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**Newhints Home Visits Cluster Randomised Controlled Trial: Impact on
Access to Care for Sick Newborns and Determinants, Facilitators and
Barriers to this.**

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Thesis submitted to the London School of Hygiene & Tropical Medicine, University of
London in fulfilment of the requirements for the degree of Doctor of Philosophy

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June, 2012

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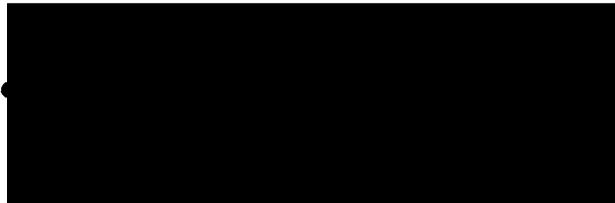
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Abstract

Background: Approximately 3.3 million (41%) of global child deaths occur among children in the first 28 days of life (the neonatal period). Neonatal death reduction is imperative to achieving the 4th millennium development goal (MDG-4) which seeks to reduce global child deaths by two-thirds its levels in 1990 come 2015.

Three direct causes: infections, asphyxia, and prematurity or low birthweight and its complications account for approximately 80% of these deaths, majority of which are preventable. Infection is the single most important cause in about a third (and up to half in high mortality settings) of all neonatal deaths. However, care seeking for sick newborns is generally poor and besieged by myriads of barriers with many newborn deaths occurring at home with no contact with health providers. Trials in south Asia have shown that prompt detection and treatment of newborn infections coupled with effective preventive measures can significantly reduce newborn deaths. The Ghana Newhints home visits cluster randomised controlled trial (CRT) is the first trial in sub-Saharan Africa to evaluate the impact of a community-based strategy on newborn care practices and neonatal mortality.

Methods: Newhints was implemented in seven contiguous rural districts of Brong-Ahafo region, covering a population of approximately 750,000 with over 120,000 women of reproductive age. Existing community-based surveillance volunteers (CBSVs) in half of the 98 supervisory zones in these districts were trained to make five home visits to women, two in pregnancy and three in the first week after birth, to promote essential newborn care and to assess and refer sick newborns.

The Newhints intervention adopted a three-pronged approach to increase newborn access to care. Firstly, during home visits in the first week of life - the time of the greatest vulnerability for the newborn, CBSVs assessed newborns for ten key danger signs and referred to health facilities when any were present. Secondly, CBSVs promoted care seeking for newborn illness by counselling families on danger signs and emphasizing the need for urgent action when newborns fell ill. Thirdly, they dialogued and problem-solved with families around barriers to accessing sick newborn care. This PhD evaluates the implementation of this strategy and its impact on access to health facility care for sick newborns and on the determinants, facilitators and barriers to this. It is guided by a conceptual framework and uses data from a variety of sources including surveillance data collected on babies born alive between November 2008 and December 2009; supervision observation records; in-depth interviews with CBSVs, mothers of referred babies and health providers; and a health facility assessment survey.

Results: The evaluation shows that 70% of mothers received postnatal visits from CBSVs and that at almost all these visits (over 95%) CBSVs carried out the range of assessments required including counting the respiratory rates, taking the temperature and weighing the baby. These assessments were of high quality with CBSVs achieving near perfect agreement ($\kappa=0.85-1.0$) with trained supervisors who were in turn validated against the study physician.

Ten percent of all babies were found with a danger sign and referred to a health facility for care. Newhints elicited an unprecedented 86% compliance with these referrals, which was not affected by known barriers such as distance and cost.

Compliance was pro-poor with compliance higher in the poorest compared to the least poor and with rural residents complying better than their urban counterparts (87.2% vs. 81.7%). At health facilities, there were substantial delays before first contact with health professionals and some babies died whilst waiting for care. 18% of babies were admitted for severe illness but a quarter were sent home without treatment. In-depth interviews revealed that some newborns had been sent home without being examined and some subsequently died.

Overall Newhints increased care seeking for severely ill newborns from 55% in the control zones (similar to pre-intervention levels of 53%) to 77% in Newhints zones: adjusted RR=1.43 (95% CI = 1.18, 1.72). This increase was pro-poor, with care seeking risks increased most in the poorest socio-economic quintiles: RR=1.94 (1.32, 2.84); $p=0.001$ whereas among the least poor, care seeking risks appeared to have reduced marginally even though it was not significant: RR=0.89 (0.59, 1.35); $p=0.6$. The interaction term was significant ($p=0.045$).

An assessment of the quality of newborn care within health facilities in the study are showed that only hospitals were capable of managing sick newborns and the quality of care in these facilities was poor. Although these hospitals had equipment for the management of newborn illness, lack of staff with the requisite newborn care skills, guidelines and protocols, poor knowledge of existing staff on newborn care and, more importantly, poor attitudes of staff remain the fundamental challenges to care for sick newborns who accessed facility care during Newhints.

Conclusion: The Newhints trial provides the first evidence from a sub-Saharan African health system setting that home visits by community volunteers including

assessment and referral of sick newborns is feasible to implement at scale; that it can be pro-poor and that it can substantially increase newborn access to health facility care. The crucial link between sick newborns in the community and survival after improving care access is quality and appropriate facility management of the sick newborn. Unless it is matched with commensurate increases in the quality of care provided at health facilities, the gains from increased access to care on newborn outcomes will be minimal.

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SECTION A:
BACKGROUND & METHODS

CHAPTER ONE: Introduction

1.1 Rationale for the PhD

Although the child survival revolution in the 1980s made considerable progress in reducing child deaths,¹ it was estimated that, globally, over 12 million child deaths occurred in 1990.^{2,3} However, during the following decade (1990-2001), child death reductions seemed to have stagnated⁴ and reducing child deaths became a human rights and a basic developmental issue. At its 55th General Assembly in September 2000, 189 countries of the United Nations (UN) committed to reducing global child deaths by two-thirds its level in 1990 come 2015 as one of the goals aimed at reducing global poverty and deprivations.⁵ This was the fourth of eight millennium development goals (MDGs) set by the UN.⁵

Subsequently, there was a call for a second child survival revolution in pivotal publications in *The Lancet* – the Child Survival Series of 2003.⁶⁻¹⁰ These publications re-focussed global public health on the neglect of the unconscionable deaths occurring in children before their fifth birthdays.⁶⁻¹⁰ Critically, the series drew attention to deaths occurring in children before the 28th day of life (the neonatal period) which were also going unnoticed and contributing approximately 37% of all child deaths.⁶⁻¹⁰ Shortly afterwards, in 2005, *The Lancet* published another series focussing primarily on neonatal deaths – The Neonatal Survival Series.¹¹⁻¹⁴ In this Neonatal Survival Series, the causes, distribution and timing of neonatal deaths were highlighted including inequities in the distribution of the burden of deaths with 99% of neonatal deaths occurring in low and middle income

countries (LMICs) at home without contact with health systems.¹¹⁻¹⁴ Three-quarters of all the neonatal deaths occurred by the end of the first week of life.¹⁵ The series also listed some tested interventions that when implemented either in health facilities or using community-based strategies could result in substantial reductions in neonatal (or newborn) mortality.¹¹ The authors observed that these interventions were not receiving adequate attention especially in the poorest countries where the burden of death was largest.¹¹

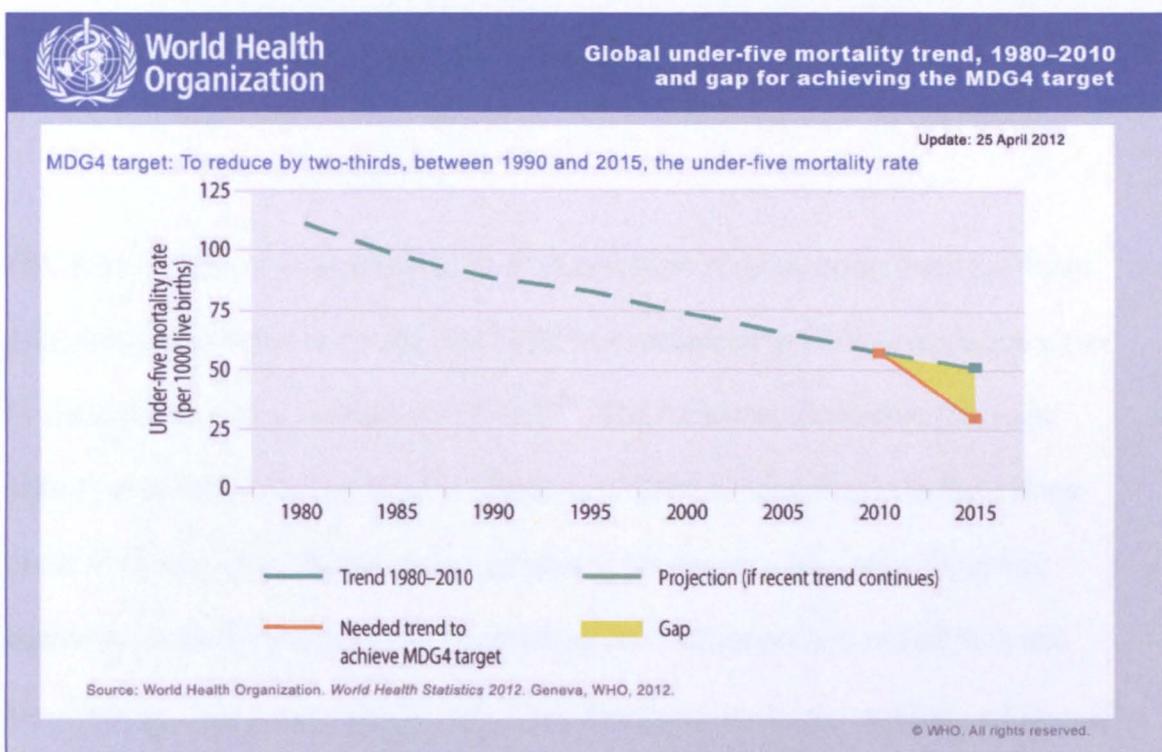


Figure 1.1 Progress towards achieving the MDG 4 which seeks to reduce child deaths by 2/3rds its level in 1990 come 2015 [Source: World Health Organization Statistics 2012. Geneva, WHO, 2012]

Tracking of the progress towards achieving the MDGs (as illustrated in Figure 1.1) has shown that dramatic reductions have been achieved with child deaths falling to just over 7.6 million by 2010.^{2, 13} This fall is attributed to improved management of diarrhoeal diseases, pneumonia and increased coverage of immunizations.² However, 3.3 million of these deaths occurred in the neonatal period representing over 41% of overall child deaths; an increase of over 4% from the proportionate

under 37% contribution in 1990.^{2, 13} With this trend, it is evident that neonatal mortality reduction is imperative to achieving the fourth millennium development goal (MDG-4).^{5, 16, 17}

In 2009, the World Health Organization (WHO) and the United Nations Children's Fund (UNICEF) issued a joint statement¹⁸ (Figure 1.2) promoting home visits by community-based agents (CBAs) to mothers and their newborns in the first week of life as a strategy for improving newborn survival.

This joint statement was premised on evidence from Asia showing that significant reductions in neonatal mortality (30-62%) were achieved in trials using home visits by community health workers (CHWs).¹⁹⁻²² The recommendations of this joint statement included community based agents (CBAs) conducting up to three home visits to, among other things, assess newborns for danger signs, refer these sick newborns to health facilities and counselling on families prompt recognition and care seeking. They were also to identify and support newborns requiring additional care (e.g. Low birthweight, sick, and babies of HIV-infected mothers) and if feasible, provide home treatment for some of these conditions.

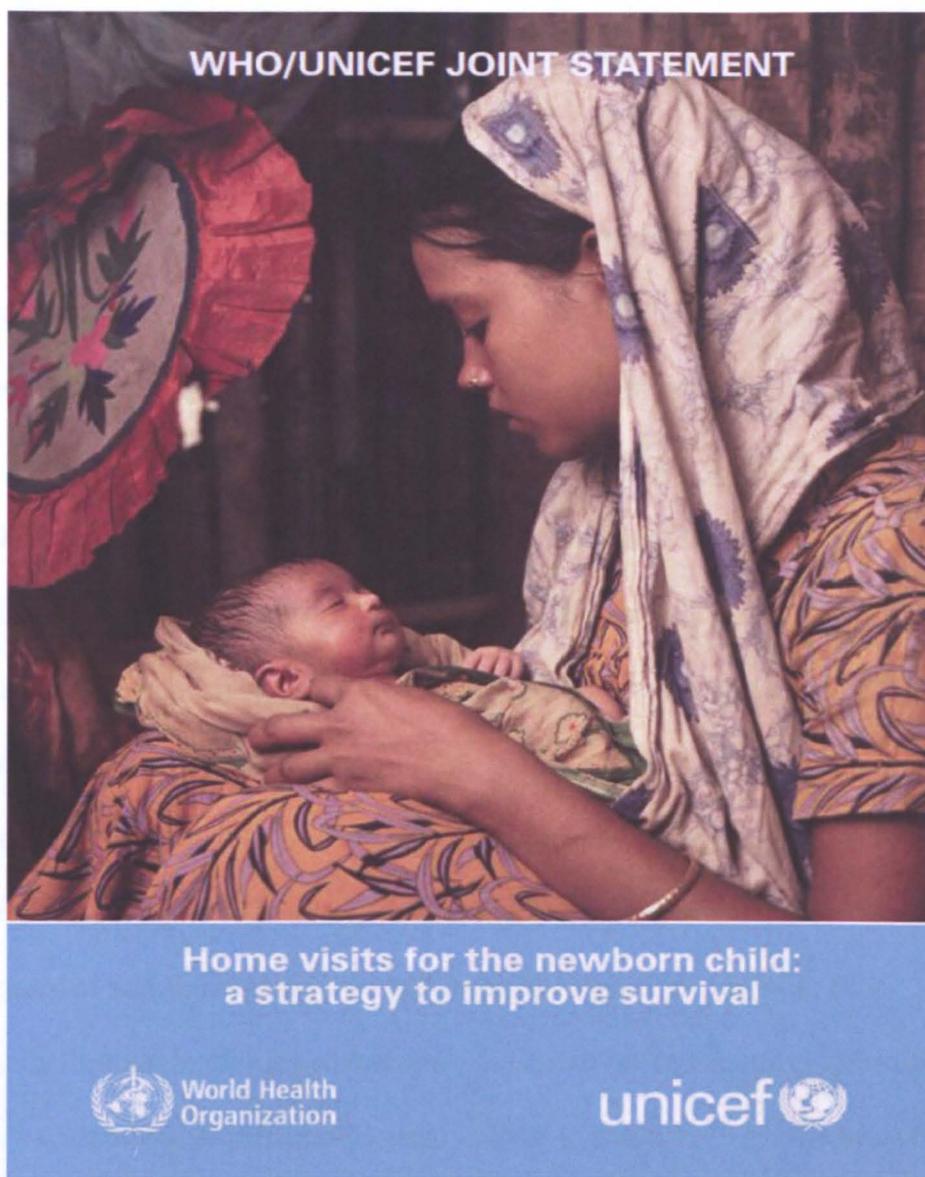


Figure 1.2: WHO/UNICEF Joint Statement¹⁸

The joint statement however recommended strengthening of health systems to support mechanisms to link families to health facilities. These recommendations have the following implicit assumptions, that:

- i. The CBAs can accurately identify illnesses in newborns in other settings other than Asia and refer to health facilities for care;
- ii. Mothers/carers will overcome care seeking barriers and be willing comply with referrals when asked to take their babies to health facilities or will accept the home treatment of newborn illnesses and

iii. This model will be feasible to implement at scale.

These recommendations by the WHO and UNICEF represent further progress on those made in the Lancet Neonatal Survival Series.¹¹ The series indicated that the evidence is unequivocal that increasing sick and vulnerable newborn access to care within health facilities can save newborn lives.¹¹ However, families' care seeking for sick newborns is poor²²⁻²⁸ and besieged by myriads of barriers including non-recognition of the illness, costs, distance and cultural practices (such as confinement or social seclusions) that prohibit out of home care seeking for sick newborns up to 40 days after birth in some cases.²²⁻²⁸ The series listed interventions that when implemented universally have the potential to substantially reduce newborn deaths (by 67% or more).¹¹ The key principle being promoted in all strategies was that interventions should be implemented in continua; from pregnancy through to childhood and from the home (or community) to health facilities with effective linkages through referral systems.^{11, 29} All the trials based on which the WHO and UNICEF made those recommendations were conducted in Asia; none had been done in sub-Saharan Africa.

The Ghana Newhints home visits cluster randomised trial³⁰ (CRT; details in section B) is the first trial in sub-Saharan Africa to evaluate the impact of a community-based home visits strategy on newborn care practices and neonatal mortality (full protocol and paper evaluating the impact on neonatal mortality and care practices are attached in appendices 1 and 2).³⁰

In summary, Newhints trained existing community-based surveillance volunteers (CBSVs) in seven contiguous rural districts of Brong-Ahafo region in Ghana to conduct these home visits to women and their families in pregnancy and in the first week of life.³⁰ The intervention adopted a three-pronged approach to increase newborn access to care: firstly, during home visits in the first week of life, the time of the greatest vulnerability for the newborn, CBSVs weighed and assessed newborns for ten key danger signs and referred to health facilities when any was present. Doing this sent a strong message to the community about the vulnerability of newborns and reinforced the second approach in which CBSVs promoted care seeking for newborn illness by counselling families on danger signs and emphasizing the need for urgent action when newborns fell ill. Thirdly, they dialogued and problem-solved with families around barriers to seeking care, both during its promotion and at the time of any referral. In addition, CBSVs counselled families on the importance of saving during pregnancy for emergencies.

My PhD evaluates the implementation of this three-pronged approach to increasing access to care for sick newborns as a core component of the Newhints intervention and the determinants, facilitators and barriers to this.

This focus on sick newborn access to care had a particular appeal to me because firstly, as a clinician, understanding the dynamics in the identification of sick newborns within communities through to their management at health facilities was extremely and directly relevant to me. Secondly, child and particularly newborn health interventions have a special appeal because I perceive them as a way of

addressing the needs of the voiceless and vulnerable in society - which was one of my personal core values. The attraction of public health to me was partly driven by my passion to find ways of empowering the patients that I see in the clinic to understand how they could prevent disease and deaths using tried and tested strategies including seeking care early when they fell ill. On my graduation from medical school, my mother shed tears but not for joy but pain. As the third of three boys, my mother had apparently yearned for a girl child all her life. She fortunately carried a foetus to term after me and lost the baby within three days of the birth. This 'only sister of mine' was delivered in a midwifery home, discharged home and died within three days. Explaining why she was influential in my decision to go to the medical school, she explained that she believed with good care, my sister could have lived. Contributing to making sure other women like my mother do not go through this is pain my mother had borne for several years became a primary professional goal in my career and this could not have been better addressed than this topic for my PhD.

1.2 PhD Conceptual Framework: Community-based strategies to increase access to care for sick newborns

The PhD is guided by a conceptual framework (Figure 1.3) and uses data from a variety of sources including surveillance data collected on all babies born alive between November 2008 and December 2009 within Newhints; directly-observed supervision records; an evaluation of quality of supervision, in-depth interviews with CBSVs, mothers of referred babies and health providers; and a health facility assessment survey. The details on the data collection and use are provided in chapter 4 of this thesis.

It was nested within the Ghana Newhints home visits cluster randomised trial (CRT). The framework conceptualizes pathways by which community-based strategies could lead to increased newborn survival through increased access to care for sick newborns. It also shows the papers presented in this thesis, the first of which addresses the key Newhints objective of increasing access to care. The other four papers are shown in the light orange boxes.

The conceptual framework commences at the top row on the left hand side in the red box (community-based strategies to reduce newborn deaths: components for improving access to care) and is joined by arrows that link the various steps along the pathways to attain the goal of increased neonatal survival (on the bottom row).

Red arrows represent pathways by which the Newhints intervention used the three-pronged approach to increase access to care for sick newborns with the aim to improve neonatal survival and the blue arrows represent alternative pathways by which other community-based strategies have been used to increase newborn access to care or survival but which were not implemented as part of the Newhints intervention and are therefore not the focus of the evaluation in this PhD.

The yellow boxes represent steps implemented within the Newhints strategy, while the grey box (appropriate management of illness) represents a necessary condition for this strategy to achieve its aim. The deep blue boxes are other community-based strategies that have been used to increase sick newborn access to care or improve neonatal survival but which were not part of the Newhints intervention.

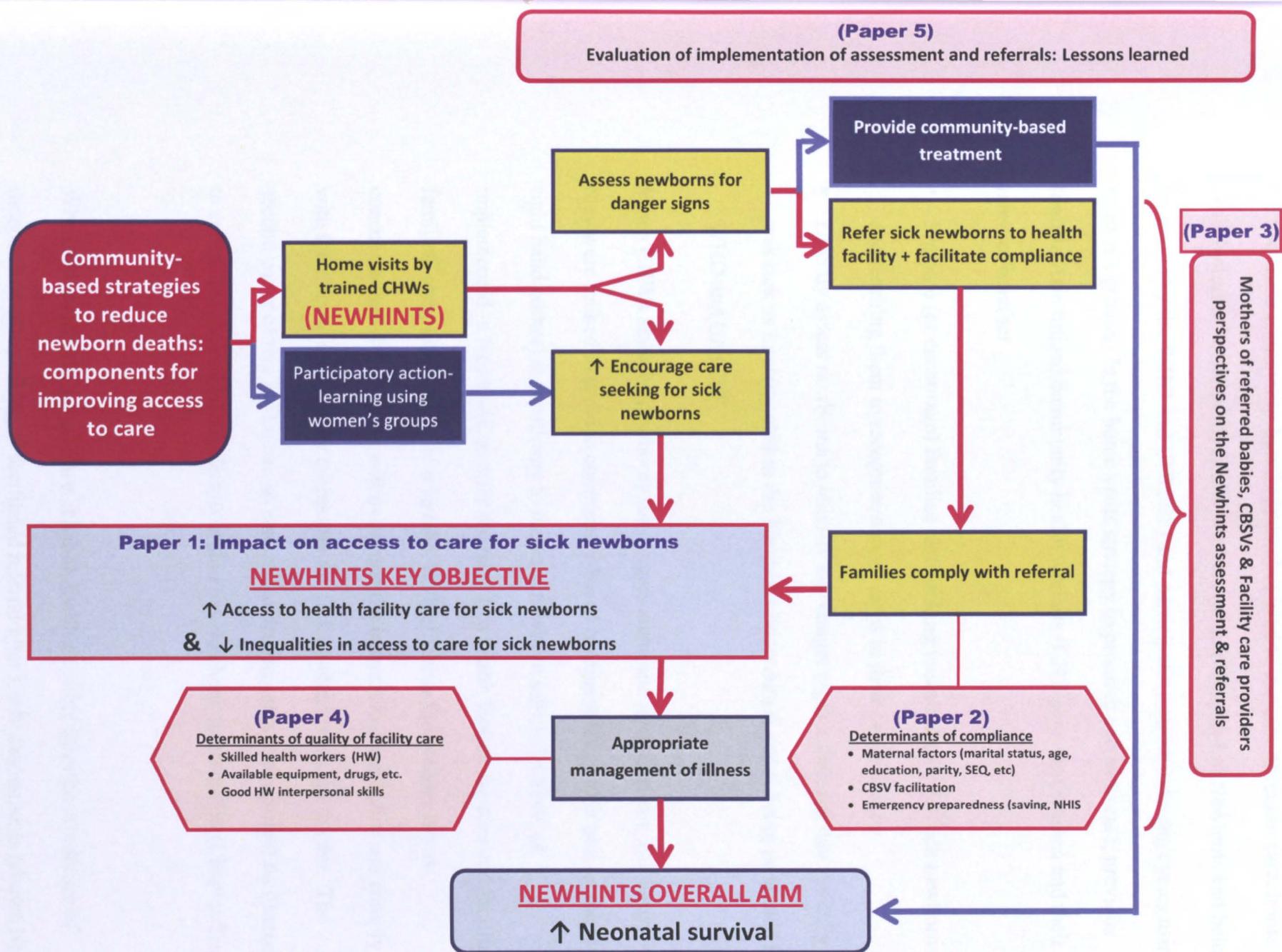


Figure 1.3 PhD CONCEPTUAL FRAMEWORK: Community-based strategies to increase access to care for sick newborns

In the first row on the left hand side, the arrows emerging from the red box show the two-main community-based approaches used to increase access to care: home visits by trained community health workers (as implemented in Newhints and being promoted by the WHO and UNICEF) and participatory action-learning cycles using women's groups. In the home visits strategy to promote access to care, previous trials in Asia trained community health workers (CHWs) to visit women and their families to either

- Promote (or encourage) families care seeking independently for sick newborns and teaching them to recognise danger signs in their newborns, or
- Directly assess newborns to identify key danger signs indicating that the baby was sick as implemented in the Newhints intervention and is being promoted by WHO and UNICEF.

When CHWs assessed newborns for dangers signs and identified any sick baby, they were trained to provide community-based treatment (deep blue box on the top right hand corner) as a pathway to increase newborn survival and/or, as implemented in Newhints, to refer the baby to a health facility for care and facilitate families' compliance with the referral. With effective facilitation, it was conceptualised that families will overcome the barriers to compliance and comply with the referral and thereby increasing the sick newborn's access to care. The second paper of this PhD thesis evaluates the determinants, barriers and facilitators to compliance with CBSV referrals within the Newhints intervention (Chapter Six).

When sick newborns access care at health facilities either through promotion of independent care seeking or facilitated referral after CHW assessments (shown by

the yellow boxes), the next key step is that these sick babies receive appropriate management of their illnesses (grey box). This is seen as the crucial step between sick newborns identified and referred from the community and survival and was evaluated in this PhD through a health facility survey presented as the fourth paper in this PhD thesis in chapter eight. The third paper of the PhD (Chapter Seven) provides the results of an exploration to understand how the referral component worked in order to inform future implementation of the strategy from the perspectives of the key stakeholders in the Newhints intervention: mothers whose babies were referred, CBSVs who carried out the referral and health facility staff who provided care of the newborn. It is represented by the box along the extreme right hand side of the framework. The final paper (Paper 5) evaluates the implementation of the assessment and referral in Newhints in order to highlight the key lessons learned and to inform continued or future implementation of the strategy. It forms the ninth chapter of this thesis.

1.3 Aims and Objectives of the PhD

1.3.1 Overall Aim

To evaluate the impact of Newhints home visits cluster-randomised intervention trial on access to health facility care for sick newborns and the determinants, facilitators and barriers to this.

1.3.2 Objectives

1. To evaluate whether the Newhints home visits intervention has increased access to facility care for sick newborns, and by so doing whether Newhints has reduced inequities in access to care
2. To explore the barriers, facilitators and key determinants to compliance with CBSV referrals of sick newborns with Newhints
3. To understand mothers', CBSVs' and health providers' perspectives on the Newhints assessment and referral of sick newborns and the implications of these for modification of future implementation and scale-up.
4. To assess the quality of care available for newborns within health facilities in the Newhints study area and to match this to demand for services in these facilities.
5. To evaluate the implementation of the CBSV assessment and referral of sick newborns to health facilities component of Newhints and highlight key lessons learned to inform scale-up and implementation in other settings.

1.4 Structure of the thesis

This thesis is presented as an assembly of five main papers written for publication in peer-reviewed journals (Table 1.1). Each paper addresses a core component in

Table 1.1: List of papers included in the PhD and links with PhD objectives

Objective	Title of paper	Thesis chapter
1	Increasing access to care for sick newborns: evidence from the Newhints home visits cluster randomised controlled trial	5
2	Achieving high compliance with community volunteer referrals of sick newborns to health facilities within the Ghana Newhints cluster randomised controlled trial: determinants, barriers and facilitating factors.	6
3	Community volunteer assessment and referral of sick babies: perspectives from mothers, volunteers and care providers in the Ghana Newhints trial.	7
4	Quality of Newborn Care: A Health Facility Assessment in Rural Ghana Using Survey, Vignette and Surveillance Data	8
5	Evaluating the Implementation of Community Volunteer Assessment and Referral of Sick Babies: Lessons learned from the Ghana Newhints Home Visits Cluster Randomised Controlled Trial	9
Trial Protocol	"NEWHINTS cluster randomised trial to evaluate the impact on neonatal mortality in rural Ghana of routine home visits to provide a package of essential newborn care interventions in the third trimester of pregnancy and the first week of life: trial protocol	Appendix 1
Impact on Mortality	Impact of the "Newhints" home visits intervention on neonatal mortality and care practices in Ghana: a cluster randomised controlled trial.	Appendix 2

the evaluation of the evidence for increased access to care for sick newborns and together, they tell a story of the sequence of events that occurred within the Newhints CRT from when a newborn falls ill in the community through CBSV visits and assessments, referrals, facility attendance till they are back home to

reconcile with families as can be seen in the conceptual framework. They form chapters five to nine in the section C (Results) of the thesis.

There are two introductory sections: Section A (Introduction) has two chapters comprising this chapter which provides the rationale and background to the thesis, the conceptual framework around which the thesis is organised and the aims and objectives of the thesis. The second chapter presents a review of relevant literature for the topic of this PhD which is guided by the conceptual framework presented in Figure 1.3.

Section B (Study Setting & Methodology) is also divided into two chapters: chapter three provides the setting for the study and an overview of the Newhints trial within which this PhD was nested and chapter 4 covers the methodology of the PhD and the details on the assessment and referral Intervention. The final section of the thesis (Section D: Summary and conclusions) presents the key findings of the evaluation of the evidence for increased access to care for sick newborns within Newhints assessment and referral system, strengths and limitations, implications for future implementation and conclusions. Two other publications on the protocol for the Newhints CRT and the impact of the intervention on NMR and newborn care practices have been included in the appendices 1 and 2 to provide context for this PhD.

1.5 Role of the author/candidate

The candidate and author of this thesis was a principal investigator and study clinician on the Newhints home visits cluster randomised controlled trial within which this PhD was nested. He was involved in the writing of the grant proposal for the Newhints study, was a member of the trial management team on the study and played lead roles in the data analysis, write-up and the dissemination of the findings of the Newhints intervention. He participated in the formative research that informed the implementation of the trial, led the cluster designation using geographical information systems, trained the CBSV trainers, participated in the training of the CBSVs, led and supported the national team of trainers who conducted the training of health facility newborn care givers on facility essential newborn care within the study area, led the Newhints team representation on an implementation committee that included members of the collaborating district health management teams of the seven Newhints districts and supported the supervision of the volunteers.

The PhD was also conceptualised by the candidate with input from the supervisor and other team of advisors on the PhD. He designed the study conceptual framework, the data collection strategy and the tools used for the data collection, conducted all the in-depth interviews as part of this PhD evaluation, led the conduct of the health facility assessment survey including conducting the detailed assessment in the select eleven facilities in the study area, supervised the extraction of referral data from the Newhints CBSV workbooks, and conducted the evaluation of the quality of supervision for the assessment and referral component of Newhints

by providing the gold standard assessment of newborns to compare with the CBSV supervisors.

The candidate also conducted all the data analysis for this PhD study, prepared the initial drafts four of the five of the papers (1, 2, 3 & 5) included in this thesis with the supervision and input primarily from the supervisor and other members of the PhD advisory team and co-authors through an iterative process. The fourth paper is co-authored but the candidate led the preparation of the data collection instruments, participated in the data collection and supported the analysis and the write-up of the results.

1.6 Ethical Clearance

The Newhints trial obtained ethical clearance from the institutional review boards (IRBs) or ethics committees (ECs) of the Kintampo Health Research Centre (the host institution for Newhints), its umbrella body, the Ghana Health Service and the London School of Hygiene and Tropical Medicine. The Newhints trial is registered on line at clinicaltrials.gov with registration number NCT00623337. The health facility assessment (presented in paper 4) also ethical clearance from KHRC and LSHTM.

1.7 Funding for the study

The Newhints CRT was funded by the World Health Organization, Saving Newborn Lives-2 programme of Save the Children, USA with funds from Bill and

Melinda Gates Foundation and the Department for International Development, UK.

The candidate was also awarded a Commonwealth Scholarship to undertake the PhD study.

References for Chapter One

1. UNICEF. *State of the World's Children 1996: The 1980s: campaign for child survival*: UNICEF; 1996 (accessed 4th July 2004).
2. Oestergaard MZ, Inoue M, Yoshida S, Mahanani WR, Gore FM, al. e. Neonatal Mortality Levels for 193 Countries in 2009 with Trends since 1990: A Systematic Analysis of Progress, Projections, and Priorities. *PLoS Medicine*. 2011; **8**(8): e1001080.
3. UNICEF. *Maternal and newborn health: where we stand*: UNICEF; 2009. Report No.: 978-92-806-4318-3.
4. UNICEF. *State of the World's Children 2003*. New York: UNICEF; 2003.
5. UN. General Assembly 56th Session. *Road map towards the implementation of the United Nations millenium declaration: report of the Secretary-General* (UN document no. A/56/326). New York: United Nations; 2001.
6. Black RE, Morris SS, Bryce J. Where and why are 10 million children dying every year? *Lancet*. 2003; **361**(9376): 2226-34.
7. Bryce J, el Arifeen S, Pariyo G, Lanata C, Gwatkin D, Habicht JP. Reducing child mortality: can public health deliver? *Lancet*. 2003; **362**(9378): 159-64.
8. Jones G, Steketee RW, Black RE, Bhutta ZA, Morris SS, Bellagio Child Survival Study G. How many child deaths can we prevent this year? *Lancet*. 2003; **362**(9377): 65-71.
9. Victora CG, Wagstaff A, Schellenberg JA, Gwatkin D, Claeson M, Habicht JP. Applying an equity lens to child health and mortality: more of the same is not enough. *Lancet*. 2003; **362**(9379): 233-41.
10. The Bellagio Study Group on Child Survival. Knowledge into action for child survival. *Lancet*. 2003; **362**: 323-27.
11. Darmstadt GL, Bhutta ZA, Cousens S, Adam T, Walker N, de Bernis L, et al. Evidence-based, cost-effective interventions: how many newborn babies can we save? *Lancet*. 2005; **365**(9463): 977-88.
12. Knippenberg R, Lawn JE, Darmstadt GL, Begkoyian G, Fogstad H, Walelign N, et al. Systematic scaling up of neonatal care in countries. *Lancet*. 2005; **365**(9464): 1087-98.
13. Lawn JE, Cousens S, Zupan J, Lancet Neonatal Survival Steering T. 4 million neonatal deaths: When? Where? Why? *Lancet*. 2005; **365**(9462): 891-900.
14. Martines J, Paul VK, Bhutta ZA, Koblinsky M, Soucat A, Walker N, et al. Neonatal survival: a call for action. *Lancet*. 2005; **365**(9465): 1189-97.
15. Zupan J. Perinatal mortality in developing countries. *New England Journal of Medicine*. 2005; **352**(20): 2047-8.
16. Travis P, Bennett S, Haines A, Pang T, Bhutta Z, Hyder AA, et al. Overcoming health-systems constraints to achieve the Millennium Development Goals.[erratum appears in *Lancet*. 2005 Jan 22;365(9456):294]. *Lancet*. 2004; **364**(9437): 900-6.
17. AbouZahr C, Wardlaw T. Maternal mortality at the end of a decade: signs of progress? *Bulletin of the World Health Organization*. 2001; **79**(6): 561-8.
18. WHO/UNICEF. *WHO/UNICEF Joint Statement: Home visits for the newborn Child: a Strategy to Improve Survival*. Geneva: WHO; 2009.

19. Bang AT, Reddy HM, Deshmukh MD, Baitule SB, Bang RA. Neonatal and infant mortality in the ten years (1993 to 2003) of the Gadchiroli field trial: effect of home-based neonatal care. *J Perinatol.* 2005; **25 Suppl 1**: S92-107.
20. Baqui AH, El-Arifeen S, Darmstadt GL, Ahmed S, Williams EK, Seraji HR, et al. Effect of community-based newborn-care intervention package implemented through two service-delivery strategies in Sylhet district, Bangladesh: a cluster-randomised controlled trial. *Lancet.* 2008; **371(9628)**: 1936-44.
21. Bhutta ZA, Memon ZA, Soofi S, Salat MS, Cousens S, Martines J. Implementing community-based perinatal care: results from a pilot study in rural Pakistan. *Bulletin of the World Health Organization*; 2008. p. 452-9.
22. Kumar V, Mohanty S, Kumar A, Misra RP, Santosham M, Awasthi S, et al. Effect of community-based behaviour change management on neonatal mortality in Shivgarh, Uttar Pradesh, India: a cluster-randomised controlled trial. *Lancet.* 2008; **372(9644)**: 1151-62.
23. Bazzano AN, Kirkwood BR, Tawiah-Agyemang C, Owusu-Agyei S, Adongo PB. Beyond symptom recognition: care-seeking for ill newborns in rural Ghana. *Trop Med Int Health.* 2008; **13(1)**: 123-8.
24. Mohan P, Iyengar SD, Agarwal K, Martines JC, Sen K. Care-seeking practices in rural Rajasthan: barriers and facilitating factors. *Journal of Perinatology.* 2008; **28 Suppl 2**: S31-7.
25. Sutrisna B, Reingold A, Kresno S, Harrison G, Utomo B. Care-seeking for fatal illnesses in young children in Indramayu, west Java, Indonesia. *Lancet.* 1993; **342(8874)**: 787-9.
26. Syed U, Khadka N, Khan A, Wall S. Care-seeking practices in South Asia: using formative research to design program interventions to save newborn lives. *Journal of Perinatology.* 2008; **28 Suppl 2**: S9-13.
27. Awasthi S, Srivastava NM, Pant S. Symptom-specific care-seeking behavior for sick neonates among urban poor in Lucknow, Northern India. *Journal of Perinatology.* 2008; **28 Suppl 2**: S69-75.
28. Choi Y, El Arifeen S, Mannan I, Rahman SM, Bari S, Darmstadt GL, et al. Can mothers recognize neonatal illness correctly? Comparison of maternal report and assessment by community health workers in rural Bangladesh. *Trop Med Int Health.* 2010; **15(6)**: 743-53.
29. Bahl R, Qazi S, Darmstadt GL, Martines J. Why is continuum of care from home to health facilities essential to improve perinatal survival? *Semin Perinatol.* 2010; **34(6)**: 477-85.
30. Kirkwood BR, Manu A, Tawiah-Agyemang C, ten Asbroek G, Gyan T, Weobong B, et al. NEWHINTS cluster randomised trial to evaluate the impact on neonatal mortality in rural Ghana of routine home visits to provide a package of essential newborn care interventions in the third trimester of pregnancy and the first week of life: trial protocol. *Trials.* 2010; **11**: 58.

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CHAPTER TWO: Literature review

“Of all the joys that lighten suffering earth, what joy is welcomed like a newborn child?” Dorothy Nolte

This chapter starts with a brief review of the newborn: in transition between intra-uterine and extra-uterine life. It highlights the physiological basis of newborn vulnerability particularly in the first week after birth. This is followed by review of relevant literature guided by the conceptual framework for the PhD given in figure 1.3.

To provide background information relevant for the rationale of the thesis, the review commences with the global epidemiology of neonatal mortality, describing the burden, distribution, trends and causes of neonatal mortality. With this background, the review then covers existing evidence on interventions to prevent newborn deaths and provides the reason for the focus on community-based strategies. This is then followed by a more detailed review of community-based interventions to increase access to care for sick newborns and their key components implemented in previous trials including the use of home visits by CHWs or women’s groups to promote independent care seeking for sick newborns by families; CHW home management of sick newborns or referral to health facilities and a brief overview of the determinants of families compliance with CHW referrals.

In addition, wider literature on care seeking practices around newborn illnesses within low and middle income country settings are presented to provide the justification for the global focus on the use of CHW home visits to identify sick newborns as a strategy to improve sick newborn access to care. The evolution and global milestones in the continued search for algorithms to guide CHW community identification of sick newborns within community settings is also reviewed and presented in this chapter. The chapter then ends with a review of existing evidence on the quality of facility care for sick newborns.

It does not cover the determinants of care seeking for newborn illness; these are included in the relevant paper in chapters 5.

2.1 The Newborn: in transition between intra-uterine and extra-uterine life

Humans (*Homo sapiens*) are placental mammals but like marsupials they deliver their foetuses in the immature state and so they have to complete their gestation outside the mother's womb, making them incapable of self-support. The newborn human, is therefore in transition between intra-uterine life where they were completely dependent on the mother's physiological functioning for survival and an independent extra-uterine life (Figure 2.1).¹ Survival in this extra-uterine immature existence exposes the newborn to challenges from an external and alien environment. The newborn therefore requires thermal protection, feeding, protection from pathogens and physical harm.²

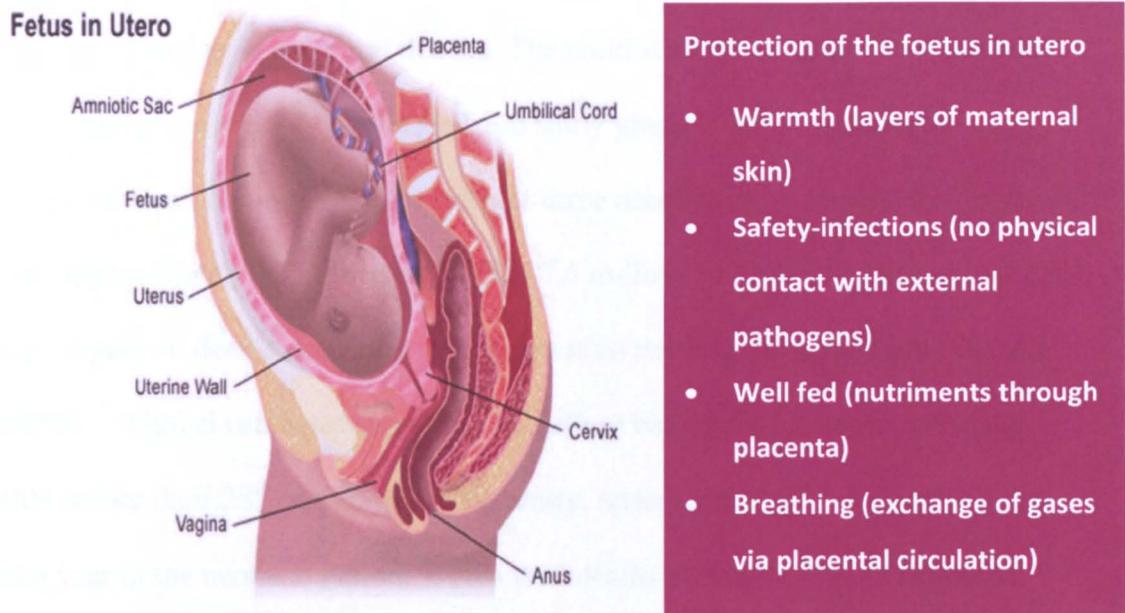


Figure 2.1: Protection for the unborn human foetus in the mothers womb

They therefore undergo rapid changes in their anatomy, physiology, biochemical functioning to respond to these. These changes include the physical effort to breath in oxygen for gaseous exchange in the lungs; physical ingestion of food for digestion and nutrients absorption, excretion of waste from digested and undigested material and maintenance of a balanced internal milieu (homeostasis) for their normal functioning, including thermo-regulation.² Whilst these changes are taking place, the newborn is very vulnerable and susceptible to the effect of environmental challenges.² This is particularly so where the adaptations are affected by congenital or birth events or low birthweight; newborns are therefore most likely to succumb and die if not adequately supported in the critical first few days after birth.³

2.2 Neonatal Mortality: Burden, distribution and causes

2.2.1. The Burden of neonatal deaths: The child survival revolutions of the early 1980s⁴ and more recently by the Bellagio study group⁵⁻⁹ led to significant reductions in child mortality over the past three decades (with under 5 deaths falling from approximately 12 million in 1990 to 7.6 million in 2009^{10, 11}) but has had very little impact on deaths occurring in babies within the first 28 days of life (neonatal deaths).¹⁰ Global estimates show that 79 million babies died between 1990 and 2009 before their 28th birthdays and currently, approximately 3.3 million still die each year in the neonatal period.¹⁰ Neonatal deaths comprise 41% of deaths of children below 5 years, a significant increase from under 37% contribution to overall child deaths in 1990.^{10, 12, 13} Deaths in the neonatal period are estimated to roughly equate the combined total of HIV and Malaria deaths in a year¹⁴ but these have been identified as global emergencies and neonatal deaths are not.

2.2.2. Distribution of Neonatal deaths: Low and middle income countries (LMICs) are burdened with 99% of global neonatal deaths.¹³ LMICs of South Asia and Sub-Saharan Africa (SSA) accounted for about 52 million out of the 79 million neonatal deaths over the past two decades (1990 - 2009) constituting about two-thirds of the global neonatal death burden.^{10, 13} In LMIC settings, the estimated neonatal mortality rate (NMR) was 33 per 1000 livebirths by 2009.¹⁰ Sub-Saharan Africa (SSA) LMICs have the highest rates of neonatal mortality which is estimated to be above 35 per 1000 livebirths currently.¹⁰

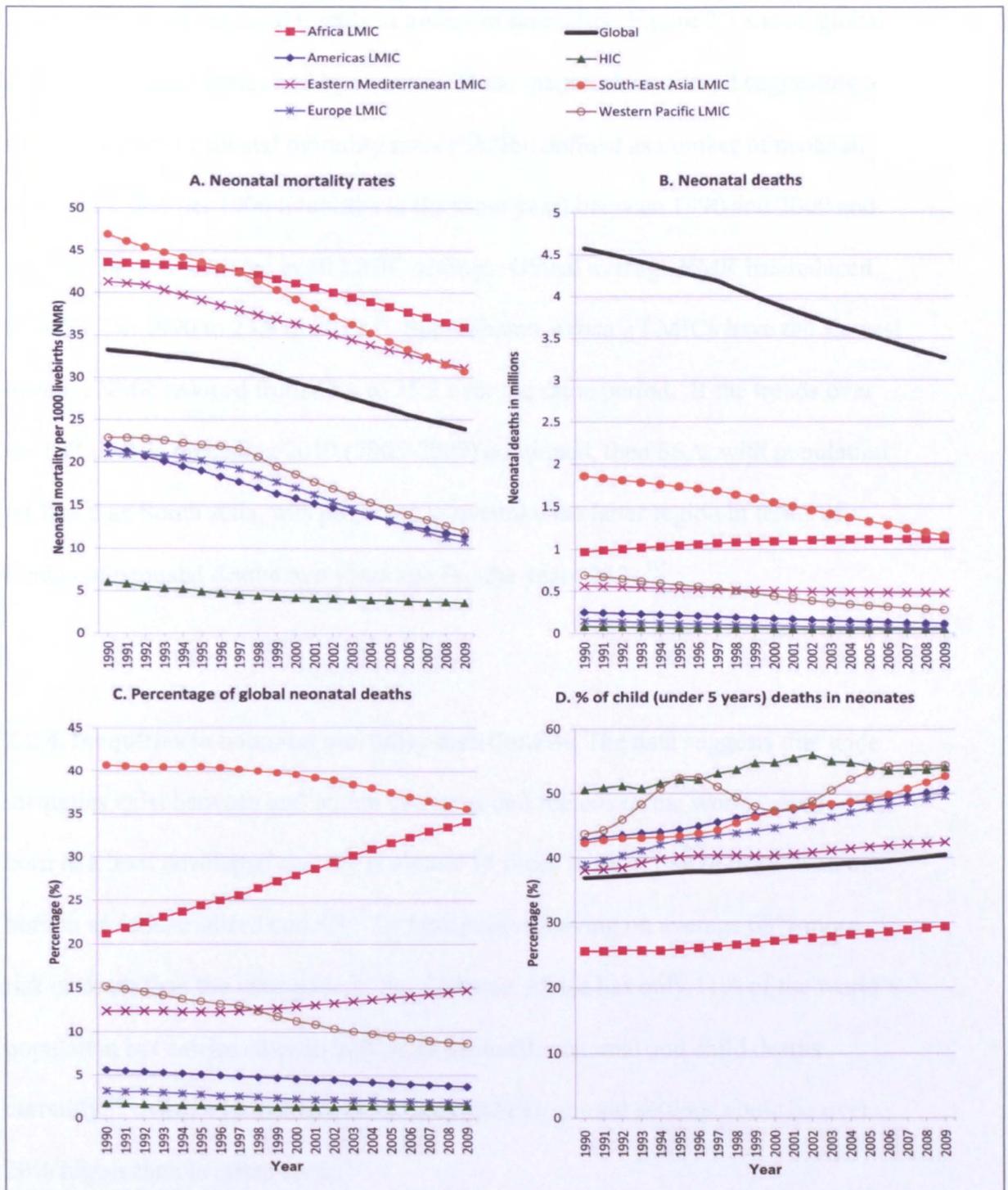


Figure 2.2: Trends in global neonatal deaths showing NMRs, total deaths, percentage of global deaths by region and percentage of child deaths in neonatal period. [Source: Oestergaard et al: Neonatal mortality levels in 193 countries in 2009 with trends since 1990: a systematic analysis of progress, projections, and priorities. PLoS Medicine, 2011]¹⁰

2.2.3. Global and regional trends in neonatal mortality: Figure 2.2 shows global trends in neonatal deaths and by regions. These graphs show a trend suggesting a decline in global neonatal mortality rates (NMRs; defined as number of neonatal deaths in a year per 1000 livebirths in the same year) between 1990 and 2009 and this decline was also true in all LMIC settings. Global average NMR has reduced from 33.2 in 1990 to 23.9 in 2010.¹⁰ Sub-Saharan Africa's LMICs have the slowest decline; NMR reduced from 43.6 to 35.9 over the same period. If the trends over the half decade preceding 2010 (2005-2009) continued, then SSA, with population far less than South Asia, was projected to overtake the latter region in terms of burden of neonatal deaths two years ago (by the year 2010).¹⁰

2.2.4. Inequities in neonatal mortality distribution: The data suggests that wide inequities exist between and within countries and regions of the world. A child born in a least developed country is almost 14 times more at risk of death than one born in an industrialised country¹¹ and the poorest having on average 68% more risk of death than the least poor.¹⁵ Sub-Saharan Africa has only 11% of the world's population but carries close to half of all neonatal, maternal and child deaths currently.¹⁶ Also, within the same country, NMRs in rural settings could be over 20% higher than in urban areas.¹⁵

2.2.5. Daily risks of neonatal death: The first week of life and particularly the 1st 24-hours provide the highest risk of death.

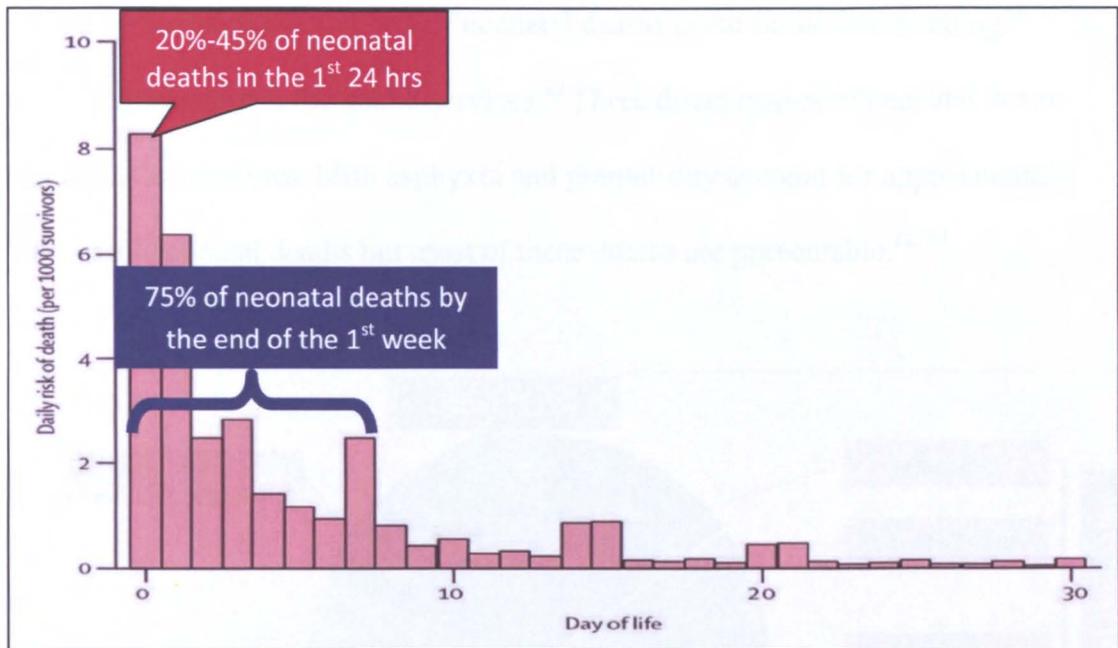


Figure 2.3: Daily Risk of Death during First Month of Life. [Adapted from Lawn & Neonatal Survival Steering Team. 4 million deaths: When, Where, Why. Lancet, 2005]¹³

An estimated 20-45%¹³ of all babies who die in the neonatal period do so in the first 24 hours after birth (Figure 2.3). Also, by the end of the first week of life, 75% of neonatal deaths are known to have occurred.¹⁷ Within the neonatal period, the average risk of deaths is estimated to be 30-fold higher than the post-neonatal period.¹³ The first week of life is therefore the riskiest period in the life of a child.

2.2.6. Causes of Neonatal Mortalities: Ascertainment of the causes of neonatal deaths is difficult in LMIC settings particularly because of lack of health systems contacts. Most estimates have relied on verbal autopsies (of variable quality) and DHS data which are bedevilled with misclassification errors, lack of homogeneity and biases.¹⁸⁻²⁴ The countries with the most neonatal deaths have the least information on these deaths.¹³

Estimates shows that about half of neonatal deaths occur in the home setting^{13, 25-28} with no contacts with the health services.²⁹ Three direct causes of neonatal deaths (figure 2.4): infections, birth asphyxia and prematurity account for approximately 80% of all neonatal deaths but most of these deaths are preventable.^{12, 30}

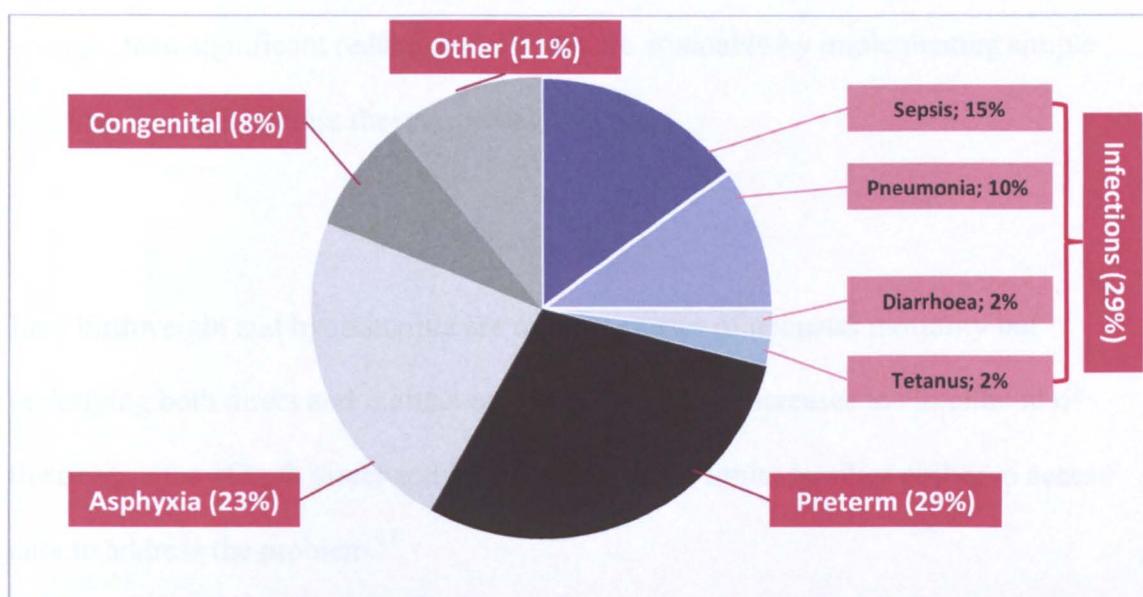


Figure 2.4: Distribution of Direct Causes of Neonatal Deaths [Adapted from Lawn et al. Causes of neonatal death for 3.6 million neonatal deaths, for 192 countries based on cause-specific mortality data and multi-cause modelled estimates. (Data source: Based on data from Child Health Epidemiology Reference Group and WHO in Black et al.)]³⁰

The remaining fifth of neonatal deaths are attributed to other causes such as congenital anomalies which are hardly possible to intervene for in LMIC settings (Figure 2.4).³¹ As can be seen from figure 2.4, neonatal infections (Sepsis/Pneumonia, Diarrhoea and Tetanus) alone are known to be the direct causes of about a third of all neonatal deaths.^{13, 30, 32, 33} There are suggestions that these estimates are conservative. In high mortality settings (when NMR is greater than 45/1000livebirths), it is projected that up to 50% or more of all and between 8% and 80% of early (1st week of life) neonatal mortalities could be due to infections.^{18,}

19, 34-41

The risk of death from infections is about eleven times higher in high compared to low-mortality countries.¹³ This is thought to present an opportunity for potential high impact on neonatal mortality in that relatively cheap interventions to address infections (such as hygiene around delivery and cord care) are known and have been tested. If infections represent the highest causes of death in high mortality settings, then significant reductions in NMR are attainable by implementing simple interventions that address these neonatal infections.

Low birthweight and hypothermia are indirect causes of neonatal mortality but underlying both direct and indirect causes is poverty; it increases the likelihood of the occurrence of both direct and indirect causes and limits families ability to access care to address the problem.¹³

2.2.7. The Fourth Millennium Development Goal: In September, 2000, at its 55th General Assembly, 189 countries of the United Nations made a promise to reduce global poverty and deprivations. These were encapsulated in eight main objectives (figure 2.5) called the Millennium Development Goals (MDGs).⁴² The fourth goal (MDG-4) aims to reduce overall child deaths by two thirds its levels in 1990 by 2015.



Figure 2.5: The Eight Millennium Development Goals

The Lancet neonatal survival series recommends that reducing neonatal mortality should be a major public-health priority but the greatest barrier to action has been its perceived complexity.²⁷ Neonatal mortality contributes about two-thirds of infant mortality worldwide⁴³ and several folds higher average risk of death compared to the post-neonatal period.¹³ It is now evident that MDG-4 will not be achieved if neonatal deaths are not addressed.¹³

2.3 Interventions to prevent newborn deaths

The Lancet neonatal survival series of 2005 identified a list of interventions (with proven efficacy and potentially effective) that could be delivered through three main service delivery modes: family-community, outreach and facility-based clinical care. The second paper, whilst promoting the implementation of these strategies, recommended that these should be delivered in packages rather than as

isolated interventions.⁴⁴ The series asserts that these interventions could be targeted so that they attain maximum benefit for the newborn when and where they were most vulnerable and at risk of dying.^{13,17}

As can be seen from the conceptual framework in Figure 1.3, the focus of this PhD thesis is on community-based strategies to increase newborn access to care.

However, the framework also includes the role of appropriate care-giving within health facilities to achieve increased newborn survival. In the next sub-sections, a summary of the recommended service delivery modes are presented to emphasize the rationale for the focus on the family-community (or community-based) approach. The core principle behind these service delivery modes is to provide care along a continuum (continuum of care) as illustrated in Figure 2.6.

There are two main continua for the provision of care: to ensure a continuum of care from home to the health facility and, secondly, to provide care in a continuum from the pre-pregnancy period, through pregnancy, childbirth, neonatal period and into infancy.^{44, 45}

In Figure 2.6, the bottom row identifies important milestones along the continuum of care from the pre-pregnancy period into infancy. It suggests that care of the baby through the neonatal period to infancy must be planned for and started in the pre-pregnancy period. In the first column on the left hand side, the service delivery modes from family-community practices through outreach to facility-based clinical

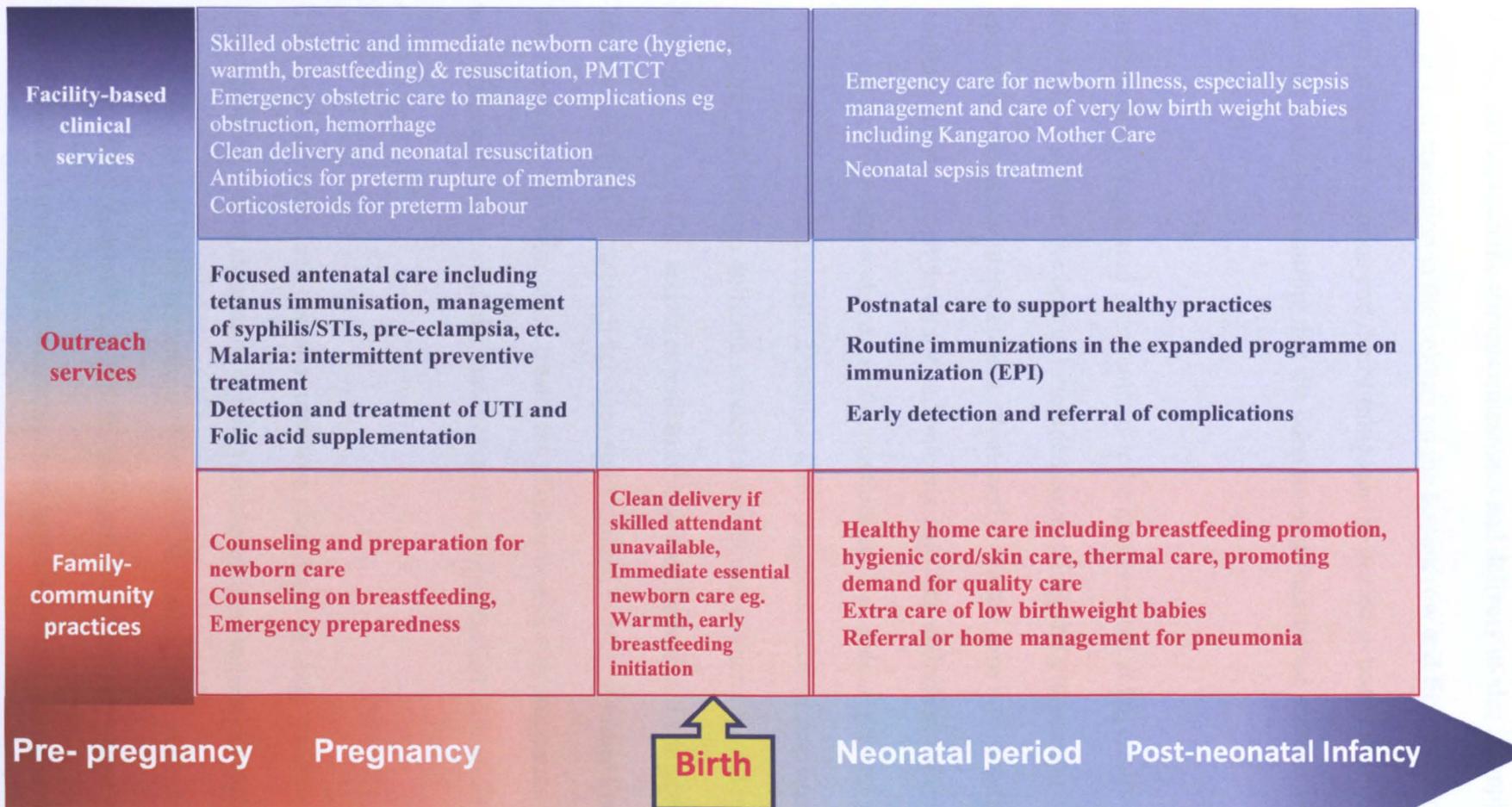


Figure 2.6: Illustration of the Continuum of Care: Family-community to Facility clinical services & pre-pregnancy through birth to infancy [Adapted from de Graft Johnson et al. The maternal, newborn, and child health continuum of care. Opportunities for Africa’s newborns: Practical data, policy and programmatic support for newborn care in Africa www.who.int/pmnch/media/publications/africanewborns/en/index.html]

are presented. The matrix therefore provides packages that could be delivered, when best they could be delivered and the mode of delivery. The lack of clear delineation between the various milestones and delivery modes is emphasized by the smooth transition in the colours on the bottom row and first column. The matrix of interventions and their timings are presented in boxes for clarity and to provide focus but ensuring that the continuum is maintained remains very critical.

In pregnancy, suggested interventions to be implemented at the family-community level (2nd row from the bottom) included counselling and preparation for newborn care and emergency preparedness. Focussed antenatal care incorporating immunisations, prophylaxis for endemic diseases like malaria using intermittent preventive treatment and preventive measures such as encouragement of treated bednet use and folate supplementation were suggested proven interventions to be implemented through outreach services for pregnant women (second row from the bottom). At facilities activities tend to be one step further in the intervention modules covered in outreach services and included treatment rather than preventive interventions. They included treatment of complications in pregnancy such as pre-eclampsia and malaria but the main focus is to target skilled care at delivery.

During birth, immediate essential newborn care (such as early initiation of breastfeeding within an hour of delivery, immediate drying and wrapping of the baby) is promoted in the community level if skilled attendance at facility is not available. These continue into the neonatal period and infancy where the care of the baby at the family and community level includes breastfeeding promotion

(exclusivity), extra care for low birthweight babies, referral to health facilities for severe newborn illness, etc. Outreach services in the neonatal and post-neonatal infancy include routine childhood immunisation services, early detection and referral of sick babies to health facilities. At the health facilities, neonatal and post-neonatal care includes early detection and treatment of neonatal illnesses including referred babies and (emergency) management of sepsis.



Figure 2.7: A busy postnatal ward in Ghana with only two nurses and a rotation student

Key characteristics of the three delivery modes are as follows:

- ***Facility-based clinical care services:*** These are usually individually-oriented and provided ‘around the clock’ at health facilities by skilled personnel.⁴⁴ The

key requirements to achieve these are adequate training of staff, well-equipped facilities, and supervision.⁴⁴ Facilities should also be equipped to ‘respond promptly to complaints from individuals; and exercise discretion in assigning a diagnosis and choosing a treatment.’⁴⁴ In the Lancet neonatal survival series, this approach was exemplified to ‘include skilled maternal and immediate neonatal care, emergency obstetric care, and emergency neonatal care’⁴⁴ services.

- ***Outreach services:*** These comprised interventions by health workers which will be ‘delivered on a periodic basis, either through static health facilities or during visits within the community’⁴⁴ to populations. Examples of interventions which could be delivered through outreaches are immunisations and antenatal care clinics (ANC). The advantage of this approach is the flexibility of delivery at both static facilities and through community visits. Though these may require some skilled personnel, they are possible to deliver with medium-skilled personnel compared to clinical services which require skilled personnel with full training in the requisite field.⁴⁴

These two delivery modes (facility-based care and outreach services) require huge capital investments and can only be the long-term goal for most LMIC settings. For instance, providing skilled care at health facilities demands enormous investment in infrastructure, human resource (training, incentives and remunerations), drugs and equipment as well as improving interpersonal skills to offset the current huge patient loads and its demands as exemplified in figure 2.7. There is also the

challenge of the ever dwindling health human resource in these settings and current global economic downturn will not allow for such capital investments in the short term.⁴⁴ For the outreach services the limitations posed logistical requirements hamper the organisation of these activities.²⁶

- ***Family-community practices:*** These were defined as ‘Family-oriented and community-oriented services supporting self-care, including the adoption of improved care practices and appropriate care seeking for illness.’⁴⁴ The Lancet neonatal survival series argued that due to the ‘widespread barriers to care seeking for neonatal illness, an important aspect of family-community care is community mobilisation and the empowerment of individuals and communities to demand quality services that respond to their needs’.⁴⁴

In the Lancet neonatal survival series, Darmstadt et al⁴⁴ also observed that the erroneous perception that only expensive, high-level technology and facility-based care can reduce mortality has been a major barrier to action on neonatal health.^{46, 47} They estimated that up to 37% (over 1.2 million) of newborn deaths could be averted by a combination of universal (90%) coverage of outreach services and family-community care including appropriate care seeking for illness and an additional 10% if there is 50% (or current) coverage of facility-based clinic services.⁴⁴ The family-community strategy emerges as the immediate option in LMIC countries but strategies to deliver effectively at scale, within health systems settings are warranted.⁴⁴

2.4 Community-based approaches to reducing neonatal mortality

Two main approaches have been used in community-based strategies to reduce neonatal mortality. These are:

- Home visits by community health workers (CHWs) and
- Community mobilisation and participatory action-learning cycles using women's groups (PAWG).

