-in-law 6 = Other relative 7 = Other (specify)		1 = Didn't go → Q5.2 (SKIP TO NEXT PROBLEM) 2 = Went without referral → Q5.5 (START A NEW LINE) 3 = Was referred → Q5.10	1 = Yes 2 = No IF YES, START AT Q5.5 WITH A NEW LINE	

Delivery Problems									
6.1 Were you sick or did you have any serious problems during this delivery?							1 = Yes 2 = No ---------- (→ Q7.1)		
Now I would like to ask you about ALL the problems you had during this delivery									
6.2 What was the first/next problem you had? PROBE FOR MORE PROBLEMS	6.3 Did you consult anybody?	6.4 If NO, why not? SKIP TO NEXT PROBLEM AT Q6.2	6.5 If YES, who was the first/next person you consulted?	6.6 What did the person you consulted do? WRITE ALL THAT APPLY	6.7 Did you have to ask permission from anyone before you could go there? If YES, who?	6.8 How long was it from the start of your illness until you received treatment?	6.9 Did you go to anyone else for help? If YES, were you referred or did you go of your own accord?	6.10 Did you go?	6.11 If NO, why not?
1	|__|		|__|		|__|	|__|__| days |__|__| hours	|__|	|__|	
2	|__|		|__|		|__|	|__|__| days |__|__| hours	|__|	|__|	
3	|__|		|__|		|__|	|__|__| days |__|__| hours	|__|	|__|	
4	|__|		|__|		|__|	|__|__| days |__|__| hours	|__|	|__|	
5	|__|		|__|		|__|	|__|__| days |__|__| hours	|__|	|__|	
6	|__|		|__|		|__|	|__|__| days |__|__| hours	|__|	|__|	
	1 = Yes → 6.5 2 = No → 6.2 (SKIP TO NEXT PROBLEM)		1 = Sing'anga 2 = TBA 3 = HSA 4 = Health worker in Mchinji 5 = Health worker outside Mchinji 6 = Grandmother 7 = Other relative 8 = Other (specify)		1 = No 2 = Husband 3 = Mother 4 = Father 5 = Mother-in-law 6 = Other relative 7 = Other (specify)		1 = Didn't go → Q6.2 (SKIP TO NEXT PROBLEM) 2 = Went without referral → Q6.5 (START A NEW LINE) 3 = Was referred → Q6.10	1 = Yes 2 = No IF YES, START AT Q6.5 WITH A NEW LINE	

Post-natal Problems									
7.1 Were you sick or did you have any serious problems after this delivery, including problems related to breastfeeding?							1 = Yes 2 = No ---------- (→ Q8.1)		
Now I would like to ask you about ALL the problems you had after this delivery									
7.2 What was the first/next problem you had? PROBE FOR MORE PROBLEMS	7.3 Did you consult anybody?	7.4 If NO, why not? SKIP TO NEXT PROBLEM AT Q7.2	7.5 If YES, who was the first/next person you consulted?	7.6 What did the person you consulted do? WRITE ALL THAT APPLY	7.7 Did you have to ask permission from anyone before you could go there? If YES, who?	7.8 How long was it from the start of your illness until you received treatment?	7.9 Did you go to anyone else for help? If YES, were you referred or did you go of your own accord?	7.10 Did you go?	7.11 If NO, why not?
1	|__|		|__|		|__|	|__|__| days |__|__| hours	|__|	|__|	
2	|__|		|__|		|__|	|__|__| days |__|__| hours	|__|	|__|	
3	|__|		|__|		|__|	|__|__| days |__|__| hours	|__|	|__|	
4	|__|		|__|		|__|	|__|__| days |__|__| hours	|__|	|__|	
5	|__|		|__|		|__|	|__|__| days |__|__| hours	|__|	|__|	
6	|__|		|__|		|__|	|__|__| days |__|__| hours	|__|	|__|	
	1 = Yes →7.5 2 = No → 7.2 (SKIP TO NEXT PROBLEM)		1 = Sing'anga 2 = TBA 3 = HSA 4 = Health worker in Mchinji 5 = Health worker outside Mchinji 6 = Grandmother 7 = Other relative 8 = Other (specify)		1 = No 2 = Husband 3 = Mother 4 = Father 5 = Mother-in-law 6 = Other relative 7 = Other (specify)		1 = Didn't go → Q7.2 (SKIP TO NEXT PROBLEM) 2 = Went without referral → Q7.5 (START A NEW LINE) 3 = Was referred → Q7.10	1 = Yes 2 = No IF YES, START AT Q7.5 WITH A NEW LINE	

Part E: Family Planning and Relationships

Now I would like to ask you some questions about family planning and sexual relationships in your family. I know that many people feel shy talking about these sorts of things, but I would like to assure you that everything you tell me will be kept in confidence.			
Family Planning			
8.1	Have you ever used family planning in the past? If yes, which methods? DO NOT READ THE LIST CIRCLE ALL METHODS MENTIONED PROBE FOR MORE ANSWERS	1 = Lactational amenorrhea 2 = Pill 3 = Norplant 4 = Depo (Injection) 5 = Condom 6 = Loop 7 = Chingwe 8 = Traditional medicine 9 = Following cycles 10 = Withdrawal 11 = Abstinence 12 = Others (specify_____) 13 = No	Q8.3 “ “ “ “ “ “ “ “ “ “ “ Q8.2
8.2	If not, why not?		
8.3	How many months pregnant were you the last time you had sex before the delivery?	|__| months	
8.4	Did you use condoms during pregnancy or since the baby was born?	1 = During pregnancy 2 = After the birth 3 = Both during the pregnancy and after birth 4 = No →	 Q8.6
8.5	How many times?	|__|__| times during pregnancy |__|__| times after the baby was born	
8.6	Do you know of a person or a place where a person can get condoms?	1 = Yes 2 = No →	 Q9.1
8.7	Where is that? DO NOT READ THE LIST CIRCLE ALL PLACES MENTIONED PROBE FOR MORE ANSWERS	1 = Health facility 2 = Grocery 3 = Bar or bottle store 4 = Community workers (e.g. CBDA, Youth Alert) 5 = Other (specify _____)	
8.8	If you wanted to, could you get yourself a condom?	1 = Yes 2 = No 3 = Don’t know	
Relationships			
9.1	How many times have you ever been married or in a long-term relationship (lasting more than 12 months)? INCLUDE CURRENT RELATIONSHIP IF MARRIED	|__|__| times	
9.2	How old were you when you first entered such a relationship?	|__|__| years	
9.3	What is your marital status now?	1 = Married 2 = Single/never married → 3 = Divorced/separated → 4 = Widowed → 5 = Other (specify)	 Q10.1 Q10.1 Q10.1
9.4	How long have you been in this relationship?	|__|__| years |__|__| months	
9.5	Does this man have any wives apart from you? If yes, how many?	1 = Yes |__| wives 2 = No →	 Q9.7
9.6	Are you the first, second, third… wife?	|__|__| rank	
9.7	How many times has this man ever been married before (including yourself)?	|__|__| times	
9.8	Taken altogether, how many children has this man ever fathered with other women (not including self, but including co-wives)?	|__|__| children	