The evidence supporting these approaches (summarised in the following sections) came from trials in South Asia as shown in Table 2.1. The table shows that these trials can be sub-classified into three groups (A, B and C headed by light orange rows in table 2.1); firstly, the group A represent home visit trials that were 'proof of principle' trials because they were implemented as efficacy trials and run parallel to the existing health systems; group B are home visit trials implemented within programme settings at scale. These were recently joined by the Ghana Newhints study (in the deep red row) which was also implemented at scale within existing health systems. Newhints is the first trial to be implemented and which reported neonatal mortality outcomes outside of Asia. As shown in the conceptual framework in Figure 1.3, these home visit trials have the added advantage of training CHWs to directly assess newborns and treat or refer to health facilities and thereby increasing newborn access to care within health facilities. The third approach (group C in table 2.1) includes trials that used the community mobilisation using the women's group (PAWG) approach.

Table 2.1: Main trials using either Home Visits by Community Health Workers or Participatory Action-learning cycles using Women's Groups approaches

Trial (country and year of publication)	Total Births	Encourage care seeking	Assessment of babies	Referral (compliance)	Home-treatment	Impact on NMR Effect (95% CI)
A. Home visits by CHWs: Proof of principle trials						
1. Bang et al ⁴⁸ (SEARCH, India, 2005)	15,107	✓	✓	✗	✓ Full	0.39 (0.27, 0.56)
2. Baqui et al ⁴⁹ (PROJAHNMO-I, Bangladesh, 2008)	31,284	✓	✓	✓ (34%)	✓ Full	0.87 (0.70, 1.08)
3. Kumar et al ⁵⁰ (SHIVGARH, India, 2008)	3,859	✓	✗	✗	✗	0.46 (0.35, 0.60)
POOLED EFFECT OF PROOF OF PRINCIPLE TRIALS (Kirkwood et al, 2012)⁵¹		Heterogeneity: I²=90.1%; P<0.0001				0.55 (0.33, 0.91)
B. Home visits by CHWs: Trials delivered in programme setting:						
1. Darmstadt et al ⁵² (PROJAHNMO-II Bangladesh, 2010)	10,478	✓	✓	✓ (54%)	✓ Partial	0.87 (0.68, 1.12)
2. Bhutta et al ⁵³ (HALA, Pakistan, 2011)	23,834	✓	✓	✓	✗	0.85 (0.76, 0.96)
3. Bhandari et al ⁵⁴ (IMNCI, India, 2012)	60,480	✓	✓	✓	✓ Partial	0.91 (0.80, 1.03)
4. Kirkwood et al (NEWHINTS, Ghana, 2012)	16,670	✓	✓	✓ (86%)	✗	0.92 (0.75, 1.12)
POOLED EFFECT: PROGRAMME SETTINGS TRIALS (Kirkwood et al, 2012)⁵¹		Heterogeneity: I²=0.0%; P<0.85				0.88 (0.82, 0.95)
OVERALL EFFECT OF HOME VISIT TRIALS (Kirkwood et al, 2012)⁵¹		Heterogeneity: I²=84.4%; P<0.0001				0.74 (0.62, 0.90)
C. Participatory action-learning using Women's groups						
1. Manandhar et al ⁵⁵ (MIRA, Nepal, 2005)	6,275	✓	✗	✗	✗	0.70 (0.53, 0.94)
2. Baqui et al ⁴⁹ (PROJAHNMO-I, Bangladesh, 2008)	32,822	✓	✗	✗	✗	0.95 (0.69, 1.31)
3. Tripathy et al ⁵⁶ (JHARKHAND & ORISSA, India, 2010)	19,030	✓	✗	✗	✗	0.68 (0.59, 0.78)
4. Azad et al ⁵⁷ (BOGRA, Bangladesh, 2010)	36,113	✓	✗	✗	✗	0.93 (0.80, 1.09)
POOLED EFFECT OF WOMEN'S GROUPS (Bahl et al, 2010)⁴⁵		Heterogeneity: NOT REPORTED				0.80 (0.66, 0.97)

* Full=implementation including the administration of injectable antibiotics, Partial=minus Injectable antibiotics.

In Table 2.1, the pooled effects of these trials on neonatal mortality are presented in the yellow-coloured rows for each of the groups of interventions (i.e. home visits in proof of principle studies (A), home visits delivered in programme settings (B) and trials using women's groups (C)). The row coloured in deep blue represents the overall effect achieved from all the main trials that used the home visits approach; a combination of trials in groups A and B in table 2.1. All three approaches include components aiming to increase access to care for sick newborns as a strategy to improve neonatal survival. This link between increased access to care for sick newborns and improved neonatal survival is illustrated in the conceptual framework for the PhD in Figure 1.3. Section 2.5 covers how these community-based strategies increased access to care for sick newborns from the main trials.

2.4.1 Home visits by community health workers/volunteers: This approach is the most commonly used in community-based trials to reduce neonatal mortality and has been endorsed by WHO and UNICEF as the strategy to improve newborn survival.⁵⁸ As shown in the conceptual framework in figure 1.3, it involves training community health workers to conduct home visits to families to perform a series of activities including assessment of newborns for danger signs, promotion of essential newborn care practices and encouraging care seeking for newborn illness by families. They also promote facility use in pregnancy, antenatal care attendance, multivitamin (iron and folate) supplementation in pregnancy, distribution of treated bednets, etc. The comparative advantage of this approach is the opportunity for direct assessment to identify sick newborns and provide management options either by referring to appropriate health facilities for care or directly treating at home. Advantages cited for the use of CHWs included their higher education,

youthfulness and their being amenable to training.⁵⁹ Also, as members of the communities they serve, they are thought to be ubiquitous in the community leading Haines et al to suggest that using them for interventions could guarantee high and equitable coverage, improve care seeking, be cost-effective and have greater acceptability.⁶⁰

Three main strategies have been used in these home visits approach to increase sick newborn access to care namely: (1) assessment to identify followed by home-treatment of sick newborns by CHWs, (2) assessment to identify sick newborns and referral to health facilities for care and (3) promoting recognition of newborn illnesses by families and encouraging care seeking for sick newborns. The evidence on how these strategies lead to increased access to care for sick newborns is presented in section 2.5 and is the main subject of the PhD thesis as illustrated in the conceptual framework in Figure 1.3.

In the SEARCH trial in Gadchiroli, Bang et al^{18, 48, 61, 62} trained female CHWs to assess sick newborns and treat with injectable antibiotics when they had danger signs. The intervention involved elaborate supervision by physicians and paediatricians to ensure quality. Neonatal mortality was reduced by 62%. Whilst this reduction was substantial, the trial was an efficacy (proof of principle) trial and was run parallel to the existing health system. The huge injection of physician time and skilled personnel were found to be non-replicable in most LMIC settings. Another pilot trial in Hala Pakistan⁶³ also reported a 30% reduction in neonatal

mortality. They linked the CHWs with 'Dias' who then administered injectable antibiotics.

The second strategy used in the home visits by CHWs was similar but did not include injectable antibiotics. Instead, CHWs assessed for the danger signs in the newborn and referred to health facilities for care. This was the strategy used for the Newhints intervention within which this PhD study was nested.⁶⁴ The strategy was initially tested in the Projahnmo-1 trial by Baqui et al in Sylhet (Bangladesh).⁴⁹ After the inception of the trial, they re-introduced treatment with injectable antibiotics in the community with the referrals or when families refused to comply with the referrals. The trial achieved 34% reduction in NMR in the last six months but overall, there was weak evidence of 13% reduction in NMR. It was also not delivered in programme setting.⁴⁹

Subsequent to these proof of principle trials, large scale trials (group B in Table 2.1) have been conducted in programme settings in Bangladesh (Projahnmo-2)⁵², Pakistan (Hala)⁵³ and India (IMNCI evaluation)⁵⁴ using this strategy. When implemented in programme settings, the large effects found in the proof of principle trials were reduced. Effect sizes ranged from 9% (IMNCI, India) to 15% (Hala, Pakistan).⁵²⁻⁵⁴ Newhints is one of the trials implemented at scale using this strategy.

The third strategy using the home visit approach was tested also in an efficacy trial in Shivgarh, India. In this trial, Kumar et al⁵⁰ trained female CHWs to conduct

home visits to promote essential newborn care practices. In another arm of the trial, the CHWs were provided with Thermospots[®] to use in the identification of babies with hypothermia and encourage care seeking at health facilities. The trial achieved 54% reduction in NMR.⁵⁰ No subsequent trial has used this strategy exclusively; it has been integrated into other strategies using the home visits approach.

Figure 2.6 shows the forest plot of a recent meta-analysis by Kirkwood et al of the impact of trials using the home visits approach on neonatal mortality.⁵¹ It is a graphical representation of the mortality effects achieved in these home visit trials which were earlier presented in table 2.1.

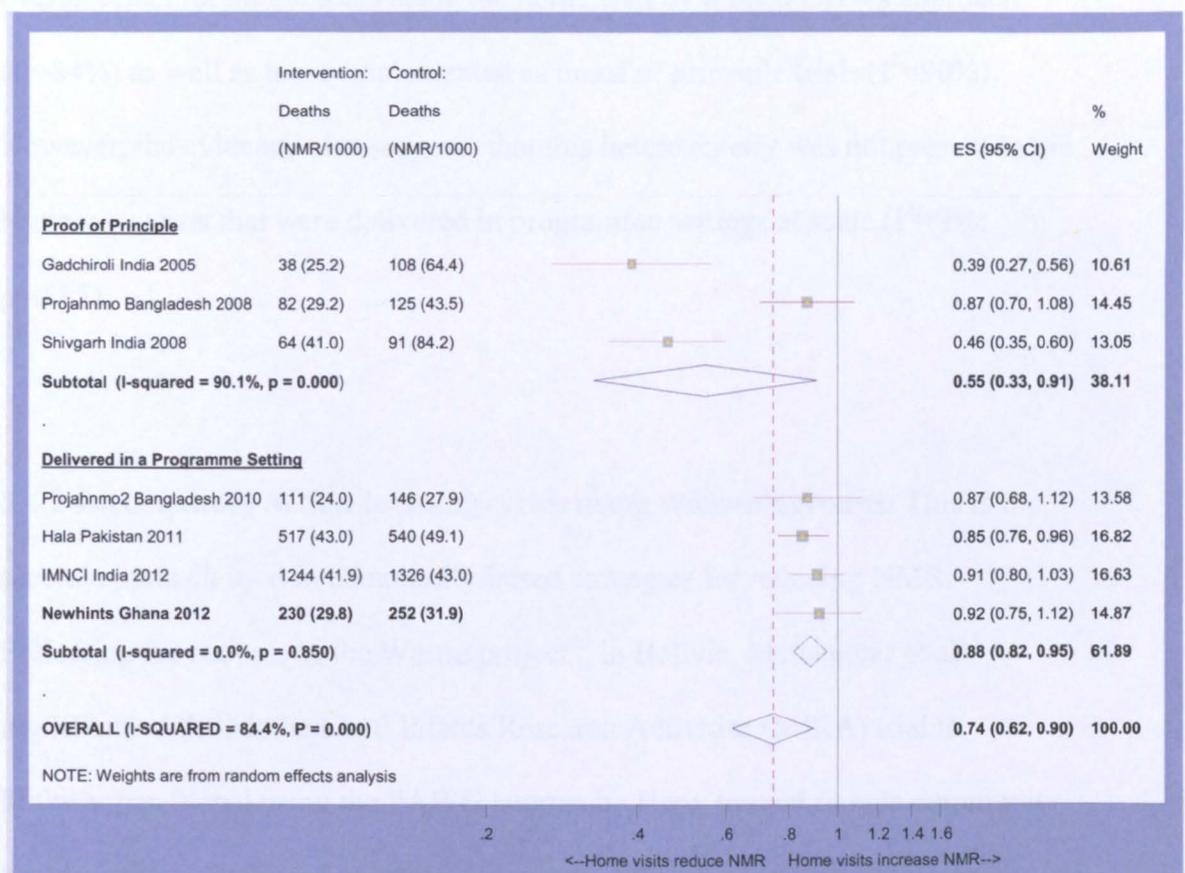


Figure 2.6: Summary of impact of community-based strategies on neonatal mortality.[Source: Kirkwood et al. Impact of the “Newhints” home visits intervention on neonatal mortality & care practices in Ghana: a cluster-randomised controlled trial. 2012]⁵¹ (Attached as Appendix 2).

This meta-analysis included the Newhints trial in Ghana and confirmed that in the large-scale trials delivered in programme settings, the overall effect size (ES) was much lower than that achieved in the proof of principle trials (12% vs. 45% reduction). Overall, the meta-analysis also show that for all studies using community-based strategies with the home visits approach, there was evidence of a significant 26% reduction in neonatal mortality; RR=0.74 (0.62, 0.90).⁵¹ The confidence intervals suggested that the data were consistent with a possible 38% reduction in neonatal mortality and this was significant.

Figure 2.6 also shows evidence of significant ($p < 0.0001$) heterogeneity in the overall effect for all the trials using the home visit by trained CHWs approach ($I^2 = 84\%$) as well as those implemented as proof of principle trials ($I^2 = 90\%$).

However, the evidence also suggests that this heterogeneity was not present in the home visit trials that were delivered in programme settings at scale ($I^2 = 0\%$; $p = 0.85$).

2.4.2 Participatory Action-learning cycles using Women's groups: This is the second approach used in community-based strategies for reducing NMR.

Following the success of the Warmi project⁶⁵ in Bolivia, Manandhar et al⁵⁵ implemented the Mothers and Infants Research Activities (MIRA) trial in Makwanpur, Nepal using the PAWG approach. Here, trained female community health workers facilitated monthly community meetings with women in their communities to discuss local perinatal challenges and devised strategies to resolve them. These community action-learning cycles promoted essential newborn care

practices but no direct interventions at the birth of the baby or when the newborn fell ill.

At evaluation, it was found that coverage of the intervention was low (only 37% of new pregnant women joined the women's groups) but 30% reduction in neonatal mortality was achieved.⁵⁵ The NMR reduction has been attributed to strong community mobilisation and empowerment⁶⁶ a key attribute that is known to magnify intervention effects and recommended to be the cornerstone of programme design.^{55, 61, 67}



Figure 2.7: A participatory women's group session in Nepal [Source: Manandhar et al. Effect of participatory intervention with women's groups on birth outcomes in Nepal: a cluster-randomised controlled trial, *Lancet*, 2004]⁵⁵

Concurrent and parallel to the MIRA trial, however, facility staff were trained in essential newborn care to improve care for sick newborns in health facilities. This concurrent activity potentially impacted neonatal mortality (an outcome of the trial)

making it impossible to disaggregate the effect of this health worker training from the MIRA trial in the attribution of the reduction in the neonatal mortality rates.

The researchers highlighted the potential low cost, sustainability and scalability of this approach suggesting it was suitable for rural communities.⁵⁵ They identified the main challenge in the implementation of this approach as bordering on how to engage users and enable them adopt positive health care behaviours.⁵⁵ They therefore advocated for replica trials to be conducted incorporating the main lessons learned in the MIRA trial.⁵⁵ Subsequently, replica trials (table 2.1) have been conducted in India⁵⁶, Malawi⁶⁸ and Bangladesh^{49, 57} and, among those completed and published half showed significant reduction in neonatal mortality but another half showed wide confidence intervals with evidence supporting no effect of the intervention^{49, 56, 57} (table 2.1).

Overall (pooled) impact on mortality: In the group C of table 2.1, a recent meta-analysis by Bahl et al⁴⁵ was presented. The analysis found an overall 20% reduction in neonatal mortality for all the four trials which used the PAWG approach with confidence intervals suggesting a possible 3%-34% reduction in neonatal mortality; Pooled effect (NMR)=0.80(0.66 – 0.97).⁴⁵ Heterogeneity between the trials was not reported.

2.4.3 Other strategies: Three other strategies were identified that have been used mainly to empower community members to increase demand for care as a strategy to improve maternal and newborn survival. These include:

- Training of traditional birth attendants

- Micro-credit schemes (including conditional cash transfers)
- Health insurance schemes and other mechanisms to remove user-fees at health facilities

All these strategies have not been implemented as trials evaluating neonatal mortality as an outcome except one that used a pre-post evaluation of micro-credit schemes.

2.4.3.1 Training of traditional birth attendants (TBAs): This is an approach that was popular in the late 1980s as an alternative to improve skilled care at delivery in safe motherhood programmes. The mechanism by which these TBAs were used to improve neonatal survival was to improve skilled care at delivery including resuscitation of the newborn and to improve referral to facilities for appropriate care.⁴⁵ In a meta-analysis of studies using this approach, Bahl et al pooled the results of 61 studies including one randomised controlled trial for the impact on neonatal mortality.⁴⁵ Twenty-one of these studies were said to have used a pre-post design. The pooled estimate of the approach on peri-neonatal mortality was 7% with 95% confidence interval ranging from 4% to 9%.⁴⁵ Bahl et al observed that the quality of the studies using this approach that were included in the meta-analysis were poor even though the single RCT using the approach achieved a 29% reduction in neonatal mortality rate, higher than that achieved in pooling all the studies together.⁴⁵ This approach has become unpopular because of the lack of evidence on improvement of skilled care at birth or neonatal mortality in studies using TBA training.^{69, 70} It was also observed by Bahl et al that most studies used

the approach as part of multi-faceted implementation of interventions and so attribution of effect to TBA training alone was not possible.⁴⁵

2.4.3.2 Micro-credit schemes (or conditional cash transfers): A relatively novel approach, which is more tailored for emerging global economies in LMIC settings, is the use of financing strategies (including conditional cash transfers) to promote and increase demand for care. Only one study has been done using this approach and which reported neonatal mortality as an outcome. In the assessment of the Janani Suraksha Yojana (JSY) programme implemented by the Indian government in which conditional cash transfers were made to the population, Lim et al⁷¹ used three approaches (matching, with-versus-without comparison and differences of differences) in the analysis of the impact of the intervention on health outcomes including neonatal mortality. The assessment showed reduction in neonatal mortality from 33.6 (32.1, 35.1) per 1000 livebirths at the baseline in 2002-2004 to 30.3 (28.8, 31.9) per 1000 livebirths at the end line in 2007-2009.⁷¹ The meta-analysis by Bahl et al reported that this represented 8% (3%, 12%) reduction in NMR.⁴⁵

In the analysis, Lim et al presented results that suggested that the intervention was a success because of the perceived impact on the major health outcomes including neonatal, peri-neonatal and perinatal mortality.⁷¹ This assessment and subsequent assertion of success by the authors has drawn some criticisms from other experts; the validity of the conclusions has been challenged in a follow-on publication in the Lancet.⁷² Das et al argued that the interpretation of the findings require caution

because the questions contained in their questionnaires used to assess the impact of the programme had internal ambiguities that limited the interpretation of the results.⁷² They concluded that the study was not robust enough to be called a success.⁷²

2.4.3.3 Health Insurance Schemes or removal of user fees at facilities: A number of countries including some in sub-Saharan Africa such as Ghana⁷³ have implemented health insurance schemes with the aim to removing user-fees charged at facilities and improve financial access to care. Specifically, Ghana has also instituted free delivery and newborn care from a British Government grant in 2008.⁷⁴ None of these schemes were implemented in trial settings, limiting the robustness of evaluations done on them and their impacts on neonatal mortality as an outcome has not been systematically reported.

2.5 Community-based interventions to increase access to care for sick newborns

As already mentioned in the previous section and in the conceptual framework in Figure 1.3, community-based interventions to increase sick newborn access to care have all included an emphasis on three main strategies:

- assessment and home-based treatment of sick newborns
- assessment and referral of sick newborns
- promoting recognition and care seeking

These strategies have been used primarily as mediators to neonatal mortality reductions through improving care of the newborn at home and increasing access to care for sick newborns. The following sections cover the rationale for this focus and an in-depth analysis of the three strategies implemented in the main trials.

2.5.1 Rationale: A very wide gap exists between current care seeking practices and what is optimal.⁷⁵ If health programmes are to deliver life-saving interventions to save newborn lives in LMICs settings, demand for care must be optimal and must drive quality of care delivery.⁴⁴ Available evidence shows that families' appropriate care seeking (defined in this context as "care seeking from a trained health professional in a health facility") around newborn illness is poor across continents.⁷⁶ Since most births occur at home and so does newborn illnesses that culminate in death, poor care seeking may contribute to neonatal mortality. Findings from studies from Africa^{77, 78} and Asia^{76, 79, 80} showed that less than 5% to 39% of (severely) sick newborns were taken for appropriate care (with a skilled provider) outside the home.^{77, 81, 82}

In the discussions of the intervention approaches in the previous section, it was evident that all the community-based approaches that impacted on neonatal mortality worked through mechanisms that sought to increase newborn access to care. Improving newborn access to care has been identified as pivotal to reducing neonatal mortality⁴⁴ and so an exploration of the implementation of these modules, the success achieved and opportunities for improving on future implementations is a useful step. The next three sections explore these strategies and situates the Newhints intervention into the body of evidence.

2.5.2. Home-based treatment with (injectable) antibiotics by CHWs: The rationale for this strategy is that infections are the single most important causes of neonatal deaths.^{13, 30} Families do not recognise illness in their newborns at home and care seeking is also poor and, if done, usually, delayed because of barriers and constraints such as distance, availability of transport, costs and availability of facilities that have to be overcome.^{77, 79, 82, 112-115} Furthermore, severe illnesses in newborns could present with non-specific signs and deteriorate rapidly resulting in deaths.²⁹ Some newborns die in the communities without contact with appropriate care.²⁹ It was therefore conceived that providing treatment for newborn illnesses at home will save lives.⁸³

The strategy was tested in two pivotal studies.^{49, 61} The SEARCH trial by Bang et al^{48, 61, 81} in Gadchiroli, India has been described in previous sections. They trained CHWs to assess newborns for danger signs and successfully treated at home with injectable antibiotics. These CHWs were supervised by physicians in the conduct of home assessments. The major advantages of this strategy are:

- Life-saving treatment can be administered to sick newborns within communities without delay.
- It is suitable for settings where access to health facilities is poor.⁶²
- Illnesses that could easily be treated at home will not be sent to health facilities to increase health worker workload with its attendant implications on quality of care.⁸⁴
- Drugs which are easy to administer such as oral antibiotics have been tested and proven to be efficacious and could be used.²⁹

Bhutta et al used a modified version in the pilot of the Hala trial in Pakistan where CHWs linked up with 'Dias' for home-based treatment.⁶³ Other non-randomised studies demonstrated effective treatment of neonates by CHWs through the administration of antibiotics and/or oral drugs in the home settings.⁸⁵⁻⁸⁸ A meta-analysis of studies implementing this model showed 27% reduction in all-cause neonatal mortality (95% CI=(18%, 35%)) and 42% reduction in pneumonia-specific mortality: RR=0.58 (0.43, 0.78).⁸⁹

Even though dramatic reductions in neonatal mortality were achieved, Zaidi et al⁹⁰ argued that the implementation of these packages had other supporting interventions like maternal education which they argue are "sustainable and prove more cost-effective" and could have impacted on the NMR reductions. They also debated that since some of these trials, with the greatest impacts were non-randomized and could not be blinded, attribution of the impact solely to the antibiotics would be erroneous since the design is not divorced from methodological inadequacies and possible biases.⁹⁰ They raised doubts about the possibility of achieving similar levels of success when replicated in other LMIC or different cultural settings.⁹⁰ Some of these studies also had roving paediatricians⁶¹ supporting the home treatments and these are hardly replicable in LMIC settings where the health human resource is already under severe attrition challenge.⁹¹

Lack of conclusive evidence regarding the efficacy and safety of community-based antibiotics use for the treatment of sick neonates is an obvious drawback.⁹⁰ Data linking aetiological factors and antimicrobial resistance from community studies are

lacking due to non-availability of culture facilities in these settings.⁹² Therefore, concerns about development of resistance to cheaper antimicrobials have been a matter of concern in health systems of some developing countries.⁹³ In some of these countries, like Ghana, non-professionally trained providers are prohibited from administering certain classes of drugs (such as antibiotics) in the community.⁹⁴ In such settings, this strategy will be difficult to implement.

2.5.3 Assessment and referral without treatment: The rationale for this strategy is that, here, the uncertainty and consequent hesitancy in shifting care of newborns (difficult even in clinical settings) onto non-professionals is by-passed. It is the most popular strategy in community trials to improve newborn survival and has been endorsed by WHO and UNICEF.⁵⁸ Effective linkages between communities and health facilities are considered critical to achieving sustained reductions in NMR in the strategy.⁴⁴ In general, expert opinions converge on the fact that promoting contacts with health facilities remains a critical gap in newborn survival initiatives.²⁷ A ranking of research priorities by experts using the Delphi and Child Health and Nutrition Research Initiative (CHNRI) methods identified community-based referral of sick newborns as one of the top priorities of current research and programme agenda worldwide.⁹⁵ Evaluation of the effectiveness of the use of CHWs to identify and refer sick newborns for prompt care is undoubtedly an international public health emergency in resource-poor settings.

Baqui et al in Projahnmo-1 (Sylhet, Bangladesh)⁴⁹ trained CHWs to assess newborns for danger signs in the home and to refer sick babies to a hospital for

care. No injectable antibiotics were to be administered in the homes. However, after the start of the trial the injectable antibiotic component was introduced when referrals were refused or when families failed to comply.⁴⁹ Large scale trials delivered in programme settings (group B in Table 2.1) have used this strategy. In almost all these trials, some home treatment was provided with the referral even though injectable antibiotics were not used. In Ghana, CHWs are not allowed to administer antibiotics within communities⁹⁴ and so in the Newhints intervention, referrals were made by the CBSVs for all danger signs to health facilities.⁶⁴

Prevalence of danger signs needing referral is estimated to be about 10%.⁹⁶ Other experts⁹⁷ suggested that this 10% estimate probably indicates high false-positive rates and that the prevalence could be lower. However, neonatology experts recommend that care should be sought for neonates upon the slightest suspicion of infection.³² Referral systems have greater successes when intervention strategies focus on both health system strengthening and community education on importance of seeking care for newborns illnesses.^{98,99} The Lancet series also recommended that health systems' strengthening (including good clinical care provision) and establishment of effective community to health facility linkages (with referral pathways), should be addressed early in programme development.⁴⁴

2.5.4 Compliance with CHW referrals and its determinants: The real success of implementing community-based referrals depends on the compliance achieved with these referrals. In the trials that implemented community-based referrals in Asia (as shown in Table 2.1), CHWs either provided full treatment at home as the first

option or initiated treatment when referral was unsuccessful or refused.^{96, 49}

Referral compliance rates were unacceptably low: varying from zero by Bang et al (1999), Gadchiroli, India who almost did not refer because the treatment was provided at home^{61, 62} to the highest recorded of 53.9% by Darmstadt et al (2010) in Mirzapur, Bangladesh.¹⁰⁰ Darmstadt et al also reported that compliance with referral was 30% less likely in the first week of life compared to post-week one for neonates in spite of efforts to address known barriers to newborn care access such as cost, distance and non-recognition of illnesses.^{52, 100} They reported that male babies, perceptions of severity, fast breathing in the baby and breastfeeding difficulties were associated with higher compliance with referral.^{52, 100} This remains the only randomised controlled trial till date that reported determinants of compliance with referrals of sick newborns using the home visits strategy.^{52, 100}

The exact reasons for the poor compliance with referrals in these trials are not explained. Several reasons could be assigned but an immediately plausible one is the option of home-treatment with the referrals within the trials in south Asia. It is plausible that families would have preferred to receive treatment at home rather than in health facilities since this option eliminates the challenges associated with access (geographical, financial and cultural) to care. If treatment at home is an alternative, it is likely that families will opt for this. Moreover, previous facility contacts may impact directly on subsequent utilisation of facilities. When families are treated at home, there is the tendency to rely on the CHW for all illnesses and this may discourage care seeking beyond the trial period. The strategy by WHO and UNICEF to improve neonatal survival through home visits in the first week strongly recommends contacts with skilled care at facilities (preferably).⁵⁸ This

recommendation requires that a full understanding of the reasons for non-compliance or facilitating factors to referral compliance are fully explored to inform future programme implementation.

2.5.5 Algorithms for community-based assessment of sick newborns: Timely and appropriate management of sick newborns is critical to saving newborn lives.^{32,}

¹⁰¹ Identification of conditions that are potentially life-threatening and which need to be treated immediately or referred promptly for appropriate care is the bedrock for the success of any community-based strategy that aims to increase newborn access to care. This is because newborn illnesses run a very rapid course and when interventions are delayed, mortality inevitably occurs.^{29, 102} Recognition of newborn illnesses by families is poor and so newborns do not contact health systems before death.^{77, 101, 103} The identification and diagnosis of newborn illnesses is difficult, more especially in developing countries^{29, 101} because they present with non-specific signs and symptoms and supporting investigations to help in diagnoses are lacking.^{29, 102}

In the early neonatal period, when three-quarters of all neonatal deaths occur, a review in the *Pediatric Infectious Disease Journal* showed that up to 80% of neonatal deaths could be due to infections.^{18, 19, 34-41} The evidence in sections 2.5.2 and 2.5.3 above confirm that with appropriate training CHWs can assess newborns for danger signs at surveillance visits for referral.^{104, 105} Being members of the same community they serve and their being 'ubiquitous' has been cited as factors that may ensure high and equitable coverage and greater acceptability.⁶⁰ The scope

of their service delivery and finding suitable algorithms to guide their surveillance for newborn illnesses is difficult¹⁰⁶ and often debated.

Algorithms to guide diagnosis of newborn illnesses in the community setting have not been finalized. Studies in the past have used either individual clinical signs or packages comprising syndromes for identification of at-risk neonates.⁴⁹ Notably, until recent, the paucity of newborn-specific interventions in global public health activities have limited the scope of evaluations addressing the validity of various clinical signs in predicting illness in newborns within community settings.

Attempts to provide some validation of known illness signs were often based on studies among older infants, in clinic settings and with inter-observer variations in the gold standards.¹⁰⁷⁻¹¹⁰

The WHO's Integrated Management of Childhood Illnesses (IMCI) was one of the first attempts globally to find algorithms for the identification of common childhood killer diseases at first level facilities.^{111, 112} The algorithm was based on the four main symptoms; cough, fever, diarrhoea and ear problems.^{111, 112} When any of these complaints were presented at first level facilities, the algorithm guided the health worker to probe for the diseases as illustrated in the table 2.2. For instance, according to this algorithm (Table 2.2), when a child presents in the facility with a fever, health workers were trained to think and investigate the "three 'M's" – malaria, measles and meningitis. Their subsequent actions depended on the availability of systems to investigate these three main killers and to treat or refer to a higher level facility where definitive care could be provided.^{111, 112} Similarly,

when children presented with a cough, health workers investigated for Pneumonia by counting the respiratory rates per minute and checked for lower chest indrawing and subsequent action was determined by the capacity of the facility as illustrated above. A complaint of ear problem led to investigation for a discharge (otitis media) or mastoiditis and diarrhoea for dysentery with the aim to quickly rehydrate (Table 2.2).^{111, 112}

These guidelines did not cover the first week of life when most newborn deaths occur; neither did the IMCI guidelines cover the neonatal period. Several countries adapted these algorithms and extended them to the newborn period without evidence of applicability for the sick newborn. This resulted in high facility to facility referral rates because of high sensitivity and low specificity.⁸⁴

Table 2.2 Initial IMCI recommended algorithm for managing sick children at 1st level facilities¹¹³

Presenting symptom	Suspected illnesses to explore for & expected actions
Fever	Malaria, Meningitis & Measles
Cough	Lower respiratory tract infection (Pneumonia): <ul style="list-style-type: none"> - Count respiratory rates and - Check for chest indrawing
Ear problem	Discharge or Mastoiditis
Diarrhoea	Rehydrate using oral rehydration therapies & investigate the cause.

The workload for staff in health facilities increased with consequent falls in the quality of care provided; albeit that health systems quality in these LMICs were already sub-optimal.⁸⁴ In sub-Saharan Africa (SSA), the only available studies

evaluating algorithms for identification of sick children were the multi-country evaluations (MCEs) of the implementation of the WHO's IMCI^{107-110, 114} which were also not specific to the neonatal period. Even in these evaluations (MCE-IMCI), variable sensitivities (76%-97%) and specificities (49-89%) were achieved for CHW infant-illness classifications.^{107-110, 114}

In community-based trials several algorithms have been tested and validated but none has been adopted as the most suitable across countries; all studies even within the same countries have used different algorithms. In the SEARCH trial, CHWs were trained to use 21 diagnostic criteria in the identification and treatment of newborn illnesses in the community.⁶¹ Subsequently, in the Projahnmo-1 trial in Bangladesh, Baqui et al validated and used a combination of signs to classify diseases of newborn and treat accordingly.⁴⁹ Eight signs including convulsions, unconsciousness, breathing more than 60 per minute, severe chest indrawing, temperature more than 38.3 or less than 35.3 degree Celsius, many and severe skin pustules and umbilical reddening were used to classify newborns as having "very severe disease" (VSD). Other twelve signs which were thought to be less severe were used in various combinations to classify newborns as having "possible severe disease" (PSD).⁴⁹

Darmstadt et al (Projahnmo-II)^{52, 115} validated and used this algorithm to measure how accurately CHWs' diagnosis of newborn illness compared with physicians. They used the classification into 'probable severe disease' and 'very severe disease' and trained CHWs to make referral or treatment decisions based on this

classification.^{100, 115} In their validation they found that, although there was rather low prevalence of neonatal sepsis (2.8%), CHW classifications had high sensitivity (73%) and specificity (98%) for very severe disease; the Kappa (coefficient of agreement) between CHWs and Physicians was 0.63.¹⁰⁰

There were obvious drawbacks in their evaluation: CHWs assessed babies within communities and these were followed later by the physician's assessment when babies contacted these health facilities/professionals. There could have been a time lag between CHW assessments and that of the physician. Since newborn illnesses could change rapidly and contacts with these physicians were often delayed, questions about the validity of the comparisons for specific danger signs such as fast breathing, lower chest indrawing and temperature, which could change very rapidly in newborns, could be raised.²⁹ In consequence, the validity of individual clinical signs of newborn illness varied because some signs depended on subjective judgements (e.g. chest indrawing) or because the signs changed very quickly over short time periods.²⁹

In search of a standardized algorithm to guide this newborn illness recognition gap, the Clinical Signs in Young Infants study,⁸⁴ commissioned by the WHO, tested the validity of individual danger signs in predicting newborn illness in six countries namely Bangladesh, Bolivia, Ghana, India, Pakistan, and South Africa. In the study, sick infants (under two months) brought to health facilities were classified into two age groups; 0-6 days and 7-59 days. In the study, trained health workers recorded 31 signs and symptoms of illness. This was followed by an independent

expert paediatrician assessment for severe disease requiring admission. Sensitivity, specificity and odds ratios for individual signs or when combined into algorithms were examined for their validity in predicting severe illness in these infants.⁸⁴ They excluded jaundice in their assessment.⁸⁴

Table 2.3: Danger signs predicting newborn illness in the Young Infants Study⁸⁴

Danger sign
1. History of difficulty in feeding
2. History of convulsions
3. Moving only when stimulated
4. Respiratory rate of 60 or more per minute
5. Severe chest indrawing
6. Temperature of 37.5°C or more
7. Temperature below 35.5°C

In the study, over 3000 early neonates (0-6 days) and over 5500 infants aged 7-59 days were assessed. The study identified twelve danger signs in predicting severe illnesses in these infants. When the algorithm was reduced to seven danger signs (Table 2.3), it predicted severe illness in newborns (0-6 days) with very high sensitivity (85%) and specificity (75%).⁸⁴

However, newborns used for this validation study were those brought in by families to access care within health facilities. This may have some intrinsic selection biases and the algorithms were selected for diagnosis of severe illness requiring admission by experts rather than as a screening tool in the community level. The

usefulness of their final algorithm as a screening tool within community-based effectiveness studies is not established.⁸⁴ Further research into the effectiveness of CHW sick-newborn identification in community settings remains an urgent priority in international public health.⁵² A recent review in the *Acta Paediatrica* by Kamath-Rayne et al¹¹⁶ made similar conclusions urging the need for further work in developing a clinical algorithm for widespread validation in various community-based settings focusing specifically and primarily on newborns within the first week of life at risk of early neonatal mortality.

2.5.6 Care seeking for sick newborns, promoting families' newborn illness recognition and independent care seeking.

2.5.6.1 Care seeking for sick newborns: Care seeking for newborn illnesses is besieged by myriads of barriers including families non-recognition of newborn illness, costs of care, poor geographical accessibility of care (or distance), non-availability of transport, negative experiences at previous health facility contacts, myths and beliefs around newborn illness, cultural practices that prohibit out of home care seeking for newborns or practice of social exclusion (such as the tradition of Rakh in Pakistan⁷⁶) where mothers are not allowed to seek care out of the home after delivery for periods extending up to 40 days.^{77, 79, 82, 117-120} Very often, but not always, the underlying cause of poor care seeking is a vicious cycle of poverty which increases the likelihood of illness and reduces the likelihood of appropriate care seeking.¹³

Due to these barriers, care seeking, if done at all, is often delayed. In the formative research for the Newhints Intervention in Ghana, Bazzano et al⁷⁷ found that care seeking for newborn illness was a “social process”. As a social process, opinions of many “stakeholders or gatekeepers” were sought as part of the decision making.^{77,}
^{121, 122} They found that the decision to seek care outside the home is often discouraged along the process.⁷⁷

Instead, home or herbal remedies are tried first since the illnesses are ascribed supernatural or metaphysical aetiology and deemed not to be amenable to allopathic care at health facilities. The phenomenon of a conglomerate of culturally-constructed illnesses labelled in rural Ghana as ‘*Asram*’ have been described.^{77, 78,}
¹²³ Similar syndromes such as the ‘*nazar*’^{76, 79} in India and Bangladesh⁷⁶ and diseases ascribed to an ‘*Upri*’⁷⁹ have been described in South Asia which are believed to be passed on to the baby by an ‘evil eye’.^{76, 80} For these illnesses, families have been found to prefer seeking home care with herbalists or traditionalists rather than orthodox health providers usually with adverse consequences. Some herbal prescriptions used in the Newhints study area in rural Ghana are as shown in Figure 2.8 being sold in open markets during the PhD data collection.



a. Dried chameleon skeleton to change the intentions of 'evil eyes' that cause 'Asram'



b. Bronze carvings of chameleon to ward off Asram



c. Odds and ends traded by medicine men to provide protection and treatment of sick newborns



d. Bronze and copper bracelets put around the ankles and below knee for protection

Figure 2.8 Items purchased and used by families to ward off diseases of the newborn. Whilst some of these are available only at herbalists' homes, some are traded in open markets

When decisions were made to seek care, it was often plural and sequential^{76, 79, 77} and various intermediary non-qualified providers were first explored. Appropriate care providers in health facilities were often contacted as the last resort.^{75, 124} The power to make care seeking decisions often lied with husbands (household heads) and in-laws.^{80, 125} However, it is clear that if neonatal deaths are to be reduced, improving newborn access to care is an imperative. Indeed Amarasiri et al¹²⁶ noted that Sri Lanka, despite dwindling economic fortunes, achieved massive reduction in

neonatal mortality from **75.5 in 1945** to **12.9 in 1991** from high levels of care seeking for neonatal illness (up to 87%) coupled with good-quality and accessible healthcare.

2.5.6.2 Promoting recognition and care seeking for sick newborns: This is the third strategy used for increasing newborn access to care in community-based approaches to reduce neonatal mortality. It is the only strategy used in the women's group approach but has also been a key component of the CHW home visits trials. In this strategy, families are provided education and counselling in order to recognise illnesses in their newborns and encouraged to seek appropriate care in health facilities when the newborns fell ill. As shown in table 2.1 and also in the PhD conceptual framework, both home visits by CHWs and the use of women's groups have promoted identification of illness and families subsequent care seeking for sick newborns. The following sections present the evidence of the impact of these approaches on care seeking for sick newborns.

Participatory action-learning cycles using Women's groups: In Nepal, Manandhar et al⁵⁵ used trained female workers to facilitate monthly meetings to discuss local perinatal challenges and devised strategies to resolve them. These community action-learning cycles promoted essential newborn care practices but no direct interventions at the birth of the baby or when the newborn fell ill.

Table 2.4 shows that the impact of the women's group approach on care seeking has been minimal. Even though Manandhar et al found almost a three-fold increase in the odds of care seeking, the levels only increased for 10% to 24% between the

control and intervention arms of the trial.⁵⁵ In Bangladesh, Azad et al found that care seeking reduced in the intervention compared to the control arm.

Table 2.4: Impact of trials using women’s group on care seeking for newborn illness & neonatal mortality rate (NMR)

Study and location	Impact on care seeking
Manandhar et al: Makwanpur (Nepal), 2004 ⁵⁵	10.0%-24.0%; 2.84 (1.65, 4.88)
Baqui et al: Sylhet (Bangladesh, 2008) ⁴⁹	Not reported
Azad et al: Bogra & others (Bangladesh, 2010) ⁵⁷	24.3%-22.5%; 0.89 (0.71, 1.13)
Tripathy et al: Jharkhand & Orissa (India, 2010) ⁵⁶	44.0%-54.0%; 1.53 (0.77, 3.05)

Home visits by CHWs: Promotion of care seeking has been a core component of all trials using the home visits approach. In addition, all these, except the one by Kumar et al in Shivgarh, India⁵⁰, trained CHWs to assess newborns. In the Shivgarh trial, only behavioural change communication strategy was implemented. Home visits by CHWs were used to either: (a) promote essential newborn care (ENC) exclusively or (b) ENC plus a Thermospot⁵⁰ to identify babies with hypothermia and to encourage care seeking.

Table 2.5: Care seeking in the Shivgarh trial⁵⁰

Illness recognition or provider used	Control	% care seeking; Rate ratio (95% CI)	
		ENC arm	ENC + Thermospot
Reported illness during newborn period	30.0%	21.9% ; 0.73 (0.60, 0.88)	21.8%; 0.73 (0.58, 0.91)
Sought care with a doctor	13.5%	22.1%; 1.63 (0.94, 2.85)	28.7%; 2.13 (1.16, 3.89)
Sought care with an auxiliary nurse/midwife	3.2%	2.4%; 0.76 (0.24, 2.39)	4.6%; 1.45 (0.53, 3.94)
Sought care with an unqualified medical practitioner	46.7%	33.1%; 0.71 (0.56, 0.89)	29.2%; 0.62 (0.41, 0.95)
Sought care with traditional healer	16.2%	14.4%; 0.89 (0.58, 1.37)	17.7%; 1.10 (0.66, 1.80)

Table 2.5 provides a summary of the impact of the Shivgarh trial on care seeking. In the trial, mothers in the control arm identified danger signs in their newborns better than those in the intervention arms (30% vs. 21.9% (a) & 21.8% (b)). Care seeking provided a mixed picture; qualified providers (doctors and auxiliary nurses/midwives) were contacted more in the intervention groups than the control (16.7% in the control vs. 24.5% in ENC arm & 33.3% in the ENC+Thermospot arm) but ENC+Thermospot arm also contacted traditional healers even more than the control group although the rate ratios were not significant.⁵⁰

All other trials using the home visits approach promoted care seeking for sick newborns as shown in table 2.1, but the rates were seldom reported. These trials have focussed on CHW assessment and referrals and promoted care seeking as an added benefit of contacts with the families.

Two meta-analyses examining the impact of the two strategies: community mobilization using women's groups or home visits by lay health workers¹²⁷ or CHWs¹²⁸ (figure 2.9) showed evidence of increased care seeking for newborn illness. In their meta-analysis, Lassi et al (figure 2.9) found that care seeking significantly increased overall by 45% for five trials which implemented the strategy, four of which used the women's group approach. Confidence intervals suggested that the data were consistent with a possible doubling of care seeking: RR=1.45 (1.01, 2.08); p-value=0.047. However, there was also evidence of a significantly high heterogeneity between the trials: $I^2=94\%$ ($X^2_{(4df)}$ p-value<0.0001).¹²⁸

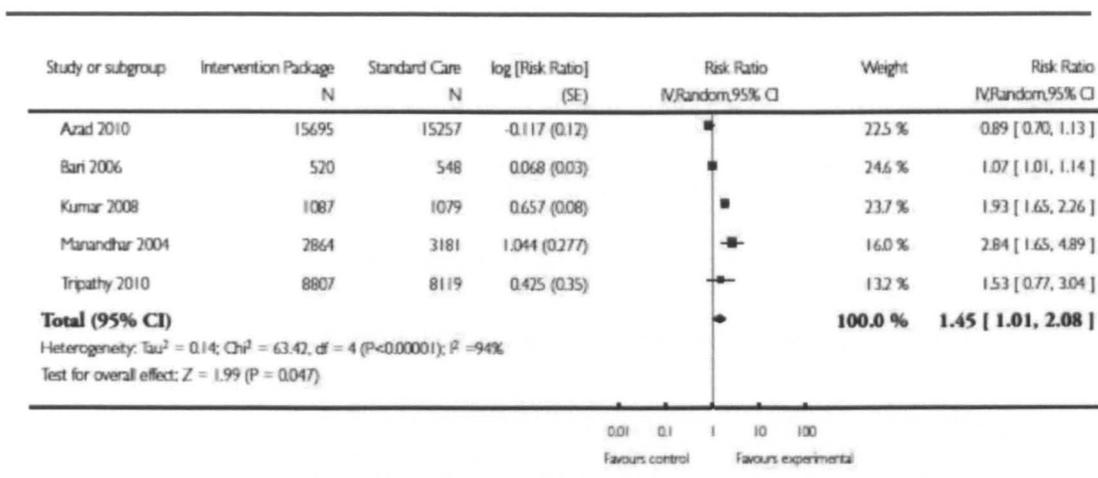


Figure 2.9 Meta-analysis of Cluster RCTs evaluating the impact of Community interventions on care seeking for newborn illness [Source: Lassi et al. Community-based intervention packages for reducing maternal and neonatal morbidity and mortality and improving neonatal outcomes. Cochrane Db Syst Rev: John Wiley & Sons, Ltd; 2010¹²⁸]

These findings were similar to an earlier review by Lewin et al¹²⁷ which used only three trials and found 33% increase in care seeking using lay health worker home visits.

2.6 Quality of newborn care in health facilities of developing country settings

The WHO/UNICEF joint statement's recommendation that families seek health facility care for newborn illnesses requires that health facility access in these LMIC settings will guarantee better-quality, life-saving care for mothers and their sick newborns.

The statement recommends strengthening of health systems but to meet these requirements, facilities must meet certain quality standards that reflect not only facilities' capability (infrastructure, drugs and supplies) but also health worker skills (to give appropriate care), attitudes (for timely and supportive care) and client expectations.^{129, 130} Quality of care has been defined differently in different studies

but most studies refer to the classification by Donabedian¹³¹ which assessed quality of facilities based on the structure, processes and the outcomes. Structure was seen as the physical infrastructure such as space, equipment and drugs that are needed for care. Processes are a combination of the knowledge based of the staff working in the facility and how this knowledge is translated into the care-giving at the facility. When structures are in place and the processes are functioning, they produce the outcomes, which is a combination of the actual care given the perceptions about this care.¹³² Perceptions also define satisfaction with the care which is defined as the “cognitive evaluation of and emotional reaction to care”¹³³ It is usually a product of actual experiences and ratings¹³² of the care.

Studies assessing facility quality of care have often focussed on older children and rarely neonates.¹³⁴⁻¹³⁷ Poor facility quality was reflected in the findings of the World development report in 2004 which concluded that, in LMIC countries, even if services are available, they are of low quality.¹³⁸ Care for newborns is often seen as complex and there is the erroneous perception that only complex technologies can guarantee quality and life-saving care for newborns.¹¹ Half a decade after this world development report, Opondo et al,¹³⁹ in Kenya described inadequate facility preparedness to provide quality care for sick newborns accessing them.

Perceptions of care have direct implications on utilisation and satisfaction with care. Long waiting times and poor clinical examinations are known to elicit client perceptions of low quality¹⁴⁰ and likely frustrate carers or discourage care-seeking. Although the World development report of 2004 was not specific for newborn care

quality, it can be hypothesized that, with the invisibility of newborns within most health facility planning in LMICs, if quality of care is poor, it is likely to be even poorer for newborn care.

Evidence suggests that improvement in service quality increases its demand even among the poorest people.¹⁴¹ In poor settings, families often by-pass local public facilities for more expensive private ones or for very distant facilities in pursuit of quality.¹⁴² Indeed good interpersonal skills have been reported to increase service use in a Congolese study.¹⁴³ Inequalities between clients are mirrored in the provider-client relationships and there is often a “social distance” between providers and clients.¹⁴⁴ The WHO has now provided guidelines in order to improve quality¹⁴⁵ but the challenges in these settings are systemic. Human resource management challenges exist; many staff are not trained in ENC and more skilled trained-personnel refuse postings to poorer communities.¹⁴⁶

Enweronu et al,¹⁴⁷ in a study conducted at a tertiary referral facility in Ghana, showed that after the establishment of a neonatal intensive care unit, referrals of out-born babies (from the community) was 4-fold higher than in-borns (within the same hospital) and interpreted this as reflecting unmet need for care in communities.¹⁴⁷ They concluded that scaling-up and improvement of emergency obstetric care (EmOC), referrals, newborn-specific human resource and neonatal resuscitation training will save more newborn lives.^{148, 149} Belay et al¹⁵⁰ found nurses trained in emergency obstetric care (EmOC) performed better than those not trained in life saving skills for newborns. However, data is lacking particularly in

sub-Saharan African settings and no study to date has systematically tested quality of facility response (in routine health system settings) when challenged with referred sick newborns from community interventions.

References for chapter two

1. NN team. Newborn's adaptation to Extra-Uterine Life; <http://www.nou-nascuti.ro/neonatology/newborns-adaptation-to-extra-uterine-life.html> [accessed 10th March. [cited; Available from:
2. About.com. Changes in the newborn at birth. Reviewed by Deirdre O'Reilly. <http://www.adam.about.com/encyclopedia/Changes-in-the-newborn-at-birth.htm>. [accessed 1st May, 2012].
3. Stoll BJ, Hansen NI, Higgins RD, Fanaroff AA, Duara S, Goldberg R, et al. Very low birth weight preterm infants with early onset neonatal sepsis: the predominance of gram-negative infections continues in the National Institute of Child Health and Human Development Neonatal Research Network, 2002-2003. *The Pediatric infectious disease journal*. 2005; **24**(7): 635-9.
4. UNICEF. State of the World's Children 1996: The 1980s: campaign for child survival. : UNICEF; 1996 (accessed 4th July 2004).
5. Black RE, Morris SS, Bryce J. Where and why are 10 million children dying every year? *Lancet*. 2003; **361**(9376): 2226-34.
6. Bryce J, el Arifeen S, Pariyo G, Lanata C, Gwatkin D, Habicht JP. Reducing child mortality: can public health deliver? *Lancet*. 2003; **362**(9378): 159-64.
7. Jones G, Steketee RW, Black RE, Bhutta ZA, Morris SS, Bellagio Child Survival Study G. How many child deaths can we prevent this year? *Lancet*. 2003; **362**(9377): 65-71.
8. Victora CG, Wagstaff A, Schellenberg JA, Gwatkin D, Claeson M, Habicht JP. Applying an equity lens to child health and mortality: more of the same is not enough. *Lancet*. 2003; **362**(9379): 233-41.
9. The Bellagio Study Group on Child Survival. Knowledge into action for child survival. *Lancet*. 2003; **362**: 323-27.
10. Oestergaard MZ, Inoue M, Yoshida S, Mahanani WR, Gore FM, al. e. Neonatal Mortality Levels for 193 Countries in 2009 with Trends since 1990: A Systematic Analysis of Progress, Projections, and Priorities. *PLoS Medicine*. 2011; **8**(8): e1001080.
11. UNICEF. Maternal and newborn health: where we stand: UNICEF; 2009. Report No.: 978-92-806-4318-3.
12. Black RE, Cousens S, Johnson HL, Lawn JE, Rudan I, Bassani DG, et al. Global, regional, and national causes of child mortality in 2008: a systematic analysis. 2010.
13. Lawn JE, Cousens S, Zupan J, Lancet Neonatal Survival Steering T. 4 million neonatal deaths: When? Where? Why? *Lancet*. 2005; **365**(9462): 891-900.
14. Lawn JE, Cousens SN, Darmstadt GL, Bhutta ZA, Martines J, Paul V, et al. 1 year after The Lancet Neonatal Survival Series--was the call for action heard? *Lancet*. 2006; **367**(9521): 1541-7.
15. Lawn J. Neonatal Survival. In: Dean TJ, et al, editor. *Disease Control Priorities in Developing Countries*. 2nd ed. Washington, D C: Oxford University Press. World Bank; 2006. p. 534.
16. Friberg IK, Kinney MV, Lawn JE, Kerber KJ, Odubanjo MO, Bergh AM, et al. Sub-Saharan Africa's mothers, newborns, and children: how many lives could be saved with targeted health interventions? *PLoS Med*. 2010; **7**(6): e1000295.

17. Zupan J. Perinatal mortality in developing countries. *New England Journal of Medicine*. 2005; **352**(20): 2047-8.
18. Bang AT, Paul VK, Reddy HM, Baitule SB. Why do neonates die in rural Gadchiroli, India? (Part I): primary causes of death assigned by neonatologist based on prospectively observed records. 2005.
19. Baqui AH, Darmstadt GL, Williams EK, Kumar V, Kiran TU, Panwar D, et al. Rates, timing and causes of neonatal deaths in rural India: implications for neonatal health programmes. *Bulletin of the World Health Organization*. 2006; **84**(9): 706-13.
20. Freeman JV, Christian P, Khattry SK, Adhikari RK, LeClerq SC, Katz J, et al. Evaluation of neonatal verbal autopsy using physician review versus algorithm-based cause-of-death assignment in rural Nepal. *Paediatric and Perinatal Epidemiology*. 2005; **19**(4): 323-31.
21. Lawn JE, Wilczynska-Ketende K, Cousens SN. Estimating the causes of 4 million neonatal deaths in the year 2000. *International Journal of Epidemiology*. 2006; **35**(3): 706-18.
22. Mulholland K. Global burden of acute respiratory infections in children: implications for interventions. 2003.
23. Rudan I, Lawn J, Cousens S, Rowe AK, Boschi-Pinto C, Tomaskovic L, et al. Gaps in policy-relevant information on burden of disease in children: a systematic review.[see comment]. *Lancet*. 2005; **365**(9476): 2031-40.
24. Kirkwood BR, Manu A, Tawiah-Agyemang C, et al. NEWHINTS cluster randomised trial to evaluate the impact on neonatal mortality in rural Ghana of routine home visits to provide a package of essential newborn care interventions in the third trimester of pregnancy and the first week of life: trial protocol. *Trials*. 2010; **10**(58).
25. Bhutta Z, Ali N, Hyder A, Walid A. *Perinatal and newborn care in Pakistan: seeing the unseen*. Karachi: Oxford University Press; 2004.
26. Costello A, Osrin D, Manandhar D. Reducing maternal and neonatal mortality in the poorest communities. *BMJ*. 2004; **329**(7475): 1166-8.
27. Lawn JE, Cousens S, Bhutta ZA, Darmstadt GL, Martines J, Paul V, et al. Why are 4 million newborn babies dying each year? *Lancet*. 2004; **364**(9432): 399-401.
28. Edmond KM, Quigley MA, Zandoh C, Danso S, Hurt C, Owusu Agyei S, et al. Aetiology of stillbirths and neonatal deaths in rural Ghana: implications for health programming in developing countries. *Paediatric and Perinatal Epidemiology*. 2008; **22**(5): 430-7.
29. Qazi SA, Stoll BJ. Neonatal sepsis: A Major Global Public Health Challenge. *Pediatric Infectious Disease Journal*. 2009; **28**(1 Suppl): S1-2.
30. Lawn JE, Kerber K, Enweronu-Laryea C, Cousens S. 3.6 million neonatal deaths--what is progressing and what is not? *Semin Perinatol*. 2010; **34**(6): 371-86.
31. Bang A, Reddy HM, Deshmukh MD. Child Mortality in Maharashtra. *Economic Political Weekly*. 2002; **37**: 4947-65.
32. Stoll B. Infections of the neonatal infant: pathogenesis and epidemiology. In: Behrman RE, Kliegman RM, Jenson HB, editors. *Nelson's Textbook of Paediatrics*. 17th ed. Philadelphia: Saunders, W. B; 2004. p. 623-40.
33. Zaidi AK, Huskins WC, Thaver D, Bhutta ZA, Abbas Z, Goldmann DA. Hospital-acquired neonatal infections in developing countries. 2005.

34. Alisjahbana A, Soeroto-Hamzah E, Peeters R, et al. Perinatal mortality and morbidity in rural West-Java, Indonesia, part II: the results of a longitudinal survey on pregnant women. *Paediatr Indones*. 1990; **30**: 179-90.
35. Baiden F, Hodgson A, Adjuik M, Adongo P, Ayaga B, Binka F. Trend and causes of neonatal mortality in the Kassena-Nankana district of northern Ghana, 1995-2002. 2006.
36. Bhandari N, Bahl R, Taneja S, Martines J, Bhan MK. Pathways to infant mortality in urban slums of Delhi, India: implications for improving the quality of community- and hospital-based programmes. 2002.
37. Chowdhury ME, Akhter HH, Chongsuvivatwong V, Geater AF. Neonatal mortality in rural Bangladesh: an exploratory study. 2005.
38. Hinderaker SG, Olsen BE, Bergsjo PB, Gasheka P, Lie RT, Havnen J, et al. Avoidable stillbirths and neonatal deaths in rural Tanzania. 2003.
39. Jalil F, Lindblad BS, Hanson LA, Khan SR, Yaqoob M, Karlberg J. Early child health in Lahore, Pakistan: IX. Perinatal events. 1993.
40. Khaliq N, Sinha SN, Yunus M, Malik A. Early childhood mortality--a rural study. 1993.
41. Leach A, McArdle TF, Banya WA, Krubally O, Greenwood AM, Rands C, et al. Neonatal mortality in a rural area of The Gambia. *Annals of Tropical Paediatrics*. 1999; **19**(1): 33-43.
42. UN. General Assembly 56th Session. Road map towards the implementation of the United Nations millennium declaration: report of the Secretary-General (UN document no. A/56/326). New York: United Nations; 2001.
43. Conway DI, McMahon AD, Smith K, Black R, Robertson G, Devine J, et al. Components of socioeconomic risk associated with head and neck cancer: a population-based case-control study in Scotland. *The British journal of oral & maxillofacial surgery*. 2010; **48**(1): 11-7.
44. Darmstadt GL, Bhutta ZA, Cousens S, Adam T, Walker N, de Bernis L, et al. Evidence-based, cost-effective interventions: how many newborn babies can we save? *Lancet*. 2005; **365**(9463): 977-88.
45. Bahl R, Qazi S, Darmstadt GL, Martines J. Why is continuum of care from home to health facilities essential to improve perinatal survival? *Semin Perinatol*. 2010; **34**(6): 477-85.
46. MacFarlane A, Johnstone A, Mugford M. *Epidemiology*. In: Rennie J, Robertson N, editors. *Textbook of neonatology*. 3rd ed. Cambridge: Churchill Livingstone; 1999. p. 3-33.
47. McKeown T, Record RG, Turner RD. An interpretation of the decline of mortality in England and Wales during the twentieth century. 1975.
48. Bang AT, Reddy HM, Deshmukh MD, Baitule SB, Bang RA. Neonatal and infant mortality in the ten years (1993 to 2003) of the Gadchiroli field trial: effect of home-based neonatal care. *J Perinatol*. 2005; **25** Suppl 1: S92-107.
49. Baqui AH, El-Arifeen S, Darmstadt GL, Ahmed S, Williams EK, Seraji HR, et al. Effect of community-based newborn-care intervention package implemented through two service-delivery strategies in Sylhet district, Bangladesh: a cluster-randomised controlled trial. *Lancet*. 2008; **371**(9628): 1936-44.
50. Kumar V, Mohanty S, Kumar A, Misra RP, Santosham M, Awasthi S, et al. Effect of community-based behaviour change management on neonatal mortality in

- Shivgarh, Uttar Pradesh, India: a cluster-randomised controlled trial. *Lancet*. 2008; **372**(9644): 1151-62.
51. Kirkwood BR, Manu A, ten Asbroek AH, Soremekun S, Weobong B, Gyan T, et al. Impact of the "Newhints" home visits intervention on neonatal mortality and care practices in Ghana: a cluster randomised controlled trial. Submitted. 2012.
 52. Darmstadt GL, Choi Y, Arifeen SE, Bari S, Rahman SM, Mannan I, et al. Evaluation of a cluster-randomized controlled trial of a package of community-based maternal and newborn interventions in Mirzapur, Bangladesh. *PLoS ONE* [Electronic Resource]. 2010; **5**(3): e9696.
 53. Bhutta ZA, Soofi S, Cousens S, Mohammad S, Memon ZA, Ali I, et al. Improvement of perinatal and newborn care in rural Pakistan through community-based strategies: a cluster-randomised effectiveness trial. *Lancet*; 2011. p. 403-12.
 54. Bhandari N, Mazumder S, Taneja S, Sommerfelt H, Strand TA. Effect of implementation of Integrated Management of Neonatal and Childhood Illness (IMNCI) programme on neonatal and infant mortality: cluster randomised controlled trial. *BMJ*. 2012; **344**: e1634.
 55. Manandhar DS, Osrin D, Shrestha BP, Mesko N, Morrison J, Tumbahangphe KM, et al. Effect of a participatory intervention with women's groups on birth outcomes in Nepal: cluster-randomised controlled trial. *Lancet*. 2004; **364**(9438): 970-9.
 56. Tripathy P, Nair N, Barnett S, Mahapatra R, Borghi J, Rath S, et al. Effect of a participatory intervention with women's groups on birth outcomes and maternal depression in Jharkhand and Orissa, India: a cluster-randomised controlled trial. *Lancet*. 2010; **375**(9721): 1182-92.
 57. Azad K, Barnett S, Banerjee B, Shaha S, Khan K, Rego AR, et al. Effect of scaling up women's groups on birth outcomes in three rural districts in Bangladesh: a cluster-randomised controlled trial. *Lancet*. 2010; **375**(9721): 1193-202.
 58. WHO/UNICEF. WHO/UNICEF Joint Statement: Home visits for the newborn Child: a Strategy to Improve Survival. Geneva: WHO; 2009.
 59. Black RA, Rounsaville BJ, Rosenheck RA, Conrad KJ, Ball SA, Rosen MI. Measuring money mismanagement among dually diagnosed clients. *The Journal of nervous and mental disease*. 2008; **196**(7): 576-9.
 60. Haines A, Sanders D, Lehmann U, Rowe AK, Lawn JE, Jan S, et al. Achieving child survival goals: potential contribution of community health workers. *Lancet*. 2007; **369**(9579): 2121-31.
 61. Bang AT, Bang RA, Baitule SB, Reddy MH, Deshmukh MD. Effect of home-based neonatal care and management of sepsis on neonatal mortality: field trial in rural India. *Lancet*. 1999; **354**(9194): 1955-61.
 62. Bang AT, Bang RA, Stoll BJ, Baitule SB, Reddy HM, Deshmukh MD. Is home-based diagnosis and treatment of neonatal sepsis feasible and effective? Seven years of intervention in the Gadchiroli field trial (1996 to 2003). *J Perinatol*. 2005; **25 Suppl 1**: S62-71.
 63. Bhutta ZA, Memon ZA, Soofi S, Salat MS, Cousens S, Martines J. Implementing community-based perinatal care: results from a pilot study in rural Pakistan. *Bulletin of the World Health Organization*; 2008. p. 452-9.
 64. Kirkwood BR, Manu A, Tawiah-Agyemang C, ten Asbroek G, Gyan T, Weobong B, et al. NEWHINTS cluster randomised trial to evaluate the impact on neonatal mortality in rural Ghana of routine home visits to provide a package of essential

- newborn care interventions in the third trimester of pregnancy and the first week of life: trial protocol. *Trials*. 2010; **11**: 58.
65. O'Rourke K, Howard-Grabman L, Seoane G. Impact of community organization of women on perinatal outcomes in rural Bolivia. *Revista panamericana de salud publica = Pan American journal of public health*. 1998; **3**(1): 9-14.
 66. Haws RA, Thomas AL, Bhutta ZA, Darmstadt GL. Impact of packaged interventions on neonatal health: a review of the evidence. *Health Policy & Planning*. 2007; **22**(4): 193-215.
 67. Lawn JE, McCarthy B, Ross SR. *The Healthy Newborn: a reference guide for program managers*. Atlanta: CDC. CARE; 2001.
 68. Lewycka S, Mwansambo C, Kazembe P, Phiri T, Mganga A, Rosato M, et al. A cluster randomised controlled trial of the community effectiveness of two interventions in rural Malawi to improve health care and to reduce maternal, newborn and infant mortality. *Trials*. 2010; **11**: 88.
 69. Jokhio AH, Winter HR, Cheng KK. An intervention involving traditional birth attendants and perinatal and maternal mortality in Pakistan. *The New England journal of medicine*; 2005. p. 2091-9.
 70. Sibley L, Buffington ST, Beck D, Armbruster D. Home based life saving skills: promoting safe motherhood through innovative community-based interventions. *Journal of Midwifery & Women's Health*. 2001; **46**(4): 258-66.
 71. Lim SS, Dandona L, Hoisington JA, James SL, Hogan MC, Gakidou E. India's Janani Suraksha Yojana, a conditional cash transfer programme to increase births in health facilities: an impact evaluation. *Lancet*. 2010; **375**(9730): 2009-23.
 72. Das A, Rao D, Hagopian A. India's Janani Suraksha Yojana: further review needed. *The Lancet*. 2011; **377**(9762): 295-6.
 73. Government of Ghana. *The National Health Insurance Act 650*. In: Government of Ghana, editor. Accra, Ghana; 2003.
 74. National Health Insurance Authority Ghana. *Providing free maternal and neonatal care through NHIS*. Accra Ghana; Ghana Health Service; 2008.
 75. Neonatal Mortality Formative Research Working G. Developing community-based intervention strategies to save newborn lives: lessons learned from formative research in five countries. *Journal of Perinatology*. 2008; **28 Suppl 2**: S2-8.
 76. Syed U, Khadka N, Khan A, Wall S. Care-seeking practices in South Asia: using formative research to design program interventions to save newborn lives. *Journal of Perinatology*. 2008; **28 Suppl 2**: S9-13.
 77. Bazzano AN, Kirkwood BR, Tawiah-Agyemang C, Owusu-Agyei S, Adongo PB. Beyond symptom recognition: care-seeking for ill newborns in rural Ghana. *Trop Med Int Health*. 2008; **13**(1): 123-8.
 78. Hill Z, Kendall C, Arthur P, Kirkwood B, Adjei E. Recognizing childhood illnesses and their traditional explanations: exploring options for care-seeking interventions in the context of the IMCI strategy in rural Ghana. *Trop Med Int Health*. 2003; **8**: 668-76.
 79. Awasthi S, Srivastava NM, Pant S. Symptom-specific care-seeking behavior for sick neonates among urban poor in Lucknow, Northern India. *Journal of Perinatology*. 2008; **28 Suppl 2**: S69-75.