Part F: Exposure to Interventions

Now I would like to ask you some questions about community activities that you are involved with in your village			
IF YOU ARE WORKING IN ANY OF THE FOLLOWING ZONES PLEASE START AT Q10.4: 4, 5, 6, 13, 18, 19, 21, 26, 30, 39, 44, 48 IF YOU ARE WORKING IN ANY OF THE FOLLOWING ZONES PLEASE START AT Q10.7: 3, 7, 8, 14, 16, 22, 27, 31, 32, 35, 46, 47 IF YOU ARE WORKING IN ANY OTHER ZONE, PLEASE START AT Q10.1			
10.1	Have you ever attended a MaiMwana women's group meeting?	1 = Yes 2 = No →	Q10.3
10.2	How many times did you go?	|__|__| times →	Q10.4
10.3	If no, why not?		
IF YOU ARE WORKING IN ANY OF THE FOLLOWING ZONES PLEASE GO TO Q10.7: 1, 9, 11, 20, 24, 25, 28, 33, 34, 40, 42, 45			
10.4	Have you ever been counselled by a MaiMwana infant feeding counsellor?	1 = Yes 2 = No →	Q10.7
10.5	How many times were you visited by her in the last 6 months?	|__| times →	Q10.8
10.6	If no, why not?		
10.7	Who have you exchanged ideas with about issues relating to pregnancy newborn care in the last 4 months? CIRCLE ALL THAT APPLY	1 = MaiMwana women's group members 2 = Other female friends from the village 3 = Other female friends from another village 4 = Female relatives 5 = Husband 6 = Nobody 7 = Other (specify _____)	
10.8	Who have you exchanged ideas with about issues relating to how to feed a b in the last 4 months? CIRCLE ALL THAT APPLY	1 = MaiMwana infant feeding counsellor 2 = Other female friends from the village 3 = Other female friends from another village 4 = Female relatives 5 = Husband 6 = Nobody 7 = Other (specify _____)	
10.9	Have you been involved in any other community activities, groups or commit in the last year? If yes, what were they?		
10.10	Do you or your husband hold any of the following positions?	1 = No 2 = Village headman 3 = Group village headman 4 = TBA 5 = Sing'anga 6 = HSA 7 = Member of village health committee 8 = Member of other community group (specify _____)	
10.11	How much control do you feel you have in making important decisions that a your and your children's health?	1 = No control 2 = Control over very few decisions 3 = Control over some decisions 4 = Control over most decisions 5 = Control over all decisions	

WCBA ID: |__|__|-|__|__|-|__|__|__|-|__|	WCBA name: first/second/other	
Interviewer ID: |__|__|	Date of interview: |__|__|/|__|__|/|__|__|	Supervisor's signature:
What is the relationship of the respondent to the infant?		1 = Mother 2 = Father 3 = Mother's relative 4 = Father's relative 5 = Neighbour 6 = TBA 7 = Other (specify _____)

Part G: The Newborn Baby

COMPLETE A SEPARATE FORM FOR EACH BABY IF THEY ARE TWINS/MULTIPLE

Now I would like you to tell me about the birth of your baby			
Details of the birth			
11.1	Is your baby a girl or a boy?	1 = Girl 2 = Boy	
11.2	What is your baby's name?		
11.3	What date was (NAME) born on?	Day/ Month/ Year __ __/__ __/__ __	
11.4	Was (NAME) born early, late, or at the expected time?	1 = Early 2 = On time 3 = Late	
11.5	After how many completed months of pregnancy was (NAME) born?	|__|__| months	
11.6	Is (NAME) one of twins?	1 = Single → 2 = Twin/multiple	Q11.8
11.7	Was (NAME) the first or second born twin?	1 = First 2 = Second	
11.8	How big was the baby?	1 = Very large 2 = Average 3 = Very small 4 = Don't know	
11.9	Was (NAME) weighed at birth?	1 = Yes 2 = No →	Q12.1
11.10	How much did (NAME) weigh? CHECK HEALTH PASSPORT	|__|__|__|__| grams	
Newborn Care			
12.1	Where was (NAME) born?	1 = Mchinji District Hospital 2 = Kapiri 3 = Kaigwazanga 4 = Kochilira 5 = Mkanda 6 = Guillime 7 = Nkhwazi 8 = Chipumi 9 = Chiwosha 10 = Ludzi 11 = Mikundi 12 = Kapanga 13 = Tembwe 14 = St Gabriel's 15 = TBA 16 = At home 17 = On the way to health facility 18 = Other (specify _____)	
12.2	Was there a fire, stove or any form of heating in the room?	1 = Yes 2 = No 3 = Don't know	

12.3	Who helped with the delivery? CIRCLE ALL MENTIONED	1 = Doctor/Nurse/Clinical Officer/Midwife 2 = Other health worker 3 = TBA 4 = Relative/friend 5 = Nobody →	Q12.6
12.4	Did the person who helped wash his/her hands with soap before the delivery?	1 = Yes 2 = No 3 = Don't know	
12.5	Did the person who helped wear gloves during the delivery?	1 = Yes 2 = No 3 = Don't know	
12.6	How was the baby delivered?	1 = Normal 2 = Breech 3 = Forceps/vacuum 4 = C-section	
12.7	Which part of the baby came out first?	1 = Head 2 = Buttock 3 = Hand/foot 4 = Cord 5 = Don't know	
12.8	What was the cord cut with?		
12.9	What was the cord tied with?		
12.10	What substances were put on the cord stump after it was cut?		
12.11	How long after birth was (NAME) wrapped up?	|__|__| hours |__|__| minutes	
12.12	How long after the birth was (NAME) bathed?	|__|__| hours |__|__| minutes	
12.13	What was the first thing the baby swallowed after he/she was born?		
12.14	Has (NAME) had a BCG immunisation (injection on left arm)? CHECK HEALTH PASSPORT AND LOOK FOR SCAR	1 = Yes 2 = No	
Post-natal Check-up			
13.1	After the baby was born, did a health professional or a traditional birth attendant check on your or your baby's health? THIS DOES NOT INCLUDE CHECKS MADE BY HEALTH WORKERS IMMEDIATELY AFTER A DELIVERY AT A HEALTH FACILITY	1 = Yes → 2 = No	Q13.3
13.2	Why was there not a check?	Go to →	Q14.1
13.3	How many days after delivery did the first check take place?	|__|__| days	
13.4	Why did you go?	1 = Normal check-up 2 = Problem for mother 3 = Problem for baby	
13.5	Where did this first check take place? FOR OUTREACH SPECIFY WHERE THE OUTREACH WAS, NOT THE HEALTH FACILITY THAT IT CAME FROM	1 = Mchinji District Hospital 2 = Kapiri 3 = Kaigwazanga 4 = Kochilira 5 = Mkanda 6 = Guillime 7 = Nkhwazi 8 = Chipumi 9 = Chiwosha 10 = Ludzi 11 = Mikundi 12 = Kapanga 13 = Tembwe 14 = St Gabriel's 15 = TBA 16 = Outreach (specify _____) 17 = Other (specify _____)	

13.6	Since the delivery, have you received a dose of Vitamin A? SHOW VITAMIN A TABLET	1 = Yes 2 = No	
Now I would like you to tell me about how you fed your baby			
Breastfeeding			
14.1	Have you ever breastfed (NAME)?	1 = Yes 2 = No →	Q14.3
14.2	How long after birth did you first breastfeed the baby/put (NAME) to the breast?	|__|__| hours |__|__| minutes	
14.3	What did you give (NAME) to drink in the first three days after delivery, before your milk began flowing regularly? PROBE 'Anything else?' RECORD ALL FOODS/DRINKS MENTIONED IF ONLY BREASTMILK WAS GIVEN, GO TO Q14.5		
14.4	Why did you give these things?		
14.5	Has (NAME) drunk any pharmaceutical medicine since he/she was born? INCLUDE LIQUID MEDICINES AND LIQUID VITAMINS OR MINERALS AND COMMERCIAL GRIPE WATER	1 = Yes (specify _____) 2 = No →	Q14.8
14.6	What was the medicine for?		
14.7	How many times did (NAME) drink pharmaceutical medicine?	|__|__| times	
14.8	Has (NAME) drunk any traditional medicine since he/she was born?	1 = Yes (specify _____) 2 = No →	Q14.11
14.9	What was the medicine for?		
14.10	How many times did (NAME) drink traditional medicine?	|__|__| times	
14.11	Has (NAME) drunk any water since he/she was born?	1 = Yes 2 = No →	Q14.13
14.12	How many times did (NAME) drink water?	1 = Only on the first day 2 = On some days 3 = Every day 4 = Other (specify) _____	
14.13	Are you still breastfeeding (NAME)?	1 = Yes → 2 = No	Q14.15
14.14	Why did you stop breastfeeding?		
14.15	Have you had any problems with breastfeeding?	1 = Yes 2 = No →	Q14.20
14.16	What were they?		
14.17	Did you go, or were you referred to a health facility because of these problems?	1 = Went without referral 2 = Was referred 3 = Didn't go	
14.18	Did you change the way you fed your child during the time you had breast problems?	1 = Yes 2 = No →	Q14.20
14.19	What did you do differently? WRITE ALL CHANGES MENTIONED		
14.22	Did you change the way you fed your baby at any time when you or the baby was sick after the delivery? CIRCLE ALL THAT APPLY	1 = No → 2 = Yes, when I was sick 3 = Yes, when the baby was sick 4 = yes, for another reason (specify _____)	Q…
14.23	What did you do differently? WRITE ALL CHANGES MENTIONED		
14.25	Did anyone else (beside yourself) ever breastfed (NAME)?	1 = Yes 2 = No → 3 = Don't know →	Q14.27 Q14.27

14.26	Why did the other person breastfeed (NAME)?		
14.27	Did you ever express your breast milk after (NAME) was born?	1 = Yes 2 = No →	Q15.1
14.28	Did you give the expressed breast milk to (NAME)?	1 = Yes 2 = No →	Q14.30
14.29	How did you give the milk to (NAME)?	1 = Cup 2 = Bottle 3 = Other (specify _____)	
14.30	Did you heat-treat your breast milk?	1 = Yes 2 = No	
14.31	Why did you express milk?		
14.32	Who explained to you how to express the milk?	1 = Health worker 2 = Sister 3 = Mother 4 = Other family member 5 = Neighbour 6 = MaiMwana IF counsellor 7 = Other (specify _____)	

Feeding recall

Now I would like you to tell me the details about how you fed (NAME)

		First I'm going to ask you about all the things (NAME) drank during the first week after birth			Now I want to ask you about all the things (NAME) drank in the last 7 days	
		15.1	15.2	15.3	15.4	15.5
		Before you gave any breast milk, was (NAME) given…	On the day he/she was born, was (NAME) given…	Between day 2 and day 7 after (NAME) was born, was he/she given…	Yesterday, was (NAME) given…	Apart from yesterday, in the last week, was (NAME) given…
01	Breast milk?					
02	Other milks?					
03	Water/dawale?					
04	Home-made gripe water/rice water/mzuwa?					
05	Phala?					
06	Other foods or drinks (specify)?					
07	Traditional medicines?					
08	Pharmaceutical medicines?					
09	Other foods or drinks given but she doesn't know what they were					
		1= Yes 2 = No	1= Yes 2 = No	1= Yes 2 = No	1= Yes 2 = No	1= Yes 2 = No

REMEMBER: **OTHER MILKS** INCLUDE COMMERCIAL FORMULA MILK, FRESH ANIMAL MILK, TINNED OR POWDERED MILK, FERMENTED OR SOUR MILK, YOGHURT, YOGGIE, CHAMBIKO AND CHEESE

Part H: Problems, Healthcare-seeking and Treatment – Baby

16.1 Has your baby been sick or had any serious problems, including problems to do with feeding?							1 = Yes 2 = No ---------- (→ Q17.1)		
Now I would like to ask you about ALL the problems your baby has had									
16.2 What was the first/next problem (NAME) had? PROBE FOR MORE PROBLEMS	16.3 Did you consult anybody?	16.4 If NO, why not? SKIP TO NEXT PROBLEM AT Q16.2	16.5 If YES, who was the first/next person you consulted?	16.6 What did the person you consulted do? WRITE ALL THAT APPLY	16.7 Did you have to ask permission from anyone before you could go there? If YES, who?	16.8 How long was it from the start of the illness until (NAME) received treatment?	16.9 Did you go to anyone else for help for (NAME)? If YES, were you referred or did you go of your own accord?	16.10 Did you go?	16.11 If NO, why not?
1	|__|		|__|		|__|	|__|__| days |__|__| hours	|__|	|__|	
2	|__|		|__|		|__|	|__|__| days |__|__| hours	|__|	|__|	
3	|__|		|__|		|__|	|__|__| days |__|__| hours	|__|	|__|	
4	|__|		|__|		|__|	|__|__| days |__|__| hours	|__|	|__|	
5	|__|		|__|		|__|	|__|__| days |__|__| hours	|__|	|__|	
6	|__|		|__|		|__|	|__|__| days |__|__| hours	|__|	|__|	
	1 = Yes →16.5 2 = No → 16.2 (SKIP TO NEXT PROBLEM)		1 = Sing'anga 2 = TBA 3 = HSA 4 = Health worker in Mchinji 5 = Health worker outside Mchinji 6 = Grandmother 7 = Other relative 8 = Other (specify)		1 = No 2 = Husband 3 = Mother 4 = Father 5 = Mother-in-law 6 = Other relative 7 = Other (specify)		1 = Didn't go → Q16.2 (SKIP TO NEXT PROBLEM) 2 = Went without referral → Q16.5 (START A NEW LINE) 3 = Was referred → Q16.10	1 = Yes 2 = No IF YES, START AT Q16.5 WITH A NEW LINE	

Illness in Infant

17.1	Has the baby had a cough?	1 = Yes 2 = No →	Q17.3
17.2	How many days continuously did the cough last?	|__|__| days	
17.3	Has the baby had any fast breathing for more than 6 hours?	1 = Yes 2 = No	
17.4	Has the baby had chest recession?	1 = Yes 2 = No	
17.5	Has the baby had difficulty in feeding?	1 = Yes 2 = No	
17.6	Has the baby had diarrhoea more than 3 times a day?	1 = Yes 2 = No →	Q17.9
17.7	For how many days did the diarrhoea last?	|__|__| days	
17.8	Was there mucus, pus or blood in the stool?	1 = None present 2 = Mucus 3 = Pus 4 = Blood	
17.9	Did the baby vomit repeatedly? THIS DOES NOT INCLUDE REGURGITATION OF MILK	1 = Yes 2 = No	
17.10	Has the baby had a high fever?	1 = Yes 2 = No →	Q17.12
17.11	How many days did the fever last?	|__|__| days	
17.12	Has the baby had any infection of the umbilical cord? PROBE ABOUT REDNESS OF DISCHARGE AROUND THE STUMP	1 = Yes 2 = No	
17.13	Has the baby had jaundice?	1 = Yes 2 = No	

RECORD TIME FINISHED INTERVIEW: __ __ : __ __

MAIMWANA PROJECT – PERINATAL VERBAL AUTOPSY

On arriving at the respondent's house – GREET THE RESPONDENT AND OFFER CONDOLENCES. ASK FOR A PRIVATE PLACE TO SIT AND CHAT, AWAY FROM OTHER PEOPLE. ASK THE RESPONDENT TO BRING HER HEALTH PASSPORT, IF SHE HAS ONE. CHAT A LITTLE BIT, TO HELP THE RESPONDENT TO FEEL RELAXED.