80. Mohan P, Iyengar SD, Agarwal K, Martines JC, Sen K. Care-seeking practices in rural Rajasthan: barriers and facilitating factors. *Journal of Perinatology*. 2008; **28 Suppl 2**: S31-7.
81. Bang AT, Bang RA, Baitule S, Deshmukh M, Reddy MH. Burden of morbidities and the unmet need for health care in rural neonates--a prospective observational study in Gadchiroli, India. *Indian Pediatrics*. 2001; **38**(9): 952-65.
82. Sutrisna B, Reingold A, Kresno S, Harrison G, Utomo B. Care-seeking for fatal illnesses in young children in Indramayu, west Java, Indonesia. *Lancet*. 1993; **342**(8874): 787-9.
83. Bang AT, Bang RA, Reddy MH, Baitule SB, Deshmukh MD, Paul VK, et al. Simple clinical criteria to identify sepsis or pneumonia in neonates in the community needing treatment or referral. *Pediatric Infectious Disease Journal*. 2005; **24**(4): 335-41.
84. Young Infants Clinical Signs Study G. Clinical signs that predict severe illness in children under age 2 months: a multicentre study. *Lancet*. 2008; **371**(9607): 135-42.
85. Bang AT, Bang RA, Tale O, Sontakke P, Solanki J, Wargantiwar R, et al. Reduction in pneumonia mortality and total childhood mortality by means of community-based intervention trial in Gadchiroli, India. *Lancet*. 1990; **336**(8709): 201-6.
86. Khan AJ, Khan JA, Akbar M, Addiss DG. Acute respiratory infections in children: a case management intervention in Abbottabad District, Pakistan. *Bulletin of the World Health Organization*. 1990; **68**(5): 577-85.
87. Mtango FD, Neuvians D. Acute respiratory infections in children under five years. Control project in Bagamoyo District, Tanzania. *Trans R Soc Trop Med Hyg*. 1986; **80**(6): 851-8.
88. Pandey MR, Daulaire NM, Starbuck ES, Houston RM, McPherson K. Reduction in total under-five mortality in western Nepal through community-based antimicrobial treatment of pneumonia. *Lancet*. 1991; **338**(8773): 993-7.
89. Sazawal S, Black RE. Effect of pneumonia case management on mortality in neonates, infants, and preschool children: a meta-analysis of community-based trials. *Lancet Infect Dis*. 2003; **3**(9): 547-56.
90. Zaidi Anita KM, Saeed Muhammad A, Bhutta Zulfiqar A, Thaver D. Community based management of neonatal sepsis in developing countries. *Cochrane Db Syst Rev*: John Wiley & Sons, Ltd; 2009.
91. Baiden F, Owusu-Agyei S, Bawah J, Bruce J, Tivura M, Delmini R, et al. An evaluation of the clinical assessments of under-five febrile children presenting to primary health facilities in rural Ghana. *PloS one*. 2011; **6**(12): e28944.
92. World Health Organization. Explore simplified antimicrobial regimens for the treatment of neonatal sepsis; 2002 30th Septembver-1st October 2002.
93. Thaver D, Ali SA, Zaidi AK. Antimicrobial resistance among neonatal pathogens in developing countries. *The Pediatric infectious disease journal*. 2009; **28**(1 Suppl): S19-21.
94. Ghana Health Service. Community Newborn Health Policy-draft. In: *Reproductive and Child Health Directorate Ministry of Health*, editor. Accra: Ghana Health Service; 2011.

95. Bahl R, Martines J, Ali N, Bhan MK, Carlo W, Chan KY, et al. Research priorities to reduce global mortality from newborn infections by 2015. *Pediatric Infectious Disease Journal*. 2009; **28**(1 Suppl): S43-8.
96. Grant CC, Wall CR, Gibbons MJ, Morton SM, Santosham M, Black RE. Child nutrition and lower respiratory tract disease burden in New Zealand: a global context for a national perspective. *Journal of paediatrics and child health*. 2011; **47**(8): 497-504.
97. Roth DE, Richard SA, Black RE. Zinc supplementation for the prevention of acute lower respiratory infection in children in developing countries: meta-analysis and meta-regression of randomized trials. *Int J Epidemiol*. 2010; **39**(3): 795-808.
98. Darmstadt GL, Kumar V, Yadav R, Shearer JC, Baqui AH, Awasthi S, et al. Community perceptions of birth weight in rural Uttar Pradesh, India: implications for care of low-birth-weight infants. *Journal of Perinatology*. 2008; **28 Suppl 2**: S53-60.
99. Iyengar SD, Iyengar K, Martines JC, Dashora K, Deora KK. Childbirth practices in rural Rajasthan, India: implications for neonatal health and survival. *Journal of Perinatology*. 2008; **28 Suppl 2**: S23-30.
100. Darmstadt GL, El Arifeen S, Choi Y, Bari S, Rahman SM, Mannan I, et al. Household surveillance of severe neonatal illness by community health workers in Mirzapur, Bangladesh: coverage and compliance with referral. *Health Policy & Planning*. 2010; (25): 112-24.
101. de Zoysa I, Bhandari N, Akhtari N, Bhan MK. Careseeking for illness in young infants in an urban slum in India. *Social Science & Medicine*. 1998; **47**(12): 2101-11.
102. Stoll BJ. Neonatal Infections: a global perspective. In: Remington JS, Klein JO, editors. *Infectious Diseases of the Foetus and Newborn Infant* 6th ed. Philadelphia, PA: Saunders WB; 2003. p. 27-57.
103. Awasthi S, Verma T, Agarwal M. Danger signs of neonatal illnesses: perceptions of caregivers and health workers in northern India. *Bulletin of the World Health Organization*. 2006; **84**(10): 819-26.
104. Darmstadt GL, Kumar V, Yadav R, Singh V, Singh P, Mohanty S, et al. Introduction of community-based skin-to-skin care in rural Uttar Pradesh, India. *Journal of Perinatology*. 2006; **26**(10): 597-604.
105. Osrin D, Mesko N, Shrestha BP, Shrestha D, Tamang S, Thapa S, et al. Implementing a community-based participatory intervention to improve essential newborn care in rural Nepal. *Transactions of the Royal Society of Tropical Medicine & Hygiene*. 2003; **97**(1): 18-21.
106. Bhutta ZA, Darmstadt GL, Hasan BS, Haws RA. Community-based interventions for improving perinatal and neonatal health outcomes in developing countries: a review of the evidence. *Pediatrics*. 2005; **115**(2 Suppl): 519-617.
107. Kahigwa E, Schellenberg D, Schellenberg JA, Aponte JJ, Alonso PL, Menendez C. Inter-observer variation in the assessment of clinical signs in sick Tanzanian children. *Transactions of the Royal Society of Tropical Medicine & Hygiene*. 2002; **96**(2): 162-6.
108. Mullany LC, Darmstadt GL, Katz J, Khattry SK, LeClerq SC, Adhikari RK, et al. Development of clinical sign based algorithms for community based assessment of ophthalmitis. *Arch Dis Child Fetal Neonatal Ed*. 2006; **91**(2): F99-104.

109. Perkins BA, Zucker JR, Otieno J, Jafari HS, Paxton L, Redd SC, et al. Evaluation of an algorithm for integrated management of childhood illness in an area of Kenya with high malaria transmission. *Bulletin of the World Health Organization*. 1997; **75 Suppl 1**: 33-42.
110. Simoes EA, Desta T, Tessema T, Gerbresellassie T, Dagne M, Gove S. Performance of health workers after training in integrated management of childhood illness in Gondar, Ethiopia. *Bulletin of the World Health Organization*. 1997; **75 Suppl 1**: 43-53.
111. Tulloch J. Integrated approach to child health in developing countries. *Lancet*. 1999; **354 Suppl 2**: S116-20.
112. Weber MW, Mulholland EK, Jaffar S, Troedsson H, Gove S, Greenwood BM. Evaluation of an algorithm for the integrated management of childhood illness in an area with seasonal malaria in the Gambia. *Bulletin of the World Health Organization*. 1997; **75 Suppl 1**: 25-32.
113. World Health Organization. WHO IMCI Chart Booklet Accessed (15 November 2010).
114. Kolstad PR, Burnham G, Kalter HD, Kenya-Mugisha N, Black RE. The integrated management of childhood illness in western Uganda. *Bulletin of the World Health Organization*. 1997; **75 Suppl 1**: 77-85.
115. Darmstadt GL, Baqui AH, Choi Y, Bari S, Rahman SM, Mannan I, et al. Validation of a clinical algorithm to identify neonates with severe illness during routine household visits in rural Bangladesh. *Archives of Disease in Childhood*. 2011; **96**(12): 1140-6.
116. Kamath-Rayne BD, MacGuire ER, McClure EM, Goldenberg RL, Jobe AH. Clinical algorithms for the identification of sick newborns in community-based settings. *Acta Paediatr*. 2012; **101**(4): 344-51.
117. Gove S, Pelto GH. Focused ethnographic studies in the WHO Programme for the Control of Acute Respiratory Infections. *Med Anthropol*. 1994; **15**(4): 409-24.
118. Herman E, Black RE, Wahba S, Khallaf N. Developing strategies to encourage appropriate care-seeking for children with acute respiratory infections: an example from Egypt. *Int J Health Plann Manage*. 1994; **9**(3): 235-43.
119. Kresno S, Harrison GG, Sutrisna B, Reingold A. Acute respiratory illnesses in children under five years in Indramayu, west Java, Indonesia: a rapid ethnographic assessment. *Med Anthropol*. 1994; **15**(4): 425-34.
120. Morrison J, Osrin D, Shrestha B, Tumbahangphe KM, Tamang S, Shrestha D, et al. How did formative research inform the development of a women's group intervention in rural Nepal? *Journal of Perinatology*. 2008; **28 Suppl 2**: S14-22.
121. Pigg S. Here, there and everywhere: place and person in Nepalese explanations of illness. *Him Res Bull*. 1989; **9**(2): 16-24.
122. Stone L. Concepts of illness and curing in a central Nepal village. *Contrib Nepalese Stud*. 1996; **18**: 55-80.
123. Okyere E, Tawiah-Agyemang C, Manu A, Deganus S, Kirkwood B, Hill Z. Newborn care: the effect of a traditional illness, asram, in Ghana. *Ann Trop Paediatr*. 2010; **30**(4): 321-8.
124. Chowdhury HR, Thompson SC, Ali M, Alam N, Yunus M, Streatfield PK. Care seeking for fatal illness episodes in neonates: a population-based study in rural Bangladesh. *BMC Pediatrics*. 2011; **11**: 88.

125. Bang AT, Bang RA, Morankar VP, Sontakke PG, Solanki JM. Pneumonia in neonates: can it be managed in the community? *Archives of Disease in Childhood*. 1993; **68**(5 Spec No): 550-6.
126. Amarasiri de Silva MW, Wijekoon A, Hornik R, Martines J. Care seeking in Sri Lanka: one possible explanation for low childhood mortality. *Social Science & Medicine*. 2001; **53**(10): 1363-72.
127. Lewin S, Munabi-Babigumira S, Glenton C, Daniels K, Bosch-Capblanch X, van Wyk Brian E, et al. Lay health workers in primary and community health care for maternal and child health and the management of infectious diseases. *Cochrane Db Syst Rev*: John Wiley & Sons, Ltd; 2010.
128. Lassi Zohra S, Haider Batool A, Bhutta Zulfiqar A. Community-based intervention packages for reducing maternal and neonatal morbidity and mortality and improving neonatal outcomes. *Cochrane Db Syst Rev*: John Wiley & Sons, Ltd; 2010.
129. Baltussen R, Ye Y. Quality of care of modern health services as perceived by users and non-users in Burkina Faso. *Int J Qual Health Care*. 2006; **18**(1): 30-4.
130. Rao KD, Peters DH, Bandeen-Roche K. Towards patient-centered health services in India--a scale to measure patient perceptions of quality. *Int J Qual Health Care*. 2006; **18**(6): 414-21.
131. Donabedian A. Quality assurance. Structure, process and outcome. *Nurs Stand*. 1992; **7**(11 Suppl QA): 4-5.
132. Coulter A. Can patients assess the quality of health care? Patients' surveys should ask about real experiences of medical care. *British medical journal*. 2006; **333**(7557): 1-2.
133. Fitzpatrick R. Scope and measurement of patient satisfaction. In: Fitzpatrick R, Hopkins A, editors. *Measurement of patients' satisfaction with their care*. London: Royal College of Physicians of London; 1993.
134. Armstrong Schellenberg JR, Mrisho M, Manzi F, Shirima K, Mbuya C, Mushi AK, et al. Health and survival of young children in southern Tanzania. *BMC Public Health*. 2008; **8**: 194.
135. English M, Esamai F, Wasunna A, Were F, Ogutu B, Wamae A, et al. Assessment of inpatient paediatric care in first referral level hospitals in 13 districts in Kenya. *Lancet*. 2004; **363**(9425): 1948-53.
136. Reyburn H, Mwakasungula E, Chonya S, Mtei F, Bygbjerg I, Poulsen A, et al. Clinical assessment and treatment in paediatric wards in the north-east of the United Republic of Tanzania. *Bulletin of the World Health Organization*. 2008; **86**(2): 132-9.
137. Mbonye AK, Mutabazi MG, Asimwe JB, Sentumbwe O, Kabarangira J, Nanda G, et al. Declining maternal mortality ratio in Uganda: priority interventions to achieve the Millennium Development Goal. *International journal of gynaecology and obstetrics: the official organ of the International Federation of Gynaecology and Obstetrics*. 2007; **98**(3): 285-90.
138. Olney DK, Pollitt E, Kariger PK, Khalfan SS, Ali NS, Tielsch JM, et al. Young Zanzibari children with iron deficiency, iron deficiency anemia, stunting, or malaria have lower motor activity scores and spend less time in locomotion. *The Journal of nutrition*. 2007; **137**(12): 2756-62.

139. Opondo C, Ntoburi S, Wagai J, Wafula J, Wasunna A, Were F, et al. Are hospitals prepared to support newborn survival? - An evaluation of eight first-referral level hospitals in Kenya. *Trop Med Int Health*. 2009; **14**(10): 1165-72.
140. Ramirez-Sanchez TJ, Najera-Aguilar P, Nigenda-Lopez G. Perception of the quality of care in the health services in Mexico. perspective of the users. *Salud publica de Mexico*. 1998; **40**(1): 3-12.
141. Osendarp SJ, Prabhakar H, Fuchs GJ, van Raaij JM, Mahmud H, Tofail F, et al. Immunization with the heptavalent pneumococcal conjugate vaccine in Bangladeshi infants and effects of zinc supplementation. *Vaccine*. 2007; **25**(17): 3347-54.
142. Johnson MS, Black R. Islands increase genetic subdivision and disrupt patterns of connectivity of intertidal snails in a complex archipelago. *Evolution; international journal of organic evolution*. 2006; **60**(12): 2498-506.
143. Sazawal S, Dhingra U, Dhingra P, Hiremath G, Kumar J, Sarkar A, et al. Effects of fortified milk on morbidity in young children in north India: community based, randomised, double masked placebo controlled trial. *BMJ*. 2007; **334**(7585): 140.
144. Black RN, Bell PM. Comment on: Weickert MO, Pfeiffer AFH (2006) Signalling mechanisms linking hepatic glucose and lipid metabolism. *Diabetologia* 49:1732-1741. *Diabetologia*. 2007; **50**(2): 493-4; author reply 5-6.
145. Black RC. Overview of the Frew settlement and new fee increases. *Texas dental journal*. 2007; **124**(10): 1020-1.
146. Li N, Wang Y, Forbes K, Vignali KM, Heale BS, Saftig P, et al. Metalloproteases regulate T-cell proliferation and effector function via LAG-3. *The EMBO journal*. 2007; **26**(2): 494-504.
147. Enweronu-Laryea CC, Nkyekyer K, Rodrigues OP. The impact of improved neonatal intensive care facilities on referral pattern and outcome at a teaching hospital in Ghana. *J Perinatol*. 2008; **28**(8): 561-5.
148. Checkley W, Buckley G, Gilman RH, Assis AM, Guerrant RL, Morris SS, et al. Multi-country analysis of the effects of diarrhoea on childhood stunting. *Int J Epidemiol*. 2008; **37**(4): 816-30.
149. Fischer Walker CL, Aboubaker S, Van de Weerd R, Black RE. Zinc for diarrhoea management in Sub-Saharan Africa: a review. *East African medical journal*. 2007; **84**(9): 441-9.
150. Rosenberg RE, Ahmed S, Saha SK, Ahmed AS, Chowdhury MA, Law PA, et al. Simplified age-weight mortality risk classification for very low birth weight infants in low-resource settings. *The Journal of pediatrics*. 2008; **153**(4): 519-24.

SECTION B:
STUDY SETTING, NEWHINTS
INTERVENTION AND
GENERAL METHODS USED
IN THE PHD

PAGE NUMBERING AS IN THE ORIGINAL THESIS

CHAPTER THREE: Study Setting, The Newhints Home Visits Cluster-Randomised Controlled Trial & Description of the Newhints Intervention

3.1 Study setting

3.1.1 The Kintampo Health Research Centre (KHRC): The KHRC is one of three such research centres established under the health research directorate of the Ghana Health Service (GHS). It was established in 1994 to serve the middle regions of Ghana - Ashanti and Brong-Ahafo primarily (Figure 3.1). The objective for its establishment, among other things, was to generate evidence-base for policy making and advocacy locally (in the Ministry of Health) and internationally through well-conducted high-quality research. It also has a mandate to support the development of research capacity and manpower for the country with particular emphasis on the regions around the middle belt of Ghana; in fact at its site in Kintampo, the KHRC is less than 100 meters away from the exact geographical centre of Ghana.

Various research activities into micronutrients (Vitamin A, Zinc and Iodine in diet or supplements), infectious diseases (primarily Malaria Drug and Vaccine trials) and maternal and child health have been conducted successfully at the centre with results which have had far reaching impacts on international public health. To ensure independence, the research centre has semi-autonomy and reports directly to the national health research directorate but makes direct input into service delivery within neighbouring district health management teams (DHMTs) and regional

health management team (RHMT). It collaborates with educational institutions like the University of Ghana, Kwame Nkrumah University of Science and Technology, Ghana, London School of Hygiene and Tropical Medicine, University of Columbia, USA as well as funding agencies like the Bill and Melinda Gates' Foundation, The World Health Organization, Department for International Development, UK, National Institute of Health, USA, etc.

3.1.2 Geography and ecology of the study area: The Newhints intervention covers an area of about 12,000 square kilometres around the geographical centre of Ghana;¹ Latitude 8° north of the Equator and Longitudes 1° to 3° East of the Greenwich meridian (Figure 3.1).

The climate of the area undergoes a transition from the wet equatorial climate in the southern districts (Nkoranza North, Nkoranza South and Techiman) to the dry, semi-arid tropical continental climate in the north (Kintampo North and Tain). Consequently, rainfall also transitions from the distinct double-maxima in the south with two distinct seasons - a major season (April to July) and a minor season (September to November) - to the single maximum towards the north occurring between June and October.



Figure 3.1: Geo-political administrative map of Ghana

Rainfall is usually convectional in type with frequent thunderstorms in the peak season. The mean annual rainfall varies between 1000 to 1700mm. The diurnal range of temperature varies between 8-14°C with daily minimum around 22°C and maximum around 37°C. Relative humidity is about 60% on average but could be very low in the harmattan season between December and March and very high in the rainy season. There is very limited cloud cover for most of the year leading to very hot days and cold nights. The vegetation is the forest-savannah transitional ecological type also undergoing a transition from the tropical rainforest in the southern districts to the tropical Sahelian savannah in the northern districts. The Brong-Ahafo region is referred to as the 'food basket' of Ghana since the vegetation supports the growth of food and cash crops almost all year round.

The area has undulating topography in the southern parts and is traversed severally rivers and their tributaries, hence the region is referred to as the main watershed of Ghana. Most of the rivers, like most West African rivers, get flooded and overflow their banks in the rainy season and dry out in the dry season between November and March. These have implications for the motorability of the roads in the study area, most of which are not tarred. Some of the areas, therefore, are hardly accessible by road in the rainy season and transportation to these villages is relatively more expensive and infrequent in the rainy seasons. The northern parts have large stretches of Sahelian plains with few relief features.

The total population of the seven districts is over 700, 000² but with most of the land dedicated to farming, the settlement areas are densely populated (175

people/square kilometres). About 120,000 are women of the reproductive ages (15 to 49 years). The annual population growth rate for the Brong-Ahafo region is about 2.2%² with only 20% of people living in the relatively urban district administrative capitals. The rural population lives in compounds in dispersed villages surrounded by farming lands. Educational attainment of the population is low especially among women with female illiteracy rate exceeding 40%.¹ There are several primary schools in the area (at least one per community) but fewer second cycle institutions (most districts have a maximum of two secondary or technical schools). There are only two diploma awarding post-secondary institutions in the area.

Subsistence farming is the main occupation but some engage in petty-trading primarily of farm produce.¹ Professing Christians (Catholics, Protestants and Pentecostals) form the majority religion (over 60%) in the area but there are also Muslims (16-19%) and traditionalists (<10%) with very famous churches and fetish shrines like the 'Kwaku Firi Shrine' located within the study area. The area is multi-ethnic but the Akans (Bonos, Asantes, Fantis and Akuapems) form the majority and their language (Akan/Twi) is spoken or understood by more than 90% of the population. There are other minority tribes such as the Banda, Mo, Badu, Dagarti, Sisala, Ga-Adangme and Grushis.

Most of the people live in shared compounds made of mud with thatched roofs or cement with aluminium roofing sheets. The median number of households per compound is six. There are over 77,000 compounds in the over 340 communities in

the study area. Compounds typically consist of related individuals from several generations and vary in size from 2-18 people with a median of 12.

Modern infrastructure is lacking in most of the communities with no electricity and potable water supplies.¹ Most of the large towns and the urban areas have markets which act as commercial nerve centres for trade within the districts. Specific days are designated as market-days on which days farmers cart their farm produce to these centres to sell and other goods and services are also bought and sold. Transport to the urban towns from most of these hard-to-reach areas is only available on these market-days.

3.1.3 Organisation of health services in Ghana and within the study area

3.1.3.1 The Ghana Health Service: The Ministry of Health (MoH) formulates policies and controls purchasing, regulation and coordination of service delivery in Ghana. It created Ghana Health Services (GHS) and Teaching Hospitals (THs) as autonomous agencies of service provision under a Ghana Government Act 525.³

The teaching hospitals act as tertiary care provision centres and support the training of health human resources. The GHS is tasked with the delivery of services to the rest of the populace. The GHS is organised administratively at three main levels: the national, regional and district levels (Table 3.1). Functionally, the GHS operates at five levels from the national to the community (village) level with three functional sub-divisions existing under the district level within DHMTs.

Table 3.1 Organisation of the Ghana Health Service showing the administrative hierarchy

Organisation of the Ghana Health Service	
Administrative Level Structure:	
National Level	<ul style="list-style-type: none"> - Ghana Health Service Council - Office of the Director General and Deputy Director General - Eight National Divisional Directors
Regional Level	<ul style="list-style-type: none"> - Regions are headed by 10 Regional Directors of Health Services (RDHS) - Supported by Regional Health Management Teams (RHMTs) - Regional Health Committees (RHCs)
Districts Level	<ul style="list-style-type: none"> - All districts are headed by District Directors of Health Services (DDHS) - Supported by the District Health Management Teams (DHMTs) - District Health Committees - Sub-district Health Management Teams (sDHMTs)

3.1.3.2 The structure of the DHMTs and health services in Newhints' districts: The DDHS together with a core-membership of DHMTs administer health within districts. Health districts usually cover a population of between 30,000 (in the small districts) to over a million in the metropolitan areas. In Newhints study area, the average health district size was just over a hundred thousand. At the district level, there is usually a district hospital (Level C facility) which acts as the primary referral centre for all the facilities within the district. These may be government-owned or quasi-government facilities owned by Christian missions (under Christian Health Association of Ghana (CHAG)), Muslim missions or corporate institutions such as the Volta River Authority Hospital in Akosombo. Service coverage and

quality varies between facilities but usually includes out-patient (OPD), in-patient, reproductive and child health (RCH), surgical, laboratory and imaging (X-ray, Ultrasonography) services. There is usually at least one medical doctor in each district hospital who acts the senior medical officer (SMO) in charge of the district hospital and a default core member of the DHMT. The range of services in the district hospital makes them the only facilities within the district capable of providing basic and (sometimes) comprehensive emergency obstetric and newborn care (BEmONC & CEmONC) services. In the Newhinta study area, only four of the seven districts (Kintampo North, Nkoranza South, Techiman and Wenchi) have established hospitals capable of providing CEmONC services. Two facilities (In Tain and Kintampo South) are being currently promoted to hospital status but lack functionality due to resource (human, equipment and range of services) constraints.

Districts are subdivided into sub-districts with a health management team (sDHMT) led by an experienced midwife or a medical assistant. These usually have Health Centres (HCs) located in the relatively bigger towns and act as the Level B facility. At this level, there is no doctor and so only basic OPD and RCH services are offered, sometimes supported by basic laboratory services. They organise outreach services to communities and run static clinics within their premises on set days. Complicated cases are then referred to the district hospital.

Community clinics or community-based health planning services (CHPS) compounds organised around village health committees form the Level A in the health delivery system at the district. Some communities do not have clinics but,

when they do, these clinics offer basic first aid to the community members and run immunization services. They also serve as point of antenatal static or outreach clinic stations and are manned by community health officers (CHOs) or community health nurses (CHNs). Their direct supervision is from the sDHMTs and they refer cases to the HCs or the district hospital.

In the relatively urban towns, there are some private providers including hospitals, maternity homes or small clinics. Each community or village usually has a traditional birth attendant (TBA), trained or untrained, and at least one health volunteer called the community-based surveillance volunteer (CBSVs) who support with community mobilization for health RCH services. Other community based health care providers are chemists/drug sellers and traditional healers.

In total, there are over 80 health facilities in the Newhints study areas made up of seven hospitals (four public) and the rest being HCs, community clinics/CHPS compounds and maternity homes; their distribution being skewed with large towns having higher concentrations of these facilities.

3.1.3 Relevant health policy framework for maternal and newborn health in

Ghana: The current policy of the MoH stipulates that every citizen above 18 years is to enrol on a national health insurance scheme (NHIS) to access free health care services in all accredited facilities at delivery point. The National Health Insurance Act (Act 650) 2003⁴ further established three types of insurance schemes one of which is the District Mutual Health Insurance Scheme (DMHIS) which would be

not-for-profit and subsidized by government in every district for residents.

Premiums are set by a decentralised body in each district to ensure affordability to the population served. Under the scheme, a baby is only covered when both parents are enrolled on the scheme.⁴

An MoH report stated that the maternal mortality ratio (MMR) for Ghana has been computed at different times by various methods and that national estimates vary from 214 to 740 per 100,000 live births.⁵ In response to the high maternal and child mortality rates with evidence that mostly the home deliveries end up in death, the government, in July 2008, secured a British government grant to make pregnancy and delivery care free of charge. Under this arrangement, the government directed that all pregnant women reporting for booking-ANC visit in any health facility should be enrolled free of charge onto the DMHIS to access free healthcare services till 3-months post-delivery which also extends to the newborn baby irrespective of place of delivery.⁶

3.2 The Newhints cluster-randomised controlled trial

The protocol for the Newhints intervention has already been published (appendix I). The aim of Newhints was to develop a feasible and sustainable community-based approach in rural Ghana to improve newborn care practices and care seeking during pregnancy and childbirth (including identification, referral and care seeking for neonatal illness), and by so doing improve neonatal survival. It was evaluated through a cluster randomised-controlled trial (CRT) design with clusters being

supervisory zones comprising groups of small villages, a big town or sub-section of relatively urban towns with 8-10 CBSVs.

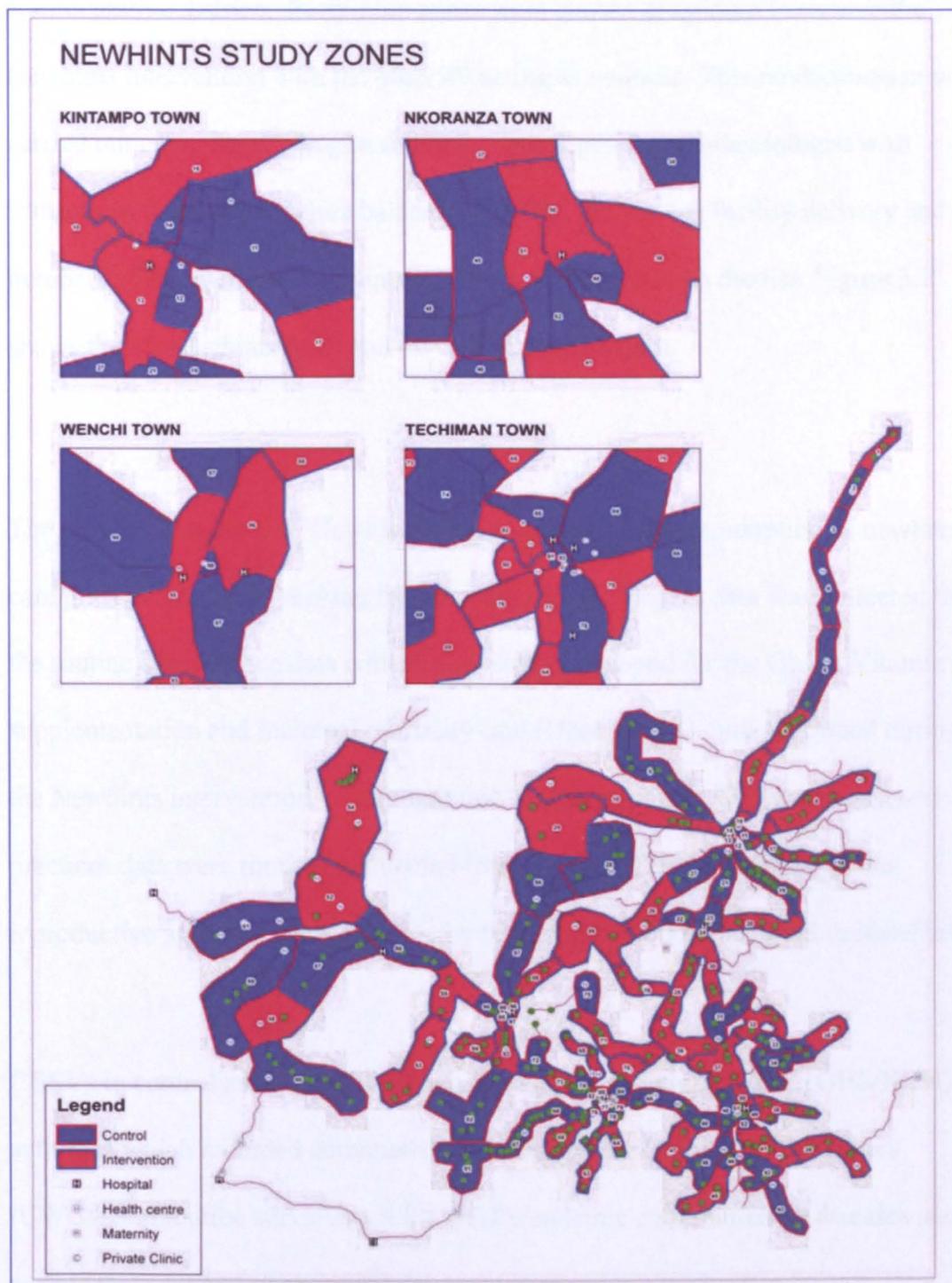


Figure 3.2: GIS Map of 7 health districts showing the Newhints zones (intervention and control) and health facilities with the big towns (inset).

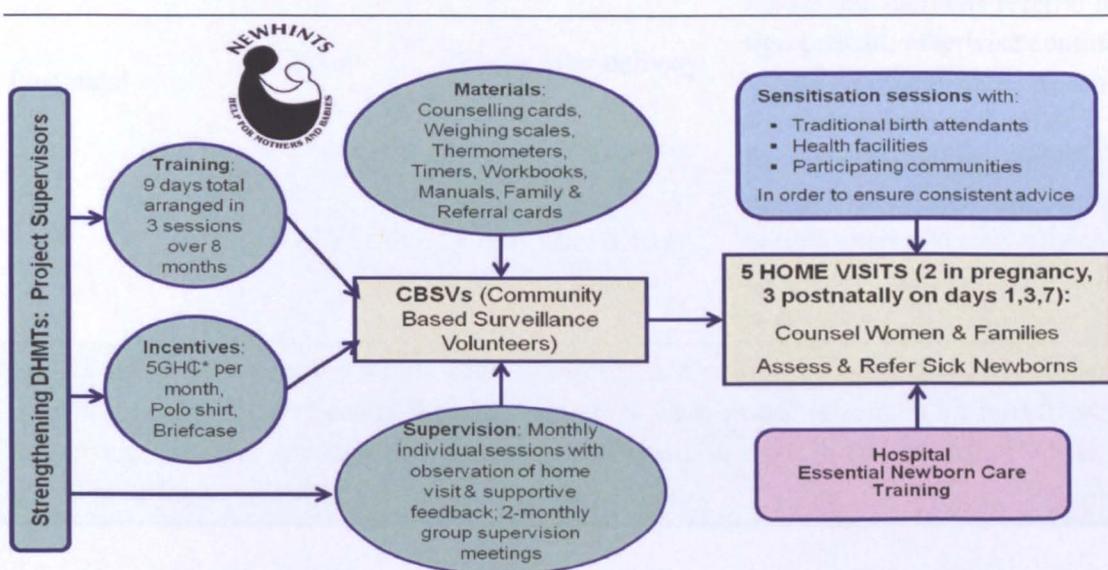
The study area was divided into 98 zones (Figure 3.2) using Geographical information systems (spatial locations), workload per zone (number of births) and other pragmatic considerations such as road linkages that will facilitate supervisor coverage using a motorbike and communities were grouped within GHS administrative districts. Forty-nine zones were chosen at random to receive the Newhints intervention with the other 49 acting as controls. This randomisation was carried out using Stata[®] programming by an independent epidemiologist with restrictions to ensure baseline balance in NMRs, percentage facility delivery and numbers of intervention/Newhints and control zones in each district. Figure 3.2 shows the 49 Newhints (red) and 49 control zones (blue).

The primary outcomes of Newhints were neonatal mortality, adoption of newborn care practices and care seeking for newborn illness. Impact data was collected from the routine surveillance data collection system developed for the Ghana Vitamin A supplementation and maternal mortality trial (ObaapavitA)⁷ and continued during the Newhints intervention.¹ Demographic, socio-economic, birth outcomes and practices data were routinely collected from the over 120 000 women of the reproductive ages under surveillance by trained fieldworkers external to Newhints.¹

CBSVs in control zones continued to carry out their routine DHMT (GHS/MoH) activities which included community mobilisation for Child Welfare Clinics (CWCs) and routine surveillance for locally endemic communicable diseases such as guinea worm and onchocerciasis.

It was estimated that a one year cohort of 15,200 babies would be sufficient to detect 25% reduction in NMR with 80% power; 20% reduction with 60% power; and 30% reduction with 93% power after adjusting for clustering. The trial therefore recruited from the 1st of November, 2008 to the end of December, 2009. Process evaluation (PE) data also collected on a sub-sample of women for the coverage, quality and timing of CBSV visits, referrals made, families' response, facility used and management at facilities as well as community reactions to the intervention.

3.3 The Newhints Intervention



*Ghana cedis (1 GH¢ approximately equal to 1 US\$ during trial)

Figure 3.3 Summary of the Newhints Integrated Intervention Package¹

Newhints was an integrated package supported through an elaborate and comprehensive organisational framework (Figure 3.3). The design was informed by a comprehensive formative research (FR) conducted before the start of the intervention. The core component was to train a network of existing community based surveillance volunteers (CBSVs) within the GHS to identify pregnant women

in the community and to conduct five home visits, two during pregnancy and three in the first week of life of the neonate.

Table 3.2: Newhints visits schedule showing timing and activities

Visit type	Newhints visit number	Time of visit	Visit activities
Ante-natal	One	On pregnancy detection	Dialogue and problem solve on birth preparation, facility delivery ANC attendance & ITN use
	Two	In 3 rd trimester of pregnancy	Dialogue and problem solve around immediate postpartum ENC ie. Immediate drying, wrapping and breastfeeding.
Post-natal	Three	Day of delivery	Assess & weigh the baby and facilitate referral if any danger sign is present. Otherwise normal or special care (for LBWIs) advised.
	Four	3 rd day after delivery	Assess and facilitate referral if danger sign present; otherwise continued normal or special care. Teach danger sign recognition to families.
	Five	7 th day after delivery	Assess, refer and facilitate compliance if danger sign present; otherwise continued normal or special care. Teach danger sign recognition to families. Encourage care seeking, immunization and CWCs.
<p>Follow-up visits were made within 24hrs of referral to check compliance, congratulate families who were able to comply or re-assess the baby when they were unable to comply for re-referral if the danger sign persists. An additional follow-up visit was also made to families of LBWIs on the 14th day after birth.</p>			

These visits were to address essential maternal and neonatal care practices, and to assess and refer very low birthweight (birthweight<1.5kg) and sick babies to health facilities for care; the focus of each visit is summarised in table 3.2.

3.3.1 Training of CBSVs: Over 400 community-based surveillance volunteers

(CBSVs), 80% of who were males (Figure 3.4) and already existing in the Ghana

Health Service, were convened and provided training to conduct the Newhints Home visits in the intervention zones. The training was conducted over nine days in three sessions. The first session lasted three days and CBSVs in groups of between 25 and 35 were trained in behavioural change communication, identification of pregnant and newly delivered mothers, counselling skills and essential newborn care. These were conducted between March and April 2008.

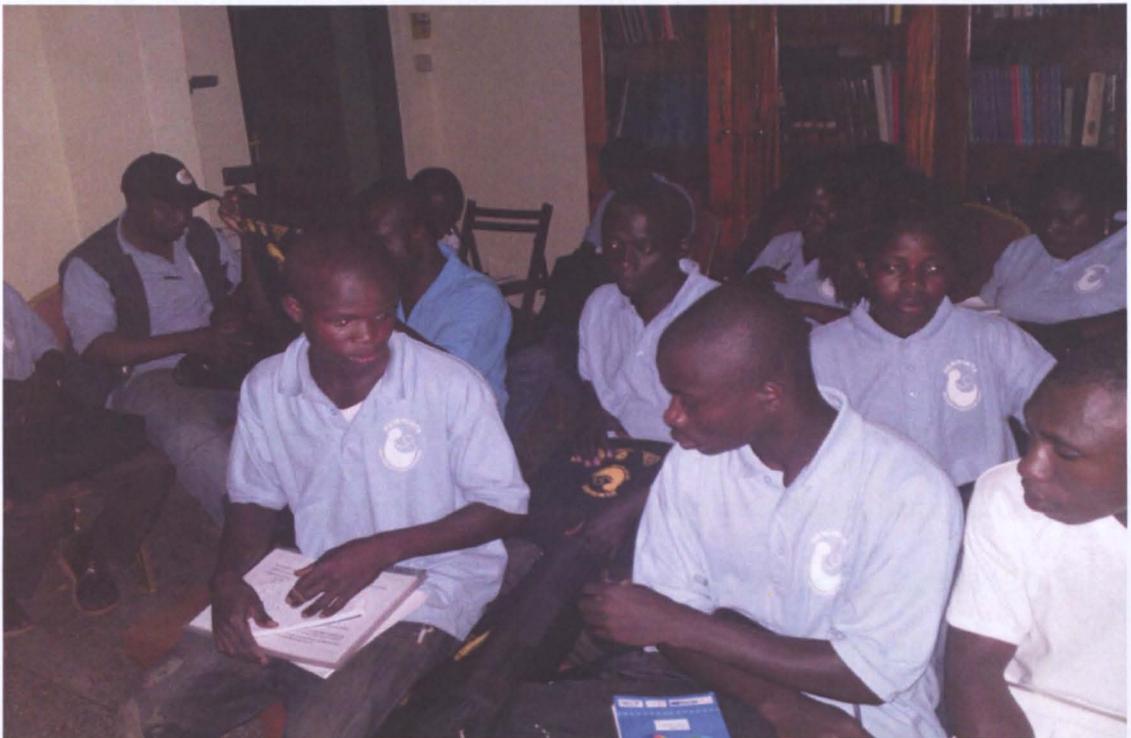


Figure 3.4: A session of the Newhints CBSVs during a training session

The second sessions (June to July, 2008) focussed on training the CBSVs in the assessment and referral of sick and low birthweight babies to health facilities. These sessions lasted four days and one day was dedicated to clinical practice sessions on newborn babies or sick newborns on admission within the main hospitals in the study area. After the in-hospital clinical assessments, the training focussed on decision making around referral, facilitation of referral (including dialogue and problem-solving around compliance barriers) and follow-up of referred babies. Training in these sessions involved interactive practical newborn

assessment video exercises using the WHO IMCI Computerized Adaptation and Training Tool (ICATT), group work, discussions of clinical case studies and scenarios and problem-solving skills. Referrals were made to the health facilities when one or more of nine danger signs (including baby not feeding well or stopped breastfeeding completely, having convulsed since birth, having developed yellow soles or palms, lethargy or moving only when stimulated, skin pustules, lower chest indrawing, fast breathing i.e. respiratory rate of 60 or more per minute validated by a second count and when the baby's temperature is too high (greater than 37.4°C or too low (less than 35.5°C)) were identified in the newborns or they very low birthweight (vLBW).

After the second sessions, CBSVs commenced work in their communities and were supported by intensive supervision. Two months into their surveillance activities, they were all reconvened for two-day refresher training sessions in October 2008. These refresher training sessions focussed on the assessment and referrals of sick babies and included one day of additional clinical practice within the main hospitals.

In the last two home visits to families, CBSVs were trained to promote care seeking for sick newborns by families. They discussed five main danger signs which families must seek care for when present in their newborns. These included babies refusing to breastfeed well or having stopped breastfeeding completely, when the baby develops fever or is too cold, when the baby develops jaundice on the skin, when the baby convulses and when the baby is lethargic or very weak. They

encouraged families to independently seek care when any of these signs were present in the baby even when the Newhints home visits were completed.

3.3.2 Materials and job aids for the CBSVs: Newhints CBSVs were provided with job aides for the delivery of the intervention (Figure 3.5).

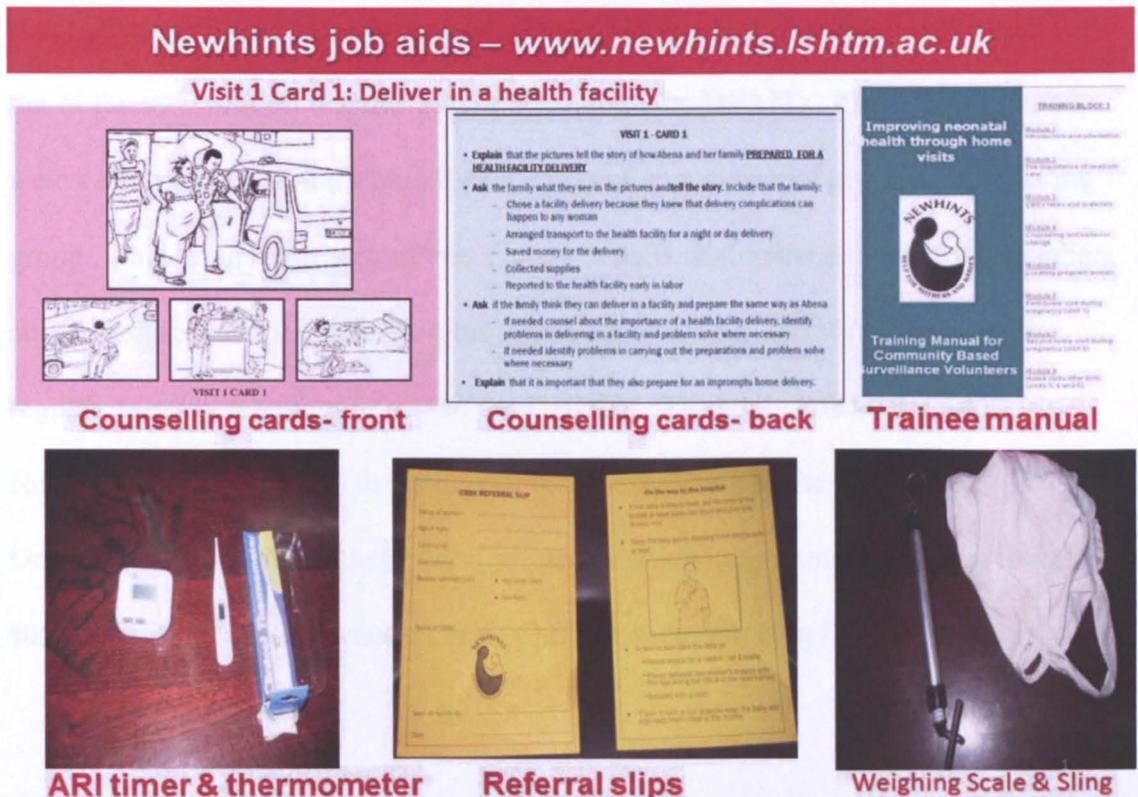


Figure 3.5: Materials (job aids) provided to CBSVs for the delivery of the Newhints Intervention

Each CBSV was provided with a bag containing a set of counselling (picture) cards for the delivery of the Newhints messages, workbooks to record visits with an incorporated diary for appointment booking, manuals from the training meant to be serve as revision material for CBSVs so that they retain the core elements of Newhints intervention, a digital clinical thermometer, a respiratory counter (stopwatch), a portable tubular weighing scale with a sling, referral cards to be

issued with every referral and a family cards to be given to all families visited in the Newhints zones.

3.3.3 Newhints Supervision and Incentives for Volunteers: Newhints involved developing a sustainable supervisory and remuneration structure for the CBSVs in accordance with intentions and plans of the GHS in order to make the eventual roll-out of the intervention feasible and to strengthen the DHMTs. The DHMTs, who were collaborators on the study, became part of an active trial progress monitoring group. This group consisted of two core Newhints trial management team members and one representative each from the seven collaborating DHMTs. They held regular monthly meetings at one of the DHMTs. The trial coordinator and Newhints study clinician (the author of this thesis) chaired these meetings. Decisions were made on the general implementation, community relations issues, sustainability of the intervention and volunteer motivation and supervision.

The CBSVs were supervised by dedicated project supervisors, District-based project supervisors (DiPS), who were project staff but based at the DHMTs. Supervision used the acronym '**GRIP**' to represent the core objectives of the supervisor-volunteer contacts. DiPS were trained to understand that supervisory contacts with the CBSVs should be aimed at achieving the following objectives:

- **Gather information from the CBSVs,**
- **Reinforce their skills,**
- **Improve the performance of the CBSVs and**
- **Provide support to CBSVs in their work when they needed it.**

There were two types of supervisory visits: individual supervisory sessions (ISS) and group supervisory sessions (GSS). In the ISS, DiPS conducted one-on-one visits to the CBSVs. At these visits, they enquired about the CBSVs progress of work and replenished their logistics where needed. At some of these ISS visits, the DiPS accompanied the CBSV into the community to conduct a visit to at least one newborn, usually a repeat of the last postnatal visits they had conducted. At these visits, the volunteer does the assessment whilst the DiPS observed the procedure for quality and CBSV coverage of the content of that visit. These were referred to as directly-observed supervision (DOS). The DiPS also simultaneously recorded their findings during the assessment by the CBSV and kept records of the CBSV performance on a structured DOS form to aid fed back to the CBSV on their performance after the visit.

In the GSS, DiPS put together CBSVs in a zone or, where zones are large, a part of the zone for a discussion on overarching issues affecting the Newhints work in the community.

The DiPS and the CBSVs were each provided workbooks to keep contact records both between the DiPS vs. CBSVs and the CBSVs vs. the families respectively.

Two Newhints research fellows regularly supervised and reviewed the DiPS' supervision by checking their records and going into the communities with them to monitor their CBSV supervision.

In keeping with the voluntary nature of the CBSVs activities and based on advice from the Ghana Health Service, each CBSV was given five Ghana cedis (approximately five US dollars during the trial) as incentive at the end of every month. They were also provided with branded polo shirts and the bag.

3.3.4 Sensitization sessions: As part of the intervention design, there were several supportive activities to promote the intervention and ensure women received consistent advice:

- i. All health workers, TBAs, Community leaders and Community members were invited to sensitization sessions where the Newhints intervention was introduced to them and their support solicited. Also,
- ii. Nurses and doctors who took direct care of pregnant women and newborns in the maternity/paediatric wards of the major hospitals, HCs and maternity homes in the area were invited and trained in a WHO-sponsored ENC training programme. The Newhints clinician (author of this thesis) who is also a national trainer in ENC coordinated and participated in the conduct of the training modules.

References for chapter three

1. Kirkwood BR, Manu A, Tawiah-Agyemang C, ten Asbroek G, Gyan T, Weobong B, et al. NEWHINTS cluster randomised trial to evaluate the impact on neonatal mortality in rural Ghana of routine home visits to provide a package of essential newborn care interventions in the third trimester of pregnancy and the first week of life: trial protocol. *Trials*. 2010; **11**: 58.
2. Ghana Health Service. Ghana Health Service-Brong Ahafo Region. 2005 [cited 11th April, 2012]; Available from: <http://www.ghanahealthservice.org/region.php?dd=6®ion=Brong Ahafo Region>
3. Government of Ghana. Ghana Health Service and Teaching Hospitals Act, <http://www.ghanahealthservice.org/ghscouncil.php>. Accra, Ghana: Government of Ghana,; 1996.
4. Government of Ghana. The National Health Insurance Act 650. In: Government of Ghana, editor. Accra, Ghana; 2003.
5. Ministry of Health Ghana. Consolidating the gains. Mid-term Review Report, 1999. Accra, Ghana; 1999.
6. National Health Insurance Authority Ghana. Providing free maternal and neonatal care through NHIS. Accra Ghana,; Ghana Health Service,; 2008.
7. Kirkwood B, Hurt L, Amenga-Etego S, Tawiah-Agyemang C, Zandoh C, al. e, et al. Effect of vitamin A supplementation in women of reproductive age on maternal survival in Ghana (ObaapaVitA): a cluster-randomised, placebo-controlled trial. *Lancet*. 2010; (375): 1640-49.

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CHAPTER FOUR: Methodology for the PhD

The results presented in the 5 papers in chapters 5 to 9 in this PhD are based on seven sources of data:

- Newhints surveillance (Section 4.1),
- Process evaluation (Section 4.2),
- Supervisory (DOS) visit records (Section 4.3),
- Evaluation of supervisor assessment quality (Section 4.4),
- CBSV workbook records (Section 4.5),
- Health facility assessment survey (Section 4.6) and
- In-depth interviews with mothers of referred babies, CBSVs who referred these babies and health facility care providers (Section 4.9).

These are described in the following sections and table 4.1 shows which data were used for which objectives in the PhD thesis. Copies of all data collection forms are attached in Appendix 3.

4.1 Newhints surveillance

The evaluation is based on all pregnancies that ended in a livebirth between 1st November 2008, after the October completion date of the Newhints training, and December 2009. In the surveillance system (first established for the ObaapavitA study¹ and continued through Newhints²) trained resident fieldworkers conducted 4-weekly home visits by to all women of reproductive ages for this data collection.

Table 4.1 Objectives of the PhD, Outcomes/Indicators/Determinants and Sources of data for analysis

Objective	Outcomes/Indicators/Determinants	Source of data
<p>1. To evaluate whether Newhints home visits has increased access to facility care for sick newborns and to evaluate whether Newhints has reduced inequities in access to care for sick newborns.</p>	<p>i. Referral compliance: % of babies referred who are taken to the health facilities & hospitals</p>	<p>PROCESS EVALUATION FORM; WOMEN & CBSV IDIs</p>
	<p>ii. Care seeking for newborn severe illness: % of newborns with severe illnesses taken to clinic/hospital for care in Newhints & control zones</p>	<p>BIRTH FORM (<i>SURVEILLANCE</i>)</p>
	<p>iii. As above by socio-economic quintiles (SEQ) & rural/urban residence</p>	<p>As above + PROFILE FORMS (<i>SURVEILLANCE</i>)</p>
<p>2. To explore the barriers, facilitators and key determinants to compliance with CBSV referrals of sick newborns with Newhints.</p>	<p>iv. Determinants of referral compliance Referral compliance by Socio-economic quintile (SEQ) & rural/urban residence</p>	<p>BIRTH, PROFILE & PROCESS FORMS (<i>SURVEILLANCE</i>) + CBSV WORKBOOK</p>
	<p>v. Barriers and facilitating factors to referral compliance</p>	<p>WOMEN & CBSV IDIs</p>
<p>3. To describe mothers' (families), CBSVs' and health providers' perspectives on the Newhints assessment and referral of sick newborns.</p>	<p>vi. Perspectives of key stakeholders (mothers, CBSVs & facility providers) on Newhints assessment & referrals</p>	<p>WOMEN, CBSV & FACILITY CARE PROVIDERS' IDIs</p>
<p>4. To assess the quality of care available for newborns within health facilities in the Newhints study area.</p>	<p>vii. Availability of inputs: essential infrastructure, drugs, equipment and human resource with requisite newborn care skills</p>	<p>HEALTH FACILITY ASSESSMENT; BIRTH & PROFILE FORMS</p>
	<p>viii. General services for newborns and essential newborn care practices</p>	
	<p>ix. Assessing demand against quality of care</p>	
<p>5. To evaluate the implementation of volunteer assessment and referral of sick newborns to health facilities within the Newhints home visits CRT and highlight the key lessons learned</p>	<p>x. CBSVs identify sick newborns in the community & refer: coverage & accuracy of assessments and referrals & families acceptance of visits.</p>	<p>ALL DATA SOURCES: BIRTH, PROFILE, PROCESS & DOS FORMS, HEALTH FACILITY ASSESSMENTS, DIPS EVALUATION & IDIS WITH WOMEN, CBSVs & HEALTH PROFESSIONALS</p>
	<p>xi. Families comply with referral: CBSV facilitation of referral compliance, CBSV conducting the follow-up visits</p>	
	<p>xii. Referred babies receive appropriate management: availability of drugs, equipment & supplies, health workers with newborn care skills, timely & appropriate care, supportive staff attitudes</p>	

This was changed to 8-weekly visits in July 2009 due constraints within the budget.³ Data collected included socio-demographic characteristics, pregnancies, births, morbidities, deaths, insurance enrolment and an inventory of household assets. They used pre-tested and standardised forms as follows:

Birth forms: These were administered to all women in the Newhints study at the first surveillance visit after birth. It included questions relating to the pregnancy, delivery and newborn care practices promoted by Newhints and specifically collected data on place of delivery, CBSV visits and referral coverage, health insurance enrolment, morbidities, care-seeking practices around severe newborn illnesses and neonatal mortality.

Profile forms: All pregnant women in the Newhints study received home visits from the fieldworkers to collect socio-demographic data. They also compiled a household assets inventory for each household and this data was used to generate wealth quintiles for the evaluation. The details of this are presented in the respective papers in chapters 5-9.

4.2 Process evaluation

Process data were collected from a sub-sample of 4006 recently-delivered mothers in the Newhints intervention zones. This comprised 64 mothers randomly selected each week from March to July 2009 from the trial surveillance database and all mothers who delivered between August and December 2009. These data covered

CBSV visits, assessments, referrals, compliance, type of health facility used, and care provided using pre-tested data collection forms, with closed- and open-ended questions, administered by trained field supervisors.

4.3 Newhints Supervisory (DOS) data

The DiPS (supervisors) completed records for 759 DOS visits between May and December 2009 in which newborn assessments were observed. Information extracted from these forms included the quality and content of the CBSV assessments, referrals made, advice given and repeat measurements made by the DiPS. These data were collated, on a continuous basis, for the evaluation of the validity of CBSV referrals.

4.4 Evaluation of quality of Supervisors (DiPS) Assessment

An evaluation of the reliability of the DiPS assessments was carried out in November 2009 at the four main hospitals by the study clinician (AM) assisted by a research officer. Each DiPS was asked to assess four babies and to record their findings onto a structured form. These assessments were observed by the study clinician who independently noted down his assessment findings. Both AM and the DiPS handed their forms to the research officer for compilation and these were entered into the Newhints database for the evaluation. Each DiPS' evaluation lasted between 50 – 60 minutes.

Clearance for the assessment was obtained from the matrons and the nurses/midwives on duty at post during on the day of the visit. Mothers whose babies were used for the assessment were also individually consented for the exercise. They were asked questions related to the babies' feeding and history of convulsion. The evaluation run for two weeks to allow for variability of the babies used for the evaluation and to allow the whole range of danger signs to be encountered.

4.5 Data extraction from CBSV workbooks

All workbooks used by CBSVs during the Newhints intervention were retrieved at the end of the trial fieldwork phase with the help of the supervisors (DiPS). Four hundred and twenty CBSV workbooks were collected and represented records of Newhints visits conducted by over 450 CBSVs since the workbooks were passed on to replacement CBSVs if one leaves the study either through resignation, emigration from the study area or death. CBSV records on visits made, referrals, age of the baby at the referral, danger sign(s) identified and the visit at which referral was made were extracted onto a standardized form by Newhints research officers under the supervision of study clinician (AM). Data were then submitted and entered into the Newhints database for analyses.

4.6 Health facility assessment (HFA) survey

Details of the HFA survey have already been published.⁴ In brief, all 86 health facilities (public and private) serving mothers and babies in the Newhints trial areas were visited between July 2009 and March 2010. Respondents were matrons (in-charge) of the maternity/newborn care units or the facility. The assessment covered: essential infrastructure, availability of equipment, drugs and supplies for newborn care; services provided; and clinical vignettes which depicted clinical case studies of newborns with respondents asked to describe the care that should be provided in these cases. Newborn conditions covered included resuscitation, thermal care, feeding practices, care of very low birthweight babies and discharge procedures. It also involved an inventory of skilled personnel who manage newborn illnesses and complications and the availability of equipment, drugs and supplies to support care for newborns.

An in-depth assessment was then carried out in eleven selected facilities where majority of births took place and where most sick newborns were treated. This in-depth assessment, as well as covering the details mentioned in the previous paragraph, explored more details on discharge procedures, care of low birthweight babies and care provider recognition of danger signs in the newborn.

4.7 Geographical Information System (GIS)

Trained field supervisors used portable geographical positioning system receivers to collect co-ordinates of all compounds within urban and large communities and centroids for all villages covered in the Newhints study area. They also collected data on roads and routes linking these villages as well as major landmarks in the big towns. These were entered into the Newhints database and merged with the list of compounds for easy analysis.

Also, the author of this thesis supervised the collection of coordinates of all health facilities serving the study population and classified these by the type of facility (hospital, health centre, community clinic or maternity home/clinic) and integrated into the study database. This was used to estimate the tracking distance from homes/villages to health facilities in the analysis of the relationship between distance from health facilities and referral compliance.

4.8 Management and analysis of quantitative data

4.8.1 Data processing: The Data management procedures used have been described in the published Newhints trial protocol (appendix 1).² These procedures were established in 2000 as part of the ObaapavitA trial using Visual FoxPro (version 6.0 Microsoft Corp Seattle WA USA),¹ and were modified to include new data collection forms developed for Newhints.² In the protocol, all forms collected on the field were manually checked for completeness and consistency before they left the field and were then submitted to a central office for review by field

coordinators. Forms were then collected from these site (field) offices on a weekly basis for submission to the computer centre for data entry.

All data were double-entered by two data entry clerks independently into Visual FoxPro® version 9.0 (Microsoft Corp. Seattle, WA, USA) programme with in-built validation checks. The two independent entries were compared by data supervisors who also conduct range and consistency checks on the data. Data inconsistencies and errors were flagged by the programme and these were resolved immediately by data managers in consultation with the trial management team (TMT). Where these errors could not be resolved by the TMT, photocopies of the forms with the errors were sent back to the field for correction and the problems were promptly resolved. Data were then cleaned tables and databases updated in four-weekly cycles and in time for the updated data to be used to generate field listings for the next 4-weekly visits by the field staff. Data were then transferred into Stata® version 11.2 (Stata Corporation, College Station, Tx., USA)⁵ for statistical analysis.

4.8.2 Outcome Definitions: Risks of referral was estimated as “the percentage of visited by CBSVs in the postnatal period who were referred for danger signs” .

Referral compliance risk was estimated as “the percentage of babies who were referred by CBSVs that were taken to a health facility (clinic/health centre/hospital)”.

Care seeking risk was defined as “the percentage of babies who were taken by families for care in a health facility out of those who were reported as severely ill”.

4.8.3 Explanatory variables and their measurements: Explanatory variables used in the analysis were classified into those related to the mother or the household, the baby and the Newhints study process as shown in table 4.2.

Table 4.2: Explanatory variables used in the regression modelling

Type of variable	Variable
Maternal/Household variables	Educational attainment; age; marital status; parity; history of previous child death; ANC attendance in pregnancy; enrolment on the NHIS; place of residence; occupation; socio-economic status (SES) or wealth quintile; ethnicity; religion; occupation; Distance from the closest main hospital.
Baby’s variables	Sex; place of birth; skilled attendance at delivery;
Newhints process variables	Coverage of CBSV visits by the second day after delivery; issuance of referral card

Association between compliance (and care seeking) and all other explanatory variables were assessed using simple chi-squared or Fisher’s exact tests.

Association between explanatory variables were also explored for the possibility of confounding in the relationship between the outcomes and the explanatory variables.

Asset indices were generated using principal components analysis from the comprehensive assets inventory and socio-demographic variables collected as part

of the surveillance (PROFILE FORM) for all pregnant women. These indices were used to split the study population into wealth quintiles (Q1 - Q5) with Q1 representing the poorest and Q5 the least poor 20% of the population.

ArcMap™ (ESRI Inc., Redlands CA, USA) version 10.0⁶ was used to produce GIS maps of the study area. Sources of referred babies were then superimposed on this base map and tracking distance between referred women's homes (in relatively bigger towns) or village centroids (for small villages) to the nearest main hospital was estimated in kilometres. Tracking distances were then categorised into 10km bands for fitting into regression models to determine whether distance from a facility determined compliance to CBSV referrals.

Percentages of referral, compliance and care seeking were estimated as the number of referrals by number of babies visited in the postnatal period, number of families that complied with CBSV referrals over the total number referred and number of severely ill newborns who were taken to a clinic or hospital for care among all those found to be severely ill respectively. Compliance with referral was the main outcome and was a binary variable. Also relative risks were modelled instead of odds ratio because when the outcome is not rare (prevalence > 10%) estimates of odds ratios tend to be exaggerated.^{7,8} for modelling risks using a binary outcome, several options have been suggested including the use of logistic regression models with post-estimation margins commands, Poisson regressions models or log binomial models.^{7,8} The first two options were not used because the logistic regression models failed to converge even with increased quadratures and the

Poisson was not used because it was thought that the compliance or not was not “strictly a Poisson process”. Log binomial models with the binomial family but the log link function was fitted for the modelling. This has the advantage of directly generating the risks and relative risks of the outcome.^{7, 8}

4.8.4 Univariable models: Marginal univariable models were fitted in generalised estimating equations (GEE) adjusted for clustering within Newhints zones for the outcome and the explanatory variables with robust standard errors. Wald test p-values were recorded and significance was assessed at the 10% level. Any variable whose association had a p-value of 0.1 or more was selected for inclusion into the multivariable model.

4.8.5 Multivariable models: Factors selected for inclusion into the multivariable determinants model were fitted into the cluster-adjusted multivariable model in GEE. The forward-stepwise approach, where factors (explanatory variables) will be introduced one at a time into the model and they will be retained in the final model only if they retain statistical significance at the 5% level in the model. The final multivariable model was then checked for fit and R^2 values used to assess the amount of the variability in the data explained by the model. All estimates will be presented with their 95% confidence intervals.

4.9 In-depth Interviews (IDIs) with key stakeholders

These were conducted with mothers whose babies were referred, CBSVs who referred these babies and health facility care providers in the four main hospitals where majority of sick newborns were taken after the CBSV referral. All IDIs were conducted by the lead author (AM) assisted by a research officer (EU) between June 2009 and March 2010 in Akan/Twi (the main language in the trial area) with sample sizes determined by saturation, where data were collected until no new information arose.

4.9.1 IDIs with mothers/carers of referred babies: Fifty-five mothers of referred babies were selected from the process database, using purposive sampling to give balance on age, education, marital status, residence, ethnicity and parity, and to include sufficient non-compliers as well as compliers. IDIs used a narrative approach supplemented by prompting using a pre-tested guide and covered all steps from the CBSV assessment, the referral, family decision making, compliance, experiences at the facility, outcome for the baby, and follow-up by the CBSV (Table 4.3). The IDIs also solicited their input into how future implementation of a similar intervention could be improved further.

More recent referrals were chosen over older ones, where available, to reduce problems with mothers' recall. Listings were generated for the fieldwork from the surveillance database. Due to the vast expanse of the area, logistical considerations were paramount in the planning for the IDIs. Potential respondents were arranged into geographically contiguous groupings for the fieldwork.

Table 4.3 Issues explored in the women's referral interviews

Issues explored in the women's referral interviews
<ul style="list-style-type: none">• Experiences with CBSV assessment and referrals,• Referral decision making and who the main gate-keepers were,• Barriers (and how they overcame them if applicable) and facilitators to compliance,• CBSV instructions around the referral• Facilities used for the care of their babies• Experiences at the health facilities.• Their perceptions on the quality of the Newhints assessment and referral and how to further improve upon it.

Interview guides were prepared for the interviews with support from my PhD supervisor and a social science expert who was also the advisor for the PhD and heavily supported the qualitative data collection. They were pretested in the study area for fine tuning before the start of interviews.

Written/thumb-printed informed consent were obtained individually from each respondent for the interview and the digital recording of the responses after the study objectives and potential benefits or harm (there was none) were explained to them and their questions addressed appropriately. Interviews were conducted in Akan (the local language) and lasted, on average, 60-90 minutes to maintaining respondent concentration and attention throughout.

4.9.2 IDIs with CBSVs: Twenty-one IDIs were conducted with CBSVs also purposively selected from Newhints' database to reflect variations of age, education, occupation, gender and district of residence. IDIs covered the number of babies they had referred, a detailed narrative for one of them (usually the most

complicated) and their referral experiences in general with perceptions on barriers and facilitators to compliance as well as families' reported experiences with facility care and also suggestions to improve future implementation of the system (Table 4.4).

IDIs lasted between 60-90 minutes and were digitally recorded. Notes on the setting, perception of the respondent's socio-economic status and nuances that contextualize responses were taken and combined with recordings for full English transcription into MicrosoftWord.

Table 4.4 Issues to be explored in the CBSVs' referral interviews

Issues to be explored in the CBSVs' referral interviews
<ul style="list-style-type: none"> • Families' acceptability (reception) for the CBSV assessment visit • Families' decision-making around the referral compliance and what the constraints and facilitators were • What made women/caretakers able to comply or not with their referrals: myths and norms, health insurance enrolment, advance preparation during pregnancy, proximity to hospitals or supportive family? • What has been the feedback from (or personal experiences with) families who complied with CBSV referrals about facility experiences? • What improvements should be made to the referral process?

Cognisant of the likelihood of respondent bias by CBSVs (because I conducted some of their training) and the possibility of them providing answers to meet what they thought were my expectations, CBSVs were reassured of confidentiality and that the IDIs were independent evaluations of the intervention and their frank responses will help improve the process. Responses were monitored closely during the interviews and appropriate corrections or alternative approaches to questioning

adopted when needed. However, in the conduct of previous evaluations CBSVs have expressed strong opinions freely on issues asked.