Consent – My name is _____. I am working with MaiMwana Project. MaiMwana is trying to improve the health of mothers and babies in Mchinji. We are doing a survey of women who have recently given birth, in order to learn about their experiences. The purpose of this interview is to try and understand why your baby died, so that we can help to prevent other babies from dying in future. I am sorry that I am going to remind you about the death of your baby. I hope you will allow me to talk about it.

We assure you that everything you tell us will be kept confidential, and will only be used for study purposes. You do not have to take part in this research if you do not want to. If you do not wish to take part, this will not affect your right to take part in other MaiMwana activities in the future. If there are any questions that you do not want to answer, you do not have to answer them. There are no wrong answers to these questions. We just want to know about the experiences of pregnant women. If you do not understand a question, please ask me to explain it again.

This interview will take about one hour. Do you agree to take part?

Yes |__|

No |__|

Zone ID: |__|__|	Village ID: |__|__|	Village name:
Household ID: |__|__|__|		Name of head of household:
WCBA ID: |__|__|-|__|__|-|__|__|__|-|__|		WCBA name: first/second/alternative
Interviewer ID: |__|__|	Date of interview: |__|__|/|__|__|/|__|__|	Supervisor's signature:
		Date received in office: |__|__|/|__|__|/|__|__|
Is the mother still alive?		1 = Yes 2 = No
What is the relationship of the respondent to the infant?		1 = Mother 2 = Father 3 = Mother's relative 4 = Father's relative 5 = Neighbour 6 = TBA 7 = Other (specify _____)

RECORD TIME STARTED INTERVIEW: __ __ : __ __

Part A: Details of the Birth

First I would like you to tell me the details about the birth of this baby			
Details of the birth			
1.1	What date was the baby born on?	Day/ Month/ Year __ __/__ __/__ __	
1.2	What date did the baby die on?	Day/ Month/ Year __ __/__ __/__ __	
1.3	Where did your baby die?	1 = At home 2 = On the way to treatment 3 = At a health facility (specify _____) 4 = At TBA's house 5 = At sing'anga's 6 = Other (specify _____)	
1.4	Was your baby a girl or a boy?	1 = Girl 2 = Boy 3 = Don't know	
1.5	What was the name of your baby? IF NOT GIVEN WRITE 'NO NAME' AND GO TO Q1.6		
1.6	Was the baby born at the expected time?	1 = Early 2 = On time 3 = Late	
1.7	After how many completed months of pregnancy was the baby born?	|__|__| months	
1.8	Was the baby one of twins?	1 = Yes 2 = No →	Q1.10
1.9	Was the baby the first or second born twin?	1 = First 2 = Second	
1.10	How big was the baby?	1 = Very large 2 = Average 3 = Very small 4 = Don't know	
1.11	Was the baby weighed at birth? CHECK HEALTH PASSPORT	1 = Yes 2 = No →	Q1.13
1.12	How much did the baby weigh? CHECK HEALTH PASSPORT	|__|•|__| kg	
1.13	Where was the baby born?	1 = Mchinji District Hospital 2 = Kapiri 3 = Kaigwazanga 4 = Kochilira 5 = Mkanda 6 = Guillime 7 = Nkhwazi 8 = Chipumi 9 = Chiwosha 10 = Ludzi 11 = Mikundi 12 = Kapanga 13 = Tembwe 14 = St Gabriel's 15 = TBA 16 = At home 17 = On the way to health facility 18 = Other (specify _____)	
1.14	Was there a fire, stove or any form of heating in the room?	1 = Yes 2 = No 3 = Don't know	
1.15	Who helped with the delivery?	1 = Doctor/Nurse/Clinical Officer/Midwife 2 = Other health worker 3 = TBA 4 = Relative/friend 5 = Nobody →	Q1.18

1.16	Did the person who helped wash his/her hands with soap before the delivery?	1 = Yes 2 = No 3 = Don't know	
1.17	Did the person who helped wear gloves during the delivery?	1 = Yes 2 = No 3 = Don't know	
1.18	How was the baby delivered?	1 = Normal 2 = TBA/relative/friend pulled the baby or pushed on the belly 3 = Health worker used forceps 4 = Health worker did a caesarean section	
1.19	Which part of the baby came out first?	1 = Head 2 = Buttock 3 = Hand/foot 4 = Cord 5 = Don't know	

Part B: Open History

Verbal autopsy	
2.1	We need to understand how and why your baby died. So please tell me the story of how the death came about, including all of the problems he/she had, from the beginning to the end. PROBE UNTIL THEY HAVE TOLD YOU EVERYTHING THEY CAN REMEMBER

Part C: Details of Illnesses Leading to the Death of the Baby

Congenital abnormalities			
3.1	Did the baby have any obvious deformity?	1 = Yes 2 = No →	 Q3.7
3.2	Can you describe it for me?		
3.3	Did the baby have a very small head?	1 = Yes 2 = No	
3.4	Did the baby have a mass or defect on the back of the head or spine	1 = Yes 2 = No	
3.5	Did the baby have a cleft lip or palate?	1 = Yes 2 = No	
3.6	Did the baby have abnormal arms or legs	1 = Yes 2 = No	
Stillbirth or live birth			
3.7	Did the baby have bruises or signs of injury?	1 = Yes 2 = No 3 = Don't know	
3.8	Was the baby born alive or dead?	1 = Alive → 2 = Dead	Q4.1
3.9	Was the baby still moving when labour started?	1 = Yes → 2 = No 3 = Don't know	Q3.12
3.10	When did you last feel the baby moving?	|__|__| Days before labour started |__|__| Hours before labour started	
3.11	Do you think that the baby had died before you went into labour?	1 = Yes → 2 = No	Q3.15
3.12	Did the baby ever cry, even a little?	1 = Yes → 2 = No	Q4.1
3.13	Did the baby ever move, even a little?	1 = Yes → 2 = No	Q4.1
3.14	Did the baby ever breathe, even a little?	1 = Yes → 2 = No	Q4.1
3.15	Did the baby look like a normal baby, or had the skin and body changed and become pulpy/puffy/mushy/swollen?	1 = Yes 2 = No 3 = Don't know	
3.16	Was anything done to try to help the baby to breathe at birth?	1 = Yes 2 = No → 3 = Don't know →	 STOP STOP
3.17	What was done to try to help the baby to breathe?	1 = Stimulation 2 = Mouth to mouth 3 = Mouth to tube or mask 4 = Bag and mask	STOP STOP STOP STOP
THIS IS THE END OF THE INTERVIEW IF THE BABY WAS A STILLBIRTH. IF YOU HAVE NOT SKIPPED TO Q4.1, STOP THE INTERVIEW HERE AND THANK THE RESPONDENT			

Now I would like to ask you some more questions about the illness of the baby before he/she died			
Breathing difficulties			
4.1	Did the baby cry at birth?	1 = Yes → 2 = No	Q4.3
4.2	How long after birth did the baby first cry?	1 = Within 5 minutes 2 = Within 5-30 minutes 3 = More than 30 minutes 4 = Never	

4.3	Was anything done to try to help the baby to breathe at birth?	1 = Yes 2 = No →	Q4.5
4.4	What was done to try to help the baby to breathe?	1 = Stimulation 2 = Mouth to mouth 3 = Mouth to tube or mask 4 = Bag and mask	
4.5	Was the baby sleepy and floppy at the time of birth?	1 = Yes 2 = No	
4.6	Did the baby ever have difficulty breathing?	1 = Yes 2 = No →	Q4.15
4.7	What was the difficulty?	1 = Intermittent breathing 2 = Fast breathing	
4.8	When did the difficulty start?	1 = Immediately at birth 2 = Not immediately but within 6 hours 3 = More than 6 hours after birth	
4.9	How long did the difficulty continue?	|__|__| days	
4.10	Did the difficulty continue until the baby died?	1 = Yes 2 = No	
4.11	Was there chest indrawing?	1 = Yes 2 = No	
4.12	Was there grunting (demonstrate)?	1 = Yes 2 = No	
4.13	Was there nostril flaring (demonstrate)?	1 = Yes 2 = No	
4.14	Did the baby have pneumonia?	1 = Yes 2 = No	
Difficulty feeding			
4.15	Did the baby ever suckle normally?	1 = Yes 2 = No →	Q4.20
4.16	Did the baby always suckle normally?	1 = Yes → 2 = No	Q4.20
4.17	When did the problem start?	1 = On the day he/she was born 2 = After the day of birth but in the first 3 days 3 = After the first 3 days	
4.18	How long did the problem continue?	|__|__| days	
4.19	Did the feeding problem continue until the baby died?	1 = Yes 2 = No	
Tetanus			
4.20	Could the baby open her mouth?	1 = Yes 2 = No	
4.21	Did the baby arch her back and have spasms? show photo	1 = Yes 2 = No	
4.22	Did the baby have tetanus?	1 = Yes 2 = No	
Diarrhoea			
4.23	Did the baby have more frequent liquid stools than usual?	1 = Yes 2 = No	
4.24	Did the baby have diarrhoea?	1 = Yes 2 = No →	Q4.27
4.25	Was there blood in the stool?	1 = Yes 2 = No	
4.26	How long did the diarrhoea continue?	|__|__| days	
4.27	Did the baby vomit everything?	1 = Yes 2 = No	
Other illness			
4.28	Did the baby have a fever?	1 = Yes 2 = No →	Q4.31
4.29	When did the fever start	|__|__| days after birth	
4.30	How long did the fever continue?	|__|__| days	

4.31	Were the baby's skin and eyes very yellow?	1 = Yes 2 = No	
4.32	Did the baby have any fits/convulsions/seizures?	1 = Yes 2 = No →	Q4.34
4.33	On which day of life?	1 = First day 2 = After first day	
4.34	Did the baby feel cold?	1 = Yes 2 = No →	Q4.37
4.35	When did the baby start feeling cold?	|__| days	
4.36	How long did the baby feel cold?	|__|__| days |__|__| hours	
4.37	Did the baby have pustules on the skin?	1 = Yes 2 = No	
4.38	Did the baby have ear discharge?	1 = Yes 2 = No	
4.39	Did the baby have red eyes with pus in them?	1 = Yes 2 = No	
4.40	Did the baby have a bright red ring on the skin around the umbilical cord stump?	1 = Yes 2 = No	
4.41	Did the baby bleed?	1 = Yes 2 = No →	Q4.43
4.42	Where did the baby bleed from?		
4.43	What did the baby's fontanelle look like?	1 = Sunken down 2 = Normal 3 = Bulging up	
4.44	Did the baby become drowsy and unconscious when he/she had been normal before?	1 = Yes 2 = No	
4.45	How long was the baby ill before he/she died?	|__|__| days	
4.46	Did the baby die suddenly without any sign of illness?	1 = Yes 2 = No	
4.47	Did the baby have some other problem that we haven't discussed?	1 = Yes 2 = No →	Q5.1
4.48	What was the problem?		

Part C: The Newborn Baby

Now I would like to ask you some details about how you looked after the baby after he/she was born			
Newborn care			
5.1	What was the cord cut with?		
5.2	What was the cord tied with?		
5.3	What substances were put on the cord stump after it was cut?		
5.4	How long after birth was (NAME) wrapped up?	|__|__| hours |__|__| minutes	
5.5	How long after the birth was (NAME) bathed?	|__|__| hours |__|__| minutes	
5.6	What was the first thing the baby swallowed after he/she was born?		
5.7	Did (NAME) have a BCG immunisation? CHECK HEALTH PASSPORT IF AVAILABLE	1 = Yes 2 = No	
5.8	Did (NAME) have oral polio vaccine? CHECK HEALTH PASSPORT IF AVAILABLE	1 = Yes 2 = No	

Post-natal Check-up			
6.1	After the baby was born, did a health professional or a traditional birth attendant check on your or your baby's health? THIS DOES NOT INCLUDE CHECKS MADE BY HEALTH WORKERS IMMEDIATELY AFTER A DELIVERY AT A HEALTH FACILITY	1 = Yes 2 = No →	Q6.6
6.2	How many days after delivery did the first check take place?	|__|__| days	
6.3	Why did you go?	1 = Normal check-up 2 = Problem for mother 3 = Problem for baby	
6.4	Where did this first check take place? FOR OUTREACH SPECIFY WHERE THE OUTREACH WAS, NOT THE HEALTH FACILITY THAT IT CAME FROM	1 = Mchinji District Hospital 2 = Kapiri 3 = Kaigwazanga 4 = Kochilira 5 = Mkanda 6 = Guillime 7 = Nkhwazi 8 = Chipumi 9 = Chiwosha 10 = Ludzi 11 = Mikundi 12 = Kapanga 13 = Tembwe 14 = St Gabriel's 15 = TBA 16 = Outreach (specify _____) 17 = Other (specify _____)	
6.5	Since the delivery, have you received a dose of Vitamin A? SHOW VITAMIN A TABLET	1 = Yes → 2 = No →	Q7.1 Q7.1
6.6	Why was there not a check?		
Now I would like you to tell me about how you fed your baby			
Breastfeeding			
7.1	Did you ever breastfeed (NAME)?	1 = Yes 2 = No → 3 = Baby died immediately, before it could be given anything →	Q7.3 Q9.1
7.2	How long after birth did you first breastfeed the baby/put (NAME) to the breast?	|__|__| hours |__|__| minutes	
7.3	What did you give (NAME) to drink in the first three days after delivery, before your milk began flowing regularly? PROBE 'Anything else?' RECORD ALL FOODS/DRINKS MENTIONED IF BREAST MILK ONLY, GO TO Q7.5		
7.4	Why did you give these things?		
7.5	Did (NAME) drink any pharmaceutical medicine after he/she was born? INCLUDE LIQUID MEDICINES AND LIQUID VITAMINS OR MINERALS AND COMMERCIAL GRIPE WATER	1 = Yes (specify _____) 2 = No →	Q7.8
7.6	What was the medicine for?		
7.7	How many times did (NAME) drink pharmaceutical medicine?	|__|__| times	
7.8	Did (NAME) drink any traditional medicine after he/she was born?	1 = Yes (specify _____) 2 = No →	Q7.11
7.9	What was the medicine for?		
7.10	How many times did (NAME) drink traditional medicine?	|__|__| times	
7.11	Did (NAME) drink any water after he/she was born?	1 = Yes 2 = No →	Q7.13