Like the women’s IDIs, interview guides were prepared and pretested before the start of interviews. Written/thumb-printed informed consent was obtained individually from each respondent for the interviews and the recordings after the study information was provided and discussed and their questions addressed appropriately. Interviews were conducted in Akan and lasted 60-90 minutes.

4.9.3 IDIs with Health workers: In-depth interviews were also conducted with 15 health facility staff (3 doctors including an expatriate paediatrician, 1 medical assistant, 9 nurses/midwives and 2 front-desk staff) from the four main referral hospitals (Holy Family Hospital (Techiman), St. Theresa’s Hospital (Nkoranza), Methodist Hospital (Wenchi) and Kintampo Hospital(Kintampo).

Table 4.5 Issues to be explored in the health facility care providers’ interviews

Issues to be explored in the Health workers’ referral interviews
<ul style="list-style-type: none"> • Use of special protocols for all sick newborns • Experiences with and perceptions of the appropriateness of the CBSVs’ referrals • Knowledge of the referral cards and whether it triggers special protocols for the newborn’s management and what exactly they do. • Challenges with dealing with the referred women and their sick newborns • Evidence for changes in women’s expectations about quality of and demand for care • Suggestions on what needs to change about the referral system

Issues explored in these interviews are as shown in table 4.5. They interviews were conducted in the both the Akan and English languages depending on the

respondent's choice. Written informed consent was obtained and confidentiality was assured. Interviews lasted 45-60 minutes and were digitally recorded.

For all the IDIs, sampling within strata were determined using saturation sampling (i.e. data were collected until no new information arose). Notes on the setting, perception of respondent's socio-economic status and nuances that contextualize responses were taken and combined with recordings for full English transcription and storage in Microsoft Word.

4.10 Processing and analysis of the IDIs

Notes and audio recordings were converted into detailed English transcripts (fairnotes) each day of the interview after returning from the field. Where this was not possible, detailed sketches of the key non-verbal information (that cannot be captured by the recorder) were written out in detail into a field notebook. These were then combined with other notes taken on the field and the digital recordings and typed out into Microsoft Word® (Microsoft Corp., Seattle, WA, USA) documents. Respondents are represented by a unique code in the transcripts known only by the interviewer (AM) and no linkages could be made between the respondent and the transcript except by this code. Respondent characteristics were also entered into a database and imported into the analysis software.

Analyses involved multiple readings of the transcripts to ensure familiarity with the data. A hybrid of the framework theory (where analytical categories/themes were generated based on the objectives of the analysis and used for the indexing/coding of the data) and the grounded theory (where themes are generated as they emerged from the coding of the data) was used. Analysis was done using NVIVO® 9.2 (QSR International Pty Ltd., Victoria, Australia) software.⁹ Themes were generated based on the objectives of the analysis for each set of interviews. Data were coded into these themes but when new themes emerged, they were created and data were then coded to them.

Simple frequencies were run on the on the main themes, respondent characteristics and responses provided in the IDIs. Language and text were analysed to provide context for the analysis. Relationships between themes were explored and hypotheses or models were generated to explain those relationships and interpreted. Report on the findings included quotations, which were either in the first person (from tape recordings) or in the third person (from my field notes). These were then triangulated with the quantitative data. During the data analysis, consistency between data sources (i.e. IDIs, and Observations) was assessed on a continuous basis to ensure internal validity.

More detailed descriptions of analyses conducted are included in each paper in chapters 5-9.

References for chapter four

1. Kirkwood B, Hurt L, Amenga-Etego S, Tawiah-Agyemang C, Zandoh C, al. e, et al. Effect of vitamin A supplementation in women of reproductive age on maternal survival in Ghana (ObaapaVitA): a cluster-randomised, placebo-controlled trial. *Lancet*. 2010; (375): 1640-49.
2. Kirkwood BR, Manu A, Tawiah-Agyemang C, ten Asbroek G, Gyan T, Weobong B, et al. NEWHINTS cluster randomised trial to evaluate the impact on neonatal mortality in rural Ghana of routine home visits to provide a package of essential newborn care interventions in the third trimester of pregnancy and the first week of life: trial protocol. *Trials*. 2010; **11**: 58.
3. Kirkwood BR, Manu A, ten Asbroek AH, Soremekun S, Weobong B, Gyan T, et al. Impact of the "Newhints" home visits intervention on neonatal mortality and care practices in Ghana: a cluster randomised controlled trial. Submitted. 2012.
4. Vesel L, Manu A, Lohela TJ, Gabrysch S, Okyere E, Owusu-Agyei S, et al. Quality of Newborn Care: A Health Facility Assessment in Rural Ghana Using Survey, Vignette and Surveillance Data. submitted. 2012.
5. StataCorp. *Stata Statistical Software: Release 11.2*. College Station, TX: StataCorp; 2009.
6. ESRI 2011. *ArcGIS Desktop: Release 10*. Redlands, CA: Environmental Systems Research Institute.; 2011.
7. McNutt LA, Wu C, Xue X, Hafner JP. Estimating the relative risk in cohort studies and clinical trials of common outcomes. *American journal of epidemiology*. 2003; **157**(10): 940-3.
8. Zou G. A modified poisson regression approach to prospective studies with binary data. *American journal of epidemiology*. 2004; **159**(7): 702-6.
9. QSR International Pty Ltd. *NVivo qualitative data analysis software: Version 9*; 2010.

SECTION C:
RESULTS - PAPERS FOR
PUBLICATION

CHAPTER FIVE: Access to Care

Increasing access to care for sick newborns: evidence from the Ghana Newhints trial

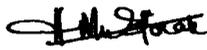
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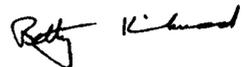
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To be submitted to: the Lancet

Candidates' Signature:



Supervisor's signature:



5.1 Introduction

Globally, an estimated 41% (3.3 million)¹ of child deaths occur in the first 28 days of life (neonatal period) and 99% of these are in low and middle income country (LMIC) settings.² Although causes of neonatal deaths are difficult to ascertain in LMIC settings because contacts are not made with health systems,³ three direct causes: infections, asphyxia, and prematurity or low birthweight and its complications account for approximately 80% of these deaths, the majority of which are preventable.^{1,4} Infection is the single most important cause contributing to about a third (and up to half in high mortality settings) of all neonatal deaths.^{5,6} Evidence exist that prompt detection and treatment of these infections as well as effective preventive measures can significantly reduce newborn deaths but complex interventions are not necessary to save newborn lives.^{7,8}

Care seeking for sick newborns is often poor;⁹⁻¹³ identified barriers include poor recognition of newborn illnesses,^{5,9,11,14} cultural practices such as seclusion after delivery and a belief in traditional remedies for some newborn illnesses, and geographical and financial inaccessibility to care.^{11,12,15,16} Most newborn deaths, therefore, occur at homes.^{17,18}

Family and community practices around care seeking for newborn illnesses can be strengthened by interventions to improve the identification of illness and the likelihood that families access appropriate care. Studies in rural India and Bangladesh have demonstrated that training community health workers/volunteers

(CHWs) to promote essential newborn care (ENC) practices and to identify and manage sick newborns (with home treatment and/or referral to hospital) can result in substantial (30%-62%) reductions in neonatal mortality.¹⁹⁻²¹ In addition, this approach has the potential to be equitable.²² No trials have been conducted to date in sub-Saharan Africa where the rates of neonatal mortality are highest.⁴

The Newhints cluster randomized controlled trial (CRT) in rural Ghana evaluated the impact of home visits by community-based surveillance volunteers (CBSVs) on ENC practices and neonatal mortality.²³ It achieved improved coverage of key ENC practices and non-significant reductions of 8% in neonatal deaths and 15% in deaths occurring after the first day, the period particularly targeted by the intervention.²⁴ The Newhints intervention adopted a three-pronged approach to increase access to care for sick newborns: firstly, during home visits in the first week of life, the time of the greatest vulnerability for the newborn,⁴ CBSVs weighed and assessed newborns for ten key danger signs and referred to health facilities when any were present. Doing this sent a strong message to the community about the vulnerability of newborns and re-enforced the second approach in which CBSVs promoted care seeking for newborn illness by counselling families on danger signs and emphasizing the need for urgent action when newborns fell ill. Thirdly, they dialogued and problem-solved with families around barriers to seeking care, both during its promotion and at the time of any referral. In addition, CBSVs counselled families on the importance of saving during pregnancy for emergencies.

In this paper, we present findings on the success of this three pronged approach and in particular assess whether it has reduced inequities in access to care for sick newborns.

5.2 Methods

Overview of Newhints trial design and study setting

Details of the Newhints trial design have already been published.^{23, 24} In brief, it was a cluster randomised controlled design with 49 of 98 supervisory zones randomised for Newhints implementation and 49 acting as controls receiving routine Ghana Health Service (GHS) programmes. In addition essential neonatal care training was done in the main health facilities covering both intervention and control zones. The trial covered seven contiguous districts (Figure 1) in Brong Ahafo Region in central Ghana and an area of approximately 12 000km² with a multi-ethnic and predominantly (80%) rural population of over 700 000,²⁵ engaged primarily in subsistence agriculture. Educational levels were low and communities, mostly served by unpaved roads, lacked modern infrastructure. Four main hospitals located in the relatively urban district capital towns of Techiman, Kintampo, Nkoranza, and Wenchi (figure 1) provided comprehensive emergency obstetric and newborn care services and were referral destinations for sub-district and community-based facilities. Distances between families and hospitals vary from a few metres for urban residents to over 80km from some villages.

Newhints was fully implemented by end of October, 2008. Data for impact as well as process evaluations were obtained through an on-going surveillance

system^{23,26} covering 120 000 women of child-bearing age. Trial participants are women with babies born between November 2008 and December 2009.

The Newhints Assessment and Referral

Training: Newhints is an integrated intervention package²⁴ which includes a 3-pronged approach to increasing access to care for sick newborns (figure 2). The core components of Newhints were training over 400 CBSVs, over nine days, to identify pregnant women and conduct five focused home visits (two during pregnancy and three in the first week after birth) to promote ENC practices, weigh and assess newborns and refer to health facilities if any of ten danger signs was present (table 1). CBSVs were provided with portable weighing-scales with colour-coded bands: red for weights below 1.5kg identifying very low birthweight (LBW) babies; yellow for weights between 1.5kg and 2.4kg identifying LBW babies; and green for weights of 2.5kg, a digital thermometer and a timer.

CBSV training involved interactive discussions, group exercises, and practical newborn assessment video exercises using the World Health Organization (WHO) IMCI Computerized Adaptation and Training Tool (ICATT). Two training days were dedicated for clinical assessments within hospitals where each CBSV assessed at least two babies.

Referral process: When CBSVs identified babies with any danger sign, they referred them to health facilities issuing them with a referral card to take along, and

counselled on the importance of keeping the baby warm and of frequent breastfeeding on the way to the facility. They also dialogued and problem-solved around barriers to compliance, followed-up within 24hrs to check compliance and discuss continued ENC (figure 2). If families had not complied, CBSVs re-assessed and referred again when danger signs persisted.

Promotion of care-seeking: At the 2nd and 3rd postnatal visits, CBSVs promoted the importance of prompt care seeking, and discussed five key illness signs: if the baby has stopped to feed or is not feeding well; if baby is too hot or too cold to touch (fever or hypothermia); if the baby is having difficult or fast breathing (dyspnoea); if the baby has become yellow all over the body (jaundice); and if the baby has become less active (lethargy).

Supervision: CBSVs were supervised by two trained district-based project supervisors (DiPS) in each district. DiPS carried out monthly visits to pay CBSV incentives, replenish their stocks, and provide supportive supervision by accompanying CBSVs into communities and directly observing them carry out home visits; in some of these visits they also carried out repeat assessments of babies. DiPS completed structured performance records for these directly observed supervision (DOS) visits and gave supportive feedback to CBSVs in order to reinforce their skills. The DiPS were supervised by Newhints research fellows.

Outcomes

Two main indicators were used to measure newborn access to care: referral compliance defined as the percentage of families who took their babies to health facilities after CBSV referrals; and overall care seeking defined as the percentage of newborns taken to a hospital or clinic among those reported by the mother in the first surveillance visit after birth (which took place up to 56 days) as having had severe illness.

Data collection

The evaluation of compliance achieved in Newhints as well as assessing whether Newhints has reduced inequities in care seeking for severely ill newborns was based on four types of data (the details are provided in the following sections): surveillance, process evaluation, assessment quality checks (of both CBSVs and DiPS) and in-depth interviews with mothers, CBSVs and health professionals.

Surveillance data: Trained resident fieldworkers identified pregnancies, births and deaths through 4-weekly home visits to all women of reproductive age. They collected data on socio-demographic characteristics for all pregnancies, including an assets inventory, and data on newborn care practices, morbidity, and mortality in the first visit after the birth was identified. From July 2009, this was amended to 8-weekly visits to follow-up pregnant women and their infants.

Process data: From March 2009, trained field supervisors visited a random subsample of 64 recently delivered women per week to collect process data on CBSV visits including coverage, assessments made, and referrals, and on compliance with referrals including its timing, facilities used, and care received. From August 2009, these data were collected from all women at the first surveillance visit after birth. In total 4006 women in the Newhints zones were interviewed.

Assessment quality checks: With the DOS form, the supervisors (DiPS) recorded the findings of the CBSVs' newborn assessment as well as their own independent findings during the observation of the CBSV home visits. In July 2009 the ability of the DiPS to assess newborns was evaluated by comparing outcome of each DiPS assessment of 4 babies to an independent assessment done by the study clinician (AM) and this took place in the 4 main hospitals in Kintampo, Nkoranza, Techiman and Wenchi.

In-depth interviews: In-depth interviews on perceptions and experiences with CBSV assessments, referrals and treatment at the health facility were conducted by the lead author (AM) with 55 recently delivered women whose babies were referred (up to 4 months after birth) purposively selected from the surveillance database to reflect balance with respect to maternal age, place of residence, ethnicity, and parity. IDIs on the same topics were also conducted with 21 CBSVs who referred babies, purposively selected to obtain balance on age, gender and place of residence, and 15 health facility staff (2 front-desk staff, 10 nurses/midwives, 3

doctors including a paediatrician) from the four main hospitals. IDIs were either in the local (Akan) language (women & CBSVs) or English (facility staff). They lasted 60-90 minutes and were digitally recorded; notes on interview settings were also made.

Data analysis

Statistical analyses were done using Stata[®] 11.2.²⁷ Principal components analysis was conducted on the assets inventory to generate a wealth index which was used to divide mothers into socio-economic status quintiles (SEQs). Simple tabulations and cross tabulations were done for the outcomes by key maternal (education, place of residence, SEQ), newborn (sex), and other factors (visited by the 2nd day after delivery, issuance of referral card) specific to Newhints. Percentage agreements and Kappa statistics were estimated for agreement between CBSVs and DiPS and between DiPS and clinician assessments. Generalised estimating equations with a log link function were used to estimate the risk ratios of care seeking by SEQs adjusted for clustering, together with 95% confidence intervals (CI).

Recordings from the IDIs together with the field notes were transcribed into English and exported into NVIVO[®] 9.2²⁸ for analysis. Analysis involved multiple reading of the transcripts to familiarise with the data, generation of themes (codes), systematic coding, and interpretation of text, language, trends, and relationships.

Ethical issues

Newhints and this evaluation received ethical approvals from LSHTM and KHRC.

Newhints is registered at clinicaltrials.gov (Number=NCT00623337).

Role of the funding source

The Newhints Home Visits CRT was funded by the World Health Organization, Save the Children's Saving Newborn Lives programme, from The Bill & Melinda Gates Foundation, and United Kingdom Department for International Development. Funders had no role in data collection, data analysis or writing of the report. The corresponding author had full access to all data and, together with the last author, the final responsibility to submit for publication.

5.3 Results

Almost 70% of 4006 recently delivered women in the process evaluation sub-sample reported receiving a postnatal visit from their CBSV, and that at these visits, almost all CBSVs assessed babies for danger signs (table 2). The quality of assessments was also high; CBSVs achieved near perfect agreement with the supervisors (Kappa=0.85-1.00) who in turn agreed almost perfectly with the study clinician (kappa>0.9).

Referral of sick newborns

10·0% of all babies assessed at postnatal visits had danger signs and were referred for facility care; compliance with these referrals was high with 86·0% taken to a health facility (table 2). The poorest families complied better than the least poor (figure 3), with an average 88·4% compliance among the four lower quintiles compared to 69·7% compliance among the least poor ($p=0.003$). Although rural families complied marginally more than urban ones, they did so less quickly (figure 4) with compliance within an hour less than half the level of their urban counterparts ($p=0.007$); this slower compliance persisted until after the second day. Maternal education did not affect compliance; this was over 85% across all educational levels (primary, secondary, or higher) and similar among those with and without formal education (86·4% vs. 85·9%; $p=0.91$).

In-depth interviews with non-compliers identified the family's perception that their baby was not severely ill and would improve spontaneously as the commonest reason for non-compliance. Unfortunately, some babies died as a result:

'I thought this was not my first time of having a baby so when he said my baby's breathing was "high", I ignored his advice; If I had listened, probably my child would be alive; the younger girls who listened to his advice have their babies now' (35-year-old Dagarti mother of three)

CBSVs advised families to go straight to hospitals, and the majority (74·0%) did so; this was higher among urban families than rural ones ($p=0.01$).

Apart from hospitals, urban residents next patronised clinics (including privately-owned facilities) whereas rural residents went to health centres (Table 3). Fifteen percent of all babies referred (18% of those whose families complied) were admitted to facilities; all admissions except one were to hospitals. Admission rates tended to be higher for babies from lower compared to higher SEQs (figure 3) and from rural compared to urban families (17·8% vs. 14·3%).

About one in four babies were sent home without treatment (table 4). This was most likely to occur at clinics; eight (44%) of the 18 babies sent there were not treated. IDIs revealed that some babies had died after contacts with health facilities and being sent home without treatment:

'...when we went there, they said there was nothing wrong with the baby. I told them the baby was seen (by the CBSV) and was said to be sick but the doctor said "look madam we are not joking here, sister (referring to the midwife) take the bed away from her and let her do what she wants" and so they sent us home....my baby was getting weaker and weaker from the time we returned from hospital and so I took her to clinic X (private). There, the doctor gave the baby blood transfusions but could not save her. Could you believe that the blood was obtained from the same hospital that turned us away? Meanwhile they said there was nothing wrong with the baby?' [35-yr-old Sisala mother who lost her 2nd twin]

Care-seeking for severely ill newborns

Five hundred and ninety babies were reported to have been severely ill in the baseline period, and 271 in the evaluation period (132 in the intervention zones and 139 in the control zones). Table 5 and figure 5 show that at baseline there was no difference in care-seeking for sick newborns between Newhints and control zones and that care-seeking tended to be higher among urban than rural families and increased with increasing SEQ. Post Newhints implementation care-seeking rates in the control zones were very similar to those at baseline. In contrast, care seeking rates were 43% higher (95% CI=18%, 72%; $p<0.0001$) in Newhints compared to control zones with the largest increases occurring among the poorest; care-seeking was increased by 94% (95% CI of increase=32%, 184%; $p=0.001$) by families from the poorest SEQ. As can be seen from figure 5, these increases occurred predominantly among rural and not urban families.

Information on both care seeking and CBSV assessments was available for a subsample of mothers who provided data for the process evaluation. This included 60 of the 132 babies in the Newhints zones perceived as severely ill, of whom 27 had been referred by CBSVs and 33 had independently recognised severe illness. The care seeking rates for the two groups were similar, 88.9% and 84.8% respectively.

5.4 Discussion

These results provide the first evidence from sub-Saharan Africa showing that implementing community volunteer-facilitated referral at scale within health system settings is feasible and potentially pro-poor. Newhints substantially increased sick

newborn access to facility care; CBSV referrals elicited 86·0% compliance (unequalled in any previous community newborn intervention) which was prompt and mainly to hospitals. Families' overall care-seeking for severe newborn illnesses increased from 55·4% in control zones (similar to baseline levels) to 77·3% within Newhints zones. This increased sick newborn access to care was pro-poor with referral compliance and care seeking higher among the poorest (or rural residents) compared to the least poor (or urban residents).

Pre-requisites for success of such interventions are assessments being carried out, on time, and accurately. Families should also be convinced to take sick newborns for care when asked. With only fourteen months of implementation, Newhints achieved 70% postnatal visit coverage which compares with 73% attained in the Projahnmo-2 trial (Bangladesh)²⁹ – one of the highest attained in a community newborn CRT although the latter only attained this in the third year of implementation. Assessment coverage in Newhints was almost universal (over 95%) and of high quality.

Newhints reduced all-cause neonatal mortality (NMR) by a modest and non-significant 9%; post-day1 NMR for singleton babies was reduced by 41% (2% - 65%, $p=0\cdot04$)²⁴ in the 7 months after improved implementation strategies were introduced. Given the high rates of compliance with referrals and the subsequent dramatic care-seeking differences between intervention and control zones, improved sick newborn access to care could have been a large contributor to any mortality reductions.

Newhints impact on access to care for sick newborns, in the short duration of implementation, was maximal among the poorest and rural families compared to the least poor and urban. This is contrary to predictions of the inverse equity hypothesis³⁰ that, in the short term, the impact of such interventions will be maximal among the least poor compared to the poorest. Several reasons could explain the pro-poor results: Newhints was specifically designed to be pro-poor by using existing CBSVs selected and living with community members. In rural settings more than urban, community cohesion is likely to be high and hence CBSV awareness and acceptability of CBSVs assessments and referrals may be higher. Geographical distance contributed to delays in care-seeking but did not prevent compliance of rural families despite the main hospitals (the preferred care seeking destination) being located in urban areas.

Directly-observed assessments as implemented in Newhints supervision were liable to the Hawthorne effect where volunteers may want to impress supervisors with their assessments skills. This supervisory approach had the advantage of directly reinforcing volunteer assessment skills and confidence but the quality of CBSV assessment may be an overestimate. In previous validation studies,^{12, 31, 32} physician assessments lagged behind CHWs' and since newborn danger signs such as breathing rate or chest indrawing can change rapidly,²⁹ the validity of comparisons remain questionable. Independent confirmation of referral compliance and care-seeking was not feasible: Newhints was not able to be present

at facilities to record care-seeking and facility record-keeping was poor with babies sent home without treatment having no contact records.

The Newhints referral process has potential for low specificity as newborns were referred to hospitals when any danger sign was present including signs of local infections. This may increase hospital workload, (admissions and bed-occupancy), costs, and possibly impact on quality of care delivered. However, newborn care experts advise prompt care-seeking at facilities on the slightest suspicion of infection.³³ Again, it may be cost-effective treating early disease (requiring minimal resources) to achieve better outcomes than severe disease. Moreover, it would be difficult for programmes to selectively reduce inappropriate care seeking without affecting appropriate ones.³⁴ The feasibility and adequacy of referring local infections to lower level facilities or training volunteers in their management should be explored in African settings.

Duality of expert opinions for community sick newborn management persists; some are in favour of community-based treatment whilst others warn about the possibility of drug resistance developing.³⁵ Studies in Asia successfully implemented home-based antibiotic treatment but subsequent referral of severely ill newborns elicited very low and often delayed compliance,^{19, 21, 36-38} with poor subsequent independent care-seeking for newborn illnesses.^{12, 31} In settings where access to health facilities is low, community treatment may be crucial to improve newborn survival but require more complex algorithms than those used in Newhints which may be difficult to feasibly implement at scale. Furthermore, if CHWs treat

rather than refer sick babies, this may appear to undermine messages that care-seeking at health facilities is important when families perceive their babies to be ill in the absence of the CHW. The results of this study show that, with adequate training and support CBSVs were able to identify sick newborns and facilitate compliance to referral even in an area where the majority of families rely on subsistence agriculture and have poor access to care.

Substantial delays at health facilities before first health worker contact, lack of requisite examination before sending babies back home without treatment, some of whom subsequently died, raised questions about the quality of health facility newborn care in the Newhints trial area. A subsequent assessment of newborn care in facilities within the trial area confirmed that, despite the Newhints facilitated essential newborn care training, quality was poor.³⁹ Quality newborn care at facilities is an imperative if community assessment and referral of sick babies is to succeed in saving newborn lives.⁷ Furthermore, if high quality is not guaranteed, it may fuel community mistrust in health services for newborns and impact adversely on care seeking practices. Sri Lanka reduced neonatal mortality from 75·5 (1945) to 12·9 (1991) only through coupling high care seeking with good-quality and accessible health care.³⁴

In conclusion, the Ghana Newhints intervention trial has demonstrated that home visits by community volunteers are an effective approach, at scale, for improving access to care for sick newborns. Harnessing the potential of CBSVs to link communities to health facilities through facilitated referrals is feasible,

acceptable and pro-poor but must be matched with improved quality of newborn care within health facilities.

Authors' contributions

The paper was drafted by AM, and reviewed and approved by all authors. BRK, AM, CTA, SOA, ZH were responsible for the design of the Newhints trial; AM, ZH, AtA, CTA, BRK for the data collection instruments; AtA, AM, CTA, BW, TG, SS, SOA for Newhints trial conduct; AM, SD, SAE, SS, BRK, AtA for database design and management; and AM for carrying out the analyses.

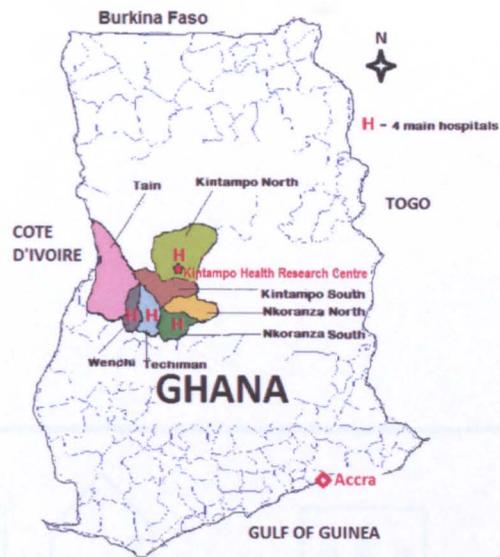


Figure 1: Map of Ghana showing Newhints trial districts.

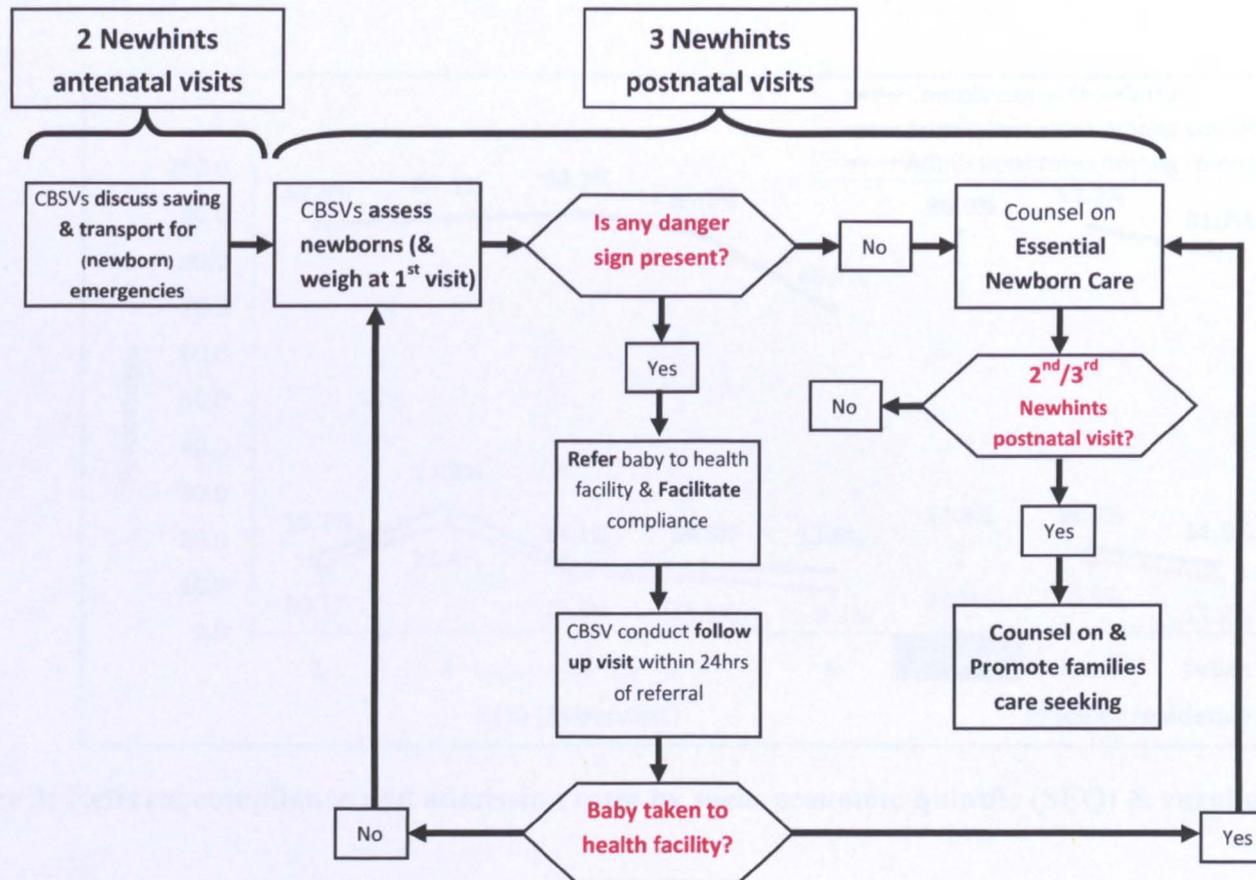


Figure 2: Newhints Algorithm for increasing access to care using 3-pronged assessment, referral and counselling approach

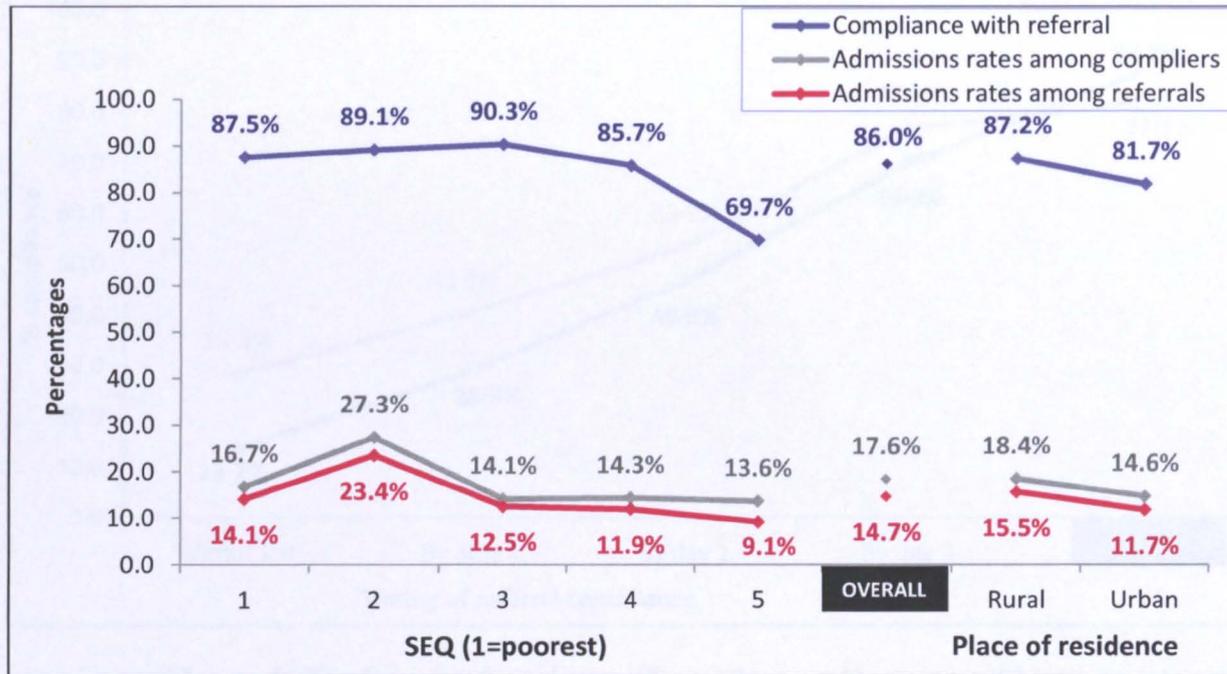


Figure 3: Referral compliance and admission rates by socio-economic quintile (SEQ) & rural/urban residence

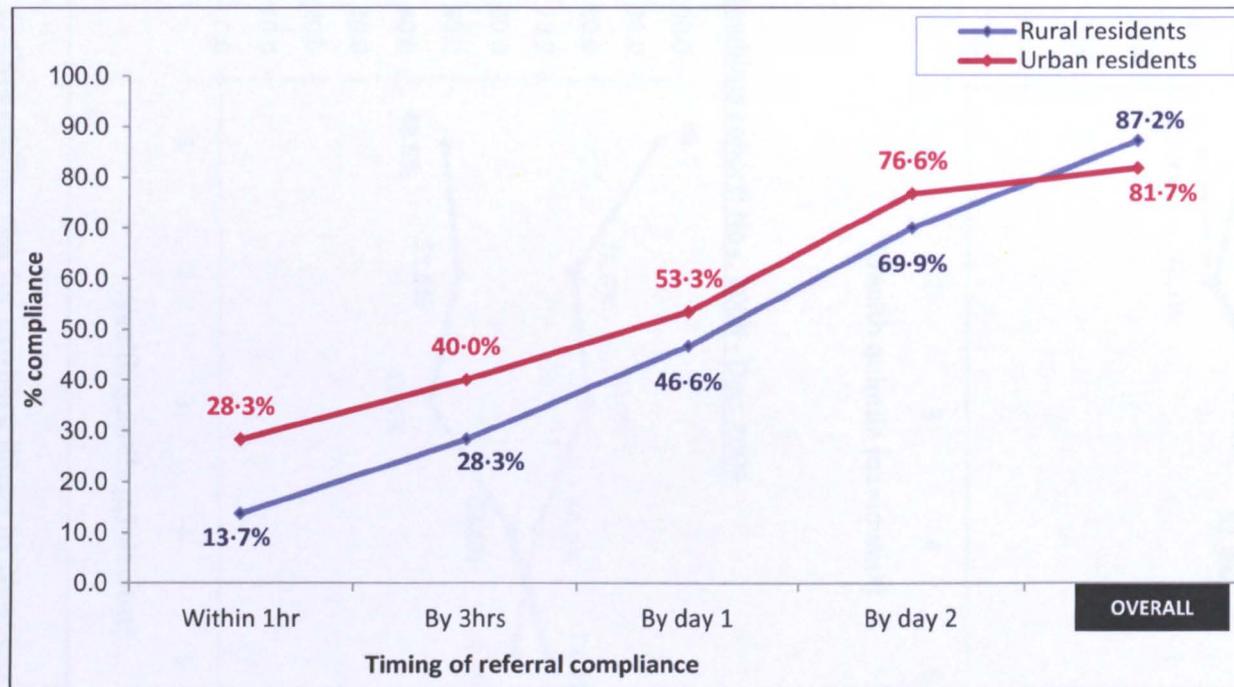


Figure 4: Timing of referral compliance by rural/urban residence

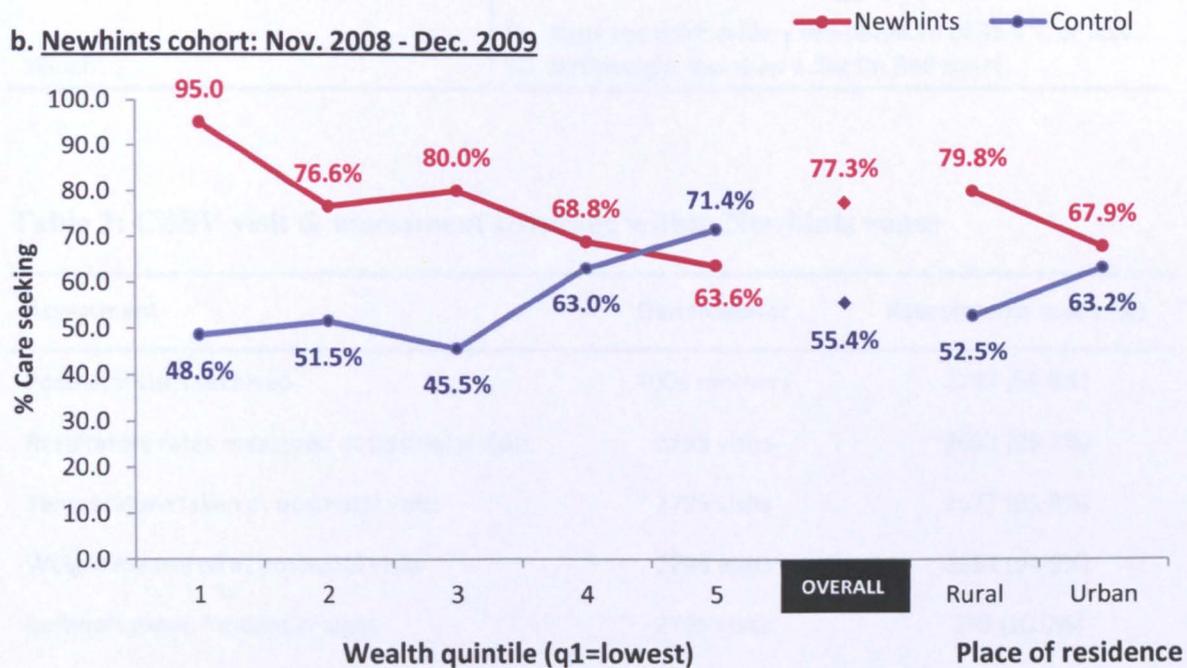
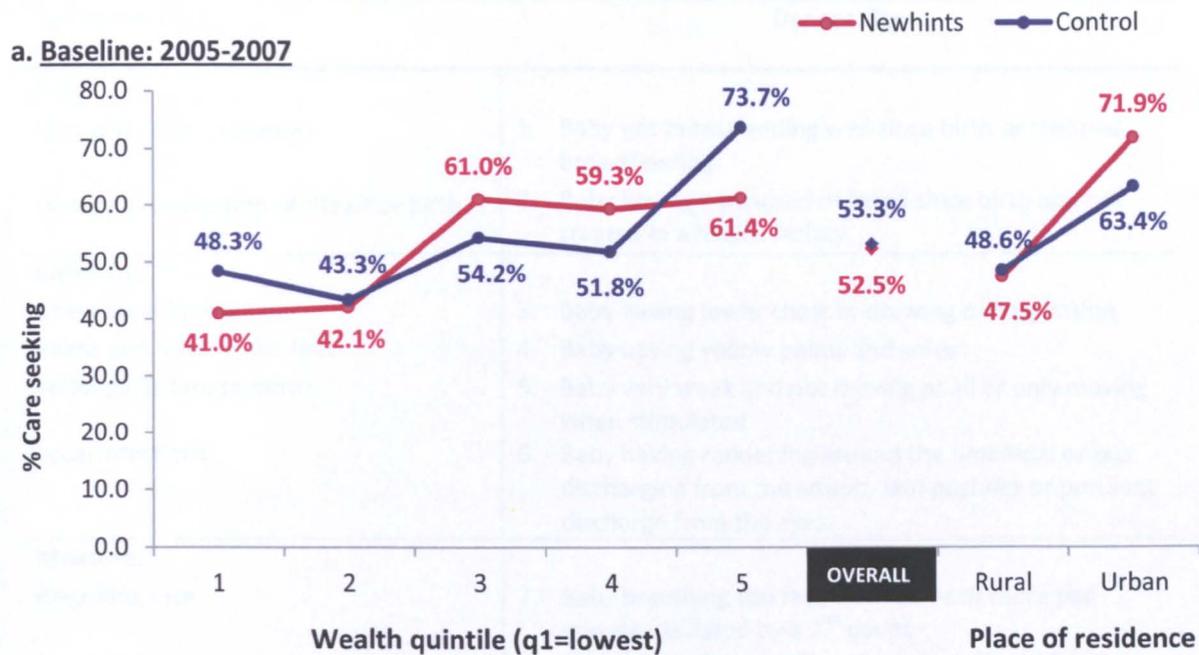


Figure 5: Care seeking risk for newborn illness by Newhints vs. Control across SEQs and by place of residence (a) Baseline & (b) Newhints cohort's

Table 1: Danger signs for newborns illness used in Newhints

Assessment	Danger sign
Ask: How is the baby feeding? History of convulsion or fits since birth.	1. Baby not breastfeeding well since birth or stopped breastfeeding 2. Baby having convulsed or fitted since birth and not treated in a health facility.
Check for: Chest movements Palms and soles of the feet Lethargy/failure to move Local infections	3. Baby having lower chest in-drawing on inspiration 4. Baby having yellow palms and soles 5. Baby very weak and not moving at all or only moving when stimulated 6. Baby having reddening around the <i>umbilicus</i> or pus discharging from the stump, <i>skin pustules</i> or purulent discharge from the <i>eyes</i> .
Measure: Breathing rate Temperature Weight	7. Baby breathing too fast: 60 breaths or more per minute validated by a 2 nd count 8. Baby having fever: axillary temperature of 37.5°C or more <p style="text-align: center;">OR</p> 9. Baby too cold: axillary temperature of 35.4°C or less 10. Birthweight less than 1.5kg (in Red zone)

Table 2: CBSV visit & assessment coverage within Newhints zones

Assessment	Denominator	Assessments made (%)
Postnatal visits received	4006 mothers	2795 (69.8%)
Respiratory rates measured at postnatal visits	2795 visits	2662 (95.2%)
Temperature taken at postnatal visits	2795 visits	2677 (95.8%)
Weight measured at postnatal visits	2795 visits	2651 (94.9%)
Referrals made for danger signs	2795 visits	279 (10.0%)
Compliance with referral	279 referrals	240 (86.0%)

Table 3: Facility used by rural/urban place of residence for complying mothers

Type of facility	Rural	Urban	Total
4 main hospitals	124 (66.3%)	37 (77.1%)	161 (68.5%)
Other hospitals	12 (6.4%)	1 (2.1%)	13 (5.5%)
Health centre	40 (21.4%)	3 (6.2%)	43 (18.3%)
Clinics [†]	11 (5.9%)	7 (14.6%)	18 (7.7%)
Total	187 (100%)	48 (100%)	235* (100%)

[†]*Clinics comprises private clinics, community clinics, CHPS compounds & maternity clinics/home*

**Details not available from 5 mothers who complied*

Table 4: Treatment given by facility type for complying mothers

Management	Type of facility used				Total
	4 main hospitals	Other hospitals	Health Centre	Clinics	
Admitted	38 (23.9%)	2 (15.4%)	1 (2.3%)	0 (0.0%)	41 (17.6%)
Treated at OPD	89 (56.0%)	6 (46.1%)	29 (67.4%)	10 (55.6%)	134 (57.5%)
Sent home without treatment	32 (20.1%)	4 (30.8%)	12 (27.9%)	8 (44.4%)	56 (24.0%)
Referred	0 (0.0%)	1 (7.7%)	1 (2.3%)	0 (0.0%)	2 (0.9%)
Total	159 (100%)	13 (100%)	43 (100%)	18 (100%)	233* (100%)

**Details not available from 7 mothers who complied*

Table 5: Risk ratios comparing care seeking in Newhints compared to control zones

(a) at baseline and (b) within the evaluation cohort

Socio-economic quintile (SEQ)	<u>Care seeking in Newhints vs. Control zones</u>			
	Baseline: 2005 - 2007		Evaluation cohort: Nov2008-Dec2009	
	Adjusted RR (95% CI)	p	Adjusted RR (95% CI)	P
OVERALL	1.00 (0.82, 1.24)	0.93	1.43 (1.18, 1.72)	<0.0001
SEQ1 (poorest)	1.00 (0.83, 1.21)	0.99	1.94 (1.32, 2.84)	0.001
SEQ 2	0.95 (0.64, 1.43)	0.82	1.53 (1.04, 2.25)	0.029
SEQ 3	1.18 (0.87, 1.59)	0.29	1.74 (1.20, 2.51)	0.003
SEQ 4	1.20 (0.82, 1.76)	0.35	1.10 (0.75, 1.60)	0.64
SEQ 5 (least poor)	0.82 (0.63, 1.07)	0.14	0.89 (0.59, 1.35)	0.60
Interaction of SEQ and intervention group	$\chi^2_{(4df)} = 5.60$	0.23	$\chi^2_{(4df)} = 9.73$	0.045

5.5 References

1. Oestergaard MZ, Inoue M, Yoshida S, Mahanani WR, Gore FM, al. e. Neonatal Mortality Levels for 193 Countries in 2009 with Trends since 1990: A Systematic Analysis of Progress, Projections, and Priorities. *PLoS Medicine*. 2011; **8**(8): e1001080.
2. Zupan J. Perinatal mortality in developing countries. *New England Journal of Medicine*. 2005; **352**(20): 2047-8.
3. Darmstadt GL, Zaidi Anita KM, Stoll B. Neonatal Infections: A Global Perspective. In: Remington JS, Klein JO, Wilson CB, Nizet V, Maldonado Y, editors. *Infectious Diseases of the Fetus and Newborn Infant*. 7th ed. Philadelphia: Saunders; 2011. p. 24.
4. Lawn JE, Cousens S, Zupan J, Lancet Neonatal Survival Steering T. 4 million neonatal deaths: When? Where? Why? *Lancet*. 2005; **365**(9462): 891-900.
5. Qazi SA, Stoll BJ. Neonatal sepsis: A Major Global Public Health Challenge. *Pediatric Infectious Disease Journal*. 2009; **28**(1 Suppl): S1-2.
6. Thaver D, Zaidi AK. Burden of neonatal infections in developing countries: a review of evidence from community-based studies. *The Pediatric infectious disease journal*. 2009; **28**(1 Suppl): S3-9.
7. Darmstadt GL, Bhutta ZA, Cousens S, Adam T, Walker N, de Bernis L, et al. Evidence-based, cost-effective interventions: how many newborn babies can we save? *Lancet*. 2005; **365**(9463): 977-88.
8. Stoll BJ. The global impact of neonatal infection. *Clinics in perinatology*. 1997; **24**(1): 1-21.
9. Syed U, Khadka N, Khan A, Wall S. Care-seeking practices in South Asia: using formative research to design program interventions to save newborn lives. *Journal of Perinatology*. 2008; **28** Suppl 2: S9-13.
10. Sutrisna B, Reingold A, Kresno S, Harrison G, Utomo B. Care-seeking for fatal illnesses in young children in Indramayu, west Java, Indonesia. *Lancet*. 1993; **342**(8874): 787-9.
11. Bazzano AN, Kirkwood BR, Tawiah-Agyemang C, Owusu-Agyei S, Adongo PB. Beyond symptom recognition: care-seeking for ill newborns in rural Ghana. *Trop Med Int Health*. 2008; **13**(1): 123-8.
12. Bang AT, Bang RA, Baitule S, Deshmukh M, Reddy MH. Burden of morbidities and the unmet need for health care in rural neonates--a prospective observational study in Gadchiroli, India. *Indian Pediatrics*. 2001; **38**(9): 952-65.
13. Kumar V, Mohanty S, Kumar A, Misra RP, Santosham M, Awasthi S, et al. Effect of community-based behaviour change management on neonatal mortality in Shivgarh, Uttar Pradesh, India: a cluster-randomised controlled trial. *Lancet*. 2008; **372**(9644): 1151-62.
14. Choi Y, El Arifeen S, Mannan I, Rahman SM, Bari S, Darmstadt GL, et al. Can mothers recognize neonatal illness correctly? Comparison of maternal report and assessment by community health workers in rural Bangladesh. 2010.

15. Okyere E, Tawiah-Agyemang C, Manu A, Deganus S, Kirkwood B, Hill Z. Newborn care: the effect of a traditional illness, asram, in Ghana. *Ann Trop Paediatr*. 2010; **30**(4): 321-8.
16. Awasthi S, Srivastava NM, Pant S. Symptom-specific care-seeking behavior for sick neonates among urban poor in Lucknow, Northern India. *Journal of Perinatology*. 2008; **28 Suppl 2**: S69-75.
17. UNICEF. Maternal and newborn health: where we stand: UNICEF; 2009. Report No.: 978-92-806-4318-3.
18. Martines J, Paul VK, Bhutta ZA, Koblinsky M, Soucat A, Walker N, et al. Neonatal survival: a call for action. *Lancet*. 2005; **365**(9465): 1189-97.
19. Bang AT, Bang RA, Baitule SB, Reddy MH, Deshmukh MD. Effect of home-based neonatal care and management of sepsis on neonatal mortality: field trial in rural India. *Lancet*. 1999; **354**(9194): 1955-61.
20. Bang AT, Reddy HM, Deshmukh MD, Baitule SB, Bang RA. Neonatal and infant mortality in the ten years (1993 to 2003) of the Gadchiroli field trial: effect of home-based neonatal care. *J Perinatol*. 2005; **25 Suppl 1**: S92-107.
21. Baqui AH, El-Arifeen S, Darmstadt GL, Ahmed S, Williams EK, Seraji HR, et al. Effect of community-based newborn-care intervention package implemented through two service-delivery strategies in Sylhet district, Bangladesh: a cluster-randomised controlled trial. *Lancet*. 2008; **371**(9628): 1936-44.
22. Haines A, Sanders D, Lehmann U, Rowe AK, Lawn JE, Jan S, et al. Achieving child survival goals: potential contribution of community health workers. *Lancet*. 2007; **369**(9579): 2121-31.
23. Kirkwood BR, Manu A, Tawiah-Agyemang C, ten Asbroek G, Gyan T, Weobong B, et al. NEWHINTS cluster randomised trial to evaluate the impact on neonatal mortality in rural Ghana of routine home visits to provide a package of essential newborn care interventions in the third trimester of pregnancy and the first week of life: trial protocol. *Trials*. 2010; **11**: 58.
24. Kirkwood BR, Manu A, ten Asbroek AH, Soremekun S, Weobong B, Gyan T, et al. Impact of the "Newhints" home visits intervention on neonatal mortality and care practices in Ghana: a cluster randomised controlled trial. submitted. 2012.
25. Ghana Health Service. Ghana Health Service-Brong Ahafo Region. 2005 [cited 11th April, 2012]; Available from: <http://www.ghanahealthservice.org/region.php?dd=6®ion=Brong Ahafo Region>
26. Kirkwood BR, Hurt L, Amenga-Etego S, Tawiah C, Zandoh C, Danso S, et al. Effect of vitamin A supplementation in women of reproductive age on maternal survival in Ghana (ObaapaVitA): a cluster-randomised, placebo-controlled trial. *Lancet*. 2010; **375**(9726): 1640-9.
27. StataCorp. Stata Statistical Software: Release 11.2. College Station, TX: StataCorp; 2009.
28. QSR International Pty Ltd. NVivo qualitative data analysis software: Version 9; 2010.

29. Darmstadt GL, El Arifeen S, Choi Y, Bari S, Rahman SM, Mannan I, et al. Household surveillance of severe neonatal illness by community health workers in Mirzapur, Bangladesh: coverage and compliance with referral. *Health Policy & Planning*. 2010; (25): 112-24.
30. Victora CG, Vaughan JP, Barros FC, Silva AC, Tomasi E. Explaining trends in inequities: evidence from Brazilian child health studies. *Lancet*. 2000; **356**(9235): 1093-8.
31. Darmstadt GL, El Arifeen S, Choi Y, Bari S, Rahman SM, Mannan I, et al. Household surveillance of severe neonatal illness by community health workers in Mirzapur, Bangladesh: coverage and compliance with referral. *Health Policy & Planning*. 2010; **25**(2): 112-24.
32. Baqui AH, Arifeen SE, Rosen HE, Mannan I, Rahman SM, Al-Mahmud AB, et al. Community-based validation of assessment of newborn illnesses by trained community health workers in Sylhet district of Bangladesh. *Trop Med Int Health*. 2009; **14**(12): 1448-56.
33. Stoll B. Infections of the neonatal infant: pathogenesis and epidemiology. In: Behrman RE, Kliegman RM, Jenson HB, editors. *Nelson's Textbook of Paediatrics*. 17th ed. Philadelphia: Saunders, W. B; 2004. p. 623-40.
34. Amarasiri de Silva MW, Wijekoon A, Hornik R, Martines J. Care seeking in Sri Lanka: one possible explanation for low childhood mortality. *Social Science & Medicine*. 2001; **53**(10): 1363-72.
35. Winch PJ, Gilroy KE, Wolfheim C, Starbuck ES, Young MW, Walker LD, et al. Intervention models for the management of children with signs of pneumonia or malaria by community health workers. *Health Policy & Planning*. 2005; **20**(4): 199-212.
36. Bang AT, Bang RA, Stoll BJ, Baitule SB, Reddy HM, Deshmukh MD. Is home-based diagnosis and treatment of neonatal sepsis feasible and effective? Seven years of intervention in the Gadchiroli field trial (1996 to 2003). *J Perinatol*. 2005; **25** Suppl 1: S62-71.
37. Bang AT, Bang RA, Tale O, Sontakke P, Solanki J, Wargantiwar R, et al. Reduction in pneumonia mortality and total childhood mortality by means of community-based intervention trial in Gadchiroli, India. *Lancet*. 1990; **336**(8709): 201-6.
38. Bhutta ZA, Memon ZA, Soofi S, Salat MS, Cousens S, Martines J. Implementing community-based perinatal care: results from a pilot study in rural Pakistan. *Bulletin of the World Health Organization*; 2008. p. 452-9.
39. Vesel L, Manu A, Lohela TJ, Gabrysch S, Okyere E, Owusu-Agyei S, et al. Quality of Newborn Care: A Health Facility Assessment in Rural Ghana Using Survey, Vignette and Surveillance Data. submitted. 2012.

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CHAPTER SIX: Compliance with Referral

Achieving high compliance with community referral of sick newborns in the Newhints intervention in Ghana: determinants, barriers and facilitating factors.

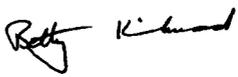
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6.1 Introduction

Forty-one percent of all child deaths occur within the first 28 days (neonatal period) of life(Black et al., 2010; Lawn et al., 2005; Oestergaard et al., 2011; Shiffman, 2010). Most newborn deaths occur at home without health systems contact and the majority from preventable causes(Z. Bhutta et al., 2004; Edmond et al., 2008; Lawn et al., 2005; Qazi & Stoll, 2009).

Care seeking practices for sick newborns in low and middle income (LMIC) countries are poor(Bazzano et al., 2008; Kumar et al., 2008; Mohan et al., 2008; Sutrisna et al., 1993; Syed et al., 2008); Bazzano et al(Bazzano et al., 2008) found that only 39% of severely ill newborns were taken to a clinic or hospital in Ghana and studies in Asia have reported even lower rates(Bang et al., 2001; Sutrisna et al., 1993; Syed et al., 2008). Many barriers beset families seeking care for newborn illnesses including failure to recognize illnesses, costs, distance to health facilities and negative health provider attitudes(Awashthi et al., 2008; Bazzano et al., 2008; Choi et al., 2010; Mohan et al., 2008; Sutrisna et al., 1993; Syed et al., 2008).

Community-based strategies to improve access to care for sick newborns include: home visits by community health workers/volunteers (CHWs) including assessment of newborns for danger signs and provision of treatment or referral(Bang et al., 2005; Baqui et al., 2008; Bhandari et al., 2012; Z. A. Bhutta et al., 2011; Gary L. Darmstadt et al., 2010a; Kumar et al., 2008); or participatory action-learning with women's groups(Azad et al., 2010; Baqui et al., 2008; Manandhar et al., 2004;

Tripathy et al., 2010). The first approach was endorsed by the World Health Organization (WHO) and United Nations Children's Fund (UNICEF) in their joint statement(WHO/UNICEF., 2009) promoting home visits as a strategy for improving newborn survival. In this statement they recommend referral to hospital or where this is not possible referral for out-patient treatment at first level facilities. They do not currently recommend treatment in the home with CHWs giving injectable antibiotics; although this has been successful in trial settings in India(Bang et al., 1999) and Bangladesh(Baqui et al., 2008), there are concerns about its safety and sustainability in routine settings. This includes costs involved and concerns about antimicrobial resistance(Winch et al., 2005b).

Of the trials evaluating the home visits approach, only the Bangladesh Projahnmo trials have reported the compliance rates achieved with CHW referral. In Projahnmo-1 in Sylhet(Baqui et al., 2008), compliance was linked to severity of illness and number of signs identified with 33.9% of babies identified as having signs of very severe illness taken to a qualified provider compared to 24.4% of babies with two or more signs and only 9.6% of babies with only one sign indicative of possible severe illness; the overall rate was 19.1%. In this trial families were offered treatment from the CHWs, including injectable antibiotics, is they were unwilling to comply with the referral; 54.2% took this option. A higher compliance rate (53.9%) was achieved in the Projahnmo-2 trial in Mirzapur(Gary L. Darmstadt et al., 2010a); CHWs in this trial could give some home treatment but were not able to give injectable antibiotics.

In this paper we present findings from a detailed evaluation on the determinants, barriers and facilitating factors to the high (86%) referral compliance achieved in the Ghana Newhints trial (B. R. Kirkwood et al., 2010; Manu et al., 2012), the first evaluation of the home visits strategy in sub-Saharan Africa, in order to inform the implementation of this strategy in other settings.

6.2 Methods

Study setting

This process evaluation was conducted within the Newhints home visits cluster randomised trial (CRT), which took place in seven districts in central Ghana covering a predominantly rural (80%) multi-ethnic population of over 700,000 (Ghana Health Service, 2005). Educational levels are generally low with subsistence farming the main economic activity. Rural communities lack modern infrastructure such as electricity and potable water, and are linked by dirt roads. Four of the district hospitals provide the highest level of care available and act as referral destinations for health centres in sub-districts and the community clinics that exist in some villages, some of which are at considerable distances from these hospitals.

The Newhints Home Visits CRT

The protocol for the trial, including details of the Newhints intervention, has been published (B. R. Kirkwood et al., 2010). It evaluated the impact of five home visits,

two during pregnancy and three in the first week of life, on neonatal mortality and newborn care practices. Existing community-based surveillance volunteers (CBSVs) in 49 of 98 supervisory zones were trained to promote newborn care practices at these visits and to assess and refer sick newborns to health facilities. After identifying a sick newborn, they issued a yellow referral card, problem-solved around barriers to compliance and encouraged promptness. They also made follow-up visits within 24 hours to check compliance and referred again if mothers had failed to comply and the danger signs persisted. CBSVs kept records in their workbooks of all visits including referrals. They were supervised by trained district-based project supervisors (DiPS) who visited them monthly to replenish their stocks and to observe them conducting a home visit. Details of the CBSVs performance were recorded on a standard form and feedback provided.

Data collection

The evaluation of referral compliance uses data from several sources: the surveillance system of all women of reproductive age; process data collected from a sub-sample of recently delivered women; CBSV workbooks; and in-depth interviews (IDIs) with mothers of referred babies and with CBSVs.

Surveillance data collection: Surveillance data on pregnancies, births, deaths and socio-economic data (including an asset inventory) were collected by resident fieldworkers through 4-weekly visits to all consenting women of reproductive age. Geographical co-ordinates of all health facilities, rural villages (centroids) and compounds in the main towns were also collected using geographical information

systems. The Newhints evaluation was based on all live births that took place between 1 November 2008 (the month after full implementation of the Newhints intervention was achieved) and 31 December 2009.

Process sub-sample: Process data on CBSV visits, assessments, referrals, compliance, health facilities used, and care provided were collected by field supervisors from a sub-sample comprising 64 randomly selected recently-delivered mothers per week from March to July 2009 and all recently delivered mothers from August to December 2009.

CBSV workbooks: Workbooks were retrieved from CBSVs at the end of the trial and data extracted by trained research officers on visits, danger signs identified and referrals made using standard forms.

In-depth interviews and referral narratives: All IDIs were conducted by the lead author (AM) assisted by a research officer (EU) between June 2009 and March 2010 in Akan/Twi (the main language in the trial area) with sample sizes determined by saturation, where data were collected until no new information arose. Fifty-five mothers of referred babies were selected from the process database, using purposive sampling to give balance on age, education, marital status, residence, ethnicity and parity, and to include sufficient non-compliers as well as compliers. IDIs used a narrative approach supplemented by prompting using a pre-tested guide and covered all steps from the CBSV assessment, the referral, family decision

making, compliance, experiences at the facility, outcome for the baby, and follow-up by the CBSV.

IDIs were also conducted with 21 CBSVs who had referred babies, purposively selected to reflect variations of age, education, gender and district of residence. IDIs covered the number of babies they had referred, a detailed narrative for one of them (usually the most complicated) and their referral experiences in general with perceptions on barriers and facilitators to compliance as well as families' reported experiences with facility care.

IDIs lasted between 60-90 minutes and were digitally recorded. Notes on the setting, perception of the respondent's socio-economic status and nuances that contextualize responses were taken and combined with recordings for full English transcription into MicrosoftWord.

Data analysis

Determinants analyses were done using Stata 11.2. Factors considered included sex of baby, maternal age, education, parity, previous facility contacts through antenatal care clinic (ANC) attendance or facility delivery, enrolment on the national health insurance scheme (removal of care costs), saving for emergencies during pregnancy, rural/urban residence, distance from the main hospitals and socio-economic quintile (SEQ). SEQ was derived from an index calculated from principal components analysis of household assets which was used to rank mothers

and divide them into quintiles. ArcMap® 10.0 was used to estimate tracking-distance between villages to the closest main district hospitals and categorised as within 20km and 20+ km groups. Generalised estimating equations (GEE) for binary outcomes using the log link function and exchangeable correlation structure, were used to estimate the risk ratios of compliance, adjusted for clustering by supervisory zone. Univariable models were fitted for overall and early (within 3hrs of referral) compliance and the potential determinants (table 1) and then a multivariable model fitted including all those factors with p-values less than 0.1.

Analysis of IDIs was done in NVIVO version 9.2 with analytical themes generated after repeated readings of the transcripts. Analysis involved exploration of language, relationships, trends and their interpretations.

Ethical considerations

The Newhints trial received ethical approvals from the LSHTM, KHRC, and GHS ethics committees. It is registered at [clinicaltrials.gov\(NCT00623337\)](https://clinicaltrials.gov/ct2/show/study/NCT00623337).

Role of the funding source

Newhints was funded by the WHO, Save the Children's Saving Newborn Lives programme, from The Bill & Melinda Gates Foundation, and the UK Department for International Development (DFID). Funders had no role in data collection, data analysis or writing of the report. The corresponding author had full access to all data and the final responsibility to submit for publication.

6.3 Results

Determinants of compliance

In total, CBSV workbooks included records for 833 newborns identified with one or more danger signs and referred at postnatal visits, the majority of whom, 710 (85.2%) complied. Only a single danger sign was present in 655 (78.6%) of these referred babies. Table 1 shows that the top five danger signs identified were signs of infection. Local infections (of the skin, eyes or umbilicus) was the most commonly identified danger sign present in 45% of referred babies (Table 1) and was the only reason for referral in 37% of those referred. With the exception of local infections and convulsions the other danger signs usually occurred together.

Compliance was high for all danger signs (range=78.9%-90.6%), including when they occurred in isolation, except for poor movement which occurred alone in only six newborns. There was weak evidence to suggest that overall, compliance was higher when more than one sign was identified with the results showing that compliance was an additional 5.2% (-0.1%, 10.5%; $p=0.08$). The difference was strongest for fast breathing, with compliance reaching 95.2% when these babies also had other danger signs, 12.3% higher (4.5%, 20.2%; $p=0.01$) than when only fast breathing was detected.

Table 2 shows that compliance with referral was high across all levels of maternal determinants, and in particular that compliance rates were similar for urban and rural families, even though many rural families lived at considerable distance from a referral facility. Only the mother's SEQ and the sex of the baby showed any

evidence of differential compliance ($p < 0.1$). These two factors were therefore included in the multivariable model. The results were very similar to the univariable findings: compliance was 23% lower (9%, 34%; $p = 0.001$) among mothers in the least poor SEQ compared to the four poorer SEQs, which had similar levels of compliance. Although weak, the results also suggested that compliance was 8% higher (-0.1%, 17%; $p = 0.07$) for female compared with male babies. In contrast, Table 3 shows that urban/rural residence was the most and only important determinant of early (within 3 hours of referral) compliance. This was 36% overall and 53% higher ($RR = 1.53(1.09, 2.15)$; $p = 0.02$) among urban than rural mothers. In addition, distance from a main referral hospital was found to influence whether mothers sought care there, or instead went to a less optimal facility. The cut off in this setting was 20km with the majority (81.9%) of mothers choosing to go to the hospital if they lived less than 20km from it with little variation within this limit. Only 44.8% of mothers who lived farther away chose to take their baby to a hospital ($p = 0.004$).

The 14% of mothers who reported that they did not comply with the referral gave one or more of the following reasons for this: thinking the baby was not sick (21%), waiting to see if the baby improved (18%), financial (13%), use of home treatment (8%), lack of transport (5%) and husband not at home (5%). Forty-one percent did not specify their reason, although notably, husband non-consent was not a reason for non-compliance. Of those that did comply, the reasons given for not being able to go to the facility on the same day as the referral were: referral made late in the evening or on a weekend or public holidays (21%), transport (17%), financial

(16%), waiting to see if the baby improved (13%) and husband not at home during referral (9%). Eighteen percent gave no reasons but no mother delayed compliance because of husband non-consent or trial of herbal/home treatment.

Facilitators to compliance

Perception of severity: Once the CBSVs had identified a danger sign, families were generally concerned about babies' health and accepted that they needed care. There was a common perception that newborns are vulnerable and 41(93%) of the 44 mothers that followed the referral instructions cited illness severity as the main reason. Mothers repeatedly used words like '*serious*', '*severe*', '*frightened*' and '*something bad might happen*'

'..but if you have suffered to get the human being and the person is said to be sick and you are being asked to take him to the hospital, would you not go?' [35-year-old Sisala mother of six]

'a baby you have just given birth to who is 'kitikiti' (very small) and is being said to have these problems; it is not an easy thing. We thought if we did not go, something bad might happen to the baby.'
[35-year-old Mo woman]

'When the CBSV told me about the sickness of the baby, I was so worried in fact I started crying because I thought the baby was going to die, '-[33-year-old Badu mother]

The perception of severity was amplified by CBSVs who reported that they often told mothers that the baby could die:

'I tell them the assessment findings and that if they do not go immediately, it could get worse and the baby could perish and that makes them eager to go.' [48-year-old female CBSV]

Both mothers and CBSVs related delayed or non-compliance to a perception that the illness was not severe especially when newborns had skin pustules; fever and breathing difficulties were seen as severe symptoms in adults let alone newborns

'if the disease is severer than this one, then I will send the baby.' [25yrs Bono hairdressing apprentice who failed to comply when her baby was referred for skin pustules]

'as for "ahobene" (fever), it is a serious disease; that was the main reason why I went' [30-year-old Bono]

Emergency preparedness and husband involvement: Following advice by CBSVs, mothers said they prepared for emergencies during the pregnancy which enabled them to comply. Thirty-three (75%) specifically said they enrolled on the NHIS or saved money during pregnancy and that facilitated compliance. This theme also emerged from the CBSV interviews; they added that involving husbands in the assessments made them more supportive of mother's referral compliance

'Nowadays, we don't need money to go to hospital; all you need is money for transport and you can go.' [30-year-old Bono enrolled on the NHIS]

'at the time he was visiting us in the pregnancy, he told us to save some money in the form of "susu" so that when we are going to deliver or if we get an emergency, we could use for the costs and we did' [35-year-old Mo farmer]

'It is usually the husbands who are fast to accept my advice and urge the women to go ... because they are the ones that tend to understand my explanations earlier.' [32-year-old male CBSV].