7.12	How many times did (NAME) drink water?	1 = Only on the first day 2 = On some days 3 = Every day 4 = Other (specify) _____	
7.13	Were you still breastfeeding (NAME), until the day he/she died?	1 = Yes → 2 = No	Q7.15
7.14	Why did you stop breastfeeding?		
7.15	Did you have any problems with breastfeeding?	1 = Yes 2 = No →	Q7.20
7.16	What were they?		
7.17	Did you go, or were you referred to a health facility because of these problems?	1 = Went without referral 2 = Was referred 3 = Didn't go	
7.18	Did you change the way you fed your baby during the time you had breast problems?	1 = Yes 2 = No →	Q7.20
7.19	What did you do differently? WRITE ALL CHANGES MENTIONED		
7.20	Did you change the way you fed your baby at any time the time when you or your baby were sick after the delivery?	1 = No → 2 = Yes, when I was sick 3 = Yes, when the baby was sick 4 = Yes, for another reason (specify _____)	Q7.22
7.21	What did you do differently? WRITE ALL CHANGES MENTIONED		
7.22	Did anyone else (beside yourself) ever breastfed (NAME)?	1 = Yes 2 = No → 3 = Don't know →	 Q7.24 Q7.24
7.23	Why did the other person breastfeed (NAME)?		
7.24	Did you ever express your breast milk after (NAME) was born?	1 = Yes 2 = No →	Q8.1
7.25	Did you give the expressed breast milk to (NAME)?	1 = Yes 2 = No →	Q7.27
7.26	How did you give the milk to (NAME)?	1 = Cup 2 = Bottle 3 = Other (specify _____)	
7.27	Did you heat-treat your breast milk?	1 = Yes 2 = No	
7.28	Why did you express milk?		
7.29	Who explained to you how to express the milk?	1 = Health worker 2 = Sister 3 = Mother 4 = Other family member 5 = Neighbour 6 = MaiMwana IF counsellor 7 = Other (specify _____)	

Feeding recall						
Now I would like you to tell me the details about how you fed (NAME)						
		First I'm going to ask you about all the things (NAME) drank during the first week after birth			IF THE BABY DIED WITHIN 7 DAYS AFTER BIRTH, GO TO Q9.1 Now I want to ask you about all the things (NAME) drank in the last 7 days before he/she died	
		8.1	8.2	8.3	8.4	8.5
		Before you gave any breast milk, was (NAME) given…	On the day he/she was born, was (NAME) given…	Between day 2 and day 7 after (NAME) was born, was he/she given…	On the day before (NAME) died, was he/she given…	Apart from the day before (NAME) died, in the last week, was he/she given…
01	Breast milk?					
02	Other milks?					
03	Water/dawale?					
04	Home-made gripe water/rice water/mzuwa?					
05	Phala?					
06	Other foods or drinks (specify)?					
07	Traditional medicines					
08	Pharmaceutical medicines					
09	Unsure of other foods or drinks given					
		1= Yes 2 = No 3 = Baby died 4 = Don't know	1= Yes 2 = No 3 = Baby died 4 = Don't know	1= Yes 2 = No 3 = Baby died 4 = Don't know	1= Yes 2 = No 3 = Baby died 4 = Don't know	1= Yes 2 = No 3 = Baby died 4 = Don't know

REMEMBER: OTHER milks Include COMMERCIAL FORMULA MILK, fresh animal milk, tinned or powdered milk, fermented or sour milk, yoghurt, cheese, and all other milk from a cow or other animal

Part H: Problems, Healthcare-seeking and Treatment – Baby

Now I would like to ask you about any help you sought for the problems (NAME) had, that we talked about earlier									
9.1 What was the first/next problem (NAME) had? CONTINUE UNTIL YOU HAVE COVERED ALL OF THE PROBLEMS MENTIONED IN PART 4	9.2 Did you consult anybody?	9.3 If NO, why not? SKIP TO NEXT PROBLEM AT Q9.1	9.4 If YES, who was the first/next person you consulted?	9.5 What did the person you consulted do? WRITE ALL THAT APPLY	9.6 Did you have to ask permission from anyone before you could go there? If YES, who?	9.7 How long was it from the start of the illness until (NAME) received treatment?	9.8 Did you go to anyone else for help for (NAME)? If YES, were you referred or did you go of your own accord?	9.9 Did you go?	9.10 If NO, why not?
1	|__|		|__|		|__|	|__|__| days |__|__| hours	|__|	|__|	
2	|__|		|__|		|__|	|__|__| days |__|__| hours	|__|	|__|	
3	|__|		|__|		|__|	|__|__| days |__|__| hours	|__|	|__|	
4	|__|		|__|		|__|	|__|__| days |__|__| hours	|__|	|__|	
5	|__|		|__|		|__|	|__|__| days |__|__| hours	|__|	|__|	
6	|__|		|__|		|__|	|__|__| days |__|__| hours	|__|	|__|	
	1 = Yes → 9.4 2 = No		1 = Sing'anga 2 = TBA 3 = HSA 4 = Health worker in Mchinji 5 = Health worker outside Mchinji 6 = Grandmother 7 = Other relative 8 = Other (specify)		1 = No 2 = Husband 3 = Mother 4 = Father 5 = Mother-in-law 6 = Other relative 7 = Other (specify)		1 = Didn't go → Q9.1 (SKIP TO NEXT PROBLEM) 2 = Went without referral → Q9.4 (START A NEW LINE) 3 = Was referred → Q9.9	1 = Yes 2 = No IF YES, START AT Q9.4 WITH A NEW LINE	

RECORD TIME FNISHED INTERVIEW: __ __ : __ __

This is the end of the interview…

This is the end of the interview. Thank you for sharing with us the details of the recent death of your baby. We hope that we will be able to learn from your experiences and help other mothers and babies in Mchinji in the future.

Feedback from the interviewer…	
Apart from the respondent, did anyone else help to answer the questions in the interview?	1 = Father of the baby 2 = Grandmother of the baby 3 = Relative of the mother of the baby 4 = Relative of the father of the baby 5 = Friend/neighbour of the mother of the baby 6 = TBA 7 = Other (specify _____)
Was the interview interrupted at all? (Explain what happened)	
Were there any other people around during the interview? (Specify who)	
Were there any questions that the respondent had problems answering? (Explain)	
Were there any questions that the respondent seemed to be holding back information on? (Explain why if possible)	
Any other comments	

Appendix 5 – Letter of ethical approval from Malawi National Health Sciences Research Committee

Telephone (Office): 789400
Telex: 44558
Fax: 789510

All communications should be addressed to Secretary for Health and Population

In reply please quote No

MINISTRY OF HEALTH AND POPULATION
P.O. BOX 30377
CAPITAL CITY
LILONGWE 3

Ref. No. MED/4/36/I/167

31st January 2003

Dr. P.N. Kazambe
Lilongwe Central Hospital
P.O. Box 30377
Lilongwe 3

Dear Dr. Kazembe,

APPLICATION FOR CLEARANCE FOR THE STUDY TITLED "IMPROVING ESSENTIAL MATERNAL AND NEWBORN CARE IN POOR RURAL COMMUNITIES IN MALAWI"

The National Health Sciences Research Committee met on Wednesday 29th January 2003 to review research proposals. I am pleased to inform you that the committee has approved the above research protocol.

Please send progress reports at least every six months to inform the committee about progress of the research project. The committee is also expecting balance of the processing fees at your earliest convenient time.

Yours sincerely,

A. Macheso
For: SECRETARY FOR HEALTH AND POPULATION

Appendix 6 – Intra-cluster correlation coefficients and intercluster coefficients of variation

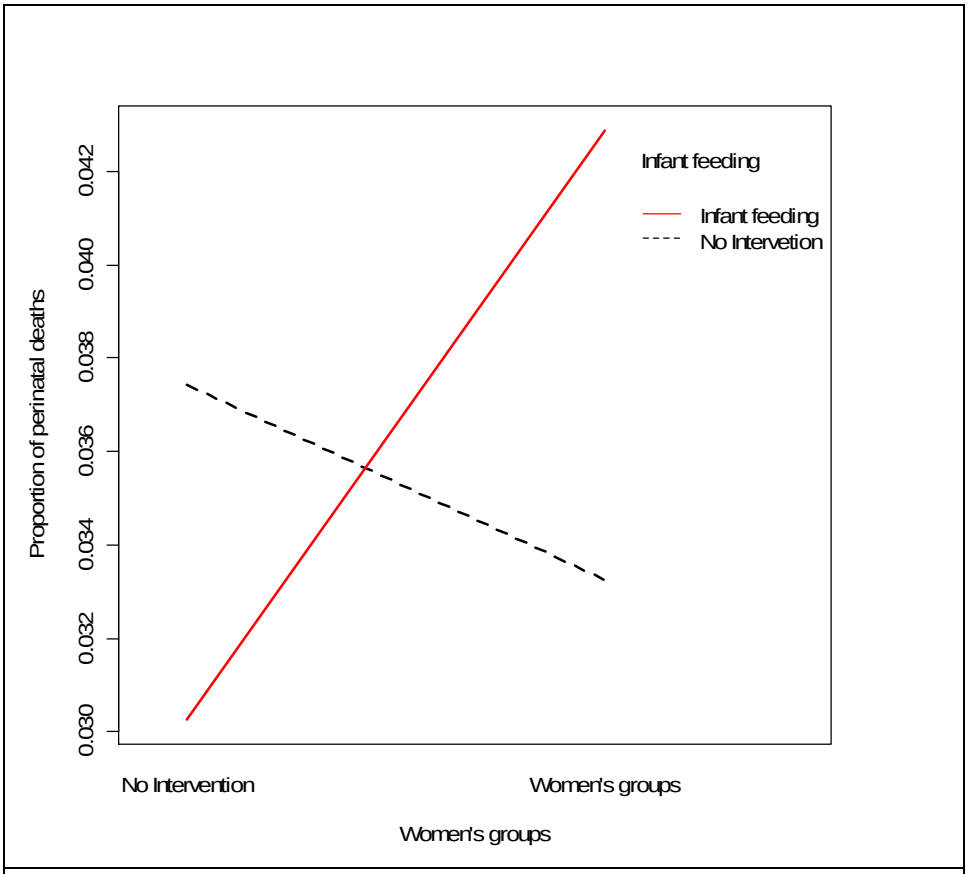
Intracluster correlation coefficients and intercluster coefficients of variation for primary and secondary outcomes

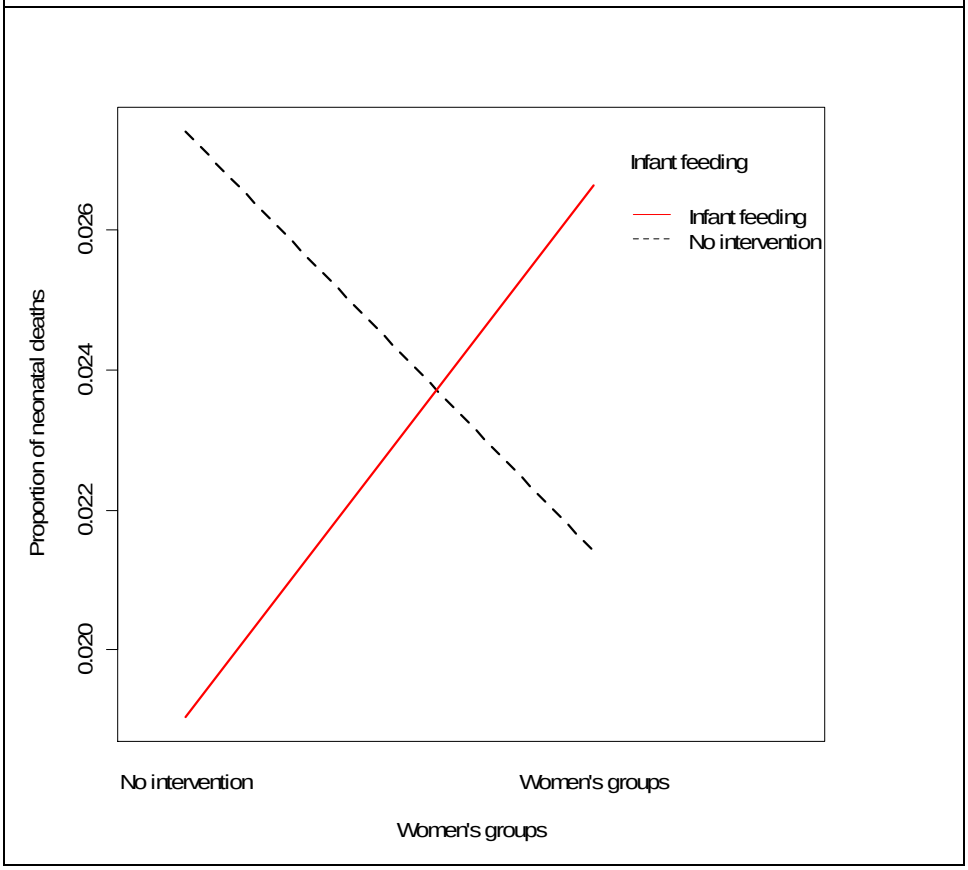
	Intra-cluster correlation coefficient (±SE)			**Intercluster coefficient of variation (±SE)**		
	All clusters (48)	Control clusters (24)	True control clusters (12)	All clusters (48)	Control clusters (24)	True control clusters (12)
Stillbirth rate per 1000 births	0.0014 (±0.0008)	<0.00001 (±0.00074)	<0.00001 (±0.0010)	0.264	<0.02	<0.02
Perinatal mortality rate per 1000 births	0.0050 (±0.0016)	0.0031 (±0.0017)	0.00076 (±0.0014)	0.368	0.297	0.140
Early neonatal mortality rate per 1000 live births	0.0058 (±0.0017)	0.0054 (±0.0024)	0.0036 (±0.0026)	0.580	0.561	0.426
Late neonatal mortality rate per 1000 live births	0.00081 (±0.00071)	0.0010 (±0.0011)	0.0010 (±0.0015)	0.347	0.392	0.357
Neonatal mortality rate per 1000 live births	0.0049 (±0.0016)	0.0058 (±0.0025)	0.0027 (±0.0022)	0.449	0.491	0.309
Infant mortality rate per 1000 live births	0.0096 (±0.0029)	0.015 (±0.0056)	0.022 (±0.011)	0.467	0.581	0.656
Maternal mortality ratio per 100,000 live births	<0.00001 (±0.00054)	<0.00001 (±0.00075)	0.00060 (±0.0013)	<0.05	<0.05	0.349
Antenatal care attendance (%)	0.037 (±0.0079)	0.032 (±0.0099)	0.019 (±0.0065)	0.044	0.043	0.056
Received any tetanus toxoid vaccine (%)	0.047 (±0.0098)	0.051 (±0.015)	0.049 (±0.021)	0.089	0.101	0.108
Received any SP (%)	0.030 (±0.0066)	0.021 (±0.0069)	0.027 (±0.013)	0.048	0.041	0.050
Always used bednet during pregnancy (%)	0.095 (±0.018)	0.11 (±0.031)	0.080 (±0.033)	0.281	0.309	0.279
Maternal morbidity (antenatal problem) (%)	0.14 (±0.026)	0.19 (±0.047)	0.19 (±0.068)	0.501	0.586	0.579
Maternal morbidity (delivery problem (%)	0.027 (±0.0059)	0.028 (±0.0088)	0.031 (±0.014)	0.494	0.501	0.534
Maternal morbidity (postnatal problem) (%)	0.082 (±0.016)	0.092 (±0.026)	0.088 (±0.036)	0.636	0.716	0.718
Skilled birth attendance (%)	0.12 (±0.02)	0.13 (±0.03)	0.16 (±0.06)	0.348	0.352	0.449
Postnatal care attendance (%)	0.17 (±0.03)	0.19 (±0.05)	0.24 (±0.08)	0.520	0.544	0.691
Infant morbidity (cough) (%)	0.10 (±0.02)	0.11 (±0.03)	0.12 (±0.05)	0.523	0.549	0.497
Infant morbidity (fever) (%)	0.06 (±0.01)	0.06 (±0.02)	0.06 (±0.03)	0.485	0.487	0.443
Infant morbidity (diarrhoea) (%)	0.008 (±0.002)	0.011 (±0.004)	0.009 (±0.005)	0.695	0.870	0.648
Exclusive breastfeeding to 6m (%)	0.14 (±0.027)	0.08 (±0.025)	0.04 (±0.021)	0.909	0.798	0.641
Ever attending women's group (%)	0.41 (±0.051)	0.09 (±0.025)*	0.07 (±0.030)**	1.048	0.281	0.265