Previous facility contacts: In their narratives, 41% of mothers mentioned the importance of having had previous contact with the health facility either during ANC or delivery in their decision making to comply with perceptions that these previous contacts would make health workers less abusive but more receptive and sympathetic to them. Of the two, ANC attendance emerged as a stronger theme. Even when mothers delivered at home, referral was perceived as an opportunity to access care for newborns.

'my previous attendance at ANC helped my decision to go because if I had not attended ANC and was taking the sick baby there, the nurses would insult me and ask why I am now coming to hospital given I failed to attend ANC.' [20-year-old Bono mother]

"when you give birth, they tell you to come and show yourself at two weeks but as you can see, it was not even two weeks but because of the home delivery I wanted to go and see them too" [30-40-year-old Frafra mother of five]

The role of the referral card: Being given a referral card by the CBSV elicited a sense of urgency around the referral making mothers want to go. In their narratives, 73% mothers perceived it as a confirmation that their baby had severe illness. Most commonly, mothers either considered that possessing the yellow card at health facilities would exempt them from any service charges or hasten their

baby's treatment. They knew also that whilst issuing the card, CBSVs promised to return and check if they went and so he might be displeased if they failed to go:

'...the card he gave me had a date on it and so I had to go on that same date' [24-year-old Bono].

'...at the durbar we were all informed that when the baby is given a yellow card then the disease is dangerous.' [Bono mother of two],

'...since he (CBSV) gave me the card and said I should show it to the madam (health professional), I thought they were not going to charge anything for the baby's care.' [35-year-old Banda farmer]

'he (CBSV) gave me a yellow card and said I should take it to the hospital, give it to the nurses and then they will treat us quickly.' [24-year-old hairdresser and mother of two]

'...because he gave me a card and said he would come back later to check if I went. What am I going to tell him if he comes and asks and I have not been able to go?' [40-year-old mother of eight]

This role of the referral card in facilitating compliance was also confirmed in CBSV narratives; they assured mothers that the card will speed up their baby's treatment at facilities.

'...I usually assure them that, with the yellow card, they will be seen and treated very quickly. This made some go to the hospital.' [24-year-old female CBSV]

CBSV counselling and support: Mothers also frequently alluded to CBSVs persistence and perseverance to ensure they complied with the referral. All those who complied with referral described how CBSVs explained to them that only hospitals could treat their newborn's illness and offered support to them in the form of transport and monies to enable them comply. They perceived these efforts by the CBSV to indicate that the CBSVs themselves thought the illness was severe. Considering therefore that CBSVs were 'doctors' and high profile members of their community, mothers thought they had to listen to what they advise.

'After he (CBSV) told us to take the baby to the madam, he did not go away but carried me at the back of his motorbike to the health centre whilst my mother walked and followed with the baby. The madam was away and so we returned home. When we got home, he asked me to go and start packing my "things" and that he wanted us to send the baby to Nkoranza hospital. When I finished packing he carried me again on his motorbike to the lorry station where I took the vehicle to Nkoranza.' [23-year-old Bono primip]

'I told him that I would wait and go the next morning but he said he wanted me to go the same day. He then offered to go to the roadside and see whether he could get a vehicle for me to take to the hospital at Nsawkaw but when did not get any, he came back to inform me but still wanted me to go and so I rather walked to Seikwa' [23-year-old Sisala married unemployed Junior High School graduate]

'I told them I did not have any money to take the baby to the hospital and they said they were going to pick me in their vehicle. Teacher (CBSV) again gave me money to take car when I am returning home from the hospital; it was 25,000 cedis' [35-year-old Tsokosi farmer]

'he is the 'doctor' and so what he says is what we all do in the community' [35-year-old Bono mother of three]

Even when some mothers were hesitant because of previous bad experiences in facilities, CBSVs persuaded them to place higher premiums on their babies' lives:

'(S)he (health professional) made it difficult to convince the women to go to the hospital for fear of being maltreated. I sometimes have to explain to them that insults were better and less painful than the death of a child before they agree to go.' [44-year-old male CBSV]

CBSVs also narrated that they perceived that mothers might not readily want to accept referral advice and so they needed to persuade them. They mentioned that they sometimes 'insist' or 'force' the mothers to go because they felt responsible for the health of newborns in their communities as exemplified in the following account of a 46-year-old male CBSV:

"When I insist that they should go to the facility, they see it as a problem and so I have to take them to the station sometimes on my motorbike to get a vehicle to the hospital. Sometimes, the referred woman might be too sick to be able to walk to the station and so I carry her on the back of the motorbike to the station and return to fetch her bags to enable her go to the facility and when I do that, they are happy to comply with the referral....I usually follow them to the lorry station and when there is a scramble for the vehicle, I approach the conductors and explain that the mother has a seriously sick baby and needs to go to the hospital promptly. I request priority seat for them and so they are able to comply...I sometimes stay at the station with them until the vehicle moves making sure that they are on their way to the hospital. The baby's life is important to me and that is why I "force" them to take the baby to the hospital"

The CBSVs conceded that their community profile was enhanced by their Newhints role especially because of the regular supervisory visits from people perceived to be coming from the health authorities (DHMTs). They explained that when community members see supervisors (DiPS) follow them into communities to observe newborn assessments, it was perceived as a confirmation of DHMTs' support for their work and it catalysed families' subsequent compliance:

'when the DiPS come and we go together for the visits, they know that we are not doing it alone and that more senior people are backing us so after

that they accept our messages more readily and are ready to comply. [26-year-old male CBSV]

Distance, transport and timing of referral: Once families understand that their newborns were sick and needed urgent care, distance to the facility ceased to be a barrier. Only four (9%) women made references to distance with concerns that travelling long distances to the health facility might adversely affect their baby's health. Others related distance to availability of transport by suggesting that compliance was relatively easier if the referral was made at specific times when vehicles would be available such as market-days or during the day rather than at night.

'I think the hospital is far from my house but since the baby is important to me, even if there was no car, I would have walked to the hospital.' [38-year-old Kusasi]

'...as for Chiraa, it is too far. Air would have entered the baby because she was still too small to travel those long distances with.' [24-year-old mother of two]

'it was a Tuesday and that was the market-day at Nkoranza so it is very easy to get a vehicle to Nkoranza on those days.' [30-year-old mother of seven; 4 dead],

Barriers to referral compliance

In IDIs with mothers, those who complied with referrals mentioned challenges that other mothers might face that could potentially prevent them from complying including availability of funds, and possible doubts about the CBSV findings. They added that they themselves were able to overcome these challenges and hence had complied with the referral. Mothers who failed to comply and CBSVs interviews indicated that very few barriers actually persisted and these were of two types: those that delayed compliance and ones that prevented it altogether.

Barriers causing delays: Reasons for delay given by mothers during the IDIs were similar to those reported above by the mothers in the process sub-sample. Mothers ascribed delays in compliance with referrals to difficulties finding money or transport to go with at the time of the referral. They related this to referrals made either at times when their husbands were not at home, at evenings or after a rainfall when transport was not readily available because link roads were not motorable. Others perceived that the danger sign might improve spontaneously and so waited at home.

'...they asked me to go to the hospital but at the time, the baby's father was away and I did not have money on me. I did not take her to hospital that day.' [34-year-old Mo mother who complied after a day]

'We only got a vehicle at around 6pm and got to the hospital at around 9pm because it rained that day and the road was not safe to ride on' [20-year-old mother who waited for 6 hours trying to secure a vehicle]

'I did not go on the Tuesday but rather Wednesday because that was the market-day and easier to get a vehicle.' [30-year-old trader]

'On the day of delivery, the baby did not breastfeed till the next day when the CBSV came and told us to go. On that day, the baby was attempting to breastfeed a little and so I thought it was going to get better. She stopped suckling again and that was what prompted me to go' [35-year-old Tsokosi mother]

Barriers causing non-compliance: When mothers failed to comply, the commonest reason cited was the perception that the illness was not severe. This was the reason for seven of the eleven non-compliers whose babies were found with skin pustules. To confirm their perceptions, two mothers sought the independent opinion of professional midwives living near their homes and the latter discouraged them from complying because they also thought the baby was not ill even though they did not check the babies like the CBSV had done. Other themes included lack of money and perceptions that the illness was due to 'Asram', a culturally constructed illness thought to be transmitted by 'evil eyes' and considered to be amenable only to traditional/herbal treatment (Okyere et al., 2010). Box 1 summarises the interview for a young first-time mother who did not comply because decisions were taken on her behalf by other family members. She lost her baby due to her grandmother's insistence that the baby had 'Asram', despite the CBSV's efforts to convince her that the baby had danger signs of severe illness.

Negative responses, both recent and past, from care providers at health facilities also posed a barrier. When referred babies were not examined at the health facility and sent home without treatment, their mothers were understandably reluctant to go

again even if the CBSV found that the danger sign(s) were still present the next day or had got worse. Neighbouring mothers were also discouraged. Other mothers feared the response they might receive from the care providers explaining that because they could not take the baby to the hospital on the referral date which was written by the CBSV on the card, they knew health workers would abuse them for coming late. A few of them gave no reason for failing to comply except that they disliked hospitals with no real basis:

'...my brother's wife had also delivered and the CBSV went to refer because he said there was something wrong with the eyes, it could not open. He also said the baby was breathing too fast but when they went to the hospital, they gave her medicine for the eyes and the nurses said there was nothing wrong with the breathing so when he told me the same thing about my baby, I did not take it serious' - [28-year-old Sisala mother]

'...you see when he gave me the card, he wrote the date on it and by the time I was ready to go, the date had passed. I thought when I go they will insult me and so I decided not to go at all.' [20-year-old Senior High School graduate]

'My soul does not like hospitals and that is why I did not go!' [25-year-old primip; completed Junior High School]

6.4 Discussion

The Newhints intervention achieved an unprecedented 85% compliance with community volunteer referrals. This compares with 34% in Projahnmo-1 (Baqui et al., 2008) and 54% in Projahnmo-2 (Gary L. Darmstadt et al., 2010a), all in Bangladesh, the only other trials that report this. This compliance was similar for all danger signs. There was some evidence that it was higher when two or more

signs were present, particularly for fast breathing, breastfeeding problems and lethargy (when baby moves only when stimulated).

These findings in contrast to the Projahnmo-2 trial in Bangladesh, where compliance was linked to signs detected with fast breathing, breastfeeding problems and lethargy associated with higher compliance (G. L. Darmstadt et al., 2010b).

Not only has Newhints demonstrated that it is possible to achieve high compliance with community volunteer referrals, but also that this strategy is pro-poor, with mothers in the least poor SEQ having a 23% lower (10%, 34%; $p=0.001$) rate of compliance than those in the poorest quintiles. This was the only significant determinant of compliance. Notably there was no difference in compliance between urban and rural location. However, urban mothers were able to get to health facilities more quickly being 53% (9%, 115%; $p=0.02$) more likely to facilities within 3hrs of referral than urban ones. This was the only determinant of early (within 3hrs of referral) compliance. In addition, distance influenced whether mothers who complied were able to go to one of the four main referral level hospitals, rather than a less optimal facility. The cut-off point for this was living within 20km of a main hospital; mothers who lived farther away than this were 45% (17%, 63%; $p=0.004$) less likely to take their babies there.

The high compliance of 85.2% recorded from the analyses of the CBSV workbook data agrees with the 86% compliance reported by mothers in the process sub-

sample(Manu et al., 2012). The difference, although very negligible, could have resulted from the differences in sampling; CBSV workbooks captured all referrals whilst the process data involved only a subsample of the population.

One important limitation of this study was that the lead author, who conducted the qualitative interviews, was a key member of the Newhints team was involved in the implementation. Whilst efforts were made to limit any biases, these were still possible especially during interviews with the CBSVs. However, the consistency in the findings from the several sources of data attests to the minimal effect of these might have had on the study validity.

Factors that facilitated compliance included mothers' perception of illness severity; advance saving and NHIS enrolment for emergencies which helped overcome cost barriers; antenatal attendance during pregnancy or facility delivery; issuance of referral card; and CBSV counselling and support. The usual barriers to care seeking such as husband non-consent, cost(Bazzano et al., 2008; Mrisho et al., 2008; Syed et al., 2008; Waiswa et al., 2008) or distance(Bazzano et al., 2008; Manandhar et al., 2004; Mrisho et al., 2008) did not seem to affect compliance when CBSVs asked mothers to go. However, distance from the main hospitals where the majority of the mothers went seemed to affect the timing of the compliance; mothers who lived in urban areas where the main hospitals were, complied quicker. Among the non-compliers, perceptions that skin pustules were

not severe enough to merit hospital attendance and beliefs around 'Asram' were common (Bazzano et al., 2008; Hill et al., 2003; Okyere et al., 2010).

A positive change in families' perceptions about newborn illness severity mediated all the facilitators to compliance and CBSV facilitation was pivotal to these changes. After CBSV assessment and referral facilitation, perceptions of vulnerability of the newborn and the severity of the illness prompted families to go. These changes were mainly attributable to effective implementation of core strategies in Newhints: firstly, they were driven by CBSV facilitation which was aided in part through their enhanced profile in the community and partly through the use of instruments, counselling cards and supervision. Families perceived them as knowledgeable and often equated them to doctors. This added weight to their referral recommendations and facilitated compliance. Post-referral follow-up visits were also useful in providing opportunities for continued dialogue with families on care of the newborn and when families failed to comply, babies were re-assessed and referred again.

Other studies have described families ascribing non-biomedical aetiologies to severe illnesses in the newborn. Formative research in the study area described the syndrome of 'Asram' as a culturally constructed illness believed to be transmitted through 'evil eyes' thought to be only amenable to home/herbal and not to hospital treatment. Similar syndromes have been found in other settings including India (Kumar et al., 2008; Mohan et al., 2008), Bangladesh (Winch et al., 2005a), Nepal (Mesko et al., 2003) and Tanzania (Mrisho et al., 2008; Thairu & Pelto, 2008).

Perpetuation of these beliefs in families may pose barriers to newborn illness care seeking.

Winch et al (Winch et al., 2005b) in their models of facilitated-compliance recommended the use of a referral slip/card. Findings from this study confirmed the significance of such a card in facilitating compliance. The Newhints referral card raised families' expectations and promoted a sense of urgency around the referral on two counts; first families perceived that with the card, they were going to be exempted from paying for facility services, if any, and secondly, it was perceived principally as a guarantee for fast treatment at facility. Families and CBSVs were disappointed when facilities' responses do not meet these expectations, in particular when babies were not examined or treated. They also raised concerns about negative health worker attitudes citing abuse and delays in care-giving at facilities. These findings accord with suggestions that previous contacts with health facilities were facilitating to subsequent utilisation if they were perceived as positive and satisfying (Coulter, 2006) and delays in care-giving and negative staff attitudes are indications of poor facility quality (Mrisho et al., 2008; Ramirez-Sanchez et al., 1998; Syed et al., 2008). This may have implications for maintaining high levels of compliance.

Implementing a strategy that could reach all babies, particularly in rural areas, where the poorest population resides, and address inequities in access to care for sick newborns was the rationale for the Newhints intervention. Many of the factors that facilitated compliance were integral to the design of the assessment and referral

strategy. Our findings confirm four things: firstly, that mothers welcome community assessments of their babies; secondly that they are willing and able to comply with referrals; thirdly that the high compliance achievable using this approach negates the necessity to offer home treatment with injectable antibiotics; and fourthly the need to have adequate geographic coverage of referral level hospitals, which in this setting would be within 20km. Taken together they demonstrate the feasibility in sub-Saharan Africa of the WHO/UNICEF strategy(WHO/UNICEF., 2009) of CHW home visits with assessment and referral of sick newborns and show that this has the potential to be a pro-poor intervention and achieve equitable coverage(Manu et al., 2012). With improved quality of care at facilities as an adjuvant, this strategy can significantly increase newborn survival(B.R. Kirkwood et al., 2012). Africa's newborns simply cannot wait any longer!

Authors' contributions

The paper was drafted by AM, and reviewed and approved by all authors. BRK, AM, CTA, SOA, ZH were responsible for the design of the Newhints trial; AM, ZH, AtA, CTA, EU and BRK for the data collection instruments; AM, and EU for qualitative data collection, AM, SD, SAE, SS, BRK, AtA for database design and management; and AM supported by ZH and BRK for carrying out the analyses.

Table 1: Compliance with referrals by danger sign (data extracted from CBSV workbooks)

Danger sign	All referred babies		Babies who had a single danger sign	
	Prevalence (%)	No (%) complied	Prevalence (%)	No (%) complied
Local infections (Skin, Eyes or Umbilicus)	377 (45.3%)	324 (85.9%)	310 (37.2%)	266 (85.8%)
Fast breathing (60+ counts/min validated by 2 nd count)	217 (26.1%)	190 (87.6%)	134 (16.1%)	111 (82.8%)
High axillary temperature (>37.4°C)	138 (16.6%)	125 (90.6%)	83 (9.9%)	73 (88.0%)
Stopped or not breastfeeding	82 (9.8%)	68 (82.9%)	36 (4.3%)	27 (75.0%)
Chest indrawing	76 (9.1%)	69 (90.8%)	22 (2.6%)	20 (90.9%)
Yellow soles & palms	53 (6.4%)	45 (84.9%)	27 (3.2%)	23 (85.2%)
Low axillary temperature (<35.5°C)	48 (5.8%)	38 (79.2 %)	24 (2.9%)	18 (75.0%)
Poor movement (moving only when stimulated)	19 (2.3%)	15 (78.9%)	6 (0.7%)	3 (50.0%)
Convulsed since birth	15 (1.8%)	12 (80.0%)	11 (1.3%)	8 (72.7%)
Very low birthweight (<1.5kg)	10 (1.2%)	9 (90.0%)	2 (0.2%)	2 (100.0%)
ALL BABIES	833 (100%)	710 (85.2%)	655 (100%)	551 (84.1%)

Table 2: Referral compliance by number of danger signs (CBSV workbooks data; N=833)

Compliance	Number of danger signs identified in baby; n (%)		
	One	Two or more	Total
Complied	546 (84.1)	153 (90.0)	699 (85.3)
Did not comply	103 (15.9)	17 (10.0)	120 (14.7)
Total	649 (100.0)	170 (100.0)	819* (100.0)

Cluster-adjusted RR (2 or more vs. 1 danger sign)=1.07 (1.01, 1.13); $\chi^2_{(1df)} p=0.015$

**14 had missing number of danger signs and excluded in this analysis*

Table 3: Distribution of respondent characteristics & determinants of referral compliance (process data; N=279)

Factor	Categories	Referrals (%)	Compliance (%)	RR (95% CI)	p
Maternal age	Below 20yrs	37 (13.3%)	81.1%	1	0.57
	20-29yrs	125 (44.8%)	88.8%	1.09 (0.92, 1.31)	
	30-39yrs	62 (22.2%)	82.3%	1.02 (0.82, 1.25)	
	40+ yrs	55 (19.7%)	87.3%	1.08 (0.91, 1.27)	
Marital status	Married	148 (53.6%)	85.8%	1	0.33
	Co-habiting	99 (35.9%)	85.9%	1.00 (0.90, 1.13)	
	Separated/divorced	10 (3.6%)	80.0%	0.96 (0.74, 1.23)	
	Single	19 (6.9%)	94.7%	1.11 (0.98, 1.27)	
Residence	Rural	219 (78.5%)	87.2%	1	0.31
	Urban	60 (21.5%)	81.7%	0.92 (0.87, 1.07)	
Maternal education	None	85 (30.8%)	85.9%	1	0.92
	Primary	76 (27.5%)	88.2%	1.04 (0.92, 1.17)	
	Middle/JHS	106 (38.4%)	84.9%	0.99 (0.88, 1.12)	
	Secondary/higher	9 (3.3%)	88.9%	1.03 (0.79, 1.34)	
Previous child death	No	212 (76.8%)	84.9%	1	0.30
	Yes	64 (23.2%)	90.6%	1.06 (0.95, 1.20)	
Number of other living children	None	71 (25.7%)	83.1%	1	0.76
	1-2	102 (37.0%)	88.2%	1.05 (0.90, 1.24)	
	3 or more	103 (37.3%)	86.4%	1.03 (0.89, 1.21)	
Place of delivery	Home	108 (38.7%)	86.1%	1	0.93
	Health facility	171 (61.3%)	86.0%	1.00 (0.90, 1.10)	
ANC attendance in pregnancy	No	9 (3.2%)	77.8%	1	0.51
	Yes	270 (96.8%)	86.3%	1.14 (0.78, 1.66)	
Sex of baby	Male	138 (49.5%)	82.6%	1	0.046*
	Female	141 (50.5%)	89.4%	1.08 (1.00, 1.17)	
Wealth quintile	q1 (poorest)	64 (22.9%)	87.5%	1	0.01*
	q2	64 (22.9%)	89.1%	1.00 (0.89, 1.11)	
	q3	72 (25.8%)	90.3%	1.01 (0.90, 1.14)	
	q4	42 (15.1%)	85.7%	0.98 (0.87, 1.10)	
	q5 (least poor)	33 (11.8%)	69.7%	0.77 (0.66, 0.91)	
Mother NHIS enrolled	No	27 (9.7%)	88.9%	1	0.70
	Yes	252 (90.3%)	85.7%	1.04 (0.88, 1.21)	
Saved money for emergencies	No	37 (13.4%)	81.1%	1	0.33
	Yes	240 (86.6%)	86.7%	0.71 (0.36, 1.40)	
Distance from main hospital	Less than 10km	97 (34.7%)	83.5%	1	0.41
	10 – 19km	71 (25.5%)	88.7%	1.08 (0.96, 1.22)	
	20 – 29km	71 (25.5%)	88.7%	1.07 (0.95, 1.20)	
	30km or more	40 (14.2%)	82.5%	1.01 (0.87, 1.17)	

* Factors included in the multivariable model

Table 4: Determinants of compliance with CBSV referral from multivariable GEE models (process data; N=279)

Factor	Categories	n (%)	Compliance	RR (95% CI)	P
Wealth quintile	q1-q4	242 (88.0%)	88.4%	1	0.001
	q5 (least poor)	33 (12.0%)	69.7%	0.77 (0.66, 0.90)	
Sex of baby	Male	138 (49.5%)	82.6%	1	0.08
	Female	141 (50.5%)	89.4%	1.07 (0.99, 1.15)	
Overall model $X^2_{(2df)}=13.08$; $p=0.001$					

6.5 References (formatted for Social Science & Medicine)

- Awasthi, S., Srivastava, N.M., & Pant, S. (2008). Symptom-specific care-seeking behavior for sick neonates among urban poor in Lucknow, Northern India. *Journal of Perinatology*, 28 Suppl 2, S69-75.
- Azad, K., Barnett, S., Banerjee, B., Shaha, S., Khan, K., Rego, A.R., et al. (2010). Effect of scaling up women's groups on birth outcomes in three rural districts in Bangladesh: a cluster-randomised controlled trial. *Lancet*, 375, 1193-1202.
- Bang, A.T., Bang, R.A., Baitule, S., Deshmukh, M., & Reddy, M.H. (2001). Burden of morbidities and the unmet need for health care in rural neonates--a prospective observational study in Gadchiroli, India. *Indian Pediatrics*, 38, 952-965.
- Bang, A.T., Bang, R.A., Baitule, S.B., Reddy, M.H., & Deshmukh, M.D. (1999). Effect of home-based neonatal care and management of sepsis on neonatal mortality: field trial in rural India. *Lancet*, 354, 1955-1961.
- Bang, A.T., Reddy, H.M., Deshmukh, M.D., Baitule, S.B., & Bang, R.A. (2005). Neonatal and infant mortality in the ten years (1993 to 2003) of the Gadchiroli field trial: effect of home-based neonatal care. *J Perinatol*, 25 Suppl 1, S92-107.
- Baqui, A.H., El-Arifeen, S., Darmstadt, G.L., Ahmed, S., Williams, E.K., Seraji, H.R., et al. (2008). Effect of community-based newborn-care intervention package implemented through two service-delivery strategies in Sylhet district, Bangladesh: a cluster-randomised controlled trial. *Lancet*, 371, 1936-1944.
- Bazzano, A.N., Kirkwood, B.R., Tawiah-Agyemang, C., Owusu-Agyei, S., & Adongo, P.B. (2008). Beyond symptom recognition: care-seeking for ill newborns in rural Ghana. *Tropical Medicine & International Health*, 13, 123-128.
- Bhandari, N., Mazumder, S., Taneja, S., Sommerfelt, H., & Strand, T.A. (2012). Effect of implementation of Integrated Management of Neonatal and Childhood Illness (IMNCI) programme on neonatal and infant mortality: cluster randomised controlled trial. *BMJ*, 344, e1634.
- Bhutta, Z., Ali, N., Hyder, A., & Walid, A. (2004). *Perinatal and newborn care in Pakistan: seeing the unseen*. Karachi: Oxford University Press.
- Bhutta, Z.A., Soofi, S., Cousens, S., Mohammad, S., Memon, Z.A., Ali, I., et al. (2011). Improvement of perinatal and newborn care in rural Pakistan through community-based strategies: a cluster-randomised effectiveness trial. *Lancet* pp. 403-412).
- Black, R.E., Cousens, S., Johnson, H.L., Lawn, J.E., Rudan, I., Bassani, D.G., et al. (2010). Global, regional, and national causes of child mortality in 2008: a systematic analysis.
- Choi, Y., El Arifeen, S., Mannan, I., Rahman, S.M., Bari, S., Darmstadt, G.L., et al. (2010). Can mothers recognize neonatal illness correctly? Comparison of maternal report

- and assessment by community health workers in rural Bangladesh. *Tropical Medicine & International Health*, 15, 743-753.
- Coulter, A. (2006). Can patients assess the quality of health care? Patients' surveys should ask about real experiences of medical care. *Br Med J*, 333, 1-2.
- Darmstadt, G.L., Choi, Y., Arifeen, S.E., Bari, S., Rahman, S.M., Mannan, I., et al. (2010a). Evaluation of a cluster-randomized controlled trial of a package of community-based maternal and newborn interventions in Mirzapur, Bangladesh. *PLoS ONE [Electronic Resource]*, 5, e9696.
- Darmstadt, G.L., El Arifeen, S., Choi, Y., Bari, S., Rahman, S.M., Mannan, I., et al. (2010b). Household surveillance of severe neonatal illness by community health workers in Mirzapur, Bangladesh: coverage and compliance with referral. *Health Policy & Planning*, 112-124.
- Edmond, K.M., Quigley, M.A., Zandoh, C., Danso, S., Hurt, C., Owusu Agyei, S., et al. (2008). Aetiology of stillbirths and neonatal deaths in rural Ghana: implications for health programming in developing countries. *Paediatr Perinat Epidemiol*, 22, 430-437.
- Ghana Health Service. (2005). Ghana Health Service-Brong Ahafo Region. Ghana Health Service.
- Hill, Z., Kendall, C., Arthur, P., Kirkwood, B., & Adjei, E. (2003). Recognizing childhood illnesses and their traditional explanations: exploring options for care-seeking interventions in the context of the IMCI strategy in rural Ghana. *Tropical Medicine & International Health*, 8, 668-676.
- Kirkwood, B.R., Manu, A., Tawiah-Agyemang, C., ten Asbroek, G., Gyan, T., Weobong, B., et al. (2010). NEWHINTS cluster randomised trial to evaluate the impact on neonatal mortality in rural Ghana of routine home visits to provide a package of essential newborn care interventions in the third trimester of pregnancy and the first week of life: trial protocol. *Trials*, 11, 58.
- Kirkwood, B.R., Manu, A., ten Asbroek, A.H., Soremekun, S., Weobong, B., Gyan, T., et al. (2012). Impact of the "Newhints" home visits intervention on neonatal mortality and care practices in Ghana: a cluster randomised controlled trial. *submitted*.
- Kumar, V., Mohanty, S., Kumar, A., Misra, R.P., Santosham, M., Awasthi, S., et al. (2008). Effect of community-based behaviour change management on neonatal mortality in Shivgarh, Uttar Pradesh, India: a cluster-randomised controlled trial. *Lancet*, 372, 1151-1162.
- Lawn, J.E., Cousens, S., Zupan, J., & Lancet Neonatal Survival Steering, T. (2005). 4 million neonatal deaths: When? Where? Why? *Lancet*, 365, 891-900.
- Manandhar, D.S., Osrin, D., Shrestha, B.P., Mesko, N., Morrison, J., Tumbahangphe, K.M., et al. (2004). Effect of a participatory intervention with women's groups on birth outcomes in Nepal: cluster-randomised controlled trial. *Lancet*, 364, 970-979.

- Manu, A., ten Asbroek, G., Soremekun, S., Weobong, B., Gyan, T., Tawiah-Agyemang, C., et al. (2012). Increasing access to facility care for sick newborns: evidence from the Ghana Newhints trial. *submitted*.
- Mesko, N., Osrin, D., Tamang, S., & al., e. (2003). Care for perinatal illness in rural Nepal: a descriptive study with cross-sectional and qualitative components. *BMC Int. Health Hum. Rights*, 3.
- Mohan, P., Iyengar, S.D., Agarwal, K., Martines, J.C., & Sen, K. (2008). Care-seeking practices in rural Rajasthan: barriers and facilitating factors. *Journal of Perinatology*, 28 Suppl 2, S31-37.
- Mrisho, M., Schellenberg, J.A., Mushi, A.K., & al., e. (2008). Understanding home-based neonatal care practice in rural southern Tanzania. *Trans R Soc Trop Med Hyg*, 102, 669-678.
- Oestergaard, M.Z., Inoue, M., Yoshida, S., Mahanani, W.R., Gore, F.M., & al., e. (2011). Neonatal Mortality Levels for 193 Countries in 2009 with Trends since 1990: A Systematic Analysis of Progress, Projections, and Priorities. *PLoS Medicine*, 8, e1001080.
- Okyere, E., Tawiah-Agyemang, C., Manu, A., Deganus, S., Kirkwood, B., & Hill, Z. (2010). Newborn care: the effect of a traditional illness, asram, in Ghana. *Ann Trop Paediatr*, 30, 321-328.
- Qazi, S.A., & Stoll, B.J. (2009). Neonatal sepsis: A Major Global Public Health Challenge. *Pediatric Infectious Disease Journal*, 28, S1-2.
- Ramirez-Sanchez, T.J., Najera-Aguilar, P., & Nigenda-Lopez, G. (1998). Perception of the quality of care in the health services in Mexico. perspective of the users. *Salud Publica Mex*, 40, 3-12.
- Shiffman, J. (2010). Issue attention in global health: the case of newborn survival.
- Sutrisna, B., Reingold, A., Kresno, S., Harrison, G., & Utomo, B. (1993). Care-seeking for fatal illnesses in young children in Indramayu, west Java, Indonesia. *Lancet*, 342, 787-789.
- Syed, U., Khadka, N., Khan, A., & Wall, S. (2008). Care-seeking practices in South Asia: using formative research to design program interventions to save newborn lives. *Journal of Perinatology*, 28 Suppl 2, S9-13.
- Thairu, L., & Pelto, G. (2008). Newborn care practices in Pemba Island (Tanzania) and their implications for newborn health and survival. *Maternal & Child Nutrition*, 4, 194-208.
- Tripathy, P., Nair, N., Barnett, S., Mahapatra, R., Borghi, J., Rath, S., et al. (2010). Effect of a participatory intervention with women's groups on birth outcomes and maternal depression in Jharkhand and Orissa, India: a cluster-randomised controlled trial. *Lancet*, 375, 1182-1192.

Waiswa, P., Kemigisa, M., Kiguli, J., Naikoba, S., Pariyo, G.W., & Peterson, S. (2008). Acceptability of evidence-based neonatal care practices in rural Uganda - implications for programming. *BMC Pregnancy & Childbirth*, 8, 21.

WHO/UNICEF. (2009). WHO/UNICEF Joint Statement: Home visits for the newborn Child: a Strategy to Improve Survival. Geneva: WHO.

Winch, P.J., Alam, M.A., Akther, A., Afroz, D., Ali, N.A., Ellis, A.A., et al. (2005a). Local understandings of vulnerability and protection during the neonatal period in Sylhet District, Bangladesh: a qualitative study.

Winch, P.J., Gilroy, K.E., Wolfheim, C., Starbuck, E.S., Young, M.W., Walker, L.D., et al. (2005b). Intervention models for the management of children with signs of pneumonia or malaria by community health workers. *Health Policy Plan*, 20, 199-212.

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CHAPTER SEVEN: Perspectives from Mothers, CBSVs & Health Providers

Community volunteer assessment and referral of sick babies: perspectives from mothers, volunteers and care providers in the Ghana Newhints trial.

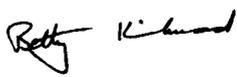
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7.1 Introduction

An estimated 3.3million newborns die each year, the vast majority in low and middle income countries (LMIC). About one third of these deaths are due to infections, [1, 2] the majority of which could be prevented[2, 3] with prompt identification and appropriate treatment. However, a large proportion of these deaths occur at home with little or no contact with the health system. Many factors constrain care-seeking for sick newborns including: poor recognition of newborn illnesses; [4-8] cost of health care, distance to and availability of health facilities; and societal norms and beliefs such as the traditional seclusion period for mother and baby, especially in the first week of life - the time of greatest vulnerability, and cultural constructs of some illnesses that are considered not to be amenable to “hospital” medicine. The World Health Organization (WHO) and United Nations Children’s Fund (UNICEF) in 2009 issued a joint statement[9] recommending home visits by community-based agents in the first week of life as a strategy to improve newborn survival, to promote essential newborn care practices and to assess newborns and refer any with signs of severe illness to a health facility. This strategy was based on evidence from home visit trials in Asia[6, 10, 11] that successfully improved newborn survival

The Ghana Newhints[12] home visits cluster-randomised trial (CRT) is the first evaluation of this strategy in sub-Saharan Africa. Newhints achieved very high compliance with referral: 86% of all mothers whose babies were referred took them to a health facility for care.[13] In this paper, which is part of the detailed evaluation of the referral and assessment component of Newhints, we present

findings on the perspectives of key stakeholders in order to inform implementation. These stakeholders were mothers (or families) who had babies referred, CBSVs who carried out the home visits and made the referrals and staff (care providers) at the health facilities where sick newborns were referred.

7.2 Methods

The Newhints home visits cluster randomised trial (CRT) and details of the intervention have already been published. The findings presented in this paper are part of a detailed process evaluation of the trial which was implemented in seven contiguous districts in the Brong-Ahafo region of rural Ghana. Newhints trained community-based surveillance volunteers (CBSVs), an existing cadre of volunteers in the Ghana Health Service (GHS) in 49 of 98 supervisory zones to conduct five home visits to women and their families; two during pregnancy to promote essential newborn care practices (ENC) and birth and emergency preparedness, and three in the first week of life to assess newborns for ten key danger signs (table 1) and refer to health facilities when any were present. When they referred a baby, CBSVs gave mothers a referral card to take to health facilities and re-visited within 24hours, to check on compliance to referral, re-assessed and referred again if mothers failed to comply and danger signs were still present. Records of all visits including referrals were maintained in workbooks provided.

CBSVs used portable weighing scales, digital thermometers and stopwatches for the newborn assessment. The scales had colour-coded bands with red for weights<1.5kg (very low birthweight), yellow for weights between 1.5-2.4kg (low birthweight) and green for weights \geq 2.5kg). Supervision was by trained District-based project supervisors (DiPS) who visited CBSVs monthly to replenish their

stocks, to observe them conducting a home visit and to provide feedback.

Newhints was fully implemented by the end of October, 2008.

The seven trial districts covered over 700,000 people with approximately 120,000 being women of reproductive age. The districts were mostly rural (80%) and lacked modern infrastructure like electricity or potable water. Educational levels were low and majority were subsistence farmers in food crops. Though multi-ethnic, Akans (Bono) form the majority group. There are more than 80 health facilities serving the area but only four main district hospitals within the urban towns of Kintampo, Techiman, Nkoranza and Wenchi were equipped to provide comprehensive obstetric and newborn care services. These were the referral destinations for all other facilities in the districts.

Sensitization sessions were organised with all health workers in the study area to introduce the intervention. This was followed by training sessions in facility essential newborn care for staff who took direct care of sick newborns in facilities where the majority of deliveries took place. The training covered assessment, classification and treatment of newborn illness using the WHO's pregnancy, childbirth, postnatal and newborn care (PCPNC) manual.

CBSVs in the other 49 zones carried on with their normal Ghana Health Services activities

Data collection & analysis

The impact of the Newhints intervention on key ENC practices and neonatal mortality was based on all babies born between November 2008 and December

2009. Data for this study were collected between May 2009 and March 2010 as part of the detailed process evaluation of Newhints. In-depth interviews including referral narratives (IDIs) were conducted with three groups of respondents: mothers of referred babies, CBSVs who referred them and care providers at the four main hospitals. These interviews were conducted by the lead author of this paper (AM). All IDIs were conducted by the lead author (AM) assisted by a research officer (EU) between June 2009 and March 2010 in Twi (the main language in the trial area) and/or English (for facility providers). They lasted between 45-90 minutes. Sample sizes were determined by saturation, that is, IDIs were collected until no new information arose. They were digitally recorded and field notes were taken to add context. The responses were then typed into Microsoft Word by combining the recordings with the field notes.

In-depth interviews with mothers: Fifty-five in-depth interviews (IDIs), were carried out with mothers of referred babies. These mothers were purposively selected from the surveillance database supporting the trial to ensure they covered a range of ages, parities, ethnicities, rural/urban residence, educational levels, marital status and compliance with the referral. After obtaining consent, referral narratives were elicited covering mothers' referral experiences from the time of CBSV assessment through to the outcome for the baby. Standardised pre-tested guides were then used to probe specific issues which included: the content and conduct of the CBSV assessments, referrals and facilitation; family decision-making including challenges and how they were dealt with if these were not covered in the narratives; CBSV follow-up visits; and, if the mother complied, the care provided at facilities

and perspectives on its quality. Other family members particularly husbands were invited to add their views if present.

In-depth interviews with CBSVs: Twenty-one similar IDIs were carried out with CBSVs who had referred babies to health facilities. They were purposively selected to ensure coverage of ages, gender, marital status, rural/urban residence and district of work. IDIs included a detailed narrative of one of their referrals and then a structured guide was used to obtain more information on their experiences with Newhints referrals regarding families' acceptability of assessment visits, referrals and follow-ups. They also reported their personal experiences plus feedback they received from mothers about what happened to them in the health facilities.

In-depth interviews with care providers: Fifteen IDIs were also conducted with care providers in the four referral level hospitals. These care providers were selected to cover all levels of personnel who mothers came into contact with whilst accessing care for their sick newborns including front-desk staff, nurses, midwives and doctors (including a paediatrician). Their experiences and perspectives on contacts with Newhints referrals and the care they provide were obtained.

All respondents were asked to provide suggestions on how the Newhints assessment and referral system could be improved in the future.

Analyses: The transcripts were exported into NVIVO 9.2 software for analysis.

Analyses involved multiple readings of the transcripts and key analytical categories (themes) generated. Data were then systematically indexed into the NVIVO software. Interpretations were made analysing relationships, texts, language and their connotations.

7.3 Results

Perspectives of mothers of referred babies

The main themes emerging from the mothers' IDIs (and their families when present) were centred around non-recognition of illness, acceptability of assessment and referrals and suggested improvements to the newhints assessment and referrals.

Recognition of newborn illness

Mothers and their families were happy with CBSV assessments and demanded more. They thought it was reassuring to know the state of health of their babies, whether ill or well. They conceded that they had not recognised their babies' illness before the CBSV assessments with 84% of the referral narratives indicating that the danger signs had not been recognized by the family prior to the CBSV assessment. Consequently, they considered assessment findings as welcome alerts to them and referrals as helpful. Commonly, mothers who complied and were treated at facilities perceived that their babies could have died if CBSVs had not referred. These views were shared by other family members who participated in the interviews especially husbands:

'The way he has the patience to visit us three times to check the health of the baby is very good. Sometimes your baby might be sick but you may not know so if he comes to do this work to check whether baby has a 'problem' and tells you to go to the hospital, it is really good and it helps we the mothers; when he says there is no 'mistake' you the mother also feels free.' **[38-year-old Bono farmer who delivered in hospital but CBSV found baby had danger sign during home visit]**

'the whole idea of them coming to our homes to check the baby and refer appropriately is very good. You see, when he came to the house, we did not know the baby was not well but he used his instruments and said the breathing was well above the normal limit.' **[Husband of 18-year-old Dagarti primip]**

'...as for the breathing, I think that is how babies breathe. They are not like we adults and so they breathe very fast. Even these two other kids I had were breathing equally fast when they were young so I thought the breathing was normal' **[28yrs Sisala mother of three]**

Of the eight out of total 55 families who recognized that the baby was ill prior to the CBSV visit only three had sought care outside of the home. Most of these newborns were perceived to have skin pustules which were considered not serious or attributed to 'Asram' (a culturally constructed illness syndrome believed to be transmitted by 'evil eyes' and treatable only using herbal/traditional remedies).

'I thought 'ntos' (skin pustules) was not a serious disease and moreover, the lesions were not big...but she (CBSV) said since it was affecting the baby's scalp, it could seep down into the head and cause the baby to die from serious disease and this why I went' **[24-year-old Bono petty trader]**

'I saw that he(baby) had a rash on the back towards the buttocks and he cried a lot and so we took him to a medicine man and he said baby had developed 'Asram'.' **[18-year-old educated primip]**

Acceptability of CBSV assessments

Mothers in rural communities particularly valued CBSV activities. They thought the CBSV were well respected and their opinions valued by all; their new roles in

newborn care were known and they were perceived as trained and knowledgeable ‘doctors’, serving their communities. Consequently, when they referred, families were willing to go. Mothers also thought that such a programme would be most useful to mothers in rural communities because they have less access to care in health facilities compared to urban residents.

‘...look he is well respected here.’ [**Grandmother of a 25-year-old Bono primip**]

‘if this man (the CBSV) was not doing any such job and told me to go, I would not; but since he is doing this job and people know, they will all go when he says they should do so; everybody is aware of his work in this community.’ [**35yrs petty trader and mother of 4**]

‘he(CBSV) is the “doctor” and I am not so if he says I should go, I wouldn’t know what is wrong with the baby so I have to go.’ [**20-25-year-old illiterate Dagarti farmer**]

‘I will say they are helping those of us who are in the villages. It may help in the big towns but they have more hospitals there and so they are better off’ [**33-year-old trained teacher**]

Mothers considered that referrals to health facilities were indications that the baby’s condition was beyond the knowledge of CBSVs and a more experienced person’s opinion was needed. CBSVs experience in newborn care was related to the duration of work and so being new in newborn care, their referrals were conceived as attempts to assist community members and which therefore merited appreciation. Moreover, their referrals were valid because they used instruments to arrive at the decisions:

‘he started not too long ago and so cannot be as good as they (health professionals) are’ [**30-40-year-old Badu mother of 5**]

‘I agreed with him to take the baby, even though I thought it was not a sickness, because I knew he wanted the best for the baby; it is not his baby; he was only doing his best for us’ [**40-year-old illiterate mother of 8; a**

doctor checked in hospital and said baby's blocked nostrils caused the fast breathing and gave no treatment]

'I was happy about the referral. I thought the baby wasn't sick but she (CBSV) used machines to check that the baby was sick. The doctor also confirmed the sickness at the hospital.' **[30-35-year-old Dagarti mother who was treated at the facility]**

Expectations of facility care

Most mothers followed CBSV recommendations to take babies to hospitals instead of health centres because they thought only the hospitals could meet their expectations.

'he explained to us that when the disease is like this, it is the big hospitals that can solve it. In our health centre, the medicines to give you are not there and so it is pointless going there' **[36-year-old Bono mother of five who went to hospital after referral]**

However, concerns about poor quality of care emerged strongly from the narratives with mothers. Mothers expected that care providers should examine their sick babies like the CBSVs did at home. They wanted to be treated quickly and thought since the disease was severe, only doctors should treat them. They also wanted to be involved in their baby's care. When these expectations were not met, they became dissatisfied with the care provided. Two types of delays emerged: some mothers delayed attendance to health facilities because they knew the doctor was unlikely to be present at the facility. There were also strong complaints about delays in time taken to be seen in hospitals. Some had anticipated and accepted delays but others felt the delays made following the referral instructions pointless:

'I was happy with the way the doctor removed the dress to expose the baby to check the rashes. Some people would have just written something for me after I told them the story without checking' **20-year-old mother of 2]**

'Mostly, the women (nurses) shouted at and manhandled her but she's never given birth before. They said she shouldn't stay inside the room whilst they treated the baby. Even if the baby cried they didn't allow her see to him.' **[A grandmother of 15-year-old first-time mother]**

'I was happy the nurses accepted me when I jumped the queue to say my baby was sick. We were seen quite quickly. We got there at 7am and were seen around 10 but my husband said it could have been worse...even people go in the morning and leave at evening.' **[18-year-old Dagarti mother seen after 3hrs of wait]**

'I advised that if she went on the Sunday, she wouldn't get 'anybody' to take care of them and so she should wait till Monday when there'll be doctors to provide care.' **[Sister/guardian of a mother who delayed compliance]**

'I got to the facility at 9am and they made me "di ako ne aba saa" (literally "go up and down several times") that when I was leaving the hospital it was 4pm...oh as for me, that was what I thought-a waste of my time! I think they did not do anything for me and if I knew that earlier I would not have gone.' **[35-year-old Mo mother who spent 7hrs in a hospital; baby was not examined but medicines were written for them]**

They were displeased when providers in the health facilities dismiss danger signs as non-existent particularly when they did not examine the babies. Families thought the response of care providers at health facilities were negative; some providers were overtly abusive to them. Moreover, the expected care quality was not available every day.

'I was not happy about that because the way they said I should go to the hospital, I thought he was going to count the breaths and check everything again to see if there was any problem but he did not do anything. I thought they did not treat the baby well.' **20-year-old single unemployed mother]**

'When I got there, she asked what was wrong with my baby and so I showed her the yellow card. There and then, she got so angry and threw the card at me and threw me out because I delivered at home.' **[35-year-old mother of four]**

'When the doctor returned, the nurse told him 'hey doctor, your people have come again.' I believe that was what "spoilt his mind" because when the nurse said that, it made the doctor think that the baby might not be sick and

was wrongly referred to the hospital and I am sure that was why he did not treat us well. It was as if you are not working with them” [35-year-old Mo trader;]

Suggested improvements in Newhints

Four main themes emerged in the interviews with the mothers around suggested improvements to the Newhints assessment and referrals. These suggestions were: firstly, CBSV activities should be extended to go beyond the newborn period; secondly, CBSVs should provide some treatment at home with the referrals; thirdly, Newhints should improve procedures that mothers go through in the health facilities and finally, quality of care in the health facilities should be improved.

When families were referred by CBSVs to health facilities, they did not follow their usual patterns of care seeking where they tried home treatments first and used health facilities as the last option. They followed CBSV recommendations and went straight to health facilities. There was also a sense of urgency in the decision making around referral compliance with mothers constantly indicating that they feared the baby could die.

‘if the person goes and the doctors say there is nothing wrong with the baby, then you are sure that it was the ‘Asram’ worrying the baby; you can then come home and treat locally’ [22-year-old Banda seamstress whose baby had fever]

‘he is a “doctor” and has been visiting our babies and so if he said the baby was sick, I will take to the hospital first. If I return and there was no improvement then I could think of local treatment.’ [30-year-old Mo mother of 3 referred with pus]

Consequently, they suggested that, with the performance of the volunteers in the assessments, the scope of their work should be extended beyond the newborn

period and also that they should provide babies first aid treatment at home before they went to hospitals.

'I think he should also see older children for their health up to 1 year' [23-year-old Sisala primip, Junior High School graduate]

'I think this work should continue forever; he should be made to give medicines to sick babies. Some babies may be seriously ill and may die by the time they get to the facility. If the CBSV can give something to take whilst they go to the facility, it might save some lives. Just like in football, when a player is injured on the field, they give some first aid on the field before taking him off' [20-year-old single unemployed mother]

'for me I think he should continue to visit the baby every week or two for as long as possible; when we go for the weighing, the nurses only return after a month and so if the baby falls ill in between, he would be of help and so if he finds any mistake with the baby, he can alert you to take the baby to the hospital' [38-year-old Bono mother of 7, completed middle school]

There was consensus among mothers who complied with referrals that, should Newhints continue into the future, the quality of care at health facilities should be improved. Even when they reported that the facility staff did not do anything they disliked, mothers still wanted their experiences to be improved suggesting a possible tendency to conceal their negative experiences or that their suggestions were not based on personal experiences. They thought an identifiable contact person within facilities would have improved their experiences there.

'...you the authorities should talk to the people in the hospital. Money is very hard to come by these days and it costs a lot to get to the facility and so if you go and this is what they are going to do for you then it is very worrying' [35-year-old Sisala mother of 6 who lost her baby after referral for chest indrawing and receiving no treatment at the hospital]

'I think you should have a representative in the hospital so that when mothers are referred, they go there to meet the person to take them through the processes in the hospital. However, if you do not put somebody there, they treat the people that are referred there as if you are not working together. The work they do in the homes is ok but the absence of people in

the hospital for you makes the work incomplete.’ [35-year-old Mo mother of five who was delayed for over 4 hours before professional contact at health facility]

Perspectives of CBSVs

The main themes that emerged from the CBSV IDIs were similar to those from the IDIs with mothers and were acceptability of visits, their community profile and its role in compliance and concerns about quality of facility response.

Acceptability of visits

All CBSVs reported that overall they were welcomed by families for visits and the assessment and that other family members showed interest in these and participated in the discussions. Occasionally, relatives who had not been seen during pregnancy visits as they had come to support the mother after birth were disapproving of the CBSVs newborn assessment. The mothers allayed their fears and allowed assessments but CBSVs thought these experiences were problematic.

‘They have faith in the work we are doing and so they receive us very well’
[48-year-old male Bono]

‘Sometimes they receive us very well and at times too some do not ‘show us a pleasant face.’ Those who come to cause ‘problems’ were usually not there when we started the pregnancy visits so when they came to “fall in” like that, they get apprehensive about what we were going to do.’ [24-year-old female Bono]

At no time did CBSVs suggest they should receive more than the minimal \$5 per month they were receiving. Some indicated that they were initially uncomfortable or lacked confidence in assessing newborns sometimes stemming from their

personal beliefs and perceptions about what community members might think when they handled their babies. With time, they became confident:

'Excuse me to say that by the time I go for the assessment, there were no 'blood issues' because the baby might have been cleaned and so I do not feel anything.' [48-year-old female Bono teacher]

'I was not confident. I used to touch my own baby but for other people's babies, never because they will be scared to allow a "stranger" touching their baby because they fear he might give the baby asram.' [46-year-old male Bono]

CBSVs reported that families' demand for assessments increased with time especially after mothers complied with referrals and received treatment. They perceived families' compliance with referrals and demand for the visits were mutually reinforcing: when families complied with referrals, they usually want more visits because they understand the benefits and share with other mothers who also then demand for assessment visits.

'They really understand the work I am doing so most of them invite me to come for the assessment. It seems they see the benefits those who allow me to examine their babies get and so they too wanted to have that' [49-year-old female Bono]

CBSVs profile in the community

Community trust was seen by CBSVs as the thrust to compliance. This trust was premised on their enhanced profile in the community; families called them 'doctors'. They believed a number of factors contributed to this new profile including the Newhints supervisory visits and their use of instruments for the assessments. Supervisory visits were perceived by community members as health

systems endorsement of their work and this also facilitated compliance and improved acceptability. Their use of instruments and job aids also signified that they have been trained in the work. As a result of these perceptions about them, CBSVs assumed personal responsibilities for newborn health outcomes in their communities, thinking that if they failed to refer a baby and the baby perishes, their reputations were at stake.

'the community members get very confident that they now have somebody in the community who can detect newborn diseases and to refer them to the hospital and truly when they go to the facilities, they are found to be truly ill' [39-year-old male Mo]

'The other thing too is that, the way we do not just say with our mouth but use the "book" (counselling cards) to illustrate what we are saying, they get the understating that we have undergone some training.' [49-year-old female Bono]

'...if I tell you his supervision did not help me, it's a big lie. When they come and we go together for the visits, families know that 'more senior people' are backing us so they accept the messages more readily and they are ready to comply.' [26-year-old male Gonja]

'If I see a newborn and do not refer and something happens, they will carry the news around town that even a doctor came to see the baby but did not know that the baby was sick and that is why the baby died. If I refer them, I know the baby will get well and I will also have my peace of mind' [46-year-old Bono Farmer]

Some also suggested that Newhints sensitization activities generated interest in the work they were doing and so community leadership also supported them to disseminate their messages about their new roles:

'They (community leaders) also played their part by organizing community meetings. We often asked permission from them to talk to the people about our work in the community and they give us the chance and they also tell the women to allow us into their homes and to receive us well. When we want

to let the community know about some issues, they make them beat the gong-gong to inform the families [50-year-old female teacher]

Though CBSVs thought most families listened to their advice and took their babies for care when referred, its timing appeared to be related to perceptions about severity of the illness. For instance fast breathing was thought to be dangerous because families associated breath with life and thought when one loses breath, it meant death. CBSVs thought families were therefore alarmed and complied quickly when their babies were found with fast breathing. There were also beliefs that when a baby develops fever, the blood dries up it was severe. In their interviews, over 80% of CBSVs thought families responded quickest when these two danger signs were identified.

'life depends on the fact that one has breath in him. Whenever you tell them that the baby was breathing too fast, they get frightened that they are about to lose the baby and so they hurry to hospital' [21-year-old female Bono]

'When one gets too hot, their blood is believed to dry up and so they fear the baby would die' [50-year-old female Badu Teacher]

CBSV interviews indicated that some mothers had challenges raising funds to comply when referred. Although removal of user fees helped, when families fail to save during pregnancy, it was difficult to comply.

'it is not what they pay in the hospital but how they will even get to the hospital. It is also about the sort of expenses they make on the way to the hospital. Some even fear the baby will be admitted and so how to feed the baby and themselves, going up and down all the time becomes a problem.' [50-year-old female]

Concerns about facility response

Previous negative experiences at health facilities were significant barriers to compliance. CBSVs thought these experiences were not always personal but shared by other community members. They described mothers' accounts and/or CBSVs' personal experiences of substantial delays in care-giving at facilities which sometimes turned fatal. Provider communications with mothers and sometimes CBSVs was poor and condescending; they were concerned about its impacts on their work:

'There was one baby I referred the 2nd time and they refused. They went to the hospital after the 1st referral after the next assessment, I referred them back, but she refused saying the first time she went to the hospital, no treatment was given and so no point going again. The baby developed high temperature but she would not be convinced. Later, the baby died.' [26-year-old male CBSV]

'I referred the baby in the morning at around seven o'clock. The mother said she took the baby to the hospital and the nurse there didn't attend to her... She said the nurse was angered by her home delivery saying 'if you sit at home to deliver and there is a problem, then you are rushing over to us!' The nurse directed her to wait and see the doctor but the baby died before the doctor came.' [47-year-old male CBSV]

Suggestions for improving Newhints

Like the mothers, CBSVs' predominant suggestion regarding improvement in the Newhints assessment and referral was regarding mothers' quality of contact with health facilities. They suggested discussions with facility care providers and thought an option was to have a dedicated contact person for referred newborns, at hospitals (where the best care can be given) who can facilitate mothers' care. They also mentioned frequently that the supervision system used in Newhints was

supportive and should continue because it enhanced family trust for them and their confidence.

'What I think is most paramount is that you find something to tell the nurses there so that they stop sending the women away' [21-year-old female Bono]

'...somebody in Newhints who will understand the work and so support the mothers over there would have helped a lot; only at the hospitals because I feel that "a hospital is a hospital" and cannot be compared with our health centre here. That is where they can get the best care.' [46-year-old male Bono Farmer]

'...oh that is the behaviour of the "doctor people". You could go any day and they will treat you like that...it is painful, to tell you the truth! The family trusted me and took my advice attend the hospital and so when they are not treated well, it retards progress in our work. If the person knows that when she goes they will "frustrate" her then she wouldn't go altogether.' [23-year-old female]

Perspectives of health facility care providers

The main themes that emerged from the narratives were the validity of CBSV referrals, families' care expectations, impact of referrals on facility workload, quality of care provided and suggested improvements for the assessment and referral system.

In general, facility care providers welcomed the Newhints referral of sick babies, describing it as 'helpful' or 'useful' to them and community members. They perceived that the system was going to improve access to care for these newborns because families do not recognise when their newborns fell ill and so do not seek care. Even when referred by the CBSV, care providers found that most of the mothers could not articulate why the baby was referred. The referrals therefore

provided 'opportunistic contacts' with mothers who were usually not reached by health services:

'it helps because the mothers don't know the baby is sick so when the volunteer goes and does his examinations to identify the illness, it is then that they prompt the mothers.' [24-year-old male hospital front-desk staff]

'they should be encouraged to continue because it helped us. Until their work came into being, some of the mothers do not know that if a baby is breathing fast, it means it is sick and so they remain at home until babies die. I think we should give them 'nkuranhye' ('motivation').' [a hospital staff midwife]

'I see mothers coming to present with minor diseases when their baby has severe jaundice. It's good to raise the mother's awareness and also show the mother the "preciousness" of their baby and that they need to take care.' [a paediatrician]

Care providers agreed that, generally, CBSV referrals were valid because the majority of the babies that were brought to the hospitals were sick:

'I think on the whole, majority of the babies came with problems; when they referred, you find babies had real problems. I think they are doing a good job' [a medical doctor]

'Any child they are sending is an 'at risk baby' and so we treat them' [55-year-old principal midwifery officer]

However, eight of the fifteen care providers were not happy when babies referred by CBSVs were found to be well. Although they do not always examine these babies, they thought, by these actions, CBSVs were avoidably increasing their already heavy workloads. They could not hide their anger at them:

'it made our work more difficult because the schedule is already 'tight' so when more work is added to it, it makes it even worse' [a hospital staff midwife]

'At times, there are so many people to take care of on the ward and you find this woman and her baby waiting 'on your neck' only for you to come and find nothing wrong with the baby; it was annoying!' **[a hospital staff midwife]**

Other care providers were of a different opinion. They perceived that the intent of CBSVs in referring to hospitals could be a realisation that a second and professional opinion was needed from providers. Moreover, caution needs to be exercised in the handling of these newborns because their illnesses were difficult to detect and they deteriorate quickly. Early reporting and treatment was considered beneficial: it reduces per capita expenditure on the baby and produced better outcomes.

'...when the volunteer went to see the baby, they did not understand something well and that is why they were sending them to us for our opinions so I think it is in order' **[a hospital snr. Midwifery superintendent trained to work in newborn unit]**

'...as for newborns, their conditions can change very quickly and if I let them go, I do not know what next will happen and so I will not take the chance.' **[A midwife orientated in newborn care]**

'They refer quite a number of the children to us and so the workload has gone up, but also, you have to look at the positive and negative sides; the other aspect is that the babies are brought to us early so we are able to manage them; the duration of admission is reduced, consumption of supplies and consumables are also reduced and so economically, it is wise. And then deaths: many used to die before even reaching us but now we see them quite early.' **[a medical doctor]**

Care providers reported mothers usually showed the referral cards. They suggested that with the referral cards mothers expectations of care were high. For instance mothers with the referral cards expected to be seen quicker than other patients and wanted only doctors to treat them.

'They think because they have been referred they have to be seen quickly although they came to meet people here.' **[57-year-old senior midwifery officer]**

To these care providers, however, there were no special protocols for the care of the newborn even if they bore the Newhints referral card. With time, some care providers suggested that babies coming with referral cards were perceived as merely coming to add to their workloads:

'Immediately they see the yellow card, some of the midwives say 'oh these Newhints people will kill us'.' **[a hospital staff midwife]**

They indicated that mothers bearing the referral card were often sceptical when care providers thought the baby was not sick and were sending them home with no treatment. They conceded that they did not always have the time to examine these babies thoroughly due to the heavy workloads and thought this made it difficult to convince mothers that their babies were not ill. Some thought it was a regrettable negligence because some babies died as a result. Others thought mothers' reactions when they were being sent home without treatment depended on the approach and that mothers understood better when babies were checked before being sent home.

'...if they are seen by a doctor, the mother feels very confident but if nobody saw the baby, even the mother will not be convinced because they have come all the way to the hospital because somebody saw something wrong with the baby only for them to be told to go home and that the baby was well' **[a snr. staff midwife]**

'I think because of the workload, pressure and human resource constraints, there's usually not much time to spend evaluating babies; and so newborns that could otherwise be unwell can be just glossed over and think that they can go home, send them home and they deteriorate and pass away.' **[A medical doctor]**

'Some show signs of scepticism but with examination and reassurance they agree especially if you tell them to return once they detect something untoward. It depends on how you approach them.' [a medical doctor]

Suggestions on the way forward for Newhints

Newhints referrals were considered essential with care providers and anticipated that it should be rolled out in other districts. Some care providers hinted that Newhints will be most beneficial if health facilities were also strengthened to support the work, citing the need for better accountability (facilities to maintain newborn contact records and feedback to CBSVs) and dedicated and staffed newborn care units to improve efficiency.

'I think the whole Ghana should be able to do this thing. I tell you they are at the grassroots, serving the people and so if the person is even at Kobeda, they know all the corners. They will get to them early, refer them and help them bring these babies to the hospital. In the end our neonatal deaths will go down to even zero possibly. If a health worker goes for outreaches, they can't have time to see everybody everywhere. I think if all communities in Ghana take on this, it will help all districts, villages, communities in the entire country.' [a midwifery officer and preceptor for trainee midwives]

'We should keep a register for their referrals. We should also call the volunteers, upon the discharge of the baby, to tell them the outcome of the management because they may want to follow-up in the community.' [a hospital snr. Midwifery officer]

"because it is helpful. As we are in the hospital here, we cannot go to all the rural areas to see all the babies in the communities. They are therefore taking on our duties in these areas and they give us the feedback and so it will help us a lot if they extend to all areas" [a principal midwifery superintendent]

7.4 Discussion

Findings from this paper add support to our earlier publication showing that compliance to Newhints referral was unprecedentedly high with 86% of mothers going to a health facility for care of their newborn when referred by CBSVs. This evaluation found that Newhints assessment visits were acceptable to families, the majority of whom did not recognise their baby's illness until the CBSV visited. Demands for these assessment visits therefore increased when families perceived their usefulness and when babies were found with danger signs and referred, the compliance was high and mainly to hospitals. The CBSVs enjoyed their roles in the community and the recognition they received from being associated with the health system. There were overwhelming concerns however about the care provided to the newborns in health facilities with suggestions that it was poor.

All three types of respondents agreed that improving health facility quality of care should be tackled in future implementation of this strategy. To alleviate families' experiences in these facilities, suggestions were made to have contact persons there who mothers could be referred to and who will support them within facilities after referrals. There were also suggestions around extending the scope of the CBSV activities to beyond the newborn period because of community trust and mothers thought it might help to have CBSVs administer some treatment with the referral.

It should be noted that all the interviews were carried out by the lead author (AM) who had participated actively in the training of the CBSVs and the health workers. Responses could have been biased because of this. In the interviews therefore,

confidentiality was assured and interviewees entreated to provide candid responses because the evaluation was meant to improve upon future implementation of the strategy. The findings indicate that, if any, these biases might have been minimal because data obtained from all the multiple sources used in the evaluation were consistent regarding the success of the intervention and the shortcomings of the health facilities.

These results also provide support for the WHO/UNICEF joint statement recommending home visits by community-based agents as a strategy for improving newborn survival.[9] Newborn illness recognition still remains a barrier to care access[5, 14-17] and so the need for interventions such as Newhints that helps families identify illnesses in their newborns is a top global public health priority. The success of the Newhints assessment and referral system[13] is attributable to many reasons, the majority of which were integral components of the implementation strategy.[12] CBSVs attributed their success at convincing families to their enhanced community profiles, leading to trust from community members and consequently the high compliance with referrals. This enhanced CBSV profile was ascribed, firstly, to the community sensitisation activities carried out as part of Newhints implementation including the involvement of community leadership who supported some CBSVs. CBSVs thought these sessions created awareness about their newborn roles. Secondly, the use of directly-observed (repeat) supervisory visits not only improved their confidence and performance but led to families associating CBSVs with the health system. Thirdly, the use of instruments and counselling cards for the identification of newborn illnesses and the subsequent delivery of referral or ENC messages suggested to families that CBSVs had

undergone training and created a sense of CBSV proficiency in newborn health issues adding credibility to their judgement on newborn health. Finally, the follow-up visits were perceived as an important strategy to re-emphasize to families the need for prompt action around newborn illnesses. All these increased assessment acceptability, demand for it and compliance with referral.

In Newhints, CBSVs perceived that families trusted them and, in consequence, positively changed their decision-making around care of their sick newborns.

Although the non-recognition barrier was still present, when CBSVs found danger signs and referred, 86% of families complied.[13] Also, when they referred families to health facilities for the danger signs, they went straight there as their first place of call. This contrasts with the Newhints formative research finding that families' care seeking around newborn illness was sequential and health facilities were used as the last option.[5] Families were genuinely concerned about their newborn's survival and with proper guidance, they will strive to save them from sickness and death.

Facility care providers confirmed the validity of CBSV referrals and thought the intervention merits roll-out at scale. They observed that an important by-product of the intervention was that it afforded them the opportunity to make contacts with some families that were hitherto not accessible to routine health services. Some of these care providers were however concerned about perceived increases in facility workload due to the referrals, particularly because to them, some of the babies referred to facilities were not ill. Whilst these might be legitimate because of the

possibility of false positive referrals, expert recommendations for newborn illness require prompt action for the earliest suspicion of illness.[18, 19] Moreover, families also had serious concerns about the quality of care provided in facilities. There was evidence of substantial delays and inadequate examination of newborns before being sent home leading to some deaths.[13] Staff attitudes were poor and posed a barrier to referral compliance. Similar findings have been reported by Sharkey et al[20] where facility contacts were made for sick infants but poor care-giving led to deaths in a South African study. Whilst it may be a legitimate call to improve upon CHW algorithms for identifying sick newborn in communities, it is known that newborn illnesses could deteriorate rapidly and too stringent algorithms to prevent all false positive referrals may be difficult to teach CHWs and also prevent some genuinely ill babies from accessing life-saving care.[21] The greater urgency will be to rather improve the quality of care for newborns in these health facilities.

Quality of care is known to impact on utilisations of health facilities and this quality is judged by a combination of the actual experiences and users' ratings of care.[22] An assessment of newborn care provided in these facilities showed that the quality was poor.[23, 24] Similar findings were reported in Kenyan hospitals by Opondo et al.[25] The Lancet neonatal series projected that when NMRs fall below 30/1000livebirths, strengthening facility care will be needed to impact on neonatal survival.[26] In the study area, the NMR fell below 30/1000 livebirths in the Newhints intervention zones.[27] Bang et al[4, 28] suggested that poor quality of facility care should fuel advocacy for home-based treatment of newborn illnesses.

However, home-based antibiotic treatment by community volunteers is prohibited in the Ghana Health Service.[29]

Global concerns have been focussed on getting sick newborns to health facilities but our findings suggest that in Newhints, families reached health facilities which appeared not prepared to receive them. We have shown that community health worker assessment and referral of sick newborns to health facilities is acceptable to families, valid, feasible to implement and can lead to substantial increases in access to care for sick newborns. Without concurrent increases in the quality of care provided at health facilities the home visits approach will not achieve its potential impact on neonatal mortality.[27] This remains the crucial link between identifying sick newborns in the community and ensuring their survival. This must be a key component in future implementations of the WHO/UNICEF home visits strategy.

Authors' contributions

The paper was drafted by AM, and reviewed and approved by all authors. BRK, AM, CTA, SOA, ZH were responsible for the design of the Newhints trial; AM, ZH, AtA, CTA, BRK for the data collection instruments; AtA, AM, CTA, BW, TG, SS, SOA for Newhints trial conduct; AM and EU conducted the in-depth interviews; AM, SD, SAE, SS, BRK, AtA for database design and management; and AM for carrying out the analyses.