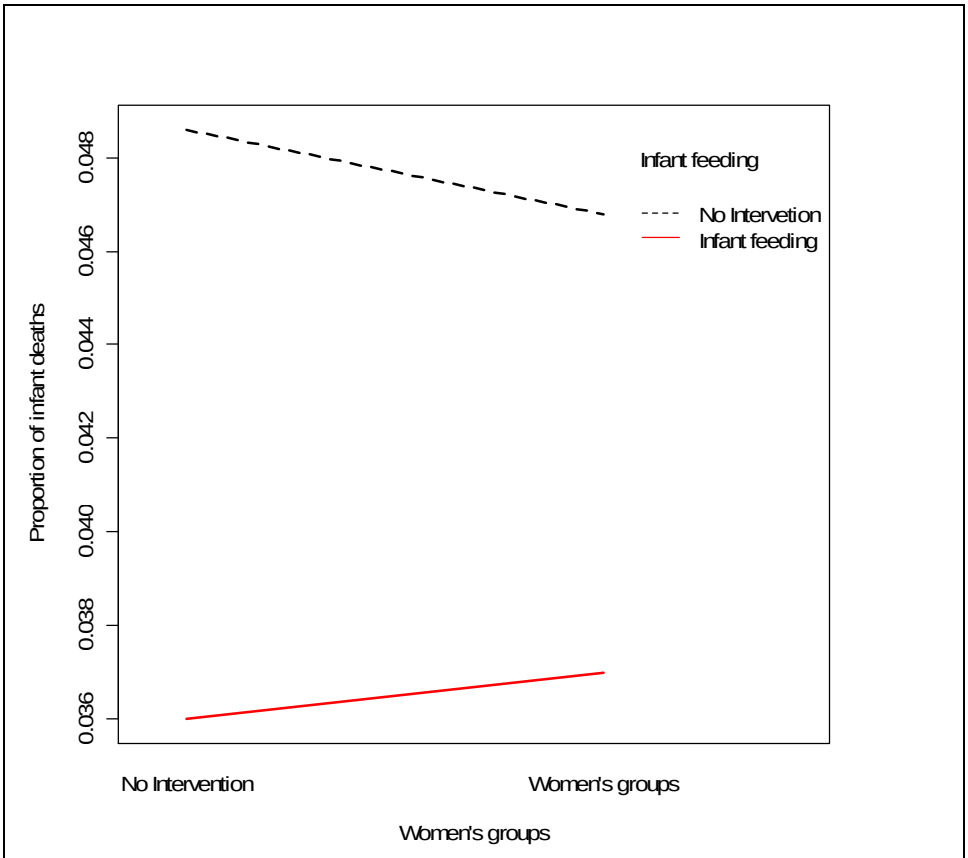
*Women's group areas and women's group plus infant feeding areas

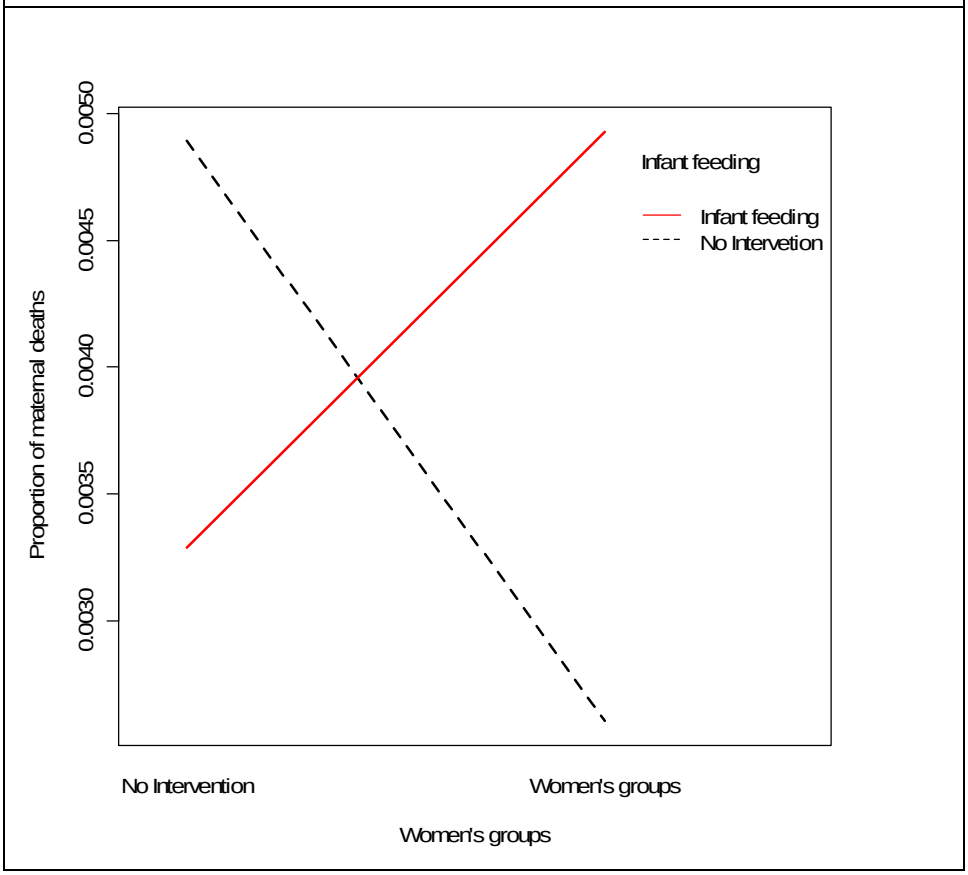
**Women's group only areas

Appendix 7 – Interaction plots for primary mortality outcomes






Proportion of infant deaths
0.036
0.038
0.040
0.042
0.044
0.046
0.048
Infant feeding
No Intervetion
Infant feeding
No Intervention
Women's groups
Women's groups


Proportion of maternal deaths
0.0030
0.0035
0.0040
0.0045
0.0050
Infant feeding
Infant feeding
No Intervetion
No Intervention
Women's groups
Women's groups