Table 1: Danger signs for newborns illness used in Newhints

ASSESSMENT	DANGER SIGN
Ask:	
How is the baby feeding?	1 Baby not breastfeeding well since birth or stopped breastfeeding
History of convulsion or fits since birth.	2 Baby having convulsed or fitted since birth and not treated in a health facility.
Check for:	
Chest movements	3 Baby having lower chest in-drawing on inspiration
Palms and soles of the feet	4 Baby having yellow palms and soles
Lethargy/failure to move	5 Baby very weak and not moving at all or only moving when stimulated
Local infections	6 Baby having reddening around the <i>umbilicus</i> or pus discharging from the stump, <i>skin pustules</i> or purulent discharge from the <i>eyes</i> .
Measure:	
Breathing rate	7 Baby breathing too fast: 60 breaths or more per minute validated by a 2 nd count
Temperature	8 Baby having fever: axillary temperature of 37.5°C or more OR 9 Baby too cold: axillary temperature of 35.4°C or less
Weight	10 Birthweight less than 1.5kg (in Red zone)

7.5 References

1. Oestergaard MZ, Inoue M, Yoshida S, Mahanani WR, Gore FM, al. e: **Neonatal Mortality Levels for 193 Countries in 2009 with Trends since 1990: A Systematic Analysis of Progress, Projections, and Priorities.** *PLoS Medicine* 2011, **8**(8):e1001080.
2. Lawn JE, Cousens S, Zupan J, Lancet Neonatal Survival Steering T: **4 million neonatal deaths: When? Where? Why?** *Lancet* 2005, **365**(9462):891-900.
3. Darmstadt GL, Bhutta ZA, Cousens S, Adam T, Walker N, de Bernis L: **Evidence-based, cost-effective interventions: how many newborn babies can we save?** *Lancet* 2005, **365**(9463):977-988.
4. Bang AT, Bang RA, Baitule SB, Reddy MH, Deshmukh MD: **Effect of home-based neonatal care and management of sepsis on neonatal mortality: field trial in rural India.** *Lancet* 1999, **354**(9194):1955-1961.
5. Bazzano AN, Kirkwood BR, Tawiah-Agyemang C, Owusu-Agyei S, Adongo PB: **Beyond symptom recognition: care-seeking for ill newborns in rural Ghana.** *Trop Med Int Health* 2008, **13**(1):123-128.
6. Kumar V, Mohanty S, Kumar A, Misra RP, Santosham M, Awasthi S, Baqui AH, Singh P, Singh V, Ahuja RC *et al*: **Effect of community-based behaviour change management on neonatal mortality in Shivgarh, Uttar Pradesh, India: a cluster-randomised controlled trial.** *Lancet* 2008, **372**(9644):1151-1162.
7. Sutrisna B, Reingold A, Kresno S, Harrison G, Utomo B: **Care-seeking for fatal illnesses in young children in Indramayu, west Java, Indonesia.** *Lancet* 1993, **342**(8874):787-789.
8. Syed U, Khadka N, Khan A, Wall S: **Care-seeking practices in South Asia: using formative research to design program interventions to save newborn lives.** *Journal of Perinatology* 2008, **28** Suppl 2:S9-13.
9. WHO/UNICEF.: **WHO/UNICEF Joint Statement: Home visits for the newborn Child: a Strategy to Improve Survival.** In. Geneva: WHO; 2009.
10. Bang AT, Reddy HM, Deshmukh MD, Baitule SB, Bang RA: **Neonatal and infant mortality in the ten years (1993 to 2003) of the Gadchiroli field trial: effect of home-based neonatal care.** *J Perinatol* 2005, **25** Suppl 1:S92-107.
11. Baqui AH, El-Arifeen S, Darmstadt GL, Ahmed S, Williams EK, Seraji HR, Mannan I, Rahman SM, Shah R, Saha SK *et al*: **Effect of community-based newborn-care intervention package implemented through two service-delivery strategies in Sylhet district, Bangladesh: a cluster-randomised controlled trial.** *Lancet* 2008, **371**(9628):1936-1944.
12. Kirkwood BR, Manu A, Tawiah-Agyemang C, al. e: **NEWHINTS cluster randomised trial to evaluate the impact on neonatal mortality in rural Ghana of routine home visits to provide a package of essential newborn care interventions in the third trimester of pregnancy and the first week of life: trial protocol.** *Trials* 2010, **10**(58).
13. Manu A, ten Asbroek G, Soremekun S, Weobong B, Gyan T, Tawiah-Agyemang C, Owusu-Agyei S, Hill Z, Kirkwood BR: **Increasing access to facility care for sick newborns: evidence from the Ghana Newhints trial.** *submitted* 2012.

14. Awasthi S, Srivastava NM, Pant S: **Symptom-specific care-seeking behavior for sick neonates among urban poor in Lucknow, Northern India.** *Journal of Perinatology* 2008, **28** Suppl 2:S69-75.
15. Choi Y, El Arifeen S, Mannan I, Rahman SM, Bari S, Darmstadt GL, Black RE, Baqui AH, Projahnmo Study G: **Can mothers recognize neonatal illness correctly? Comparison of maternal report and assessment by community health workers in rural Bangladesh.** *Trop Med Int Health* 2010, **15**(6):743-753.
16. Hill Z, Kendall C, Arthur P, Kirkwood B, Adjei E: **Recognizing childhood illnesses and their traditional explanations: exploring options for care-seeking interventions in the context of the IMCI strategy in rural Ghana.** *Trop Med Int Health* 2003, **8**:668-676.
17. Okyere E, Tawiah-Agyemang C, Manu A, Deganus S, Kirkwood B, Hill Z: **Newborn care: the effect of a traditional illness, asram, in Ghana.** *Ann Trop Paediatr* 2010, **30**(4):321-328.
18. Stoll B: **Infections of the neonatal infant: pathogenesis and epidemiology.** In: *Nelson's Textbook of Paediatrics*. 17th edn. Edited by Behrman RE, Kliegman RM, Jenson HB. Philadelphia: Saunders, W. B; 2004: 623-640.
19. de Zoysa I, Bhandari N, Akhtari N, Bhan MK: **Careseeking for illness in young infants in an urban slum in India.** *Social Science & Medicine* 1998, **47**(12):2101-2111.
20. Sharkey AB, Chopra M, Jackson D, Winch PJ, Minkovitz CS: **Pathways of care-seeking during fatal infant illnesses in under-resourced South African settings.** *Transactions of the Royal Society of Tropical Medicine & Hygiene* 2012, **106**(2):110-116.
21. Amarasiri de Silva MW, Wijekoon A, Hornik R, Martines J: **Care seeking in Sri Lanka: one possible explanation for low childhood mortality.** *Social Science & Medicine* 2001, **53**(10):1363-1372.
22. Coulter A: **Can patients assess the quality of health care? Patients' surveys should ask about real experiences of medical care.** *British medical journal* 2006, **333**(7557):1-2.
23. Vesel L, Manu A, Lohela TJ, Gabrysch S, Okyere E, Owusu-Agyei S, ten Asbroek AH, Kirkwood BR: **Quality of Newborn Care: A Health Facility Assessment in Rural Ghana Using Survey, Vignette and Surveillance Data.** *submitted* 2012.
24. Howe LD, Manu A, Tawiah-Agyemang C, Kirkwood BR, Hill Z: **Developing a community-based neonatal care intervention: a health facility assessment to inform intervention design.** *Paediatr Perinat Epidemiol* 2011, **25**(2):192-200.
25. Opondo C, Ntoburi S, Wagai J, Wafula J, Wasunna A, Were F, Wamae A, Migiro S, Irimu G, English M: **Are hospitals prepared to support newborn survival? - An evaluation of eight first-referral level hospitals in Kenya.** *Trop Med Int Health* 2009, **14**(10):1165-1172.
26. Darmstadt GL, Bhutta ZA, Cousens S, Adam T, Walker N, de Bernis L, Lancet Neonatal Survival Steering T: **Evidence-based, cost-effective interventions: how many newborn babies can we save?** *Lancet* 2005, **365**(9463):977-988.
27. Kirkwood BR, Manu A, ten Asbroek AH, Soremekun S, Weobong B, Gyan T, Danso S, Amenga-Etego S, Tawiah-Agyemang C, Owusu-Agyei S *et al*: **Impact of the "Newhints" home visits intervention on neonatal mortality and care practices in Ghana: a cluster randomised controlled trial.** *Submitted* 2012.

28. Bang AT, Bang RA, Baitule S, Deshmukh M, Reddy MH: **Burden of morbidities and the unmet need for health care in rural neonates—a prospective observational study in Gadchiroli, India.** *Indian Pediatrics* 2001, **38**(9):952-965.
29. Ghana Health Service: **Community Newborn Health Policy-draft.** In. Edited by Reproductive and Child Health Directorate Ministry of Health. Accra: Ghana Health Service; 2011.

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CHAPTER EIGHT: Health Facility Assessment

Quality of Newborn Care: A Health Facility Assessment in Rural Ghana Using Survey, Vignette and Surveillance Data

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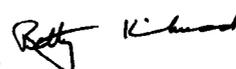
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8.1 Introduction

The 3.3 million newborn deaths that occur in the first month of life account for 41% of under-five mortality and are disproportionately concentrated in low and middle income countries (LMICs).¹⁻³ The majority (75%) occur in the first week, particularly on the first day (25-50%)^{2,4} and can be saved through simple, cost-effective and low technology interventions.^{5,6} The World Health Organization (WHO) and the United Nations Children's Fund (UNICEF) recommend home visits by trained community-based agents (CBA) to promote essential newborn care (ENC) practices and to assess and then treat or refer sick newborns as a strategy to save newborn lives in LMICs.⁷ However, this strategy does not address a large proportion of deaths that occur on the first day, such as those due to birth asphyxia and those that happen before the CBA has had a chance to visit. Furthermore, assessing and referring sick newborns can only save lives if they receive appropriate care when they reach health facilities.

Several studies have reported inadequacies in the quality of facility care for maternal and child health in LMICs.⁸⁻¹¹ However, few have focussed on the quality of neonatal care.^{12,13} The latest Countdown report, taking stock of maternal, newborn and child survival, highlighted a major gap in evidence regarding quality of facility care for newborns in LMICs, both immediately after delivery and of the sick newborn in the postnatal period.^{1,14}

This paper addresses this evidence gap. First, it presents data on the structural capacity and quality of immediate and essential newborn care in all health facilities serving mothers and babies in seven districts in the Brong Ahafo Region of Ghana. These districts are the study area for evaluating the impact of the

Newhints home visits intervention on newborn care practices, access to care for sick newborns and neonatal mortality. Second, this paper links quality with demand for facility care assessed by the number of deliveries and newborn admissions that were recorded as taking place in the Newhints trial.

8.2 Methods

Setting

This health facility assessment (HFA) was carried out in all health facilities serving mothers and babies in the seven Newhints trial districts in the Brong Ahafo region of central, rural Ghana: Kintampo North and South, Nkoranza North and South Tain, Techiman and Wenchi. They are situated in a forest-savannah transitional zone. There are more than 120,000 women of reproductive age with over 15,000 live births per year.¹⁵ The neonatal mortality rate in the area is 32 per 1000 live births. The Newhints intervention was designed to improve newborn survival through home visits by community-based surveillance volunteers (CBSV) to promote essential newborn care (ENC) practices and to refer sick and very LBW babies to health facilities.¹⁵ Mothers were encouraged to go straight to one of the four main district hospitals in Kintampo, Techiman, Nkoranza and Wenchi, which acted as the referral destinations for all other facilities within the study area.

There are a total of 86 facilities serving mothers and babies in the Newhints trial districts, 64 of which perform deliveries (Figure 1). These include a regional hospital located outside the seven districts but acting as the regional referral centre, four main district hospitals, four other district hospitals - two in newly formed

districts and two in adjoining districts which some women use, four private hospitals, 37 health centres, 12 private maternity homes, and 24 clinics. As part of strengthening facilities for the implementation of the Newhints intervention, formative research carried out found inadequacies in the skills of facility staff to care for sick and vulnerable newborns referred to them. Thus, a training of facility staff in ENC was recommended. A WHO-sponsored facility ENC training was organised for all staff who took care of sick newborns. Forty midwives and nurses from the largest facilities where most deliveries and sick newborns were taken for care received a four-day ENC facility training using the WHO's Pregnancy, Childbirth, Postpartum and Newborn Care (PCPNC) guidelines.^{16 17} This training involved assessing newborns for danger signs, classifying their illness and treating or referring where needed. Practical sessions were conducted in two of the four main hospitals as part of the training.^{15 18}

Health Facility Assessment: Content and Data Collection

The HFA was conducted by a physician who was assisted by a research officer in all 86 facilities between June and December 2010. It was carried out with either the head of the facility's joint maternity/newborn ward, or with the most senior nurse/midwife available at the time of the interview. Informed consent was obtained from all respondents.

The HFA included sections on infrastructure (observed); antenatal, obstetric and newborn care provided; referral practices; and vignettes to capture correct practices, one on ENC and two on obstetric care. Additional information captured from the first eleven facilities surveyed included: profile of human resources for

managing sick newborns, reasons for delayed discharge of newborn babies, and a vignette encapsulating care for very LBW. These eleven facilities were the four main district hospitals, and a purposive sample of other facilities focusing on the largest; these were one of the two new (other) district hospitals, the largest private hospital, two of the three largest maternity homes and three of the five largest health centres.

Vignettes: The two vignettes relating to newborn care are shown in tables 1 and 2. The ENC vignette comprised three parts (A, B & C) on resuscitation, immediate newborn care of a stabilised baby, and thermal care. The very LBW vignette included two parts (A & B) on immediate care of very LBW babies and breastfeeding advice. The vignettes were read to each respondent, who was asked to describe the steps of care to be taken.¹⁹ The interviewer marked whether or not the respondent mentioned each of a list of best practice actions specified in the WHO PCPNC guidelines.¹⁷ A score out of ten was calculated for each part of the vignette based on the best practice actions mentioned. The points allocated to each action are shown in tables 1 and 2 and reflect expert opinion on the relative importance of the actions to immediate newborn survival. Sixteen experienced paediatricians were asked to allocate ten points between the actions in each part to reflect their opinion on each action's importance. They were asked to allocate only whole or half points (e.g. 2.5). Averages were then taken of the points they allocated to determine the score given to each action.

Scores of 8 (80%) out of 10 or above could only be achieved if only one of the lowest scoring items were missed; facilities achieving this level have therefore

been categorized as high quality. Scores below 5 (50%) occurred when at least two of the highest scoring items were missed; facilities that scored in this range were therefore categorized as low quality. Facilities in the middle 50%-79% were categorized as moderate quality.

Indicators of Quality of Care

Quality of newborn care was assessed by classifying it into two components defined by Donabedian:^{20 21} (1) structure, characteristics of the setting in which care is administered; and (2) process, the essential procedures in the delivery of care. Structural capacity indicators included percent of facilities with: 1) infrastructure indicators - a clean water source, reliable electricity, fridge for storage of vaccines, drugs and blood, and sink with soap for hand washing; 2) essential newborn care equipment - bag and mask, oxygen cylinder, suction machine / nasal aspirator, incubator, baby scale, cup to measure expressed breast milk, and IV fluid and infusion set; 3) essential drugs necessary for care of the newborn – ampicillin, gentamicin, diazepam and dexamethasone; and 4) profile of human resources for managing sick newborns. Process indicators included: (1) vignette scores; (2) whether or not each of the reasons were mentioned for delayed discharge of newly-delivered babies listed in the PCPNC guidelines; and (3) two indicators capturing ENC practices that should be promoted by facilities: percent of babies born in facilities where breastfeeding was initiated within one hour of birth and percent of babies born in facilities where bathing was delayed for at least six hours based on surveillance data for the Newhints trial.

Matching Quality to Demand

Results from the HFA were matched with the demand for health facility services, using data from the Newhints trial on the number of deliveries by type of facility, and on the number of admissions for sick newborns. Details of the trial protocol including the surveillance system have already been published.¹⁵ The evaluation cohort comprised births occurring between November 2008 and December 2009.¹⁵

Demand is also presented by socio-economic quintiles (SEQ). This is based on an asset index calculated using principal components analysis of a list of household assets collected from women during pregnancy. The asset scores were ranked and divided into quintiles.

Ethical Approval

The HFA and the Newhints trial (clinicaltrials.gov, NCT00623337) were approved by ethical committees at the Kintampo Health Research Centre and the London School of Hygiene and Tropical Medicine.

8.3 Results

Infrastructure Indicators

Table 3 shows the availability of clean water, electricity, fridge for storage of vaccines, drugs and blood, and sink with soap for hand washing. These were available all the time at regional, main district and private hospitals, but two of the other district hospitals did not have reliable electricity as well as the majority of the

health centres and clinics. Additionally, health centres and clinics did not all have a clean water supply or fridges for storage of vaccines. A sink with soap for hand washing was generally available in majority of the facilities.

Essential Equipment for Newborn Care

Table 4 presents the availability of essential equipment necessary for post-delivery newborn care. The majority of hospitals had all functioning resuscitation equipment. The exceptions were one of the main district hospitals and private hospitals that lacked a bag and mask. Maternity homes had an overall better availability of resuscitation-specific equipment than did health centres and clinics. Most facilities, apart from one clinic and one maternity home, had a baby scale to identify very LBW babies. However, one of the four main district hospitals did not have a functioning incubator and two did not have cups to measure expressed breast milk. The other four district hospitals and one of the private hospitals lacked these pieces of equipment. Intravenous (IV) fluids and infusion sets as well as baby scales were overall widely available in all facilities.

Essential Drugs for Sick Newborns

Table 5 shows the availability of IV/IM ampicillin and IM gentamicin, first line antibiotics for newborn sepsis; IV diazepam, an anticonvulsant used for mothers and babies; and IM dexamethasone, a drug used primarily in hospitals to prevent breathing problems in premature babies. As can be seen, the regional and main district hospitals had all drugs apart from one main district hospital, which

lacked dexamethasone. Other district hospitals only had a complete stock of diazepam while private hospitals lacked only dexamethasone. Diazepam was the only drug that the majority of health centres, clinics and maternity homes stocked while more than 50% of maternity homes and clinics had gentamicin; less than 40% of lower level facilities had ampicillin and none had dexamethasone. This is a major shortcoming in any facility performing deliveries.

Profile of Human Resources for Managing Sick Newborns

A total of 30 doctors and 44 medical assistants/nurses/midwives were identified as being capable of managing newborn illness in the four main district hospitals and other seven facilities where the more detailed HFA was performed. Of these personnel, only one doctor was professionally trained to deliver newborn care. However, when the HFA was conducted, only 23 (31%) of these individuals were present at their posts: these were 8 (26.7%) doctors and 15 (34.1%) medical assistants/nurses/midwives. None of the doctors in the 11 focus facilities had attended the ENC training conducted before the implementation of the Newhints intervention, whereas 55% of medical assistants/nurses/midwives capable in managing newborns had attended. However, only 21% of the latter were at their posts during the assessment. Interviews revealed that some of these individuals were posted to work in different departments of the hospitals where their newborn skills were not being utilised.

Vignette 1: Quality of Newborn Care

The scores corresponding to each of the three parts related to the essential newborn care vignette plus total score are shown by facility type in figure 2. Only three of the 64 facilities, two main district and one private hospital, scored 80% or higher overall and were classified as providing high quality of ENC; 76.6% (49) achieved low quality scores. A larger number of facilities (5 hospitals, 3 health centres, 1 clinic and 1 maternity home) scored more than 80% on part A, life-saving resuscitation. The regional hospital scored less than 80% for all three parts of the vignette. Only one main district hospital scored over 80% for parts B and C on immediate newborn care and thermal care respectively, two on immediate resuscitation and two for all three parts combined. Lower level facilities achieved only low to moderate scores for the three parts, apart from two maternity homes on part A and one on the parts B and C, and provided overall low quality of ENC.

Vignette 2: Quality of Care for Very LBW Babies

Quality of care for very LBW babies, for the subset of 11 facilities, was overall slightly better than that seen for ENC (Figure 3). With respect to the management of very LBW babies, the six hospitals were split between moderate and high quality scores while most of the lower level facilities, apart from one maternity home, scored low. Quality of care related to feeding was high for three hospitals and two lower-level facilities, and moderate for one hospital and three lower-level facilities.

Delayed Discharge for Newly Delivered Babies

Maternity/newborn ward matrons in the 11 focus facilities generally did poorly in listing the reasons to delay discharge of newly delivered babies (Table 6). Only four of the thirteen were mentioned by more than half of respondents. Three said that they never delay the discharge of any baby under any circumstances; two of these respondents were from health centres and one from a clinic. In contrast, one respondent was able to list 12 danger signs missing only “eye infection.” She was the matron in one of the main referral level hospitals.

ENC Practice Indicators

Data from the Newhints trial were available for 10343 babies born in facilities who had survived the first day and who had data on initiation of breastfeeding and delayed bathing. Table 7 shows that large coverage gaps exist for both of these two immediate newborn care behaviours that should be promoted in all facilities. Overall, only 48.3% of babies born in facilities were breastfed within one hour of birth and bathing was delayed for 6 or more hours in only 42.5% of them. Delayed bathing for at least 6 hours was highest for babies born in the main district hospitals (47.8%), although this ranged from 5.9% to 68.1%. However, initiation of breastfeeding among those born in the main district hospitals (46.0%; range 39.3%, 58.7%) lagged behind health centres, private hospitals and other district hospitals. Large gaps in adoption remain.

Assessing Quality Against Demand

The right-hand side of Figure 4 shows where 15884 live births occurred between November 2008 and December 2009: 32.1% were born at home and 67.9% in health facilities. The majority of facility deliveries occurred at the four main district hospitals (n=5998, 37.7% of all births and 56% of facility births), followed by health centres (n=2337, 14.7%), maternity homes (n=1298, 8.2%), other district hospitals (n=525, 3.3%), clinics (n=326, 2.1%), private hospitals (n=226, 1.4%) and the regional hospital (n=72, 0.5%). Figure 4 also shows that women in lower quintiles were more likely to have home births and less likely to deliver in facilities. It was the wealthier women delivering in the main district hospitals who were provided the best available quality of care for their newborns. There were 98 admissions for ill babies; 85 (87%) of which were made at the main district hospitals with only four (4.1%) at the regional hospital.

The majority of facility deliveries and admissions for illness occurred in the four main district hospitals. These facilities possessed the infrastructure necessary to function, and were superior to other facilities, scoring highest for quality of care. However, each of these four hospitals lacked personnel trained in ENC and at least one piece of key equipment or dexamethasone, an essential drug administered to women experiencing preterm labour in order to mature foetal lungs and prevent birth asphyxia in their babies. One hospital capturing 981 births, 9.9% of which were LBW, lacked both a functioning incubator and a bag and mask for resuscitation. Two of the other main district hospitals in which 2234 babies were born (7.1% LBW) did not have a cup to measure expressed breast milk. And one hospital capturing 2783 births (10% LBW) did not have a supply of

dexamethasone. None of these hospitals were identified as providing overall high quality of immediate and essential newborn care.

Eleven facilities scored highly on quality of immediate newborn resuscitation but two of these, a private hospital and a clinic, did not have a functioning bag and mask. Thus we estimate that only the 5278 babies born in these 9 facilities had access to high quality, basic resuscitation; this represents 33.2% of all births. Only one of these (a district hospital) also scored highly on immediate newborn care, as did the private hospital and a maternity home; together they delivered 9.7% of all babies. And, three of the 11 facilities, representing 20.3% of births, had a high quality score for the provision of thermal care. Nearly 50% of facility-born LBW babies were born in the two main district hospitals that received high scores for the quality of care for very LBW babies. Three of these four facilities scored highly on care related to breastfeeding of very LBW babies with all four delaying discharge of newly delivered babies in the presence of feeding problems and a very LBW.

8.4 Discussion

Principal Findings

Nearly 70% of women delivered in health facilities. Delivery of high quality newborn care is particularly critical in the main district hospitals since they captured 56% of facility births and 87% of neonatal admissions. They possessed the infrastructure necessary to function, superior to other facilities. However, almost all facilities lacked certain equipment and drugs; one or more main district

hospitals experienced gaps in availability of incubators, cups to measure breast milk, bag and masks and dexamethasone. Interviews suggested that the main district hospitals did not have adequate staff to manage newborn babies.

Additionally, facility respondents in the 11 focus facilities, including hospitals, performed poorly in identifying danger signs that require keeping newborns in hospitals for longer. Quality scores for care of very LBW babies were moderate to high in most facilities. However, only three hospitals achieved an overall high score for quality of ENC; and there were large gaps in coverage of early initiation of breastfeeding and of delayed bathing for all facility births. This represents a missed opportunity.

Strengths and Limitations

This paper addresses a major evidence gap regarding facility care of newborns in LMICs. The National Health Insurance Scheme's (NHIS) free delivery and newborn care has been operational in the Brong Ahafo region since 2008,²²⁻²⁴ which has the highest coverage of all regions in Ghana.²⁵ The NHIS has led to an increase in facility deliveries in the Brong Ahafo Region²⁴ while the Newhints intervention has substantially increased care-seeking.²⁶ This analysis has identified the supply-side components of facility newborn care that need to be strengthened in order to match the demand for services and to increase newborn survival.²⁷

A separate paper²⁸ evaluating the assessment and referral of sick newborns by community volunteers (CBSVs) in the Newhints intervention describes the health facility response based on in-depth interviews with mothers of referred

newborns, CBSVs who referred them and health facility staff. All three groups identified concerns about inadequacies in the quality of care provided to newborns.

The HFA was largely based on self-reports. Vignettes were not intended as clinically complex and comprehensive practicals, but rather as purposely simplified evaluations of crucial, basic newborn care in the first day of life aiming to emphasize the most obvious gaps. They tested the best practice by asking about intended care, which may differ slightly from actual care and could overestimate quality. Because vignette interviews were conducted with the highest level nurse/midwife present, results could be interpreted as reflecting the highest quality of care available. Outcome indicators of quality defined by Donabedian²⁰ as “the effects of care on health status of patients,” such as neonatal mortality and maternal perceptions of care, were not investigated in this analysis. However, outcome indicators of quality of care are often difficult to evaluate since they can be affected by multiple other factors besides care administered at a health facility.

Comparison to Formative Research and Other Studies

A small HFA,¹⁸ investigating the capacity of seven facilities in the Brong Ahafo region, was conducted in 2006 as part of the formative research for Newhints;¹⁵ the HFA presented in this paper is considerably more extensive with respect to its content, administration and link with demand. The formative assessment identified gaps in the availability of equipment, inadequate promotion of immediate initiation of breastfeeding and delayed bathing, and quality of immediate resuscitation.¹⁸ This HFA shows that little improvement in capacity and quality of newborn care has been achieved since the formative research. Although

facility ENC training was arranged before the implementation of Newhints for staff from the largest 15 facilities, none of the doctors in the main district hospitals attended these training sessions and only a fifth of the medical assistants/nurses/midwives who attended were present at their posts at the time of the HFA; some were no longer caring for newborns. These findings emphasise the critical need for continuous ENC training and retention of trained staff. This needs to be coupled with availability of essential equipment, particularly for LBW babies as facilities tended to have higher scores of quality associated with the care for very LBW babies and delayed discharge, but lacked all the equipment necessary to manage these babies.

Waiswa and colleagues²⁷ also identified poor knowledge of newborn care and availability of proper equipment in Ugandan facilities. Nearly 25% of first week deaths and 9% of overall neonatal mortality can be saved with immediate, basic resuscitation using a bag and mask; few babies require advanced resuscitation²⁹⁻³² Bag and masks are inexpensive, simple to use and easy to acquire.³⁰ However, Lee and colleagues³³ reported poor quality of neonatal resuscitation in various countries around the world due to lack of proper equipment and trained staff. Although bag and masks were widely available in health facilities in Ghana, low to moderate quality scores for immediate newborn resuscitation likely resulted from lack of properly trained staff. We estimated overall that a maximum of 33% of babies were born in facilities potentially capable of providing high quality newborn resuscitation; they achieved high vignette score and had a bag and mask. This is higher than the estimates from Wall and colleagues.³⁴ They observed from six African national service provision assessments that only 2-12% of health workers performing deliveries were trained in newborn resuscitation and

8-22% had proper equipment available, and concluded that resuscitation was available for less than 25% of babies and if only about 50% of women deliver in facilities in many African countries, then accessibility to this life-saving intervention is reduced to about 12.5% of babies.³⁴ Facility training in basic resuscitation in LMICs, the first vital life-saving intervention, can avert about 30% of intrapartum-related neonatal deaths.³⁴

What is already known on the subject

Global strategies to save newborn lives include promotion of facility delivery and community based approaches to increase access to care for sick and vulnerable newborns.

Several studies have reported inadequacies in the quality of facility care for maternal and child health in low and middle income countries.

However, an evidence gap exists regarding quality of newborn facility care.

What this study adds

Detailed assessment of quality of immediate and essential newborn care (ENC) in all types of facilities, with indicators linked to demand.

Key gaps in ENC equipment, drugs and/or personnel and essential life-saving actions were found in all facilities. We estimate that only 33.2% of babies born in facilities had access to high quality, basic resuscitation.

Promotion of early initiation of breastfeeding and delayed bathing was inadequate for all facility births.

A one-off ENC facility training course had very little impact on the quality of care provided.

This paper has highlighted major gaps in availability of essential newborn care equipment and drugs, trained personnel, quality of ENC and provision of care for very LBW babies, and promotion in facilities of key ENC practices. Strategies to increase access to facility delivery and care for sick and very LBW babies cannot

achieve their potential in saving newborn lives unless they focus on improving the quality of newborn care available at health facilities.

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Data sharing: Data are available on request.

Competing interests: All authors have completed the Unified Competing Interest form at www.icmje.org/coi_disclosure.pdf (available on request from the corresponding author) and declare that (1) LV, AtA, AM, SS, CTA, EO, ZH and BRK have support from DfID, WHO and SNL for the submitted work; (2) the authors have no relationships with any companies that might have an interest in the submitted work in the previous 3 years; (3) their spouses, partners, or children have no financial relationships that may be relevant to the submitted work; and (4) the

authors have no non-financial interests that may be relevant to the submitted work.

There are no competing interests.

Contributors: LV drafted the paper and conducted the analysis with input, review and approval from all authors. The study was conceived by AM, BRK, AtA, ZH, CTA and SOA, who were also responsible for the design and conduct of the Newhints trial. The HFA was designed by AM, LV, SG, and BRK and conducted by TL, EO, SG and AM. The corresponding author had full access to all the data and together with the last author responsibility for the decision to submit for publication.

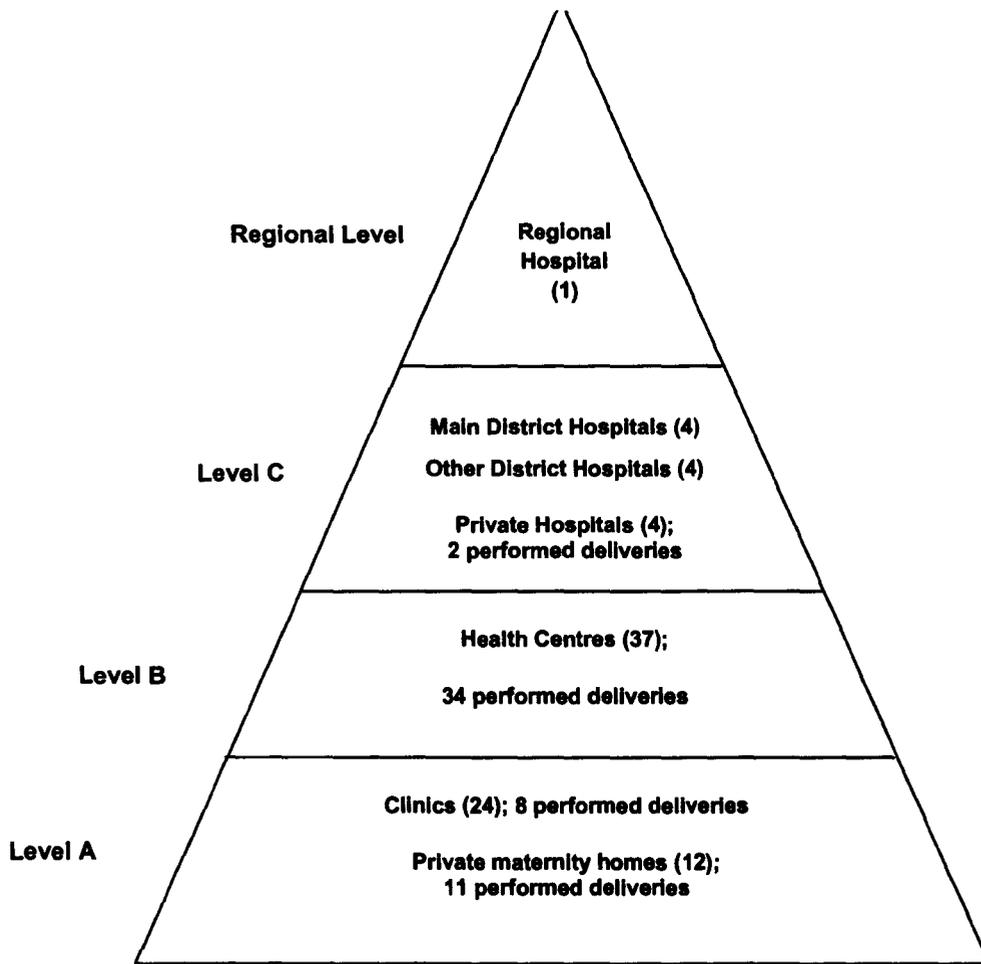


Figure 1. Hierarchy of health facilities in the Brong Ahafo Region, Ghana

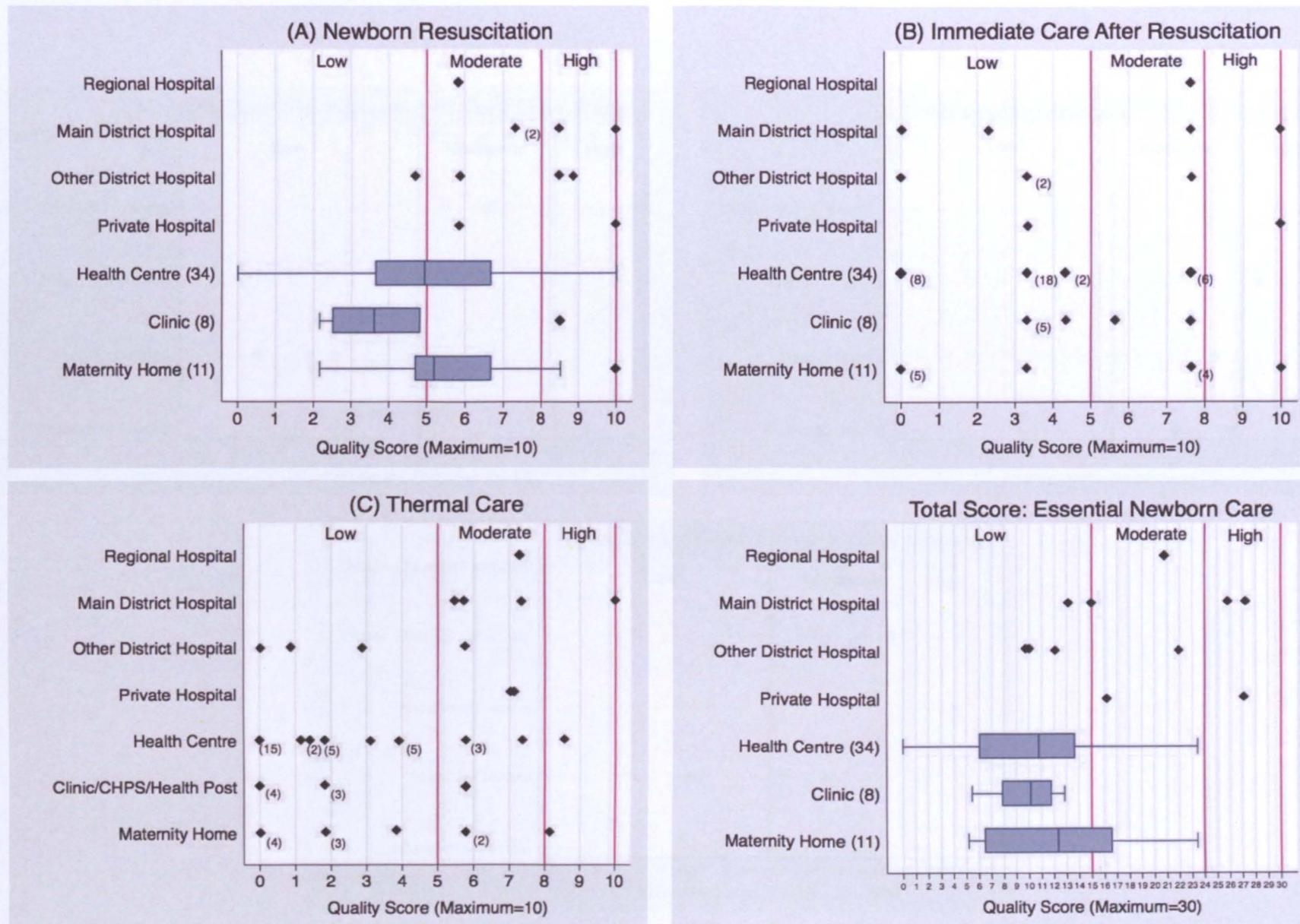


Figure 2. Vignette 1 (Essential newborn care): Individual or box plot scores by type of facility

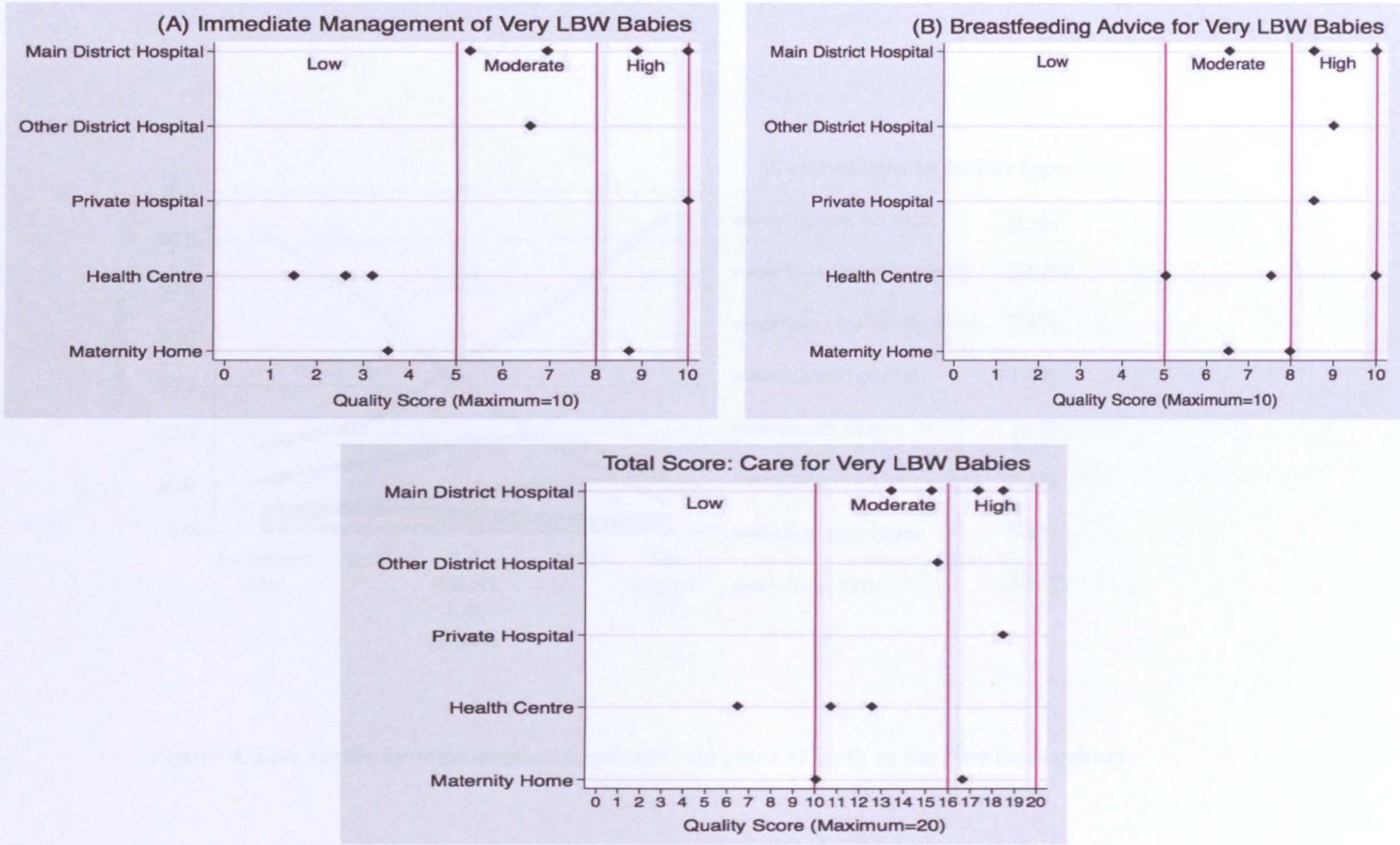


Figure 3. Vignette 2 (Care for very LBW babies): Individual scores by type of facility

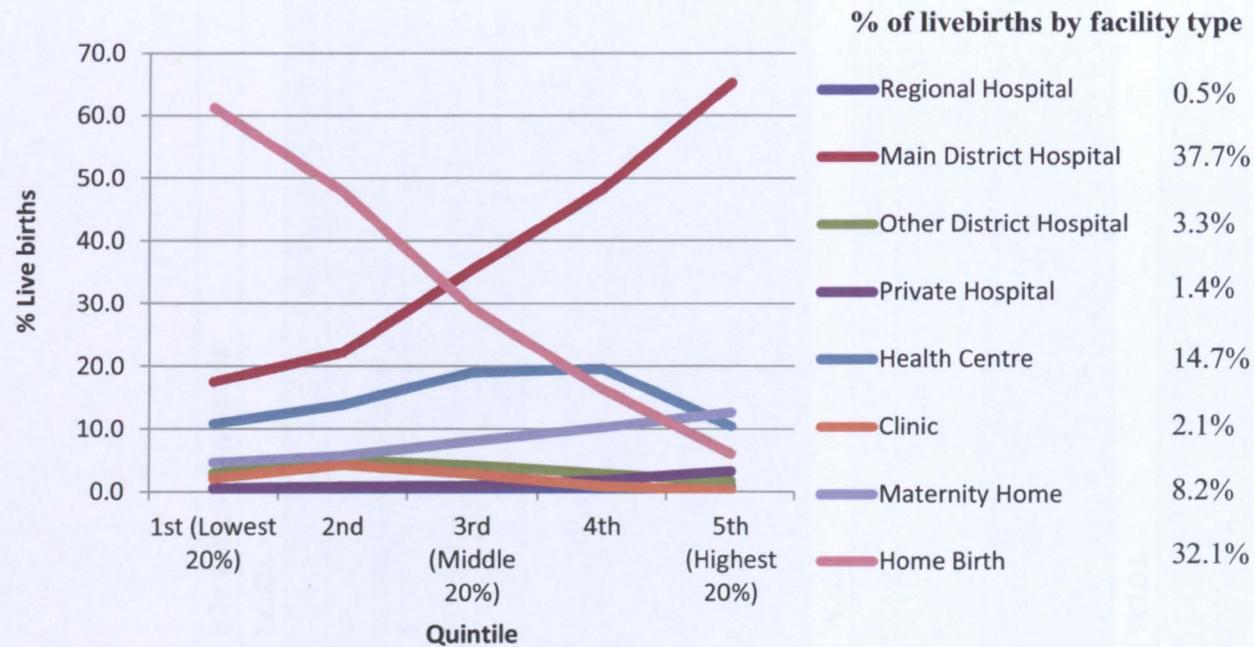


Figure 4. Live births by socio-economic quintile and place of birth in the Newhints cohort

Table 1. Vignette 1 (Essential newborn care) questions

VIGNETTE 1		
A) A woman in labour presents at this facility. The Fetal Heart Rate is more than 160bpm. On examination, her cervix is fully dilated and the baby has the head in the perineum. The baby is delivered and is normal weight, but it does not cry after delivery. What would you do for this baby? DON'T PROMPT!		
ACTION		SCORE
1)	Dry quickly and vigorously	2.66
2)	Examine and suction the mouth	2.16
3)	Ensure extra warmth for the baby	1.50
4)	Use bag and mask to ventilate if baby does not cry after suctioning	2.53
5)	Apply cardiac massage if ventilation alone does not help	1.16
TOTAL SCORE (A)		10
B) Suppose the resuscitation was successful, what would you do next? DON'T PROMPT!		
ACTION		SCORE
1)	Initiate breastfeeding immediately	3.31
2)	Keep in skin-to-skin contact with the mother	4.34
3)	Ensure and encourage hygiene	2.34
TOTAL SCORE (B)		10
C) During routine checking on the baby after about 2hrs, you see the baby sleeping alone and the mother is sleeping not in touch with baby. There is no covering on the baby since it wriggled out of the mother's cloth. What would you do? DON'T PROMPT!		
ACTION		SCORE
1)	Feel if baby is too cold	1.28
2)	Take the temperature with a thermometer	1.53
3)	Give skin-to-skin care / kangaroo mother care by mother or put in incubator for rewarming	3.94
4)	Prevent draught in the room: check if windows are closed, switch off any fans on the ward	1.41
5)	Ask mother to breastfeed the baby	1.84
TOTAL SCORE (C)		10
MAXIMUM SCORE FOR VIGNETTE		30

Table 2. Vignette 2 (Care for very LBW babies)

VIGNETTE 2		
A) A 17yr-old woman pregnant for 8 months delivered a baby at home. A trained community volunteer weighed the baby and found it to be 1.4kg. As a result, she referred the baby to your facility. What would you do for this baby? DON'T PROMPT!		
ACTION		SCORE
1)	Detain for thorough examination	1.50
2)	Ensure breastfeeding is established and provide support if necessary	2.05
3)	Put the baby in an incubator OR skin-to-skin with the mother	2.13
4)	Teach the mother to keep baby skin-to-skin / kangaroo mother care position (if in incubator, when taken out)	1.92
5)	Check cord dressing and other potential sources of infection	1.28
6)	Encourage and ensure hygiene in care	1.12
TOTAL SCORE (A)		10
B) Mother says the baby is not breastfeeding and was contemplating giving glucose solution. What would you do? DON'T PROMPT!		
ACTION		SCORE
1)	Watch her breastfeed her baby and teach her good positioning and attachment	3.03
2)	Examine the baby's mouth to ensure there are no anatomical deformities	1.47
3)	If baby not breastfeeding, teach her to express the milk and feed with a clean cup	2.50
4)	Encourage infant formula only if exclusive breast milk is not possible and mother can afford	1.00
5)	Educate her and encourage her to practise exclusive breastfeeding for the 1st 6 months of the baby's life	2.00
TOTAL SCORE (B)		10
MAXIMUM SCORE FOR VIGNETTE		20

Table 3. Availability of basic infrastructure in facilities that deliver babies

Type of Facility	Number	Always Available			
		Clean Water Source	Reliable Electricity	Fridge for Storage	Sink with Soap
Regional Hospital	1	1 (100%)	1 (100%)	1 (100%)	1 (100%)
Main District Hospital	4	4 (100%)	4 (100%)	4 (100%)	4 (100%)
Other District Hospital	4	4 (100%)	2 (50%)	4 (100%)	4 (100%)
Private Hospital	2	2 (100%)	2 (100%)	2 (100%)	2 (100%)
Health Centre	34	25 (74%)	2 (6%)	29 (85%)	32 (94%)
Clinic/CHPS/Health Post	8	5 (63%)	1 (13%)	6 (75%)	8 (100%)
Maternity Home	11	11 (100%)	7 (64%)	9 (82%)	9 (82%)
Total	64	52 (81%)	19 (30%)	55 (86%)	60 (94%)

Table 4. Availability of essential equipment for post-delivery newborn care

Type of facility	Number	Resuscitation Equipment			Care for Very LBW Babies & Feeding Problems			General
		Bag & Mask	Oxygen Cylinder	Nasal Suction/Aspirator	Incubator	Baby Scale	Cup to measure Breast Milk	IV Fluids & Infusion Sets
Regional Hospital	1	1 (100%)	1 (100%)	1 (100%)	1 (100%)	1 (100%)	1 (100%)	1 (100%)
Main District Hospital	4	3 (75%)	4 (100%)	4 (100%)	3 (75%)	4 (100%)	2 (50%)	4 (100%)
Other District Hospital	4	4 (100%)	4 (100%)	4 (100%)	1 (25%)	4 (100%)	1 (25%)	4 (100%)
Private Hospital	2	1 (50%)	2 (100%)	2 (100%)	1 (50%)	2 (100%)	1 (50%)	2 (100%)
Health Centre	34	28 (82%)	12 (35%)	31 (91%)	1 (3%)	34 (100%)	12 (35%)	34 (100%)
Clinic/CHPS/Health Post	8	5 (63%)	0 (0%)	6 (75%)	0 (0%)	7 (88%)	2 (25%)	7 (88%)
Maternity Home	11	10 (91%)	8 (73%)	11 (100%)	0 (0%)	10 (91%)	6 (55%)	10 (91%)
Total	64	52 (81%)	31 (48%)	59 (92%)	7 (11%)	62 (97%)	25 (39%)	62 (97%)

Table 5. Availability of essential drugs for newborn survival

Type of Facility	Number	Management of Sepsis		Managing Convulsions	Preventing Birth Asphyxia in Preterm Deliveries
		IV/IM Ampicillin	IM Gentamicin	IV Diazepam	IM Dexamethasone
Regional Hospital	1	1 (100%)	1 (100%)	1 (100%)	1 (100%)
Main District Hospital	4	4 (100%)	4 (100%)	4 (100%)	3 (75%)
Other District Hospital	4	2 (50%)	3 (75%)	4 (100%)	1 (25%)
Private Hospital	2	2 (100%)	2 (100%)	2 (100%)	0 (0%)
Health Centre	34	8 (24%)	14 (41%)	32 (94%)	0 (0%)
Clinic/CHPS/Health Post	8	3 (38%)	6 (75%)	7 (88%)	0 (0%)
Maternity Home	11	4 (36%)	3 (52%)	9 (82%)	0 (0%)
Total	64	24 (38%)	33 (52%)	59 (92%)	5 (8%)

Table 6. Reasons for delayed discharge of newly delivered babies by maternity/newborn ward matrons in 11 facilities

Classification	Reasons for Delayed Discharge after Birth	Type of Health Facility			
		Hospital (n=6)	Health Centre* (n=3)	Maternity Home* (n=2)	Total (n=11)
Signs of severe infection	Lethargy	4 (66.7%)	1 (33.3%)	1 (50.0%)	6 (54.5%)
	Grunting	1 (16.7%)	1 (33.3%)	0 (0.0%)	2 (18.2%)
	Breathing Difficulty	1 (16.7%)	1 (33.3%)	0 (0.0%)	2 (18.2%)
	Chest Indrawing	2 (33.3%)	0 (0.0%)	0 (0.0%)	2 (18.2%)
	Hypothermia	1 (16.7%)	0 (0.0%)	0 (0.0%)	1 (9.1%)
	Fever	5 (83.3%)	1 (33.3%)	0 (0.0%)	6 (54.5%)
Other signs	Inability to Breastfeed	6 (100.0%)	1 (33.3%)	1 (50.0%)	8 (72.3%)
	Convulsed	2 (33.3%)	0 (0.0%)	0 (0.0%)	2 (18.2%)
	Jaundice	2 (33.2%)	0 (0.0%)	1 (50.0%)	3 (27.3%)
	Skin Pustules	1 (16.7%)	0 (0.0%)	0 (0.0%)	1 (9.1%)
	Eye Infection	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
	Sick	3 (50.0%)	1 (33.3%)	0 (0.0%)	4 (36.4%)
	Very Low birth Weight	5 (83.3%)	1 (33.3%)	0 (0.0%)	6 (54.5%)

*Two health centres and one maternity home reported that they never delayed newborn discharge, and therefore gave no reasons.

Table 7. Key behaviours by type of facility

Place of Delivery	Births	Initiate Breastfeeding <1hr	Delay Bathing > 6hrs
Regional hospital	65 (0.6%)	26 (40.0%)	21 (32.3%)
Main district hospital	5680 (54.9%)	2615 (46.0%)	2715 (47.8%)
Other district hospital	505 (4.9%)	282 (55.8%)	171 (33.9%)
Private hospital	216 (2.1%)	113 (52.3%)	42 (19.4%)
Health centre	2288 (22.1%)	1341 (58.6%)	998 (43.6%)
Clinic/CHPS/health post	320 (3.1%)	116 (36.3%)	41 (12.8%)
Maternity home	1269 (12.3%)	502 (39.6%)	411 (32.4%)
Total	10343*(100.0%)	4995 (48.3%)	4399 (42.5%)

* Total number of babies born in facilities who survived the first day and had information on both behaviours

8.5 References

1. WHO. Countdown to 2015 decade report (2000-2010): taking stock of maternal, newborn and child survival. *World Health Organization: Geneva, Switzerland* 2010.
2. Lawn JE, Kerber K, Enweronu-Laryea C, Cousens S. 3.6 million neonatal deaths--what is progressing and what is not? *Semin Perinatol* 2010;34(6):371-86.
3. Oestergaard MZ, Inoue M, Yoshida S, Mahanani WR, Gore FM, Cousens S, et al. Neonatal mortality levels for 193 countries in 2009 with trends since 1990: a systematic analysis of progress, projections, and priorities. *PLoS Med* 2011;8(8):e1001080.
4. Lawn JE, Cousens S, Zupan J. 4 million neonatal deaths: when? Where? Why? *Lancet* 2005;365(9462):891-900.
5. Darmstadt GL, Bhutta ZA, Cousens S, Adam T, Walker N, de Bernis L. Evidence-based, cost-effective interventions: how many newborn babies can we save? *Lancet* 2005;365(9463):977-88.
6. UNICEF. Levels & Trends in Child Mortality: Estimates Developed by the UN Inter-agency Group for Child Mortality Estimation: United Nations Children's Fund, 2011.
7. WHO/UNICEF Joint Statement. Home visits for the newborn child: a strategy to improve survival. 2009.
8. Nolan T, Angos P, Cunha AJ, Muhe L, Qazi S, Simoes EA, et al. Quality of hospital care for seriously ill children in less-developed countries. *Lancet* 2001;357(9250):106-10.
9. Althabe F, Bergel E, Cafferata ML, Gibbons L, Ciapponi A, Aleman A, et al. Strategies for improving the quality of health care in maternal and child health in low- and middle-income countries: an overview of systematic reviews. *Paediatr Perinat Epidemiol* 2008;22 Suppl 1:42-60.
10. Fauveau V, de Bernis L. "Good obstetrics" revisited: too many evidence-based practices and devices are not used. *Int J Gynaecol Obstet* 2006;94(2):179-84.
11. van den Broek NR, Graham WJ. Quality of care for maternal and newborn health: the neglected agenda. *BJOG : an international journal of obstetrics and gynaecology* 2009;116 Suppl 1:18-21.
12. English M, Ntoburi S, Wagai J, Mbindyo P, Opiyo N, Ayieko P, et al. An intervention to improve paediatric and newborn care in Kenyan district hospitals: understanding the context. *Implementation science : IS* 2009;4:42.
13. Opondo C, Ntoburi S, Wagai J, Wafula J, Wasunna A, Were F, et al. Are hospitals prepared to support newborn survival? - An evaluation of eight first-referral level hospitals in Kenya. *Trop Med Int Health* 2009;14(10):1165-72.
14. USAID. Profiles of Health Facility Assessment Methods. MEASURE Evaluation.
15. Kirkwood BR, Manu A, Tawiah-Agyemang C, Ten Asbroek A, Gyan T, Weobong B, et al. NEWHINTS cluster randomised trial to evaluate the impact on neonatal mortality in rural Ghana of routine home visits to provide a package of essential

- newborn care interventions in the third trimester of pregnancy and the first week of life: trial protocol. *Trials* 2010;11:58.
16. Campbell H, Duke T, Weber M, English M, Carai S, Tamburlini G. Global initiatives for improving hospital care for children: state of the art and future prospects. *Pediatrics* 2008;121(4):e984-92.
 17. WHO. Integrated management of pregnancy and childbirth. Pregnancy, childbirth, postpartum and newborn care: a guide for essential practice. 2006.
 18. Howe LD, Manu A, Tawiah-Agyemang C, Kirkwood BR, Hill Z. Developing a community-based neonatal care intervention: a health facility assessment to inform intervention design. *Paediatr Perinat Epidemiol* 2011;25(2):192-200.
 19. Peabody JW, Luck J, Glassman P, Jain S, Hansen J, Spell M, et al. Measuring the quality of physician practice by using clinical vignettes: a prospective validation study. *Ann Intern Med* 2004;141(10):771-80.
 20. Donabedian A. The quality of care. How can it be assessed? *JAMA* 1988;260(12):1743-8.
 21. Donabedian A. Evaluating the quality of medical care. 1966. *Milbank Q* 2005;83(4):691-729.
 22. Agyepong IA, Adjei S. Public social policy development and implementation: a case study of the Ghana National Health Insurance scheme. *Health Policy Plan* 2008;23(2):150-60.
 23. Witter S, Garshong B. Something old or something new? Social health insurance in Ghana. *BMC Int Health Hum Rights* 2009;9:20.
 24. Dzakpasu S, Soremekun S, Manu A, ten Asbroek G, Tawiah C, Hurt L, et al. Free national health insurance for pregnant women in Ghana: impact on health facility delivery and insurance coverage in the Brong Ahafo Region *Manuscript not published* Submitted 2012.
 25. Ghana Statistical Service (GSS), Ghana Health Service (GHS), Macro I. Ghana Demographic and Health Survey 2008. *Accra, Ghana: GSS, GHS and ICF Macro* 2009.
 26. Kirkwood BR, Manu A, Asbroek AH, Soremekun S, Weobong B, Gyan T, et al. Impact of the “Newhints” home visits intervention on neonatal mortality and care practices in Ghana: a cluster randomised controlled trial. Submitted 2012.
 27. Waiswa P, Kallander K, Peterson S, Tomson G, Pariyo GW. Using the three delays model to understand why newborn babies die in eastern Uganda. *Trop Med Int Health* 2010;15(8):964-72.
 28. Manu AA, Hill Z, Asbroek Gt, Tawiah-Agyemang C, Okyere E, Owusu-Agyei S, et al. Community volunteer assessment and referral of sick babies: perspectives from mothers, volunteers and care providers in the Ghana Newhints trial. *Submitted* 2012.
 29. Lawn JE, Wilczynska-Ketende K, Cousens SN. Estimating the causes of 4 million neonatal deaths in the year 2000. *Int J Epidemiol* 2006;35(3):706-18.

30. Wall SN, Lee AC, Carlo W, Goldenberg R, Niermeyer S, Darmstadt GL, et al. Reducing intrapartum-related neonatal deaths in low- and middle-income countries- what works? *Semin Perinatol* 2010;34(6):395-407.
31. WHO. Safe Motherhood. Basic newborn resuscitation: a practical guide. *geneva: World Health Organization* 1997.
32. Lawn JE, Kinney M, Lee AC, Chopra M, Donnay F, Paul VK, et al. Reducing intrapartum-related deaths and disability: can the health system deliver? *Int J Gynaecol Obstet* 2009;107 Suppl 1:S123-40, S40-2.
33. Lee AC, Cousens S, Wall SN, Niermeyer S, Darmstadt GL, Carlo WA, et al. Neonatal resuscitation and immediate newborn assessment and stimulation for the prevention of neonatal deaths: a systematic review, meta-analysis and Delphi estimation of mortality effect. *BMC Public Health* 2011;11 Suppl 3:S12.
34. Wall SN, Lee AC, Niermeyer S, English M, Keenan WJ, Carlo W, et al. Neonatal resuscitation in low-resource settings: what, who, and how to overcome challenges to scale up? *Int J Gynaecol Obstet* 2009;107 Suppl 1:S47-62, S63-4.

CHAPTER NINE: Evaluating the Implementation of CBSV Assessment & Referral

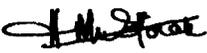
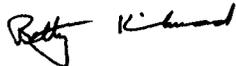
Evaluating the Implementation of Community Volunteer Assessment and Referral of Sick Babies: Lessons learned from the Ghana Newhints Home Visits Cluster Randomised Controlled Trial

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9.1 Introduction

Improving access to care for sick newborns is key to reducing the 3.3 million babies who die each year within 28 days of birth (neonatal period).^{1,2} The majority of these deaths occur in low and middle income (LMIC) countries, in settings where most births and illness that lead to death occur at home,^{3,4} with no health facility contacts.^{2,4} This is because families do not recognise newborn illness⁵⁻⁷ and when they do, care seeking is poor^{4,5,7-9} and often besieged with barriers such as costs, distance, availability of services, and social seclusion prohibiting out of home care seeking.⁷⁻¹¹ Community-based strategies are therefore urgently needed.¹

The World Health Organization (WHO) and United Nations Children's Fund (UNICEF) in 2009 issued a joint statement recommending home visits by community-based agents (CBAs) as a strategy to improve newborn survival.¹² This promotes examining babies in the first week after birth and referring any with danger signs or conditions requiring additional care, teaching families how to identify signs of illness and counselling on the importance of prompt health facility care seeking. This strategy was based on evidence from studies in Asia which successfully reduced neonatal mortality through home visits by community health workers (CHWs).^{5,13-18}

The Newhints cluster-randomised controlled trial (CRT)¹⁹ in Ghana is the first trial to evaluate this approach in sub-Saharan Africa. It demonstrated evidence of reduction in post-day1 newborn mortality, achieved by increasing coverage of

essential newborn care (ENC) practices and by improving access to care for sick newborns through high compliance with community volunteer referrals and improved care-seeking.^{20 21} This paper presents a detailed evaluation of the implementation of the assessment and referral component of the Newhints intervention and shares the lessons learned in order to inform scale-up and implementation of this core component in other settings.

9.2 Methods

Study setting & the Newhints Trial

Setting: Details of the Newhints intervention and the cluster randomised trial (CRT) are given elsewhere.¹⁹ The trial was conducted in seven contiguous districts in the Brong-Ahafo region of Ghana covering 12,000sqkm,¹⁹ a population of approximately 700,000²² with over 120,000 women of reproductive age and more than 15,000 babies born each year. The neonatal mortality rate at baseline was 32/1000 livebirths.²³ Eighty percent of the population live in villages comprising scattered compounds surrounded by farmlands and lacking modern infrastructure. The area is multi-ethnic, educational levels are low and subsistence farming is the main economic activity.

Four main district hospitals located in urban centres (figure 1) act as referral destinations for over 80 other facilities serving the area. All communities have community based surveillance volunteers (CBSVs), selected by their communities to support district health management teams (DHMTs) in community mobilization

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for health programmes. They are predominantly male (about 80%) with at least primary education (over 90%).

The Newhints cluster randomised trial: Newhints was an integrated intervention based on extensive formative research and developed in collaboration with the District Health Management Teams (DHMTs) in the seven districts with input from national and international experts. CBSVs in 49 Newhints out of 98 supervisory zones (comprising 8-12 CBSVs) were trained to promote essential newborn care (ENC) practices through five home visits, two in pregnancy and three in the first week after birth, the time of the greatest vulnerability for the newborn,⁴ to weigh and assess newborns for ten key danger signs (table 1) and refer to health facilities when any was present.²¹ This simple checklist approach was adopted rather than an algorithm with branches and actions based on specific signs as this was both quicker to explain and more easily understood by community volunteers. CBSVs in the 49 control zones continued normal activities. The impact of the Newhints intervention was evaluated on the cohort of babies born between November 2008 and December 2009.

Conceptual framework for the evaluation of assessment and referral component

Figure 2 shows the conceptual framework adopted by the Newhints intervention for increasing access to care for sick newborns through community assessment and referral as a strategy to improve survival. There are three main steps, each with a

specific goal. These are (1) sick newborns are identified in the community and referred (2) families comply with referrals and (3) referred babies receive appropriate management at health facilities. The framework shows the rationale for each step, the strategy used to achieve the goal and the key requirements for success. The strategies are outlined below. The rationale and the evaluation of the key requirement for success are discussed in detail in the section on findings, drawing together data from the formative research and the process evaluation.

STEP 1

CBSV training: CBSV training was in three phases, totalling nine days. The first phase (3 days, in March 2008) covered behaviour change communication, counselling skills, promotion of ENC practices and saving for emergencies in pregnancy, childbirth and the newborn. The 4-day second phase in June/July 2008 focussed on assessment and referrals. It involved interactive practical newborn assessment video exercises using the WHO IMCI Computerized Adaptation and Training Tool (ICATT). One day was dedicated to clinical practice sessions at the major health facilities, where each CBSV trainee assessed at least two babies using digital clinical thermometers, stop-watches and portable weighing-scales with colour-coded bands: red for weights below 1.5kg identifying very low birthweight (LBW) babies; yellow for weights between 1.5kg-2.4kg identifying LBW babies; and green for weights of 2.5kg and above. Decision-making around referral, facilitation of referral compliance and problem-solving skills were discussed in detail using case stories and cards with various weights, respiratory rates and temperature measurements.

The third phase was a 2-day refresher course in October 2008 which was convened in response to supervisors' feedback and focussed solely on the assessment and referral decision-making. One of these two days used clinical practice sessions in the major health facilities.

Community introduction of CBSVs: A series of activities were carried out within communities to promote awareness of the Newhints intervention and achieve acceptability of CBSV visits. These included meetings with community opinion leaders, traditional birth attendants (TBAs) and durbars with community members, at which certificates were awarded to CBSVs at the end of their training.

Supervision of CBSVs: CBSVs were supervised by trained district-based project supervisors (DiPS) who visited CBSVs monthly to replenish their stocks. This included joining the CBSV on a repeat home visit and providing supportive supervision, observing and recording their performance on a structured directly-observed supervision (DOS) form and providing feedback at the end of the session. The DiPS also organised bimonthly zonal group sessions to discuss overarching community concerns and problem-solve around them.

STEP 2

CBSVs actively *engaged family members* who were involved in the care of the newborn in the assessment. When a baby was identified with a danger sign, they issued the family with a *referral card* to take along to the health facility, dialogued with them to elicit barriers to compliance and *problem-solved* around these barriers. They also conducted a *follow-up visit* within 24hrs of referral to check compliance and when mothers failed to comply, they assessed the baby again and referred to a health facility if danger signs persisted.

STEP 3

Sensitisation sessions were organised for all facility care providers in the study area in order to introduce Newhints and to harmonize Newhints CBSV messages with those of the Ghana Health Services (GHS). Implications of the intervention on GHS routine services and the use of the referral card for identifying referred sick babies were also discussed. Newhints also facilitated a WHO-sponsored 4 day ENC facility training course for staff who took direct care of sick newborns from the top 15 facilities including the four main district hospitals in the study area. These were selected to cover facilities where most births and sick newborn care occurred.

Evaluation data collection

Data were gathered to evaluate each requirement in the conceptual framework from five sources: process data; supervisory (DOS visit) records; quality control of DiPS

assessment; health facility assessment (HFA); and in-depth interviews including referral narratives (IDIs) with mothers, CBSVs and facility care providers.

Process data: Process data were collected from a sub-sample of 4006 recently-delivered mothers in the Newhints intervention zones. This comprised 64 mothers randomly selected each week from March to July 2009 from the trial surveillance database and all mothers who delivered between August and December 2009. These data covered CBSV visits, assessments, referrals, compliance, type of health facility used, and care provided using pre-tested data collection forms administered by trained field supervisors.

DOS records: DiPS completed records for 759 DOS visits between May and December 2009 in which newborn assessments were observed. Information extracted from these forms included the quality and content of the CBSV assessments, referrals made, advice given and repeat measurements made by the DiPS.

Evaluation of the quality of DiPS' assessment: An evaluation of the reliability of the DiPS assessments was carried out in November 2009 at the four main hospitals by the study clinician (AM) assisted by a research officer. Each DiPS was asked to assess four babies and to record their findings onto a structured form. These assessments were observed by the study clinician who independently noted down

his assessment findings. Both AM and the DiPS handed their forms to the research officer for compilation.

Health facility assessment survey: Details of the HFA survey have already been published.²⁴ In brief, all 86 health facilities (public and private) serving mothers and babies in the Newhints trial areas were visited between July 2009 and March 2010. Respondents were matrons (in-charge) of the maternity/newborn care units or the facility. The assessment covered: essential infrastructure, availability of equipment, drugs and supplies for newborn care; services provided; and clinical vignettes which depicted clinical case studies of newborns with respondents asked to describe the care that should be provided in these cases. Newborn conditions covered included resuscitation, thermal care, feeding practices, care of very low birthweight babies and discharge procedures.

In-depth interviews (IDIs): IDIs were conducted between June 2009 and March 2010 with three groups of respondents using saturation sampling with the sample size determined by conducting interviews until no new information arose. IDIs lasted between 45-90 minutes and were digitally recorded. Fieldnotes on the setting, perception of the mothers' socio-economic status and nuances that added context to the responses were taken.

Fifty-five recently-delivered mothers with babies referred by CBSVs were selected from the process database using purposive sampling to obtain balance on age,

educational attainment, marital status, residence, ethnicity, parity and compliance with referrals. IDIs involved a narrative of the referral experience complemented by probing using a pre-tested interview guide to cover details of experiences from the CBSV assessment, referral, compliance decision making, compliance, facility used and care provided, outcome for the baby, and CBSV follow-up visits.

Similar IDIs were also conducted with 21 CBSVs who had referred babies, purposively selected from the trial CBSV database to cover all ages, level of education, gender and district. Topics covered in these IDIs included the number of babies they had referred, a detailed narrative of the most complicated referral, family reactions to the visits and the referrals, their perceptions on barriers and facilitating factors to families compliance, care provided to referred babies as reported by families, and their experiences at the follow-up visits.

IDIs were also conducted with 15 facility care providers covering all levels of staff that mothers would come into contact with including a paediatrician, doctors, nurses, midwives and front-desk staff. The interview covered experiences with Newhins referred babies and their mothers, perceptions on the validity of the CBSV referrals, mothers' expectations of care, care provided for newborns, and challenges with providing this care.

Data analysis

Data analyses were carried out in Stata version 11.2. Principal components analysis was used to calculate an asset index (using household assets) from which socio-economic quintiles (SEQs) were derived after ranking mothers and dividing them into quintiles. Agreements between assessments were compared using Kappa statistics, with the DiPS as standard for the DOS assessments and the clinician for the DiPS' evaluation. The interpretation of the Kappa was based on acceptable standard²⁵ where 1 means perfect agreement and 0 means no agreement. Kappa of <0.40 was interpreted as fair or slight agreement, 0.40 – 0.60 moderate agreement, 0.61-0.80 as substantial agreement and 0.81-0.99 almost perfect agreement. Sensitivity and specificity of CBSV assessments and referrals were also estimated and 95% confidence intervals (95% CI) were reported on all estimates.

The IDIs were transcribed into MicrosoftWord by combining the recordings with the fieldnotes. Analyses were done in NVIVO 9.2 and involved generation of themes from multiple reading of the transcripts, systematic indexing/coding of the data into these themes and exploration of relationships and their contextual interpretations.

9.3 Findings

Step 1: Identify sick newborns in the community and refer

Rationale: The rationale for this step was that formative research leading to the implementation of Newhints found that families do not recognize illnesses in their newborns within the homes and care seeking for sick newborns is poor.^{8 11} IDIs with mothers and CBSVs confirmed the need for this approach. The majority of families had not recognised their newborn was ill before the CBSV's assessment. Also recognition without action happened.

'At times it can be very difficult because the family members do not know that the baby is sick but because I have already discussed things with them at the pregnancy visits, they learn to trust me and so they comply.' [27-year-old female CBSV, a teacher by profession]

'I saw that the baby was discharging from the eyes and there were rashes on the body but I did not do anything about it. As for the breathing, I have never seen babies breathe before and so I did not know until he came. And the hot body too, I thought that was the way newborn babies were and so I did not think it was any problem.' [24-year-old Dagarti primip, Junior High School (JHS) graduate]

1.1. Acceptability of assessment visits: Both mothers and CBSVs reported that the Newhints assessment visits were welcomed and acceptable to families. Mothers were happy that the work of the CBSV was helping them know when their newborns were ill in order to seek care. Some explained that they were pleased with the assessment visits because it was reassuring to know the state of health of their newborns.

'The way he has the patience to visit us three times to check the health of the baby is very good. Sometimes your baby might be sick but you may not know so if he comes to do this work to check whether baby has a 'problem' and tells you to go to the hospital, it is really good and it helps we the mothers; when he says there is no 'mistake' you the mother also feels free.' [38-year-old Bono farmer]

The CBSVs also confirmed that they were well received and that other family members who were invited to participate in the assessment joined in the discussions around the findings. They added that families were in fear their newborns could die if the babies had an illness and they did not know and therefore positively demanded assessment visits. The demand was reinforced by hearing experiences from other mothers whose babies had been referred and successfully treated at the facility.

'They really understand the work I am doing so most of them invite me to come for the assessment. It seems they see the benefits that those who allow me to examine their babies get and so they too wanted to have that' [49-year-old female Bono CBSV]

1. 2. Coverage of CBSV assessments & referrals: Table 1 shows details of the CBSV assessment and the percentage of assessments during which they checked each of the danger signs. The latter is based on the DOS forms completed by DiPS during supervisory visits and on reports from mothers in the process sample. Process data showed that 70% of mothers received CBSV visits in the postnatal period, and that at these visits, 76% of babies had their respiratory rates counted, temperature taken and weights measured. Coverage of these assessments individually was very high, approximately 95% on each. DOS data confirmed this

high coverage of both individual and complete assessments. CBSVs were observed to check for at least 8 danger signs in 92% of visits, and for nine or ten danger signs in 79% of visits. The DOS data also shows that, on average, 95% of the assessments that required the use of instruments were conducted as compared to 88% of those checked by observation. Thirteen percent of babies had danger signs and were referred at DOS visits compared to 10% reported on the process form.

1.3. Accuracy of CBSV assessments and referrals: Table 2 shows that CBSV assessments strongly agreed with the DiPS assessments made during the DOS visits; with coefficients of agreement between the two ranging between 0.75 for count of respiratory rates and 1.0 for lethargy (or when baby moves only when stimulated) or very low birthweight (vLBW) babies, indicating excellent to near perfect agreement. Apart from observing for local infections, The sensitivities of CBSVs diagnosis for signs checked by observation were relatively low (57%-59%) with just over 40% detected by the DiPS missed by the CBSV; the exception was local infections with a sensitivity of 95%. The sensitivity was also high for danger signs using instruments (80%-100%). However, specificities were close to 100% for all danger signs, except for the confirmatory 2nd respiratory rate count that had a specificity of 91%. The evaluation of the DiPS quality of assessment also showed that the DiPS achieved near perfect agreement with the study physician; Kappa=0.9-1.0. These findings suggest that CBSVs can accurately assess babies for danger signs at home visits.

1.4. Accuracy of referrals: Referral decisions made by the CBSVs at these DOS visits also achieved excellent agreement with the DiPS; Kappa=0.87 (0.82, 0.92),

with 80% sensitivity and 100% specificity. CBSVs are accurately referring babies based on the danger signs they noted with no false positives but failing to refer some as they had failed to detect some signs. Validity and accuracy of CBSV referrals also emerged as a theme in the IDIs with facility care providers. They commended the diagnostic acumen of the CBSVs and confirmed that the majority of their referrals were valid and accurate.

'they sometimes identify problems that even some of us struggle to find; I think whatever training they were given must have been of a very good standard.' [a medical doctor in a district hospital]

Step 2: Families comply with referrals

Formative research identified that mothers' ability to seek care for a sick newborns was often besieged with many barriers including costs, distance to facilities and norms and beliefs that some illnesses such as a culturally constructed syndrome of 'Asram' were not-for-hospital illnesses so that, even when illnesses were identified, appropriate care was not sought.^{8 11 26} Addressing these barriers was seen as key to achieving high compliance with referrals. The Newhints strategy therefore explicitly did so by training the CBSV to engage families during the assessments and involve them in the decision making around the referral. They were also trained to issue referral cards to the mothers whenever a baby was referred, to stress the importance of promptness of compliance, and to encourage them to take the baby to a hospital. They then elicited any barriers that the families were facing in being able to take the baby to the hospital and problem-solved around them. The CBSVs returned the next day for a follow-up visit to check compliance. If the baby

hadn't been taken to a health facility, they re-assessed and referred again if the danger signs persisted.

2.1. CBSVs facilitate referral compliance

Trust for CBSVs: Trust by families was seen by CBSVs as crucial to convincing mothers to comply with referrals. In their IDIs, CBSVs thought families trusted them because of their enhanced profiles as 'doctors' for their communities and were cautious to protect this reputation by promptly referring babies to facilities. They perceived that if they failed to refer and the baby dies, they will be seen as incompetent.

'We know she is a doctor and knows her job so we decided to listen to her advice. We were ready to send the baby and this decision was easy for us because she is a doctor. [20yrs Mo mother with 8yrs formal education]

'If I see a newborn and do not refer and something happens, they will carry the news around town that even a doctor came to see the baby but did not know that the baby was sick and that is why the baby died. If I refer them, I know the baby will get well and I will also have my peace of mind' [46-year-old male Bono CBSV; father of 7]

Involved families in assessments: DOS data showed that 84% of the times, CBSVs involved family members, other than the mother, in the assessment and the discussions of the findings. In their IDIs, mothers, other family members and the CBSVs, confirmed involvement of other family members in discussions around referrals and compliance:

“I entered the room with him where the baby was and when we got there, he (CBSV) said he was coming out again to wash his hands. He came out and washed his hands and asked me to call everybody at home who normally helped in the care of the baby. At the time, my mother and my eldest daughter were around and so I called them to join us.” **[38yrs Mo mother of five with 3yrs of formal education]**

‘When I got to the house, I invited ‘the man of the house’ to come and participate in the visit. During the pregnancy whenever I invited him, he always said I should go ahead and have the meeting with the women. On that day, the baby was crying excessively and so when I invited him for the assessment he got interested and came to sit to see what I did’ **[48-year-old CBSV; Baby was referred and husband accompanied the mother and baby to a hospital].**

Issued referral card: During the DOS visits, CBSVs issued all mothers whose babies were referred with referral cards. In their narratives, the mothers suggested that the CBSVs explained to them that with the card, they were going to be seen promptly at health facilities. CBSVs also confirmed this adding that the card made mothers want to go. When describing how they identified Newhints babies, facility care providers mentioned that they always came bearing the referral card. They added that, with the card, mothers wanted to be treated quickly even if they came to meet other people in the facility waiting to be attended:

‘He gave me a card, it was a yellow card and said I should take along and if I put it in the hands of the ‘doctors’, it will make them see the baby quickly for us.’ **[24-year-old Bono mother of 2]**

‘I tell them not to join the queue but to go directly to the nurses and tell them that they were from Newhints with showing of the yellow card and they will be taken care of and that makes them go’ **[21-year-old CBSV]**

'The mothers come with a card. They have a special card that they give to them to bring along. At times when you ask the mother, she says 'a boy came to check my baby and asked us to come and see the doctor. When you look at the card, you see they are from Newhints. '[46yrs enrolled midwife]

"You will see that yellow card, and then they want to be treated quickly; even though they come to meet other people here they want to be treated early. '[57yrs snr. midwifery officer]

Overcoming barriers: The CBSVs elicited perceptions of vulnerability around newborns in the families in order to emphasize the need for prompt compliance with referrals. Other barriers such as cost and distance ceased to be important considerations once the baby's illness was perceived to be severe. This removal of compliance barriers was also related to emergency preparation during pregnancy; data showed 86% of mothers said they saved during the pregnancy for emergencies and 87% also enrolled on the National Health Insurance Scheme which provided free facility care for sick newborns.

"I could then see clearly that the child was very sick after he explained to us so I was ready to send him to the hospital". [15yrs Bono mother with 7yrs formal education]

'he told us to go to the hospital the same day; he came to the house at around 8-9 in the morning but I explained that my mother was not around at the time because she had gone to the farm. I could not carry the baby by myself to the hospital because it was my first delivery and I did not have the experience.' [20yrs primip; a teacher]

'at the time he was visiting us in the pregnancy, he told us to save some money in the form of 'susu' so that when we are going to deliver or if we get an emergency, we could use for the costs and we did'[35yrs mother; a farmer]

In some cases, when mothers were found to be handicapped and could not afford to take the baby, CBSVs contacted other family members to solicit support to enable the mother comply with the referral. They also directly supported mother with loans and gift money to enable them comply. Where mothers thought transport was the barrier, CBSV went to get a vehicle for them or negotiated for them to be given the priority to take their sick baby to hospital:

'After telling us, the CBSV accompanied me to my husband's house to disclose his findings to him and his brother (they live in the same house). There, immediately he finished, the man (husband) did not even ask any question and just went and brought me money to take along to the hospital. They believe him 'very much'. **[18y-year-old Dagarti farmer and primip]**

'I told him that I would wait and go the next morning but he said he wanted me to go the same day. He then offered to go to the roadside and see whether he could get a vehicle for me to take to the hospital and Nsawkaw but when he went and did not get one, he came back to inform me but still wanted me to go and so I rather walked to Seikwa' **[23-year-old Sisala primip, completed JHS]**

2.2. Referral compliance: Process data showed that compliance with referrals was unprecedentedly high with 86% of mothers taking their babies to a health facility, three-quarters of these going to hospitals.²⁷ There was evidence to suggest that compliance was pro-poor with the poorest mothers complying more than the least poor (88.4% vs. 69.7%) and rural residents more than urban (87.3% vs. 81.7%)²⁷ Although distance did not seem to affect compliance, with the spatial spread of referrals and mothers who complied with them. showing no evidence of clustering (Figure 1), urban mothers who lived closer to the hospitals had better means of transport and were able to reach facilities faster than rural ones.

2.3. Follow-up visits: The DOS data showed that CBSVs assured families that they were going to return for follow-up visits in 92% of all the referrals they made. In IDIs with the mothers and the CBSVs, they indicated that this assurance to return and check on compliance made mothers want to comply. CBSVs were also motivated to follow up on referrals because they wanted to know what happened in the facility; the mothers appreciated this.

'He gave me a card and said he would come back later to check if I have been able to go. What am I going to tell him if he comes and asks and I have not been able to go?' [40yrs Bono mother of 8]

'Yes, I think so! If I had not told them I will return to check the next day, even if they would have gone, they would not have gone on the same day- they would have waited for some time before taking action.' [39yrs male Mo CBSV]

Step 3: Referred babies receive appropriate management

The rationale for this step was that timely and appropriate management of sick newborns can prevent newborn deaths.^{1 28} Our formative research showed that even though hospitals in the study area were capable of managing sick newborns because they have the equipment, drugs and infrastructure, technical skills of staff were lacking.²⁹ The Newhints team therefore organised the facility ENC training for staff in the largest facilities. No other direct intervention (such as supply of drugs, equipment or changes in infrastructure) was made within the health facilities.

3.1 Equipment, drugs and supplies: The health facility assessment survey²⁴ showed that only hospitals had all the requisite equipment, drugs and supplies for the management of sick newborns. However, even though these hospitals were connected to the national power grid, the power supply was not reliable and only two had stand-by generators. There was over-reliance on equipment such as incubators which were inadequate in number. These incubators usually carried more than two babies at a time. Some of these were sick babies whilst others might not be sick but vulnerable such as low birthweight babies. The risks of nosocomial cross-infection were very high. Only one had a dedicated newborn care unit. Kangaroo Mother Care for premature or low birthweight babies was not practised.

3.2 Health worker newborn care skills: Newhints ENC training did not seem to make any lasting difference to the quality of newborn care provided in the trial districts. Apart from one paediatrician, no health worker had had specialised/formal training in newborn care. Doctors and clinicians failed to attend the Newhints facility ENC training. Instead nurses and midwives who did not provide definitive treatment for newborns attended. The health facility assessment found that only 19% of nurses or midwives reported as capable of managing sick newborns were at post in the top eleven health facilities²⁴ and these were mainly the respondents to the assessment questionnaire. Just over 10% of these had been trained in facility ENC. Follow-on interviews revealed that staff placement policies played a role in the skills deficit because some ENC trained staff were still at post had been moved to other units where their newborn skills were not utilised; others had left. Moreover, management protocols for sick newborn care were non-existent in all the facilities.

'...but the other is the question of quality and quality; because even for the older nurses, with no additional training, they cannot do what you expect them to. When the experienced few are on leave, it leaves you with nobody to step in.' **[A paediatrician]**

'There is none; we keep our protocols in our heads and teach the juniors among us how we work here' **[A senior midwife]**

There were suggestions, however, from care provider responses in the IDIs that if trained staff were placed properly and supported, the outcome for sick newborns could have been different. Respondents who had additional training in sick newborn care seemed to have better understanding of newborn vulnerability and had a different attitude towards Newhints referred babies:

'...as for newborns, their conditions can change very quickly and if I let them go, I do not know what next will happen and so I will not take the chance.' **[A midwife trained by the Paediatrician to support in a newborn care unit]**

'Mostly they say the baby is having fast breathing. Some are due to cord sepsis. I think if infection is setting in, fast breathing is the first sign. So when you see fast breathing and you send them home, you might be doing the wrong thing. I detain them overnight and oftentimes, sepsis is seen by the next day. In some cases you see reddening around the cord so the doctor then puts them on five days of antibiotics.' **[An ENC trained midwife]**

3.3 Timely and appropriate care: Table 3 shows evidence of substantial delays within health facilities before sick newborns were seen. These delays were worst in the four main district hospitals where over a third of mothers were kept waiting for more than three hours. These delays sometimes resulted in deaths. Also, Newhints

process data showed that about a quarter of referred babies were sent home without treatment often with the decision made without proper examination of the newborn.²⁷ IDIs with mothers, CBSVs and doctors confirmed that some babies subsequently died after health facility contacts:

'I referred the baby in the morning at around seven o'clock. The mother said she took the baby to the hospital and the nurse there didn't attend to her... She said the nurse was angered by her home delivery saying 'if you sit at home to deliver and there is a problem, then you are rushing over to us!' The nurse directed her to wait and see the doctor but the baby died before the doctor came.' [47-year-old CBSV]

'we have nothing to say about how they treated us over there 'bro' (interviewer)...they are doing their work and they said there was nothing wrong with the baby but he died, what can you do?' [35-year-old Sisala mother who lost her 2nd twin after she complied with referral and was sent home without treatment]

'I think because of the workload, pressure and human resource constraints, there's usually not much time to spend evaluating babies; and so newborns that could otherwise be unwell can be just glossed over and think that they can go home, send them home and they deteriorate and pass away.' [A medical doctor]

3.4 Supportive health worker attitudes: Staff attitudes were perceived as very poor with both CBSVs and mothers suggesting that interventions to improve families' experiences within facilities should be a priority for continued or future implementation of the Newhints intervention. Mothers reported being abused when they took their sick newborns for care in the facilities especially if they delivered at home or failed to attend ANC during the pregnancy.

'When I got there, she asked what was wrong with my baby and so I showed her the yellow card. There and then, she got so angry and threw the card at me and threw me out because I delivered at home.' **[35-year-old mother of four]**

'Mostly, the women (nurses) shouted at and manhandled her and I told them she's never given birth before. They said she shouldn't stay inside the room whilst they treated the baby. Even if the baby cried they didn't allow her see to him.' **[A grandmother of 15-year-old first-time mother]**

9.4 Discussion

A summary of the key lessons learned the strength and weaknesses of the evaluation, how the evidence generated compares with prevailing knowledge about CHW assessment and referrals, and overall conclusions are presented in the next four sections.

Summary of lessons learned

1. Family recognition of sick newborns remains very poor and recognition without action is common. Home visits to identify and refer sick newborns are a necessary and effective strategy to improve access to care for sick newborns. These visits are welcomed by families.
2. Training CBSVs to conduct home visits and accurately assess and refer sick newborns can be achieved in just 9 days. Six of the 9 days focussed on this component with two days of clinical practice sessions. Scale up should

therefore be logistically feasible to achieve even in LMIC settings with weak economy and health systems.

3. The use of the clinical practice sessions are crucial to build volunteer confidence at handling newborn babies and to provide them practical exposure to how newborn assessments will be within communities because of the use of real babies and the opportunity to interact with mothers who hail from communities comparable to theirs.
4. A simple checklist for danger signs with referral when any one of them is present works well with community volunteers, and is preferable to a clinical type algorithm. The checklist approach takes less time to explain, is more easily understood and does not appear to lead to false positive referrals.
5. Effective supervision and monitoring is essential, and should include observation of home visits to reinforce skills and ensure and maintain quality implementation of this strategy. These observations can be best achieved by carrying out additional visits to newborns rather than relying on supervision coinciding with scheduled home visits, as these do not happen on a regular basis.
6. Supervised home visits had the unexpected benefit of enhancing the volunteer profile in the community and associating them with the health services, reinforcing the importance of compliance with any referrals.
7. With proper facilitation and planning, high compliance with CHW referrals is achievable even for rural families. However, distance to referral level facilities remains a barrier in ensuring prompt access to care for sick newborns.

8. Increasing access to care through community assessment and referral is a poor approach with the potential to reach all newborns regardless of wealth or place of residence, as confirmed by the high compliance rates achieved across socio-economic quintiles and in rural as well as urban areas.
9. Issuing a referral card makes a difference. It has several roles. It emphasises the importance of the referral, promotes a sense of continuity between community volunteers' assessment and referral and facility care, and allows effective triaging of referred newborns at health facilities.
10. Increasing access to care for sick newborns is necessary but not sufficient to ensure newborn survival; it must be matched with improved quality of facility care. This should be tackled in parallel to implementation of home visit programmes not only through health worker training, but through on-going quality improvement strategies.
11. Community-based assessment and referrals could lead to increases in workload at health facilities especially which impact on the quality of care and should be an early consideration in implementation. However, if CHW assessment and referrals have high specificity, as was the case in Newhints, increased facility workload is probably indicative of the unmet need for newborn care within communities.
12. Community-based strategies that increase access to care for sick newborns may not be perfect; there is always the possibility of false positive referrals. However, these may have merits in that they provide "opportunistic" contacts with families who were otherwise not reachable within routine health programmes. In addition, encouraging such referrals will likely result in sick

newborns being seen early which may prove economically and medically prudent - reducing facility expenditure per capita sick newborn and result in better outcomes.

13. With the proven ability of CBSVs to accurately assess newborns for danger signs, a possible modification might be that they are also trained to treat minor ailments in the home and provide pre-referral antibiotics in recognition of the long distances to facilities. However, caution needs to be exercised as this may inadvertently reduce referral compliance. This unexpected consequence may explain the difference in the very high compliance achieved in Newhints which did not include any treatment, and the much lower compliance observed in the other trials that did.

Strengths and limitations

This evaluation followed a detailed conceptual framework and covered every aspect of the implementation of the assessment and referral component of the Newhints strategy and its rationale. These details and the lessons learned will provide important information to programme implementers about all aspects of the intervention strategy that need consideration before implementation.

A potential limitation of the evaluation is that the DOS visits measured the ability of CBSVs to conduct the assessments but not necessarily what they did. CBSVs might modify their behaviours because they knew they were being observed.

However, process data and the IDIs confirmed that the CBSVs routinely carried out the assessments. Another possible limitation is that the IDIs were conducted by the lead author who was actively involved in the training and implementation of the study. It is possible that responses from CBSVs and health professionals could have been biased. However, all the various sources of data including the IDIs provided a convergent evidence of the success of the implementation. The effect of bias, if any, is therefore likely to have been minimal. Finally, as implementation takes time to bed in, it would have been ideal both to evaluate the impact and the implementation over a longer period.

Comparison with other evidence

Table 4 compares the Newhints approach to increasing access to care for sick newborns with that used in other trials evaluating the home visits strategy. As can be seen, it is the first trial in sub-Saharan Africa that implemented a community-based strategy to increase newborn access to care through home visits. This was done in close collaboration with DHMTs using an existing cadre of community volunteers (CBSVs) within a programme setting.¹⁹ It is also clear from the table that the short duration of training in Newhints is only comparable with implementation of IMNCI in India in Bhandari et al's trial which trained for eight days.¹⁵ Most other trials involved training over extended periods of time.^{5 13 17 18 30} In many LMICs, the added costs due to provision of training logistics including travel costs for trainees and/or their housing, hiring of venue and compensation for trainers' times will escalate the cost of implementation. Newhints assessment and referral only draws parity with the Bhandari et al¹⁵ in the number of postnatal visits

conducted by CHWs; all other trials except Kumar et al visited more often in the neonatal period. Kumar et al however did not implement assessment and referral except the use of Thermospots for hypothermia detection.⁵ All but one of the trainers in Newhints were non-clinicians.^{20 31}

Notably, of all the trials that implemented the home visits strategy, Newhints was evaluated over the shortest duration of implementation (14 months) but the results show that coverage of postnatal visits in Newhints compares with many other trials that were implemented for longer (table 4).

The unprecedented high compliance with Newhints referral is the most important finding of this evaluation.²⁷ No trials have reported such high compliance levels to community volunteer referrals. The checklist for referrals was simple to teach and reliable, drawing heavily from previous Asian studies^{13 17 32} and the WHO multi-country Young Infants Study.³³ Although suggestions from facility care providers may be true that some newborns were wrongly referred to them leading to an increase in their workload, questions still remain about babies sent home from facilities without treatment who subsequently died.^{27 34} The Newhints assessment and referrals achieved very high specificity for CBSV referrals suggesting that the increased facility workload³⁴ may rather be reflecting the unmet need for sick newborn care within communities.

Facility quality of care is the crucial link between referred sick newborns and survival. This lesson supports the Lancet series' recommendation that isolated community or facility interventions without linkages between them will not deliver optimal results.¹ Facilities in the Newhints study were ill prepared to provide appropriate management for sick newborns,²⁴ similar to findings reported by Opondo et al³⁵ in another study in Africa. Oftentimes, care for sick newborns is equated to sophistication and high technology but this is erroneous.¹ The other option is to explore the possibility of administering some treatment within communities for minor ailments. CHWs have been trained in Asian studies to administer antibiotics successfully within communities.^{13 14 32} Whilst this has merits in providing timely and life-saving care closer to the community and could reduce workload at health facilities and its consequent impact on quality of care, it may also have several drawbacks. First it may inadvertently reduce referral compliance and careseeking. Most studies in Asia that employed treatment as part of the strategy recorded very low care seeking and poor compliance with referrals.¹³
^{14 18} Secondly, providing volunteers with algorithms to selectively treat newborns based on set criteria may require complex algorithms with increased training requirements.

9.4 Conclusions

In conclusion, this detailed evaluation has demonstrated successful implementation of the assessment and referral component of the Newhints intervention with achievement of every key requirement in the conceptual framework. This has important implications for the implementation of the home visits strategy in other

settings in sub-Saharan Africa: CBAs can be used to deliver home visits, they can identify sick newborns through accurate assessments and refer to health facilities for care, and families will comply when asked. Moreover we have demonstrated that this approach is feasible to implement, can be delivered at scale and is potentially pro-poor even when delivered within health systems of resource-limited country settings. However, the home visits approach cannot attain its full potential in increasing newborn survival, while the current poor quality of care within health facilities remains. This is the crucial and missing link that must be tackled in parallel.

Authors' contributions

The paper was drafted by AM, and reviewed and approved by all authors. BRK, AM, CTA, SOA, ZH were responsible for the design of the Newhints trial; AM, ZH, AtA, CTA, BRK for the data collection instruments; AtA, AM, CTA, BW, TG, SS, SOA for Newhints trial conduct; AM, SD, SAE, SS, BRK, AtA for database design and management; AM, AtA, ZH and BRK for the development of the conceptual framework and AM for carrying out the analyses.

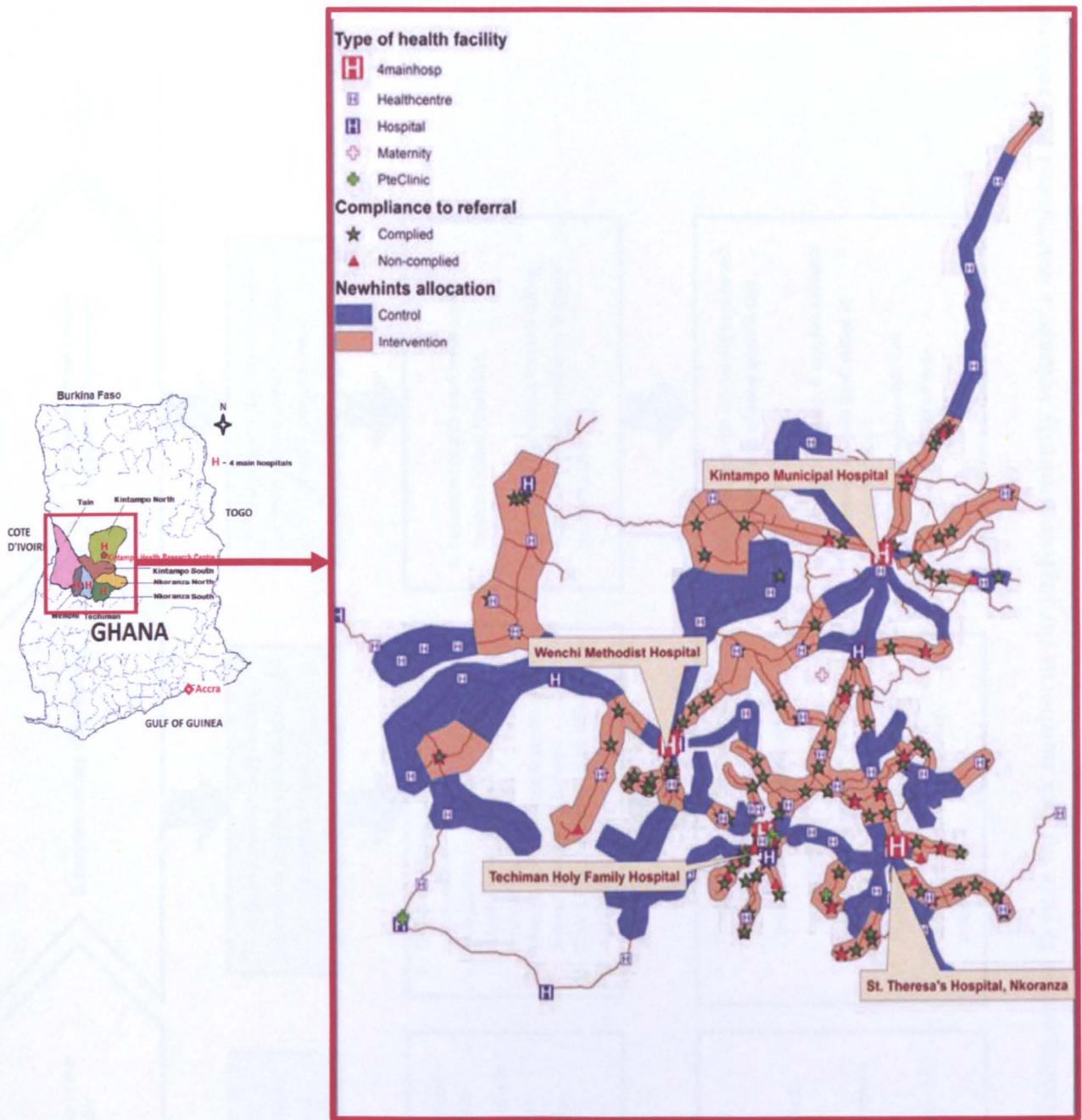


Figure 1: Map of the Ghana showing Newhints study districts and sources of referrals within Newhints; appearance of a red star is when some a village has some mothers who complied and some who did not

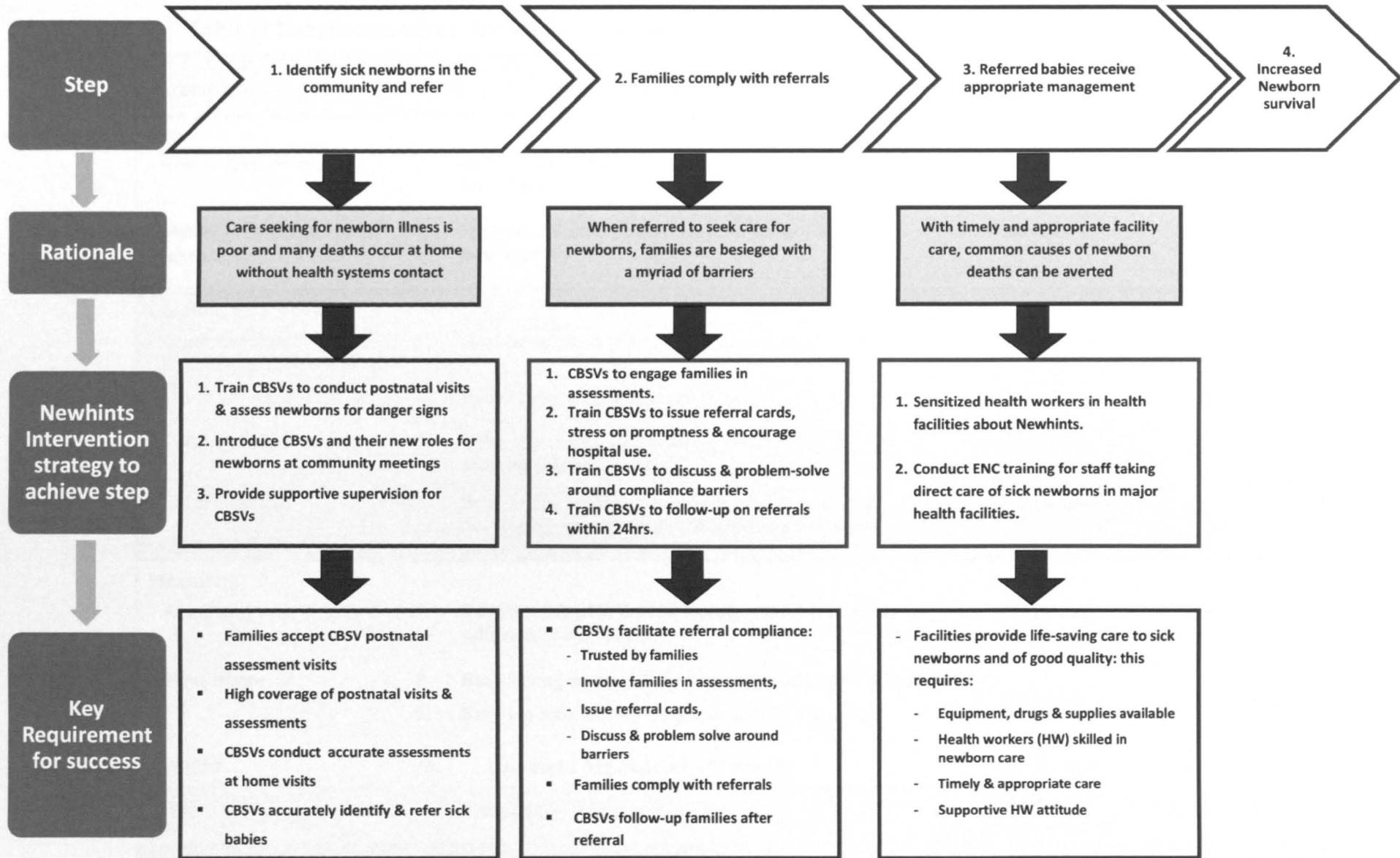


Figure 2: Conceptual framework for increasing access to care for sick newborns through community volunteer assessment and referral

Table 1: Danger signs for referrals and coverage achieved

ASSESSMENT	DANGER SIGN	Coverage of assessments	
		DOS (N=759)	Process (N=2795)
Ask:			
How is the baby feeding?	1. Baby not breastfeeding well since birth or stopped breastfeeding	740 (97.5%)	-
History of convulsion or fits since birth.	2. Baby convulsed or fitted since birth and not treated in a health facility.	641 (84.5%)	-
Check for:			
Chest movements	3. Baby having lower chest in-drawing on inspiration	656 (86.4%)	-
Palms and soles of the feet	4. Baby having yellow palms and soles	682 (89.9%)	-
Lethargy/failure to move	5. Baby very weak and not moving at all or only moving when stimulated	671 (88.4%)	-
Local infections	6. Baby having reddening around the <i>umbilicus</i> or pus discharging from the stump, <i>skin pustules</i> or purulent discharge from the <i>eyes</i> .	672 (88.5%)	-
Measure:			
Respiratory rate	7. Baby breathing too fast: 60 breaths or more per minute validated by a 2 nd count	742 (97.9%)	2,662 (95.2%)
Temperature	8. Baby having fever: axillary temperature of 37.5°C or more	747 (98.4%)	2,677 (95.8%)
	9. Baby too cold: axillary temperature of 35.4°C or less		
Weight	10. Less than 1.5kg (red zone of the scale)	671 (88.4%)	2,651 (94.9%)*
COVERAGE OF ASSESSMENTS		8+ signs - 91.9%	2116 (75.7%)
		9+ signs - 78.8%	
REFERRALS MADE		101 (13.1%)	279 (10.0%)

*This represents weight assessed at first postnatal visit

Table 2: Accuracy of CBSV assessments compared to DiPS during DOS visits (N=759)

Danger sign	Danger sign present (DiPS)	% Agreement	Kappa (95% CI) [*]	Sensitivity (95%CI)	Specificity (95% CI)
OBSERVED SIGN					
Chest in-drawing	22 (2.9%)	99.3%	0.85 (0.71, 1.00)	59.1% (36.4%, 79.3%)	99.9% (99.3%, 100.0%)
Only moves when stimulated	7 (0.9%)	100.0%	1.00 (1.00, 1.00)	57.1% (18.4%, 90.1%)	100.0% (99.5%, 100.0%)
Yellow soles	14 (1.8%)	99.6%	0.84 (0.66, 1.00)	57.1% (28.9%, 82.3%)	100.0% (99.5%, 100.0%)
Local infections (Eye/Skin/Cord)	61 (8.0%)	99.6%	0.97 (0.94, 1.00)	95.1% (86.3%, 99.0%)	100.0% (99.5%, 100.0%)
MEASURED WITH INSTRUMENT					
Respiratory rate(1 st count) 60+/min	93 (12.3%)	94.9%	0.75 (0.67, 0.83)	73.1% (62.9%, 81.8%)	97.5% (95.9%, 98.5%)
Respiratory rate(2 nd count) 60+/min	57 (7.5%)	91.6%	0.83 (0.69, 0.96)	92.7% (80.1%, 98.5%)	91.2% (76.3%, 98.1%)
Hypothermia: temperature <35.5°C)	10 (1.3%)	99.9%	0.94 (0.82, 1.00)	80.0% (44.4%, 97.5%)	99.9% (99.3%, 100.0%)
Fever: temperature>37.4°C	23(3.0%)	99.3%	0.90 (0.81, 0.99)	100.0% (85.2%, 100.0%)	99.3% (98.4%, 99.8%)
Very low birthweight (<1.5kg)	1 (0.1%)	100.0%	1.00 (1.00, 1.00)	100.0% (2.5%, 100.0%)	100.0% (99.5%, 100.0%)
REFERRED	127 (16.7%)	96.6%	0.87 (0.82, 0.92)	79.5% (71.5%, 86.2%)	100.0% (99.4%, 100.0%)

**P<0.001 for all the Kappa statistics.*

Table 3: Timeliness of care at health facilities for mothers who complied with referrals

Waiting time before 1 st health worker contact	Type of health facility: n (%)		
	Four main district hospitals	Other facilities	Total
Less than 30 minutes	25 (15.5%)	30 (38.0%)	55 (23.7%)
30+ minutes but less than 1hr	37 (23.0%)	20 (25.3%)	57 (24.6%)
1hr but less than 3hrs	41 (25.5%)	15 (19.0%)	56 (24.1%)
3+ hours	55 (34.2%)	9 (11.4%)	64 (27.6%)
Total	158 (68.1%)	74 (31.9%)	232* (100.0%)

**Details were missing for 8 respondents*

Table 4: Newhints assessment and referral of sick newborns: comparison with other trials using CHW home visits

Trial (country and year of publication)	Days of training	Duration of Trial (Months)	Number of routine PN* visits	Coverage of PN* visits	Assessment of babies	Referral (compliance)	Home-treatment	Facility support*	Impact on NMR Effect (95% CI)
Home visits by CHWs: Proof of principle trials									
1. Bang et al (SEARCH, India, 2005)	180	84	8	93%	✓	✗	✓ Full	-	0.39 (0.27, 0.56)
2. Baqui et al (PROJAHNMO-I, Bangladesh, 2008)	42	30	3	46-79%	✓	✓ (34%)	✓ Full	✓	0.87 (0.70, 1.08)
3. Kumar et al (SHIVGARH, India, 2008)	14	17	2	65%	✗***	✗	✗	-	0.46 (0.35, 0.60)
Home visits by CHWs: Trials delivered in programme setting									
1. Darmstadt et al (PROJAHNMO-II Bangladesh, 2010)	36	36	4	70%	✓	✓ (54%)	✓ Partial	✓	0.87 (0.68, 1.12)
2. Bhutta et al (HALA, Pakistan, 2011)	90+	25	5	24%	✓	✓ (not reported)	✗	✗	0.85 (0.76, 0.96)
3. Bhandari et al (IMNCI, India, 2012)	8	28	3	90%	✓	✓ (not reported)	✓ Partial	✓	0.91 (0.80, 1.03)
GHANA NEWHINTS INTERVENTION	9	14	3	70%	✓	✓ (86%)	✗	✗	0.91 (0.74, 1.13)

*PN=postnatal **Facility support=direct intervention in health facilities excluding training such as provision of (or ensuring) drugs, equipment supply, infrastructure etc. ***One arm checked for hypothermia; Full=implementation includes administration of injectable antibiotics, Partial=minus Injectable antibiotics

9.5 References

1. Darmstadt GL, Bhutta ZA, Cousens S, Adam T, Walker N, de Bernis L, et al. Evidence-based, cost-effective interventions: how many newborn babies can we save? *Lancet* 2005;365(9463):977-88.
2. Oestergaard MZ, Inoue M, Yoshida S, Mahanani WR, Gore FM, al. e. Neonatal Mortality Levels for 193 Countries in 2009 with Trends since 1990: A Systematic Analysis of Progress, Projections, and Priorities. *PLoS Medicine* 2011;8(8):e1001080.
3. Kinney MV, Kerber KJ, Black RE, Cohen B, Nkrumah F, Coovadia H, et al. Sub-Saharan Africa's mothers, newborns, and children: where and why do they die? *PLoS Med* 2010;7(6):e1000294.
4. Lawn JE, Cousens S, Zupan J, Lancet Neonatal Survival Steering T. 4 million neonatal deaths: When? Where? Why? *Lancet* 2005;365(9462):891-900.
5. Kumar V, Mohanty S, Kumar A, Misra RP, Santosham M, Awasthi S, et al. Effect of community-based behaviour change management on neonatal mortality in Shivgarh, Uttar Pradesh, India: a cluster-randomised controlled trial. *Lancet* 2008;372(9644):1151-62.
6. Choi Y, El Arifeen S, Mannan I, Rahman SM, Bari S, Darmstadt GL, et al. Can mothers recognize neonatal illness correctly? Comparison of maternal report and assessment by community health workers in rural Bangladesh. *Trop Med Int Health* 2010;15(6):743-53.
7. Syed U, Khadka N, Khan A, Wall S. Care-seeking practices in South Asia: using formative research to design program interventions to save newborn lives. *Journal of Perinatology* 2008;28 Suppl 2:S9-13.
8. Bazzano AN, Kirkwood BR, Tawiah-Agyemang C, Owusu-Agyei S, Adongo PB. Beyond symptom recognition: care-seeking for ill newborns in rural Ghana. *Trop Med Int Health* 2008;13(1):123-8.
9. Awasthi S, Srivastava NM, Pant S. Symptom-specific care-seeking behavior for sick neonates among urban poor in Lucknow, Northern India. *Journal of Perinatology* 2008;28 Suppl 2:S69-75.
10. Winch PJ, Alam MA, Akther A, Afroz D, Ali NA, Ellis AA, et al. Local understandings of vulnerability and protection during the neonatal period in Sylhet District, Bangladesh: a qualitative study. 2005.
11. Okyere E, Tawiah-Agyemang C, Manu A, Deganus S, Kirkwood B, Hill Z. Newborn care: the effect of a traditional illness, asram, in Ghana. *Ann Trop Paediatr* 2010;30(4):321-8.
12. WHO/UNICEF. WHO/UNICEF Joint Statement: Home visits for the newborn Child: a Strategy to Improve Survival. Geneva: WHO, 2009.
13. Baqui AH, El-Arifeen S, Darmstadt GL, Ahmed S, Williams EK, Seraji HR, et al. Effect of community-based newborn-care intervention package implemented through

two service-delivery strategies in Sylhet district, Bangladesh: a cluster-randomised controlled trial. *Lancet* 2008;371(9628):1936-44.

14. Bang AT, Reddy HM, Deshmukh MD, Baitule SB, Bang RA. Neonatal and infant mortality in the ten years (1993 to 2003) of the Gadchiroli field trial: effect of home-based neonatal care. *J Perinatol* 2005;25 Suppl 1:S92-107.
15. Bhandari N, Mazumder S, Taneja S, Sommerfelt H, Strand TA. Effect of implementation of Integrated Management of Neonatal and Childhood Illness (IMNCI) programme on neonatal and infant mortality: cluster randomised controlled trial. *BMJ* 2012;344:e1634.
16. Azad K, Barnett S, Banerjee B, Shaha S, Khan K, Rego AR, et al. Effect of scaling up women's groups on birth outcomes in three rural districts in Bangladesh: a cluster-randomised controlled trial. *Lancet* 2010;375(9721):193-202.
17. Darmstadt GL, Choi Y, Arifeen SE, Bari S, Rahman SM, Mannan I, et al. Evaluation of a cluster-randomized controlled trial of a package of community-based maternal and newborn interventions in Mirzapur, Bangladesh. *PLoS ONE [Electronic Resource]* 2010;5(3):e9696.
18. Bhutta ZA, Soofi S, Cousens S, Mohammad S, Memon ZA, Ali I, et al. Improvement of perinatal and newborn care in rural Pakistan through community-based strategies: a cluster-randomised effectiveness trial. *Lancet*, 2011:403-12.
19. Kirkwood BR, Manu A, Tawiah-Agyemang C, ten Asbroek G, Gyan T, Weobong B, et al. NEWHINTS cluster randomised trial to evaluate the impact on neonatal mortality in rural Ghana of routine home visits to provide a package of essential newborn care interventions in the third trimester of pregnancy and the first week of life: trial protocol. *Trials* 2010;11:58.
20. Kirkwood BR, Manu A, ten Asbroek AH, Soremekun S, Weobong B, Gyan T, et al. Impact of the "Newhints" home visits intervention on neonatal mortality and care practices in Ghana: a cluster randomised controlled trial. *submitted* 2012.
21. Manu A, ten Asbroek G, Soremekun S, Weobong B, Gyan T, Tawiah-Agyemang C, et al. Increasing access to facility care for sick newborns: evidence from the Ghana Newhints trial. *submitted* 2012.
22. Ghana Health Service. Ghana Health Service-Brong Ahafo Region: Ghana Health Service, 2005.
23. Kirkwood BR, Manu A, ten Asbroek AH, Soremekun S, Weobong B, Gyan T, et al. Impact of the "Newhints" home visits intervention on neonatal mortality and care practices in Ghana: a cluster randomised controlled trial. *Submitted* 2012.
24. Vesel L, Manu A, Lohela TJ, Gabrysch S, Okyere E, Owusu-Agyei S, et al. Quality of Newborn Care: A Health Facility Assessment in Rural Ghana Using Survey, Vignette and Surveillance Data. *submitted* 2012.
25. Viera AJ, Garrett JM. Understanding interobserver agreement: the kappa statistic. *Family medicine* 2005;37(5):360-3.

26. Hill Z, Kendall C, Arthur P, Kirkwood B, Adjei E. Recognizing childhood illnesses and their traditional explanations: exploring options for care-seeking interventions in the context of the IMCI strategy in rural Ghana. *Trop Med Int Health* 2003;8:668-76.
27. Manu A, Hill Z, ten Asbroek G, Soremekun S, Gyan T, Weobong B, et al. Increasing access to facility care for sick newborns: evidence from the Ghana Newhints trial. *submitted 2012*.
28. Qazi SA, Stoll BJ. Neonatal sepsis: A Major Global Public Health Challenge. *Pediatric Infectious Disease Journal* 2009;28(1 Suppl):S1-2.
29. Howe LD, Manu A, Tawiah-Agyemang C, Kirkwood BR, Hill Z. Developing a community-based neonatal care intervention: a health facility assessment to inform intervention design. *Paediatr Perinat Epidemiol* 2011;25(2):192-200.
30. Bang AT, Bang RA, Stoll BJ, Baitule SB, Reddy HM, Deshmukh MD. Is home-based diagnosis and treatment of neonatal sepsis feasible and effective? Seven years of intervention in the Gadchiroli field trial (1996 to 2003). *J Perinatol* 2005;25 Suppl 1:S62-71.
31. Kirkwood BR, Manu A, Tawiah-Agyemang C, al. e. NEWHINTS cluster randomised trial to evaluate the impact on neonatal mortality in rural Ghana of routine home visits to provide a package of essential newborn care interventions in the third trimester of pregnancy and the first week of life: trial protocol. *Trials* 2010;10(58).
32. Bang AT, Bang RA, Baitule SB, Reddy MH, Deshmukh MD. Effect of home-based neonatal care and management of sepsis on neonatal mortality: field trial in rural India. *Lancet* 1999;354(9194):1955-61.
33. Young Infants Clinical Signs Study G. Clinical signs that predict severe illness in children under age 2 months: a multicentre study. *Lancet* 2008;371(9607):135-42.
34. Manu AA, Hill Z, Tawiah-Agyemang C, Asbroek Gt, Soremekun S, Okyere E, et al. Achieving high compliance with community referral of sick newborns in the Newhints intervention in Ghana: determinants, barriers and facilitating factors. *Submitted 2012*.
35. Opondo C, Ntoburi S, Wagai J, Wafula J, Wasunna A, Were F, et al. Are hospitals prepared to support newborn survival? - An evaluation of eight first-referral level hospitals in Kenya. *Trop Med Int Health* 2009;14(10):1165-72.

SECTION D:
CONCLUSIONS &
RECOMMENDATIONS

CHAPTER TEN: Conclusions and recommendations

10.1 Key findings

1. Increasing access to care for sick newborns:

- Newhints substantially increased sick newborn access to facility care.
- CBSV referrals elicited 86·0% compliance (unequalled in any previous community newborn intervention) which was prompt and mainly to hospitals.
- Families' overall care seeking for severe newborn illnesses also increased from 55·4% in control zones (similar to baseline levels) to 77·3% within Newhints zones.
- Newhints' increased sick newborn access to care was pro-poor with referral compliance and care seeking higher among the poorest (or rural residents) compared to the least poor (or urban residents).
- Increasing access to care through community assessment and referral as a pro-poor approach has the potential to reach all newborns regardless of wealth or place of residence. This was confirmed by the high compliance achieved across all socio-economic quintiles and in rural as well as urban areas.

2. Achieving high compliance with referrals:

- **Factors that facilitated compliance included:**
 - **mothers' perception of illness severity,**
 - **advance saving and NHIS enrolment for emergencies which helped overcome cost barriers;**
 - **antenatal attendance during pregnancy or facility delivery;**
 - **issuance of referral card; and**
 - **CBSV counselling and support.**

- **A positive change in families' perceptions about newborn illness severity mediated all the facilitators to compliance and CBSV facilitation was pivotal to these changes.**

- **These changes were mainly attributable to effective implementation of core strategies in Newhints:**
 - **They were driven by CBSV facilitation which was aided in part through their enhanced profile in the community and partly through the use of instruments, counselling cards and supervision.**
 - **Families perceived them as knowledgeable and often equated them to doctors. This added weight to their referral recommendations and facilitated compliance.**
 - **Post-referral follow-up visits were also useful in providing opportunities for continued dialogue with families on care of the newborn and when families failed to comply, babies were re-assessed and referred again.**

- Even though mothers are still not completely autonomous when it came to decision making on care seeking for their sick babies, targeting and involving other family members in assessment visits meant the usual barriers to care seeking such as husband non-consent and cost did not seem to affect compliance when CBSVs asked mothers to go.
- Distance from the main hospitals where the majority of the mothers went seemed to affect the timing of the compliance; mothers who lived in urban areas where the main hospitals were, complied quicker.
- Among the few non-compliers,
 - Waiting to see whether the illness was going to improve spontaneously
 - perceptions that skin pustules were not severe enough to merit hospital attendance and
 - beliefs around ‘Asram’ as an illness that is not amenable to orthodox medical treatment were common

3. Community response to the Newhints assessment and referral of sick newborns:

- Newhints assessment visits were acceptable to families, the majority of whom did not recognise their baby’s illness until the CBSV visited.
- Demands for these assessment visits therefore increased when families perceived their usefulness and when babies were found with danger signs and referred, the compliance was high and mainly to hospitals.

- The CBSVs enjoyed their roles in the community and the recognition they received from being associated with the health system.

4. Use of community health workers for assessment and referral of sick newborns:

- Family recognition of sick newborns remains very poor and recognition without action is common. Home visits to identify and refer sick newborns are a necessary and effective strategy to improve access to care for sick newborns. These visits are welcomed by families.
- *Extending the scope of CBSV activities:* Mothers whose babies were referred in Newhints suggested that CBSVs should be made to continue the assessments in the homes 'forever' but particularly advocated for assessment visits to cover the whole of the first year of life of the baby.
- A simple checklist for danger signs with referral when any one of them is present works well with community volunteers, and is preferable to a clinical type algorithm. The checklist approach takes less time to explain, is more easily understood and does not appear to lead to false positive referrals.

5. Training of CHWs for assessment and referral of sick newborns:

- Training CBSVs to conduct home visits and accurately assess and refer sick newborns can be achieved in just 9 days. Six of the 9 days focussed on this component with two days of clinical practice sessions. Scale up should

therefore be logistically feasible to achieve even in LMIC settings with weak economy and health systems.

- The use of the clinical practice sessions are crucial to build volunteer confidence at handling newborn babies and to provide them practical exposure to how newborn assessments will be within communities because of the use of real babies and the opportunity to interact with mothers who hail from communities comparable to theirs.

6. Supervising CHW community assessment and referral of sick newborns and the use of referral cards:

- Volunteer trust and faith in the supervisory system is crucial ingredient for success: CBSVs suggested that the Newhints supervisory system helped them in two ways to achieve success in their assessments and referrals:
 - It enhanced their community profile since community members associated them with the health systems and this was thought to be key to compliance and acceptability of the assessment visits.
 - It improved their confidence in the assessments and referrals
- Effective supervision and monitoring is essential, and should include observation of home visits to reinforce skills and ensure and maintain quality implementation of this strategy.
- Repeat visits during supervisions to actively observe CHW home visits and assessments rather than passively tying supervision to scheduled home visits is

imperative for success. It will enable reinforcing and maintaining CHW assessment skills, build their confidence and promote community acceptability. Also our experience has shown that it is rare for supervisory visits to coincide with volunteer assessment visits within communities.

- Supervised home visits had the unexpected benefit of enhancing the volunteer profile in the community and associating them with the health services, reinforcing the importance of compliance with any referrals.
- Issuing a referral card makes a difference. It has several roles:
 - It emphasizes the importance of the referral,
 - It promotes a sense of continuity between community volunteers' assessment, referral and facility care, and
 - It will allow for effective triaging of referred newborns at health facilities.

7. Quality and unmet need for newborn care within health facilities:

- Increasing access to care for sick newborns is necessary but not sufficient to ensure newborn survival; it must be matched with improved quality of facility care.
- There were overwhelming concerns however about the care provided to the newborns in health facilities with suggestions that it was poor.

- To alleviate families' experiences in these facilities, suggestions were made to:
 - have contact persons there who mothers could be referred to and who will support them within facilities after referrals.
 - extend the scope of the CBSV activities to beyond the newborn period because of community trust and
 - mothers thought it might help to have CBSVs administer some treatment with the referral.

- Linked to the perceived bad experiences in the health facilities, mothers suggested that staff of the facilities be 'talked to' to improve the quality of care they provide. They linked this to:
 - the substantial delays in these facilities
 - the lack of clinical assessments before decision making on the care of their babies, and
 - the poor and non-supportive interpersonal skills of the staff in these facilities

- Improvement in quality of facility newborn care should be tackled in parallel with implementation of home visit programmes not only through health worker training, but through on-going quality improvement strategies. All three types of respondents agreed that improving health facility quality of care should be tackled in future implementation of this strategy.

- Community-based assessment and referrals could lead to increases in workload at health facilities which may impact on the quality of care and should be an early consideration in implementation.

- If CHW assessment and referrals have high specificity, as was the case in Newhints, increased facility workload is probably indicative of the unmet need for newborn care within communities.
- Community-based strategies that increase access to care for sick newborns may not be perfect; there is always the possibility of false positive referrals. However, these may have merits in that they provide “opportunistic” contacts with families who were otherwise not reachable within routine health programmes.
- Encouraging CHW referrals, even if some are false positives, will likely result in sick newborns being seen early which may prove economically and medically prudent: reducing facility expenditure per capita sick newborn and resulting in better treatment outcomes.
- *Improving families experiences at facilities:* A suggested strategy to alleviate families’ frustrations in the health facilities when they go to access care for their sick newborns is to identify a contact person in the facilities to whom all babies referred will be directed and who will help families manoeuvre the complex procedures in the health facilities and receive timely care. This was thought to be particularly useful in the big hospitals and this view was shared by CBSVs too.
- *Better linkages with health facilities:* Mothers suggested an improvement in the links between the CHWs and facility care providers because they ascribed their

negative treatment received at health facilities to perceived lack of understanding of these providers on the CBSVs work in Newhints.

8. What more could CHWs do?

➤ *Treatment of minor ailments or pre-referral care:*

- With the proven ability of CBSVs to accurately assess newborns for danger signs, a possible modification might be that they are also trained to treat minor ailments in the home and provide pre-referral antibiotics in recognition of the long distances to facilities.
- There were suggestions from some mothers that CBSVs should be trained to provide some treatment at home whilst they wait to go to health facilities for definitive treatment. Cognisant of how urgent the CBSV wanted them to go to the facility and having made them perceive that the illness in the newborn was severe, they feared that the baby might even die before they got to the facility and thought some initial treatment could save some lives.
- However, caution needs to be exercised as community treatment of ailments by CHWs may inadvertently affect referral compliance. This unexpected consequence may explain the difference in the very high compliance achieved in Newhints (which did not include any treatment) and the much lower compliance observed in the other Asian trials that did.

9. Suggested improvements to CHW assessment and referrals by health professionals:

➤ *Developing algorithms for CHWs to curb avoidable increases in workloads:*

Some care providers at the health facilities thought CBSVs in Newhints referred too many babies to them particularly with fast breathing. They suggested that CHWs should be provided with algorithms for the referral of sick newborns where referrals should not be based on only one sign. Newhints did not use an algorithm but a simple checklist of ten danger signs but achieved very high specificity.

➤ *Facility strengthening:* Health workers suggested that the CHW referral system was laudable but should be more holistic and include:

- Strengthening health facilities in general to respond to referrals
- Training health professionals in newborn care skills due to inadequacy of skilled staff for newborn care and
- Keeping a separate area for newborn care in facilities, using trained staff with requisite skills.

➤ *Better accountability for newborn contacts with health facilities:* Providers thought there was the need for them to be held accountable for newborn contacts. They suggested that they should be made to:

- Keep records of all newborn contacts with their facilities including treatment outcomes.
- Feedback on management outcomes to CHWs reiterating that this will allow for possible follow-up of these babies at the community level.

- *Roll-out Newhints assessment and referrals in other parts of the country:* Care providers were convinced that the Newhints assessment and referral system was beneficial and would augment health service delivery. They cited the opportunistic contacts they had to mothers who were hitherto not reached by routine services. They therefore recommended that the intervention be extended to other districts throughout the country so that they might also benefit from it.

10.3 Strengths and limitations

10.3.1 Study strengths: The strengths of this evaluation were many and included the following:

- 1.** This evaluation is the first of its kind evaluating community health worker assessment and referral of sick newborns in a cluster-randomised trial in sub-Saharan Africa.
- 2.** The evaluation was guided by a conceptual framework from start to finish and data on every aspect of the intervention was used for the evaluation. This comprehensive coverage of all aspects of the assessment and referral intervention for sick newborns will be key source of information for future implementation of similar interventions in other settings particularly in sub-Saharan Africa.
- 3.** The evaluation used a population-based surveillance data. This type of data is very rare in global public health particularly from sub-Saharan Africa. Being nested within the Newhints cluster-randomised controlled design - which is the

optimal (gold standard) for trials - provides reliable and robust evaluation and adds weight to the findings of this evaluation.

4. The evaluation was done using mixed methods. The use of qualitative data together with the quantitative data produced a more complete picture for the evaluation of the assessment and referrals. In-depth interviews and narratives allowed for vivid description of the key stakeholders' (respondents) personal experiences with the implementation (the emic or viewpoint of these people who could best be described as 'insiders'). This is be critical for future implementation.
5. The author/researcher understood the settings and the contextual factors as well as the medical implications of various actions and this allowed for vivid depiction of findings and enhanced comprehension.
6. The directly-observed visits used in the evaluation of the validity of assessments was optimal since it eliminated the lag between assessment in communities by CHWs and reviewing clinicians as applied in other studies because newborn illness could have changed rapidly and this change could have occurred in the interval.

10.3.2 Study limitations:

1. The IDIs were conducted by the lead author who was actively involved in the training and implementation of the study. It is possible that responses from CBSVs and health professionals could have been biased. However, all

the various sources of data including the IDIs provided a convergent evidence of the success of the implementation.

2. The use of qualitative methods lends themselves to the researchers own interpretations which may be influenced by his biases and idiosyncrasies.
3. A potential limitation of the evaluation is that the DOS visits measured the ability of CBSVs to conduct the assessments but not necessarily what they did. CBSVs might modify their behaviours because they knew they were being observed. However, process data and the IDIs confirmed that the CBSVs routinely carried out the assessments.
4. Non-tracking of referred babies from the community to the facilities to directly observe and describe the care given rather than rely on reported practices was one of the weaknesses in this study. Recall biases were possible, however, all sources of data were consistent and coherent in their findings and so these are likely to be minimal.
5. Implementation takes time to bed in, it would have been ideal both to evaluate the impact and the implementation of the assessment and referral system in the Newhints intervention over a longer period but budgetary constraints limited the duration of the study. Even over this relatively short period, the intervention was found to be successful.
6. Outcome indicators of quality of health facility care defined as “the effects of care on health status of patients,” such as neonatal mortality were not directly assessed in this evaluation. Neonatal mortality has been published

in the main outcome paper for Newhints and has been published separately (attached as appendix 2). However, the difficulty in evaluating outcome indicators of quality has been established in this thesis since they can be affected by a variety of confounders besides care administered at a health facility.

10.4 Conclusions & Recommendations

10.4.1 Conclusions: In conclusion, this evaluation of a community based strategy to increase sick newborn access to care in health facilities and by so doing improve neonatal survival was comprehensive and guided by a conceptual framework. It has provided evidence in support of the WHO/UNICEF joint statement recommending home visits as a strategy for improving newborn survival. In addition, it has demonstrated that community health workers or volunteers can:

1. be successfully trained and used for home visits to accurately assess and make valid referrals of sick newborns for care in health facilities and this will be acceptable to families,
2. facilitate families' compliance with referrals through dialogue and problem-solving around barriers,
3. be used to achieve very high compliance with referrals and therefore increasing access to care for sick newborns, and
4. through their referrals and promotion equitably increase families care seeking for severely ill newborns and this could be potentially pro-poor.

However the increased access to care for sick newborns can only translate into newborn survival if they are matched with improved quality of care for sick newborns in health facilities and this is the crucial link in the sick newborn survival chain.

10.4.2 The next steps...

Integration of the findings of this comprehensive evaluation of the evidence for using community-based home visits strategy to increase sick newborn access to care and the impact of the Newhints intervention on neonatal mortality shows that in spite of the many successes achieved, key gaps remain and present opportunities for future work. The key questions are:

1. What more can we do about reaching babies with care on the day they are born - which carries the highest lifetime risk of death - and how can we effectively link referred babies from the community to health facilities?
2. How do we improve the quality of newborn care in health facilities and provide some guarantee of survival to newborns who are sent there?
3. What more can CHWs be used for in the pursuit of the child survival objectives especially in resource-poor settings faced with dwindling health human resources?
4. Could peer-supervision be an answer to maintaining CHW motivation, commitment and quality of assessment and referral intervention delivery?

10.4.2.1 Reaching day one births for assessments – the role of mobile telephony:

Reaching mothers and their babies is crucial to save newborns since up to half of newborn deaths occur within 24 hours of birth. Reaching newborns at this crucial period could save many more lives. One of the mechanisms to achieve this is the use of mobile telephony. Increasingly, communities in LMIC countries are being linked to mobile telephony. Enhancing community profile of CHWs and equipping them with mobile phones could provide families with means of contacting the volunteer immediately labour sets in so that skilled care at delivery could be arranged for the family either through arranged transport or domiciliary midwifery care.

Alternatively, when volunteers are contacted right after birth of the baby, they could promptly assess babies and refer 'at risk' babies for facility care. This is potentially feasible to implement and could build into existing programmes and impact on both maternal and neonatal survival. If a contact person is identified for newborn care in health facilities, CHWs could also communicate with health facilities through them when referrals are made from the communities. This will re-assure mothers and their families of care at facilities and to ensure mothers are welcomed when they get there. CHWs could even discuss the danger signs identified with these qualified providers for advice on peri-referral care.

10.4.2.2 Improving the quality of newborn care in health facilities: An

intervention in health facilities within the Newhints study area and indeed most

PAGE NUMBERING AS IN THE ORIGINAL THESIS

advocated for extending the scope of their activities. CBSVs could be trained to provide cord care for newborns in the community and hence eliminate one of the major causes of sepsis in communities. They could be provided with chlorhexidine or methylated spirit to provide to families for cord care and as part of their routine postnatal visits teach families in the use of these for cord care. They could also provide aseptic circumcision care for male babies and could also be provided with simple checklist to manage benign skin sepsis in the community and refer if not responding to treatment.

There are advocacy for them to continue home visits for the entire first year of life from families but may require integrating their services with regular health system growth monitoring activities and promoting care seeking for sick newborns.

Another critical period when their skills could have been used would be in the introduction of supplementary feeding where they could be trained to promote healthy, locally available food supplements and to provide oral rehydration therapy for childhood diarrhoeal diseases.

10.4.2.4 Sustainable community assessment & referral supervision – the role of peer supervisors: Supervision is key and has been rightly identified by the CBSVs in Newhills as crucial for success. When health services providers are given the added duty of supervising volunteers, these are tied with routine services but they usually hardly have enough time to complete their core activity to supervise volunteers in a way that will enhance confidence. Some of these activities already face logistical challenges and are not always carried out. Peer-supervisors who

could be CHWs who are promoted based on performance and leadership skills and provided additional training. It will increase contact times between volunteers and supervisors and reduce professional health worker time input. However, such a system is not devoid of challenges: for this to be successful, these peer-supervisors must be linked and integrated with existing health systems and should also be supported in the discharge of their duties. This is urgently warranted and potentially feasible to implement.

APPENDICES

NEWHINTS cluster randomised trial to evaluate the impact on neonatal mortality in rural Ghana of routine home visits to provide a package of essential newborn care interventions in the third trimester of pregnancy and the first week of life: trial protocol

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Abstract

Background: Tackling neonatal mortality is essential for the achievement of the child survival millennium development goal. There are just under 4 million neonatal deaths, accounting for 38% of the 10.8 million deaths among children younger than 5 years of age taking place each year; 99% of these occur in low- and middle-income countries where a large proportion of births take place at home, and where postnatal care for mothers and neonates is either not available or is of poor quality. WHO and UNICEF have issued a joint statement calling for governments to implement "Home visits for the newborn child: a strategy to improve survival", following several studies in South Asia which achieved substantial reductions in neonatal mortality through community-based approaches. However, their feasibility and effectiveness have not yet been evaluated in Africa. The Newhints study aims to do this in Ghana and to develop a feasible and sustainable community-based approach to improve newborn care practices, and by so doing improve neonatal survival.

Methods: Newhints is an integrated intervention package based on extensive formative research, and developed in close collaboration with seven District Health Management Teams (DHMTs) in Brong Ahafo Region. The core component is training the existing community based surveillance volunteers (CBSVs) to identify pregnant women and to conduct two home visits during pregnancy and three in the first week of life to address essential care practices, and to assess and refer very low birth weight and sick babies. CBSVs are supported by a set of materials, regular supervisory visits, incentives, sensitisation activities with TBAs, health facility staff and communities, and providing training for essential newborn care in health facilities.

Newhints is being evaluated through a cluster randomised controlled trial, and intention to treat analyses. The clusters are 98 supervisory zones; 49 have been randomised for implementation of the Newhints intervention, with the other 49 acting as controls. Data on neonatal mortality and care practices will be collected from approximately 15,000 babies through surveillance of women of child-bearing age in the 7 districts. Detailed process, cost and cost-effectiveness evaluations are also being carried out.

Trial registration: <http://www.clinicaltrials.gov> (identifier NCT00623337)

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Background

Although the child survival revolution of the 1980s led to dramatic reductions in overall child mortality, it has had little impact on deaths taking place in the first 28 days of life (the neonatal period). There are just under 4 million neonatal deaths, accounting for 38% of the 10.8 million deaths among children younger than 5 years of age taking place each year[1]; 99% of these occur in low- and middle-income countries[1]. Tackling neonatal mortality is therefore essential if the millennium development goal of reducing child mortality by two-thirds between 1990 and 2015 is to be achieved[1].

Common direct causes of neonatal deaths in developing countries are known: infections (pneumonia, neonatal tetanus, sepsis, and diarrhoea), asphyxia, birth injuries and complications of preterm birth[1]. Indirect causes of neonatal deaths such as low birth weight and hypothermia are also important [2] as is the link between maternal health and neonatal outcomes [1,2]. Postnatal care for mothers and neonates in developing countries, particularly when deliveries occur at home, is either not available or is of poor quality. Interventions are urgently needed, particularly those directed at improving family newborn care practices and community level health service delivery; the Lancet neonatal series suggests that 15-32% of neonatal deaths could be prevented through promotion of a few key practices: clean home delivery, hygienic cord care, thermal care, early and exclusive breastfeeding and care seeking for illness[3].

Trained community workers are considered by many to be pivotal to newborn care in the community, as they can act as catalysts for community actions and also be providers of care[4], and several studies in South Asia have shown that substantial mortality reductions can be achieved with this approach[5-8]. Projects in Nepal[9] and Bolivia[10] have demonstrated that substantial improvements in neonatal survival can also be achieved through encouraging community organisation and participation in women's groups.

Based on the successes from the studies in South Asia, WHO and UNICEF have issued a joint statement calling for governments to implement "Home visits for the new-born child: a strategy to improve survival" [4]. However, the feasibility and effectiveness of community approaches to reduce newborn mortality have not yet been evaluated in Africa, where the epidemiology of neonatal deaths and the health system are very different from South Asia. Progress in reducing neonatal mortality has been slower in Sub-Saharan Africa than in any other region in the world, and projections on percentage of skilled attendance at delivery suggest that this will remain static at just above 40% over the period to 2015[11]. Complementary strategies, such as delivering community-based interventions, are urgently required[3]. This paper presents the protocol for a cluster randomised controlled trial to evaluate the impact of such a community-based intervention on newborn care practices and neonatal mortality in rural Ghana. This is called Newhints: NEWborn Health INTervention Study.

Methods

Aim

To develop a feasible and sustainable community-based approach in rural Ghana to improve newborn care practices and careseeking during pregnancy and childbirth, and by so doing improve neonatal survival.

Primary objectives

1. To link with District Health Management Teams (DHMTs) to develop a feasible and sustainable intervention to improve newborn care practices and care-seeking through training the current network of community based surveillance volunteers (CBSVs) to identify pregnant women in the community and to conduct two home visits during pregnancy and three in the first week of life of the neonate.
2. To evaluate the impact of these home visits on all cause neonatal mortality.
3. To evaluate their impact on newborn care practices.

Secondary objectives

4. To assess the coverage and quality of the service provided and the family and community response to the service.
5. To assess the cost of implementing the intervention, and the cost-effectiveness of any impact.
6. To evaluate whether the impact of the intervention on neonatal mortality differs between home- and facility-based deliveries.
7. To evaluate the impact of the intervention on age- and cause-specific neonatal mortality.

Setting

The Newhints trial is part of a long-term collaboration between the London School of Hygiene & Tropical Medicine, the Institute of Child Health and the Kintampo Health Research Centre (KHRC) in the Ghana Health Service. Newhints is based at KHRC and covers seven contiguous districts in the Brong Ahafo Region of Ghana: Kintampo North, Kintampo South, Wenchi, Tain, Techiman, Nkoranza North, and Nkoranza South. These districts also formed the study area for the vitamin A and maternal mortality "ObaapaVitA" trial. More than 15,000 babies are born within this area each year; the neonatal mortality rate is 31 per 1000 live births and approximately 50% of births occur at home[12].

The study area lies within the forest-savannah transitional ecological zone, and has two distinct rainy seasons from April to July and from September to October. The area is densely populated (175 people/square mile) with a total population of approximately 600,000 persons, and more than 100,000 women of reproductive age. The annual population growth rate is currently 3.1%; only 10% of the population in the study area live in the urban district administrative centres. The rural population lives in compounds, containing houses with mud walls, and thatch or aluminium roofs, in dispersed villages surrounded by farming land. The main occupation is subsistence farming and the main crops are yam, maize and millet. The population is multi-ethnic and education levels are low.

There are 4 district hospitals (3 hospitals are currently shared by two districts) that provide clinical (outpatient and inpatient) and maternity services and act as the first referral point for sub-district and community based health care facilities. The sub-district has an administrative centre located in a small town and usually has a health centre that provides basic maternal and child health (MCH) care. At community level there are a small number of additional government health centres and private facilities that provide basic MCH services. Each village also usually has one or more traditional birth attendants (TBAs), trained or untrained, one or more community-based surveillance volunteers (CBSVs) who assist the DHMT with registration of births, mobilisation of the community for activities such as national immunisation days, registration of deaths, and with community child welfare outreach clinics. Other community based health care providers are chemists/drug sellers and traditional healers.

Overview of Trial Design

The Newhints intervention is being evaluated through a cluster randomised controlled trial design. The clusters are Newhints zones which correspond to supervisory units of about 8-12 CBSVs. There are 98 Newhints zones in total; 49 zones randomised for implementation of the Newhints intervention, with the other 49 zones acting as controls. The trial planning started in October 2006. The Newhints intervention was developed and fully implemented in the intervention zones by the end of 2008. Impact data on neonatal mortality and newborn care practices is being collected through ongoing surveillance of all women of child-bearing age and their infants in the trial area, and will be based on approximately 15,000 babies born from 1 January 2009. Detailed process, cost and cost-effectiveness evaluations are also being carried out. Data collection is expected to be completed in April 2010 and analysis will take place throughout 2010.

The Newhints Intervention

Newhints is an integrated intervention package (Figure 1) based on extensive formative research [13], and developed in close collaboration with the District Health Management Teams (DHMTs), with input from key national neonatal policy makers and programme coordinators, and experts in neonatal health, behaviour change communication and working with community volunteers.

DHMT collaboration

The Newhints intervention was developed in close collaboration with the DHMTs. Each DHMT designated a member to be the liaison person for all Newhints-related activities, to attend regular DHMT-Newhints meetings involving all districts in the trial area, and to take a lead role in introducing the Newhints intervention to the health facilities and communities. The DHMTs receive a small quarterly budget to cover costs of their participation. In addition, there are 2 district project supervisors (DiPS) based in each DHMT; they participate in other community DHMT activities, such as the national immunization campaigns, as well as supervising the CBSVs. All DiPS are provided with a motorbike and fuel and maintenance costs are covered by the project.

Home visits by CBSVs

The core component of the intervention is five home visits by CBSVs to pregnant women and their babies. Two visits are targeted during pregnancy and three during the first week of life of the neonate; the timing and focus of each visit is summarised in Table 1. The visits involve family members as well as the pregnant woman and use storytelling and a counselling and problem solving approach concerning key gaps in care practices identified during the formative research. At the first visit after birth, the CBSV weighs the baby, and advises mothers of low birthweight (LBW) babies (<2500 g) about a package of special care comprising skin to skin contact, frequent breastfeeding, wiping rather than bathing the baby, and special attention to hygiene. The CBSVs also refer any very LBW babies (<1500 g) to hospital. In addition, the CBSVs assess all babies at each of the three postnatal visits and refer to hospital any baby who has one or more of the following danger signs: not able to feed since birth or stopped feeding well; convulsed or fitted since birth; fast breathing: two counts of 60 breaths or more in one minute; chest in-drawing; high temperature: 37.5°C or more; very low temperature: 35.4°C or less; only moves when stimulated; yellow soles; pus from umbilical stump or red umbilical stump; pus from eyes; and boils with pus. They conduct follow-up visits for referred babies within 24 hours, and an additional postnatal visit to LBW babies at the end of the second week.

CBSV Materials and Equipment

CBSVs are provided with a set of materials that aim to motivate and give credibility as well as serving functional roles. These are: picture ID; waterproof Newhints bag; Newhints polo shirt; manual; workbook; counselling and assessment cards; tubular weighing scales and slings; digital timers to measure respiratory rates; digital thermometers; cotton rolls and 70% ethanol for disinfecting thermometer; referral slips; and family cards to record appointments, births, birthweights and referrals and which also have key message reminders. CBSVs, who work in areas that are too large to be covered easily on foot, are provided with a bicycle.

Training of CBSVs

It was decided that this complex intervention would be best introduced to the CBSVs in two phases of training with phase 1 focusing on identifying pregnant and delivered women in the community, behaviour change communication, essential newborn care and on the use of counselling cards. Three-day training courses with 30-40 CBSVs per course took place during February and March 2008 in locations accessible to the CBSVs such as schools, churches and health facilities with CBSVs travelling to the training venue each day for the 3-day course.

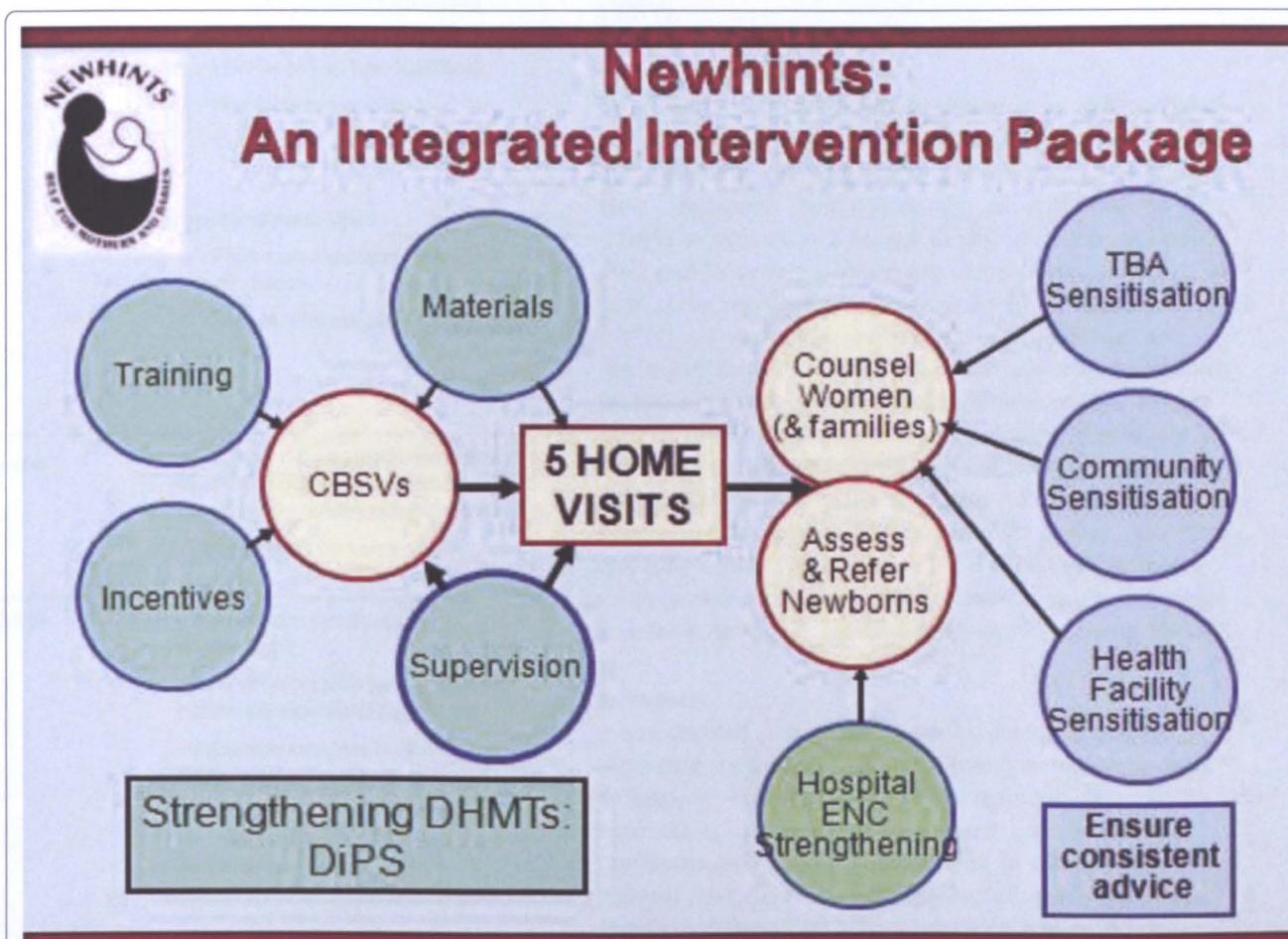


Figure 1 Newhints integrated intervention package details.

Training was led by teams of 2-4 Newhints staff, who had attended a training of trainers (ToT) session conducted by the Newhints clinician (AM), who had himself attended a UNICEF run training of trainers course. It utilized a competency based approach. Facilitator and participant guides and a set of overheads were developed by adapting various WHO, UNICEF and SNL manuals.

Phase 2 training focussed on weighing, assessing the newborn for danger signs and referring, and on promoting special care for low birthweight babies; it also included a review of phase 1 activities. It started with a ToT workshop conducted by Dr Rajiv Bahl (WHO) in Accra in May 2008 for eight Newhints trainers. The content of the training package was finalised during the ToT to be delivered over four days with a maximum of 25 participants per session, and involving practical sessions where CBSVs could practise weighing and assessing newborns. The Newhints district project supervisors (DiPS) were trained at the end of May 2008. The second phase of training for the CBSVs started on June 2, and was completed on 12 July 2008. In addition, CBSVs received a 2-day refresher training course at the end of October and beginning of November 2008.

Table 1: Newhints visit schedule and content

Early pregnancy

Key messages:

- Promote and plan for a facility delivery
- Plan for a clean home delivery
- Plan for emergencies
- Sleep under a treated bed net

Supporting messages:

- Encourage antenatal care attendance
- Seek care for maternal danger signs

3rd trimester

- Dry, wrap & breastfeed immediately after delivery (plus 2nd assistant during home delivery to facilitate this)
- Delay bathing for at least a day

Day of birth

- Weigh and assess the baby for danger signs
- Refer very low birth weight (LBW) & potentially sick babies to hospital
- Encourage exclusive breastfeeding (EBF)
- Encourage good thermal care (bath with warm water, dry immediately and wrap well)
- Encourage special care for LBW babies (Skin to skin contact, delay bathing at least 3 days, hygiene, frequent breastfeeding)

Day 3

- Assess baby for danger signs & refer sick babies
- Reinforce EBF, thermal care
- Teach newborn danger signs & encourage prompt care-seeking

Day 7

- Assess baby for danger signs & refer sick babies
- Reinforce EBF, thermal care, prompt care-seeking
- Encourage bed net use, immunisations

Other visits

- Follow-up visits within 24 hours for referred babies
 - Visit at 14 days for LBW babies
-

A total of 406 CBSVs were fully-trained, with all intervention communities having one or more trained CBSVs.

Supervision of CBSVs

There are two District Project Supervisors (DiPS) based in each DHMT, who have been trained in supervisory skills and who are responsible for supervising CBSVs in their catchment areas. They aim to visit each of their CBSVs at least once a month to directly observe a home visit and to problem-solve any issues. They also aim to hold group meetings every two to three months where CBSVs can share their experiences and problems are discussed. In addition, they hold meetings with community leaders to provide feedback and stimulate interest in the intervention. They also carry out regular checks on all CBSV equipment and arrange replacements as necessary. A set of materials have been developed to support supervision including a workbook to record activities and issues raised, a monthly CBSV tally sheet to record visits carried out and participation in group meetings, and forms to record detailed observation of home visits.

Incentives

It was decided during the formative research that providing a monthly monetary incentive would be key in keeping CBSVs active and maintaining motivation. An amount of 5 Ghana cedis per month (approximately \$5) was determined in discussion with national and district level representatives of the Ghana Health Service to be both sustainable and sufficient to motivate CBSVs. These monthly incentives are distributed by the DiPS during supervisory visits.

Hospital essential newborn care strengthening

As CBSVs are trained to refer very low birthweight and sick babies, and as the formative research identified some inadequacies in the current provision of newborn care, it was considered essential to update skills and knowledge of staff in the main health facilities. In response to a joint request from the DHMTs and Newhints team, endorsed by the National Reproductive and Child Health Coordinator, WHO conducted a national ToT workshop in "Strengthening Essential Newborn Care in Health Facilities" in Accra in July 2008. Two training workshops were then held later in July at Techiman and at Nkoranza hospitals for staff from the 10 largest health facilities, including the district hospitals, that provide care and services for newborns; these were facilitated by the Newhints clinician (AM) and others trained at the national workshop.

Supportive activities

There are several supportive actions to promote the intervention and ensure women receive consistent advice from health facility staff, traditional birth attendants (TBAs) and other community members. Each of these has their own protocol.

- **Health facility sensitization:** The DHMTs organised meetings in each district during September and October 2007 and invited sub-district teams, and those in charge of health facilities together with the public health nurses and midwives who help in the delivery of babies and who take care of pregnant mothers. At these meetings, the Newhints team outlined the proposed intervention and discussed its implications for the health facilities. This included a detailed discussion of the newborn care practices being promoted in order to harmonise messages between the trial and health facility staff, and feedback on findings of the health facility survey conducted during the formative research. In addition, the six district hospitals were visited in June and July 2008 in order to refresh the memory of health workers in the hospital regarding Newhints, to introduce and explain the referral strategy and the use of the referral slip, and to discuss prioritization of babies with referral slips.

- **Community leaders sensitization:** Introductory visits were made during December 2007 and January

2008 to all 191 communities in the intervention zones by teams of one DHMT representative, one Newhints supervisor (DiPS) and one NewHints researcher. Appointments were made with community leaders, who invited key members of their community; the CBSVs also attended. The meetings aimed to garner community leader support for Newhints activities, and to raise the profile of the CBSVs. They lasted 1 to 2 hours and took the form of presentation, demonstration and discussion. The questions that were raised centred on issues around implementation, community involvement, financial support and the content of Newhints intervention messages. These fed into the CBSV training manual and the TBA sensitization and community-wide meeting (durbar) protocols. The community leaders were formally asked if they would like their CBSVs to carry out Newhints activities; all agreed.

- **TBA sensitization:** A series of TBA sensitisation meetings were held in February 2008 in each district to garner their support for Newhints activities, to help ensure that TBA advice would not conflict with Newhints advice, and to discuss behaviours that TBAs may control such as hand washing, early bathing and immediate drying and wrapping. All TBAs (trained and untrained) who were known to be active within the intervention communities were invited.

- **Community durbars:** Community wide meetings were organised by the DHMT-Newhints teams during July and August 2008, and chaired by the community chiefs. Their purpose was to introduce the importance of newborn care to the community, to explain the rationale, content and structure of the Newhints intervention, to discuss the importance of community support for its success, and to present the fully trained CBSVs with their Newhints T-shirt, bag and certificate.

Mapping zones

An inventory was carried out of all CBSVs working in the trial area and data collected on their socio-economic status, level of education, and current workload and schedule. The trial area was then divided into a total of 98 supervisory zones. Their boundaries were defined in discussion with the DHMTs, based on feasibility of coverage within the zone by bicycle, size of communities, geographical access from one community to another, and the total number of CBSVs covered aiming for about 8 CBSVs per zone. There were a few larger zones as villages were never divided between zones and some had more than 8 resident CBSVs, and a few smaller ones in geographically separated communities. The large towns were divided into zones of geographical non-contiguous areas, based on size, population and already established CBSV work areas.

Randomisation

Meetings were held in each district in November 2007 to introduce the Newhints trial to all CBSVs, to explain the proposed randomization process and to obtain their cooperation and support for this; 686 CBSVs (91%) attended. Forty-nine zones were then selected at random for implementation of the Newhints intervention, with the other 49 zones acting as control. This was carried out by an independent epidemiologist using restricted stratified randomisation to ensure balanced numbers of intervention and control zones in each of 10 strata. These were the four large towns (Kintampo, Nkoranza, Techiman and Wenchi) and the six districts (Kintampo North, Kintampo South, Nkoranza, Tain, Techiman and Wenchi) minus these towns; note this took place before Nkoranza was divided into two districts, Nkoranza North and Nkoranza South. Restricted randomisation used available surveillance data to ensure that intervention and control arms were also balanced with respect to the following criteria: absolute differences of less than 2/1000 live births for neonatal mortality rates, less than 2.5% for the percentage of deliveries in a health facility, and less than 2.5% for the percentage of deliveries in a private hospital, in each of 2004, 2005 and 2006. An additional selection criterion was to ensure that the 4 pilot zones (which had been chosen at random) were allocated to the intervention group.

Intervention Zones

The Newhints intervention as described above was implemented in the 49 intervention zones. All pregnant women and newborns living in these zones were therefore potential recipients of the intervention receiving home visits from CBSVs, in addition to routine maternal and child health (MCH) care currently available.

Control Zones

Pregnant women and newborns living in the control zones continued to benefit from the routine MCH care currently available, which includes: antenatal clinics (ANC), Infant Welfare Clinics (IWC), access to free delivery with skilled attendants, access to TBA delivery and care, and routine interactions with CBSVs concerning outreach MCH and immunisation clinics. In addition control zones benefitted from the hospital essential newborn care strengthening and health facility sensitisation that covered all facilities in the trial area.

Sample size

The sample size was determined by the primary outcome, all cause neonatal mortality, using the baseline neonatal mortality rate (NMR) of 31 per 1000 live births and the intraclass correlation coefficient (ICC) of 0.0007256, where the ICC[14] is defined as the ratio of the between zone variation to the total variation. This suggests that a total sample size of 15,200 livebirths would have 80% power to detect a 25% reduction in NMR at the 5% significance level, 93% power to detect a 30% reduction and 60% power to detect a 20% reduction. This sample size should be achieved by the number of livebirths that take place in a year in the trial area. The evaluation will be based on data collected for all babies born from 1 January 2009; this is 1 month after the intervention was fully implemented, and 6 months after CBSVs started assessing babies in July 2008 as well as counselling about newborn care practices.

Impact evaluation

The primary outcomes are all cause neonatal mortality and key care practices; these will be compared between intervention and control zones. Secondary outcomes are age and cause-specific neonatal mortality. All required data are being collected through the surveillance system of 4-weekly home visits to all women of reproductive age established for the ObaapaVitA vitamin A and maternal mortality trial that took place from December 2000- October 2008[15]. This surveillance has been continued for the Newhints trial.

Resident fieldworkers are responsible for a fieldwork area (FWA) of four contiguous clusters of compounds, visiting women in one cluster per week over a 4-weekly cycle. Each week, fieldworkers

receive an updated listing of women to be visited that week, and their pregnancy status, arranged by compound. A MONTH form is completed for each woman, and includes questions on whether she was present, if not whether she had died, any morbidity requiring treatment outside the home or hospitalisation, her pregnancy status, and a question on the outcome of the pregnancy, completed when a pregnancy ends. There is a scheduled 4-week fieldwork break each year over Christmas.

Other forms are completed as required. A PROFILE form collecting socio-demographic information is completed as soon as a woman reports that she is pregnant. A birth results in: a BIRTH form collecting data on pregnancy, delivery, the baby (or babies), newborn care practices and contact with CBSVs; and monthly INFANT form(s) completed until the baby reaches 12 months of age collecting data on their status, and exposure to key child survival interventions. These forms were revised to ensure that they capture data on practices promoted by the Newhints intervention.

Verbal post-mortems (VPMs) are carried out for all neonatal deaths in the trial area. A surveillance supervisor visits the household and interviews the mother or care-taker about the circumstances surrounding the death, including an open history, and specific questions on symptoms. All VPMs are reviewed by two experienced doctors, who independently code the likely cause of death. If they disagree, the form is reviewed by a third doctor; if their diagnosis matches one of the other two, this is accepted. If not, they meet to discuss the case and attempt to reach agreement. If this is not possible the cause is coded as unable to be determined.

Data Management

The trial impact evaluation outcomes will be derived from the surveillance database which was established in 2000 using Visual FoxPro (version 6.0 Microsoft Corp Seattle WA USA), and which was modified to include new data collection forms developed for Newhints. All forms are manually checked for completeness and consistency before they leave the field, collected and processed on a weekly basis. Independent double data entry with verification is carried out together with range and consistency checks, and inter-table consistency checks. Any queries identified are resolved promptly by the trial management team, and the database updated. New data are added to the database within 4 weeks of collection, and in time for the updated data to be used to generate field listings for the next 4-weekly visit. Copies of the surveillance database will be made and frozen within three months after the completion of the fieldwork.

Participant flow & comparability of treatment arms

A flow diagram will be completed showing the number of zones, pregnancies, livebirths, neonatal deaths and loss to follow-up in the intervention and control arms, together with a map showing the locations of the intervention and control zones. Intervention and control zones will be compared with respect to the following variables: neonatal mortality rate, the percentage of skilled attendants at delivery and percentage of deliveries occurring in health facilities in 2007 (baseline); level of education of mothers, their ethnic group of origin, marital status and parity, and occupation (used as proxy indicator for the level of income), since these are known either to be related to the neonatal mortality rate or to effect peoples' knowledge, attitudes and practices on neonatal care. No statistical significance tests will be carried out on these comparisons [14,16]. However, analyses will be carried out both including and excluding these potential *a priori* confounders.

Intention-to-treat analyses

The primary analysis for each outcome will be intention-to-treat, where intention to treat is defined by a woman's zone of residence. All analyses will account for the cluster-randomised design using random effects logistic regression and will be carried out both with and without adjustment for potential confounders (see above); individual-level methods are statistically more efficient than cluster-level methods, and are preferred when a large number of clusters have been randomised, as is the case in this trial, as they readily allow adjustment for covariates [16]. Quadrature checks will be carried out to confirm the reliability of the results; should these fail generalized estimating equations (GEE) and robust standard errors will be used instead [16]. The estimated effect of the intervention will be

presented as a relative risk together with a 95% confidence interval. The intraclass correlation (ICC) and coefficient of variation (k) will be reported. Random-effects logistic regression will also be used to explore whether there are any differences in impact of the intervention: between facility- and home-based deliveries; between urban and rural areas; and between the four zones included in the pilot and the other intervention zones.

Secondary analyses

With a public health intervention, such as Newhints, it is impossible to ensure every eligible recipient receives the intervention in exactly the way it was intended. Thus it is likely that only a proportion of pregnant women residing in intervention zones will receive all five home visits at the timing intended; others may not have received any, or fewer visits, or visits later than intended, in particular the first post-natal visit may not have taken place within 24 hours as intended. Secondary analyses will therefore also be carried out to examine whether the impact of the intervention varies according to the number and timing of home visits each woman has received, and the average quality of the intervention delivered in the zone, as assessed by the process indicators measured on a sub-sample of women (see below). This will be explored both using individual quality indicators and by dividing intervention zones into quintiles, based on a quality index derived using principle component analysis [17].

Process evaluation and intervention monitoring

All aspects of the intervention process are being fully documented and evaluated on an ongoing basis using a variety of methods and data sources:

- *CBSV Programme:* The CBSV database will provide data on the following: Profile of the CBSVs (age, gender, ethnicity); Number (& %) of CBSVs trained, & retrained; CBSV attrition and replacement rate; Number (& %) of CBSVs who received incentive payment each month. This will be supplemented by in-depth interviews with a sample of CBSVs, and issues raised during group meetings.
- *Supervisor performance:* This is being assessed on an ongoing basis using data collected from the DiPS workbooks, monthly log sheets and observations of supervisory visits by their supervisors. Indicators include: % CBSVs who received supervisory visits each month; % CBSVs who were directly observed during supervisory visits each month; % of CBSVs who attended group meetings in each 2 monthly period; frequency of supervisory visits per CBSV; Frequency of group meetings per CBSV. In addition supervisor performance will be assessed by % supervisory visits observed by a senior newhints team member that were conducted according to protocol; and % supervisors scoring at least 80% in test assessing their knowledge of counselling cards and protocol.
- *Coverage and timing of CBSV visits:* Detailed information concerning CBSV visits is collected on a PRO-CESS form administered to a random subsample of 200-300 recently delivered women each month. Indicators include: % recently delivered women who received full complement of 5 home visits; % visited according to schedule; % who received ante-natal visits; % who received post-natal visits; % who received first postnatal visit within 24 hours after delivery.
- *Quality of CBSV visits:* This will be assessed using the detailed DOS reporting forms completed by the supervisors during their observations of home visits, supplemented by information collected on the PROCESS form. The % CBSVs delivering the intervention according to protocol will be reported for the following: counselling cards & interactions; weighing & assessment for danger signs; referral & care seeking; correct card filling.

In-depth interviews and focus group discussions will also be carried out with a range of respondents (recently-delivered women, their families, CBSVs, TBAs, health facility staff) to explore all aspects of the intervention delivery and response to recommendations. Special sub-studies will focus on the provision of special care for low birthweight babies, and the assessment and referral of sick and

very low birthweight babies.

Summary statistics and graphs showing trends over time will be compiled for all the process indicators, and determinants of quality of intervention delivery explored. The transcripts from in-depth interviews and focus group discussions will be formally analyzed using Nvivo software. Key analytical categories will be identified and the interviews systematically indexed into these categories and interpreted in order to make recommendations concerning intervention implementation, identify factors contributing to success, document barriers encountered and strategies adopted to tackle them, and identify issues important for scaling up.

Cost and cost-effectiveness evaluation

A detailed costing of the development, set-up, and implementation of the Newhints intervention is being carried out with the following objectives: to estimate cost per life saved, if Newhints successfully reduces neonatal mortality; to estimate the incremental cost-effectiveness of Newhints relative to current practice, and compared with other newborn health interventions (in Ghana and elsewhere); to evaluate the financial sustainability (measured in terms of incremental budget implications) of the programme for the DHMTs; and to model the costs of scaling-up to regional/national levels. Both financial and economic costs will be considered. Formative research costs will be included as programme development costs; however, all other research costs will be excluded. A provider perspective will be taken and costs up to district level will be included.

Financial cost data will be collected from a variety of sources including itemized project accounting records, activity diaries, and semi-structured interviews and time sheets to determine the time allocation of Newhints team members between research and programme activities. The incremental costs of increased health facility utilization attributable to the intervention will be estimated by combining utilization data from the BIRTH and INFANT forms with data extracted from hospital records and direct observation in health centres on the quantities of drugs and supplies used for deliveries and newborn admissions, and unit cost data obtained from hospital pharmacists and regional medical stores. The economic cost of CBSV time will be quantified using information on the number and average duration of CBSV visits and other Newhints activities per month extracted from CBSV records, DOS and PROCESS forms, while in-depth interviews with CBSVs will explore the opportunity cost of this time, including possible seasonal variations.

Informed consent

Informed consent was sought in late 2007 from all women of reproductive age living in the intervention and control zones for permission to use their surveillance data for the evaluation of NewHints, in addition to its use for the ObaapaVitA trial. Resident surveillance fieldworkers read an information sheet and consent form to the women in their own local language and checked for understanding before requesting consent. Agreement was indicated by signature or other imprint on prepared consent forms. Women were assured of their right to refuse consent without prejudice to their position in the ongoing ObaapaVitA trial (which finished in October 2008), or to any community or health services received. There were no refusals. This consent procedure is being applied on an ongoing basis for new women who move into the trial area and are recruited into the surveillance system. In addition, in the intervention zones, the CBSVs will, as per usual practice, obtain permission to make home visits from each pregnant woman identified.

Individual informed consent is also being sought from those selected for in-depth interviews and focus group discussions as part of the process and cost evaluations, and will follow a similar procedure. Interviewers read an information sheet and consent form to potential participants in their own local language and check for understanding before consent is requested. Agreement to participate in the interview is indicated by signature or other imprint on prepared consent forms. The individual's right to refuse consent or to stop the interview at any time after consent has been given will be preserved without prejudice to their position in other ongoing research, or to any

community or health services received. They will not be required to provide explanation for such decisions.

No informed consent is being obtained from the DiPS or the CBSVs regarding collection of routine data from workbooks to monitor progress, or for recording observation of home visits, since such monitoring is an integral part of normal supervision activities, necessary to ensure the integrity of the intervention.

Confidentiality of all data collected is maintained at all times and is accessible only to senior project staff and to the trial monitoring committees. This includes information collected during the process evaluation except where it relates to routine monitoring of performance of CBSVs and supervisors. All women and babies in the surveillance database are identified by a unique ID number. The database is stored on a security protected server, with password access only by senior project staff. The data forms are stored in secure record stores and will be kept for a minimum of 5 years after the end of the trial.

Trial monitoring

The Trial Steering Committee (TSC) has 12 external members, chosen to facilitate dissemination and uptake of any findings within Ghana as well as to provide technical support; members include key policy makers from the Ghana Health Service at national and regional level, national WHO and UNICEF representatives and advisers with expertise in obstetrics, demography, statistical methods, clinical trials and health services research. It is also attended by the principle investigators, members of the trial management team and representatives from the participating DHMTs and funding bodies. The Data Monitoring and Ethics Committee (DMEC) has five members, with expertise in epidemiology and medical statistics (including the design and analysis of cluster randomised trials), obstetrics, maternal health and community medicine. Both committees meet annually to examine trial conduct and progress and to advise the trial management team. The DMEC are not carrying out any interim analyses, as the Newhints intervention is health promoting and does not involve any drugs or medical procedures, and as the evaluation is based on births occurring over a period of just one year.

Ethical approval

The trial protocol was reviewed and approved by the ethics committees of the Ghana Health Services, the Kintampo Health Research Centre and the London School of Hygiene and Tropical Medicine. It is registered with clinicaltrials.gov (identifier NCT00623337).

Dissemination of Trial Findings

Trial findings will be shared promptly with the Technical Steering Committee, and discussed with the local District Health Management Teams. Local dissemination meetings with the study populations will be held. A CD will be compiled containing all intervention materials plus a detailed implementation evaluation report of lessons learned and shared widely. Policy briefs will be prepared and circulated nationally and internationally to relevant policy and donor organisations, and if possible a national workshop held to discuss the findings, lessons learnt concerning implementation and policy implications.

Trial findings will also be disseminated in scientific meetings and papers on: the impact of the intervention on neonatal mortality; impact on neonatal care practices; any intervention differences by place of delivery or between rural and urban zones; process outcomes, and lessons learned concerning working with volunteers, supervision, monitoring performance; training volunteers to assess babies and how well do they do; strategies to promote coverage; factors influencing response to specific care recommendations including special care for low

birthweight babies and referrals; and cost-effectiveness of the intervention.

Requests to analyse or publish data from persons external to the study will be entertained 3 years after the data-bases are frozen. The requesting researcher in addition to at least 2 persons from within the project team will author such publications and acknowledgement will be given to the project team including the collaborators.

Competing interests

The authors declare that they have no competing interests.

Authors' contributions

The paper was drafted by BRK; all authors reviewed the paper, approved the final manuscript, and had major inputs to the trial design and intervention development. BRK, AM, CTA, SOA, ZH were responsible for the overall design; AM, ZH, BW, TG, SOA for DHMT coordination; AM, SD, BW, TG for mapping zones; ZH, CTA, AM, GA, BRK for development of the home visits content; AM, ZH, BRK, BW, TG, SS, GA for the training and supervision materials; ZH, EL, AM, TG, BW, GA, for sensitisation protocols; ZH, CTA, AM, BW, TG, SS, SD, BRK, GA for data collection instruments; SD, SS, BRK, GA for database design and management; BRK, AM, CTA and ZH for the analysis plan; and CP, KH for design of the cost and cost-effectiveness evaluation.

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References

1. Lawn JE, Cousens S, Zupan J: 4 million neonatal deaths: when? Where? Why? *Lancet* 2005, 365(9462):891-900.
2. Bhutta ZA, Darmstadt GL, Hasan BS, Haws RA: Community-based interventions for improving perinatal and neonatal health outcomes in developing countries: a review of the evidence. *Pediatrics* 2005, 115(2Suppl):519-617.
3. Darmstadt GL, Bhutta ZA, Cousens S, Adam T, Walker N, de Bernis L: Evidence-based, cost-effective interventions: how many newborn babies can we save? *Lancet* 2005, 365(9463):977-88.
4. WHO-UNICEF Joint Statement: Home visits for the newborn child: a strategy to improve survival: World Health Organization. 2009 [http://whqlibdoc.who.int/hq/2009/WHO_FCH_CAH_09.02_eng.pdf]. Accessed 13 May 2010.
5. Bang AT, Bang RA, Baitule SB, Reddy MH, Deshmukh MD: Effect of home- based neonatal care and management of sepsis on neonatal mortality: field trial in rural India. *Lancet* 1999, 354(9194):1955-61.
6. Baqui AH, El-Arifeen S, Darmstadt GL, Ahmed S, Williams EK, Seraji HR, *et al.*: Effect of community-based newborn-care intervention package implemented through two service-delivery strategies in Sylhet district, Bangladesh: a cluster-randomised controlled trial. *Lancet* 2008, 371(9628):1936-44.
7. Kumar V, Mohanty S, Kumar A, Misra RP, Santosham M, Awasthi S, *et al.*: Effect of community-based behaviour change management on neonatal mortality in Shivgarh, Uttar Pradesh, India: a cluster- randomised controlled trial. *Lancet* 2008, 372(9644):1151-62.
8. Bhutta ZA, Memon ZA, Soofi S, Salat MS, Cousens S, Martines J: Implementing community-based perinatal care: results from a pilot study in rural Pakistan. *Bull World Health Organ* 2008, 86(6):452-9.
9. Manandhar DS, Osrin D, Shrestha BP, Mesko N, Morrison J, Tumbahangphe KM, *et al.*: Effect of a participatory intervention with women's groups on birth outcomes in Nepal: cluster-randomised controlled trial. *Lancet* 2004, 364(9438):970-9.
10. O'Rourke KH-GL, Seoane G: Impact of community organisation on perinatal outcomes in rural Bolivia. *Rev Panam Salud Publication/Pan Am Public Health* 1998, 3(1):9-14.
11. AbouZahr C, Wardlaw T: Maternal mortality at the end of a decade: signs of progress? *Bull World Health Organ* 2001, 79(6):561-8.
12. Edmond KM, Quigley MA, Zandoh C, Danso S, Hurt C, Owusu Agyei S, *et al.*: Aetiology of stillbirths and neonatal deaths in rural Ghana: implications for health programming in developing countries. *Paediatr Perinat Epidemiol* 2008, 22(5):430-7.
13. Hill Z, Manu A, Tawiah-Agyemang C, Gyan T, Turner K, Weobong B, *et al.*: How did formative research inform the development of a home-based neonatal care intervention in rural Ghana? *J Perinatol* 2008, 28(Suppl 2):S38-45.
14. Kirkwood BR, Sterne JAC: Essential medical statistics. 2nd edition. Malden, Mass.: Blackwell Science; 2003.
15. Kirkwood BR, Hurt L, Amenga-Etego S, Tawiah C, Zandoh C, Danso S, *et al.*: Effect of vitamin

A supplementation in women of reproductive age on maternal survival in Ghana (Obaapa VitA): a cluster-randomised, placebo-controlled trial. *Lancet*. 2010, 375(9726):1640-9.

16. Hayes RJ, Moulton LH: Cluster randomised trials. Boca Raton: CRC Press; 2009.
17. Armitage P, Berry G, Matthews JNS: Statistical methods in medical research. 4th edition. Malden, MA: Blackwell Science; 2001.

Appendix 2: Impact of Newhints on newborn care practices & neonatal mortality

Impact of the “Newhints” home visits intervention on neonatal mortality and care practices in Ghana: a cluster randomised controlled trial

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ABSTRACT

Background: The 3.3 million newborn deaths that occur each year account for 41% of all child deaths in developing countries. In 2009, WHO & UNICEF issued a joint statement “Home visits for the newborn child: A strategy to improve survival” based on promising evidence from trials in South Asia. The Newhints trial provides the first evidence from sub-Saharan Africa.

Methods: The Newhints cluster randomised trial was carried out throughout 7 districts in Brong Ahafo Region, Ghana, and involved 98 zones each covering 8-12 community based surveillance volunteers (CBSVs) who encourage attendance at maternal and child health outreach and immunisation clinics. Forty-nine zones were randomised for implementation of the Newhints intervention with the other 49 acting as controls. CBSVs in Newhints zones were trained to identify pregnant women and to make 2 home visits during pregnancy and 3 in the first week of life to promote essential newborn care (ENC) practices, to weigh and assess babies for danger signs, and to refer as necessary. Primary outcomes are the neonatal mortality rate (NMR) and coverage of key ENC practices. The main secondary outcome is post day 1 NMR, relevant as Newhints did not tackle birth asphyxia, a major cause of newborn deaths. The evaluation is based on deliveries that took place between November 2008 (the month after Newhints training was completed) and December 2009, using data collected through an ongoing surveillance system. Intention-to treat analyses used random effects logistic regression to account for the cluster-randomised design, with relative risks (RR) derived using the marginal standardisation technique. A meta-analysis was also carried out including the Newhints findings.

Findings: A total of 16,329 deliveries took place between November 2008 and December 2009, resulting in 16,168 livebirths; the status at one month was known for 15,619 (96.6%) of these. A total of 482 neonatal deaths were recorded; the NMR in control zones was 31.9/1000 livebirths. Overall 72% of mothers in Newhints zones reported having at CBSV visits during pregnancy and 63% postnatal visits. This coverage increased substantially from June 2009 after new implementation strategies were introduced and reached almost 90% for pregnancy visits by the end of the trial, and about 75% for postnatal visits.

Newhints significantly increased coverage of key ENC behaviours. The largest increase was for careseeking, with 77.3% of sick babies in Newhints zones taken to a hospital or clinic compared to 55.4% in control zones, a relative increase of 43% (95% CI 17%, 76%; $P=0.001$). Newhints achieved modest non-significant reductions of 8% (95% CI -13%, 25%; $P=0.405$) in overall neonatal mortality, and 15% (95%CI -13%, 37%; $P=0.27$) in post day-1 mortality. The reductions were higher for singleton births, and after coverage was improved, with a 41% reduction (95%CI 2%, 65%; $P=0.042$) in post day 1 NMR among singletons born between June and December 2009.

Interpretation: The reduction in neonatal mortality achieved by Newhints is consistent with the reductions achieved in the 3 trials carried out in programme settings in South Asia. As there is no suggestion of any heterogeneity ($P=0.85$) between the trials, the summary estimate provides the best evidence for the likely impact of the home visits strategy delivered within programmes in sub-Saharan Africa as well as South Asia. This is a reduction in NMR of 12% (95% CI 5%, 18%). A more substantial impact could be achieved if this was accompanied by improvements in quality of

delivery and neonatal care in health facilities, and if innovative, effective strategies could be developed to increase coverage of home visits on the day of birth.

Trial registration: www.clinicaltrials.gov (identifier NCT00623337)

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Introduction

Each year 3.3 million babies die within the first 28 days of life (the newborn or neonatal period); newborn deaths account for 41% of all child deaths in developing countries^{1,2}. Another 3.2 million babies are stillborn³. Effective interventions exist that could prevent the vast majority of these deaths⁴. The challenge is to identify strategies that can feasibly be implemented in the short term to ensure that newborns have access to these life-saving interventions. In 2009, WHO & UNICEF issued a joint statement “Home visits for the newborn child: A strategy to improve survival” and called on all governments in low and middle income countries to implement this⁵. In particular they recommend 3 visits during the first week of life to promote essential newborn care (ENC), to examine newborns for danger signs and treat or refer as appropriate, and to counsel the family on danger signs and the importance of prompt careseeking for the newborn.

This strategy was based on promising evidence from South Asia showing that home visits promoting ENC practices and treating or referring sick babies can reduce neonatal mortality. This included 3 proof of principle trials; the Gadchiroli^{6,7} (70% reduction) and Shivgarh⁸ (54% reduction) trials in India and the Projahnmo trial in Sylhet, Bangladesh⁹ (34% reduction in the last 6 months of the 30 month intervention) and encouraging results from a pilot study in Hala, Pakistan¹⁰. Since the joint statement, results have been reported from three trials testing the impact of home visits delivered in a programme setting. All were in South Asia and all achieved substantially lower reductions in neonatal mortality than the proof of principle trials; they were the Projahnmo2 trial in Mirzapur, Bangladesh¹¹ (13% reduction), the Hala trial in

Pakistan¹² (15% reduction), and an evaluation of the integrated management of the newborn and childhood illnesses (IMNCI) programme in Haryana, India¹³ (9% reduction). Key features of the trials are summarised in Table 1.

This paper presents findings from the Newhints¹⁴ trial which tested the impact of the home visits strategy delivered in a programme setting in Ghana. It provides the first evidence for this strategy from sub-Saharan Africa.

Methods

The overall aim of the Newhints cluster randomised controlled trial was to develop and evaluate a feasible and sustainable “home visits” intervention to improve newborn care practices and careseeking, and by so doing improve neonatal survival. It was carried out in 7 predominantly rural districts in Brong Ahafo Region, Ghana: Kintampo North, Kintampo South, Nkoranza North, Nkoranza South, Tain, Techiman and Wenchi. Detailed methodology has been published previously¹⁴.

Randomisation

The trial area comprised 98 supervisory zones each covering 8-12 community based surveillance volunteers (CBSVs); 49 zones were randomised for implementation of the Newhints intervention with the other 49 acting as controls (Figure 1). Randomisation was carried out by an independent epidemiologist using restricted randomisation to ensure balance within districts and main towns and with respect to neonatal mortality rates (within 2/1000 livebirths), percentage of deliveries in a health facility (within 2.5%) and percentage of deliveries in a private facility (within 2.5%) using available

surveillance data in each of the three years before the trial planning started (2004-6).

Interventions

Newhints zones: Newhints is an integrated intervention package (Figure 2), based on extensive formative research¹⁵ and developed and implemented in close collaboration with the District Health Management Teams (DHMTs) of the trial districts. The core component was training the CBSVs in the 49 intervention zones to identify pregnant women in their community and to conduct five focussed home visits, two during pregnancy and three after birth on days 1, 3 and 7. The content of each visit and an overview of the intervention components are given in the published trial protocol¹⁴. All pregnant women and newborns living in Newhints zones were potential recipients of the home visits, in addition to the routine maternal and child health (MCH) care available.

Over 400 CBSVs were trained for a total of 9 days organised in 3 phases over an 8 month period from March to October 2008 (Table 2); all intervention communities had at least one trained CBSV. In the first phase CBSVs were trained to counsel and problem solve around ENC behaviours, and in the second to weigh newborns, check them for danger signs and refer if necessary. The third phase was refresher training with a focus on the newborn assessment procedures. All Newhints materials including training manuals and counselling cards can be found on the website (<http://newhints.lshtm.ac.uk>).

An additional set of implementation strategies to improve coverage of both home visits and supervisory visits were introduced between February and May 2009; these

included monthly tally sheets by CBSV for supervisors to record visits made, introduction of repeat home visits to enable supervisors to observe CBSVs in action, group meetings with CBSVs about how coverage could be improved, introduction of compound registers for CBSVs to complete for their catchment areas, and recruitment of 47 new CBSVs for areas with heavy workloads.

Control zones: Pregnant women and newborns living in the control zones continued to benefit from the routine MCH care available, which included: antenatal clinics (ANC), access to free facility delivery, postpartum check-ups, infant welfare clinics, and routine CBSV activities concerning outreach MCH and immunisation clinics. In addition control zones benefitted from the hospital ENC strengthening and sensitisation activities that covered all health facilities in the trial area.

Trial Hypotheses and Objectives

The underlying hypotheses are that the CBSVs would achieve a high coverage of the Newhints home visits, that these home visits would lead to improved ENC practices and increased access to care for sick newborns, and that this would save newborn lives. The primary objectives were therefore to evaluate the impact of Newhints on all cause neonatal mortality, and on ENC practices including careseeking.

Participants

The evaluation is based on all pregnancies that ended in a live or stillbirth between November 2008 (the month after Newhints training was completed) and December 2009, using data on pregnancies, births and deaths collected through the surveillance system of all women of reproductive age established for the ObaapaVitA trial of

vitamin A and maternal mortality¹⁶ and continued for the Newhints trial. The surveillance system was based on 4-weekly home visits by resident fieldworkers to all women of reproductive age; in July 2009 this was amended to 8-weekly visits and restricted to pregnant women and infants due to budgetary constraints. It was estimated that this would be sufficient to achieve the required sample size for livebirths (see below).

Informed consent was sought from all women for permission to use their surveillance data for the evaluation of NewHints, and from any women who moved in during the course of the trial. Surveillance fieldworkers read an information sheet and consent form to the women in the local language and checked their understanding. Agreement was indicated by signature or other imprint on prepared consent forms. Women were assured of their right to refuse consent without prejudice to their continuation in the surveillance, or to any community or health services received. There were no refusals. In addition, in the intervention zones, the CBSVs, as per usual practice, obtained permission to make home visits to pregnant and recently delivered women they identified.

Outcomes

The primary mortality outcome is the all cause neonatal mortality rate (NMR), which includes all deaths that happen in the first 28 days of life, expressed per 1000 livebirths. Secondary outcomes include age and cause-specific neonatal mortality rates, the most important of which is the post day 1 neonatal mortality rate (days 2-28) for the following reasons. Firstly, Newhints does not target birth asphyxia, a major cause of day 1 deaths. Secondly, this avoids any difficulty in distinguishing between early

neonatal deaths and postpartum stillbirth deaths using data from verbal post-mortems. All mortality outcomes are calculated including and excluding twins as twins are much more likely to be premature and to die, and as twinning rates are higher in Ghana than in South Asia where the other trials have been conducted¹⁷.

The primary behaviour outcomes are the percentages of mothers practising the Newhints recommended behaviours. These are derived from the BIRTH form administered at the first surveillance visit that occurred after birth; this included questions relating to the pregnancy, delivery and newborn care practices promoted by Newhints. The denominator used for the outcome depends on the timing of the recommended practice. Thus for behaviours during pregnancy, the denominator is pregnancies (ending in a live or a stillbirth), except for birth preparedness where it is restricted to those ending after February 2009 when questions on this were added. As hygiene behaviours at delivery targeted home births, these are the denominator. For behaviours on the day of birth, the denominator is babies who survived the first day, and for exclusive breastfeeding at 28 days, the end of the neonatal period, the denominator is those babies with information on exclusive breastfeeding in the last 24 hours collected between days 26 to 32 after birth. Newborn bednet use was promoted during the visit on day 7; the indicator for this is therefore the percentage of babies who slept under a bednet during the past 24 hours, with the denominator babies who were visited within the first 2 months of life but after day 7 (ie days 8-56) and who were alive at the visit. Finally, the denominator for careseeking is babies visited within 2 months of birth reported as having been severely ill.

In addition, we also evaluated the impact of the Newhints intervention on the coverage gaps for the key recommended behaviours. The coverage gap¹⁸ is the difference between the percentage of mothers practising the behaviour and the ideal complete coverage of 100%. It is this group of mothers that were not already practising or planning to practise the recommended behaviours that the Newhints intervention sought to change.

Sample Size

The sample size was determined by the primary outcome. Using baseline data for the NMR (31/1000 livebirths) and intraclass correlation coefficient¹⁹ (0.0007256), we calculated that a total sample size of 15,200 livebirths would have 80% power to detect a 25% reduction in NMR at the 5% significance level, 93% power to detect a 30% reduction and 60% power to detect a 20% reduction.

Statistical Methods

Intention-to treat analyses were carried out to compare Newhints and control zones with respect to each outcome, where intention to treat is defined by zone of residence at pregnancy recruitment. These used random effects logistic regression to account for the cluster-randomised design, with relative risks (RR) derived using the marginal standardisation technique and the 95% confidence intervals (CIs) estimated via the delta method²⁰. Analyses were carried out in Stata version 11.2²¹.

We also updated the meta-analysis of the effect of home visits on neonatal mortality carried out in 2010 by Gogia and Sachdev²² to include results from recent trials and the Newhints results presented here. We divided the trials into two groups: proof of

principle trials and trials carried out in a programme setting and carried out meta-analyses for each group separately and combined using random effects model to calculate pooled RRs and 95% CIs, and the genetic inverse variance method to estimate between-trial heterogeneity²³.

Ethical approval and Trial Monitoring

The trial protocol (clinicaltrials.gov: NCT00623337) was approved by ethics committees of the Ghana Health Service, the Kintampo Health Research Centre and the London School of Hygiene and Tropical Medicine. The trial conduct was overseen by the Trial Steering Committee (TSC) and Data Monitoring and Ethics Committee (DMEC). The TSC had 12 external members, chosen to facilitate dissemination and uptake of any findings within Ghana as well as to provide technical support; members included key policy makers from the Ghana Health Service at national and regional level, national WHO and UNICEF representatives and advisers with expertise in obstetrics, demography, statistical methods, clinical trials and health services research. It was attended by representatives from the participating DHMTs and funding bodies. The Data Monitoring and Ethics Committee (DMEC) had five members, with expertise in cluster randomised trials, obstetrics, newborn health, maternal health and community medicine.

Role of the funding source

Funding was provided by the World Health Organization, Saving Newborn Lives/Save the Children USA and the UK Department for International Development (DFID). The funders had no role in data collection, data analysis or writing of the report. The

corresponding author had full access to all the data and had final responsibility for the decision to submit for publication.

Results

Trial profile and comparability of Newhints and control zones

Figure 3 shows the trial profile. 98 zones were randomised. A total of 19,981 women were identified as pregnant from November 2008, the start of the trial, of whom 1372 were still pregnant at the end. There were thus 18,609 eligible pregnancies, 9,435 in the 49 control zones and 9,174 in the 49 Newhints zones. Three groups of pregnancies were not included in the analysis of neonatal mortality: 908 (4.9%) where women were lost to follow-up during pregnancy, 1216 (6.5%) that ended early and did not result in a live or stillbirth, and 156 (0.8%) where women moved resulting in a change of treatment arms. The analysis was therefore based on 16,329 deliveries that took place between November 2008 and December 2009. These resulted in 16,168 livebirths; the status at one month was known for 15,619 (96.6%) of these, and a total of 482 neonatal deaths were recorded. The number of pregnancies (15,990; 97.9%), livebirths (15,536; 96.1%) and neonatal deaths (407; 84.4%) among singletons are also shown in the flow chart.

The Newhints zones were comparable to the control zones both at baseline for key outcomes (Table 3) and in terms of the socio-demographic characteristics of pregnant women (Table 4).

Coverage of Newhints home visits

Overall 72% of women in the Newhints zones reported having at least one CBSV visit during pregnancy and 63% at least one postnatal visit. As can be seen in Figure 4 this coverage increased substantially after the new strategies were introduced reaching almost 90% coverage of pregnancy visits by the end of the trial, and about 75% coverage of postnatal visits. Just over half (53%) of the first postnatal visits took place on the day of delivery or the day after.

Impact on key behaviours

The denominators for the analyses of the impact of the Newhints intervention on key promoted behaviours are shown in Table 5 with the results in Table 6. As can be seen Newhints significantly increased the coverage of all key behaviours except for antenatal care (which was re-enforced rather than targeted) and facility delivery (which increased considerably over the whole area with the introduction of the National Health Insurance Scheme, which provides free delivery and newborn care, and exemption of registration fees for pregnant women). The largest relative increase was for careseeking with sick babies in Newhints zones 43% more likely to be taken to a hospital or clinic than sick babies in control zones; the 95% CI is an increase between 17% and 76% (P=0.001).

What is striking is the high coverage in the control area of many of the key behaviours. What is also striking is the extent to which Newhints was able to reduce the coverage gap in these. For example, although there was a modest 10% relative increase in babies exclusively breastfed at one month in Newhints compared to control zones (86.1% vs

79.6%), this increase represented a 41% reduction (95% CI: 20%, 56%) in the coverage gap for exclusive breastfeeding at one month. Similarly Newhints reduced the coverage gap for hand washing with soap by home birth attendants by 43%, for bednet use by 23% for pregnant women and 29% for babies, and for careseeking for sick newborns by 55%.

Impact on neonatal mortality

There were 230 neonatal deaths in the Newhints zones compared to 252 in control zones: adjusted RR 0.92; 95% CI 0.75, 1.13; P=0.405 (Table 7). Also shown are the results for post day 1 NMR and analyses restricted to singletons. Column (a) shows the findings over the duration of the trial while column (b) shows the findings from June to December 2009, after the new implementation strategies to improve coverage of home visits and supervisory visits were introduced. As can be seen the RRs are lower corresponding to larger reductions in mortality for post day 1 NMR, the deaths particularly targeted by the intervention, and also lower for singletons. The adjusted RR for post day 1 NMR for singletons was 0.77 (95% CI 0.57, 1.04; P=0.085) corresponding to a 23% reduction in mortality.

As expected the RRs are lower after improved implementation was achieved. The adjusted RR achieved for post day 1 NMR in the last 7 months of the trial was 0.74 (95% CI 0.47, 1.17; P=0.204) and for singletons was 0.59 (95% CI 0.35, 0.98; P=0.042); these correspond to reductions in mortality of 26% and 41% respectively..

Discussion

Newhints achieved a modest 8% reduction (95% CI -13%, 25%; $P=0.405$) in overall neonatal mortality. As can be seen from the meta-analysis results in Figure 5, this is similar to the modest reductions in mortality achieved in the other 3 trials testing the impact of home visits delivered in a programme setting. This summary estimate is an overall reduction of 12% (95% CI 5%, 18%). As there is no suggestion of any heterogeneity between the trials ($P=0.85$), this summary estimate appropriately reflects the combined evidence of the reduction in neonatal mortality that might be achieved through home visits delivered in a programme setting. Individually the trials were not powered to detect a reduction of this level; Newhints was designed to have 80% power to achieve a 25% reduction. However, together these 4 trials do have sufficient power. Thus although the 95% confidence interval for the reduction achieved by Newhints included zero, as did the CIs for 2 of the other 3 trials, the 95% CI for the summary estimate does not.

As can also be seen in Figure 5, the reductions achieved in the 3 proof of principle trials were considerably higher. The meta-analysis estimate is a 45% reduction (95% CI 9%, 67%) but there was marked heterogeneity ($P<0.0001$).

We also looked at the impact of the Newhints intervention on post day-1 mortality; Newhints would not be expected to have more than a marginal impact on day 1 deaths because it does not tackle deaths from birth asphyxia, a major cause of early deaths; and because of the logistic difficulties inherent in CBSVs attending promptly after birth. Although Newhints achieved a high coverage of postnatal visits, only 53% of

these took place on the day of birth or the day after. The reduction achieved in post day-1 mortality was 15% (95%CI -13%, 37%; P=0.27) and, as expected, this was larger than for overall mortality. It is similar to the 14% reduction (95% CI 5%, 21%) achieved for post day-1 mortality in the Haryana trial¹³.

The observed reduction in mortality in the Newhints zones is supported by high compliance by the families with the CBSV referrals of sick babies, 86% of whom were taken to a health facility, and a remarkable 73% to hospital²⁴. It is also supported by increased coverage of essential newborn care (ENC) practices including a substantial improvement in care-seeking with 77% of families taking babies they perceived as severely ill to a clinic or hospital in Newhints zones compared to 55% in control zones, a relative increase of 43% (95% CI 17%, 76; P=0.001). In addition, for practices where coverage was already high (such as exclusive breastfeeding and use of bednets), Newhints substantially reduced the coverage gaps remaining.

However, the impact on mortality achieved may have been limited by several factors. Firstly, the home visits approach does not tackle asphyxia, a major cause of neonatal deaths. Secondly, the difficulty in getting to families on the day of birth means that many babies are not assessed at the time of highest mortality risk; potentially preventable early deaths are missed and the introduction of special care sick behaviours for low birthweight babies is delayed. Thirdly, the potential increase in coverage of key preventive behaviours achievable by the Newhints intervention was limited because many of these were already practised by a large proportion of women. Fourthly, there may be problems with the quality of newborn care in health facilities failing to save preventable newborn deaths among facility births on the day of delivery (70% of births

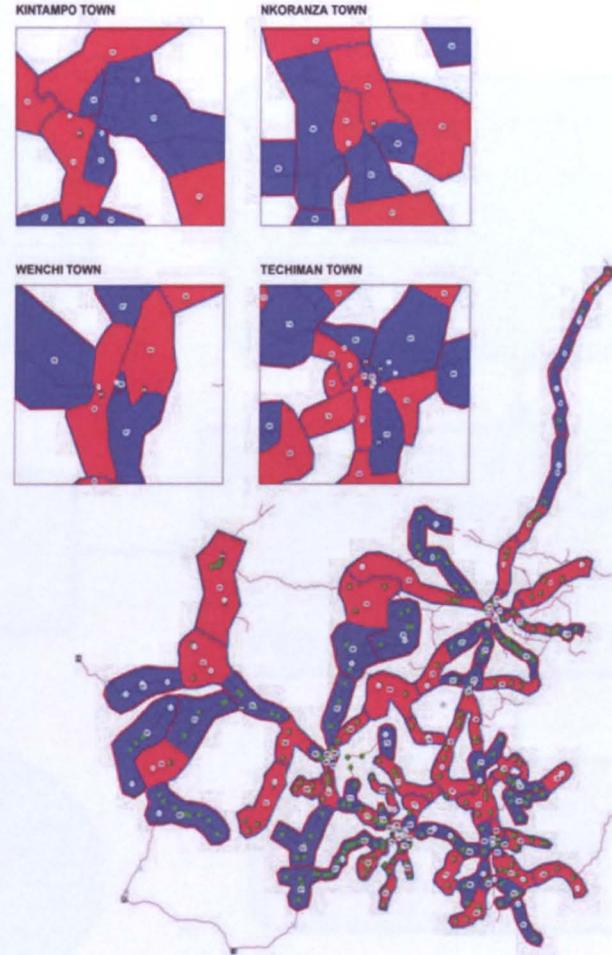
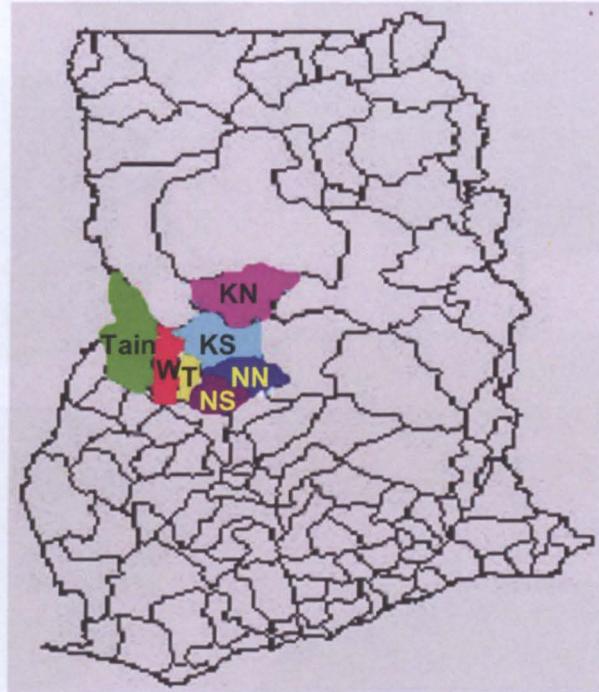
took place in a facility) or to provide adequate care for sick newborns referred by the CBSVs or taken by their families²⁵.

Finally, the evaluation took place immediately after the Newhints intervention was fully implemented and over a relatively short timeframe (14 months), whereas it takes time for teething problems to be ironed out and programmes to become embedded. Note that the 13% reduction included in Figure 5 for the Projahnmo trial is based on the full trial evaluation period of 30 months; the reduction achieved in the last 6 months was 34% (95% CI 7%, 53%), which is considerably higher⁹. Similarly, when the Newhints analyses were restricted to the 7 month period after the introduction of new implementation strategies, all impact estimates were higher. The adjusted RR for post day 1 NMR in the last 7 months of the trial was 0.74 corresponding to a 26% reduction in mortality (95% CI -18%, 53%; P=0.204); for singletons the reduction in mortality was 41% (95% CI 2%, 65%; P=0.042).

The Newhints trial provides the first evidence of the potential for the home visits strategy to reduce neonatal deaths in sub-Saharan Africa. The meta-analysis suggests that the impact achieved is consistent with reductions achieved in trials carried out in south Asia in programme settings, and with the meta-analysis estimate of 12% (95% CI 5%, 18%). A more substantial impact could be achieved if the Newhints home visit intervention was accompanied by improvements in quality of neonatal care in health facilities, and if innovative, effective strategies could be developed to increase coverage of home visits on the day of birth. The reduction in neonatal mortality would also be expected to be higher if implemented in settings with large coverage gaps in key preventive behaviours.

Authors' contributions

The paper was drafted by BRK, and reviewed and approved by all authors. BRK, AM, CTA, SOA, ZH were responsible for the design of the Newhints trial; ZH, AM, AtA, CTA, BW, TG, SS, BRK for intervention content and data collection instruments; AtA, AM, CTA, BW, TG, SS, SOA for trial conduct; SD, SAE, SS, BRK, AtA for database design and management; and SS for carrying out the analyses.



(a) Map of Ghana showing 7 trial districts: Kintampo North, Kintampo South, Nkoranza North, Nkoranza South, Techiman, Wenchi, Tain

(b) Schematic map of trial area showing trial zones
■ Newhints zones ■ Control zones

Figure 1: Trial location and randomisation of zones

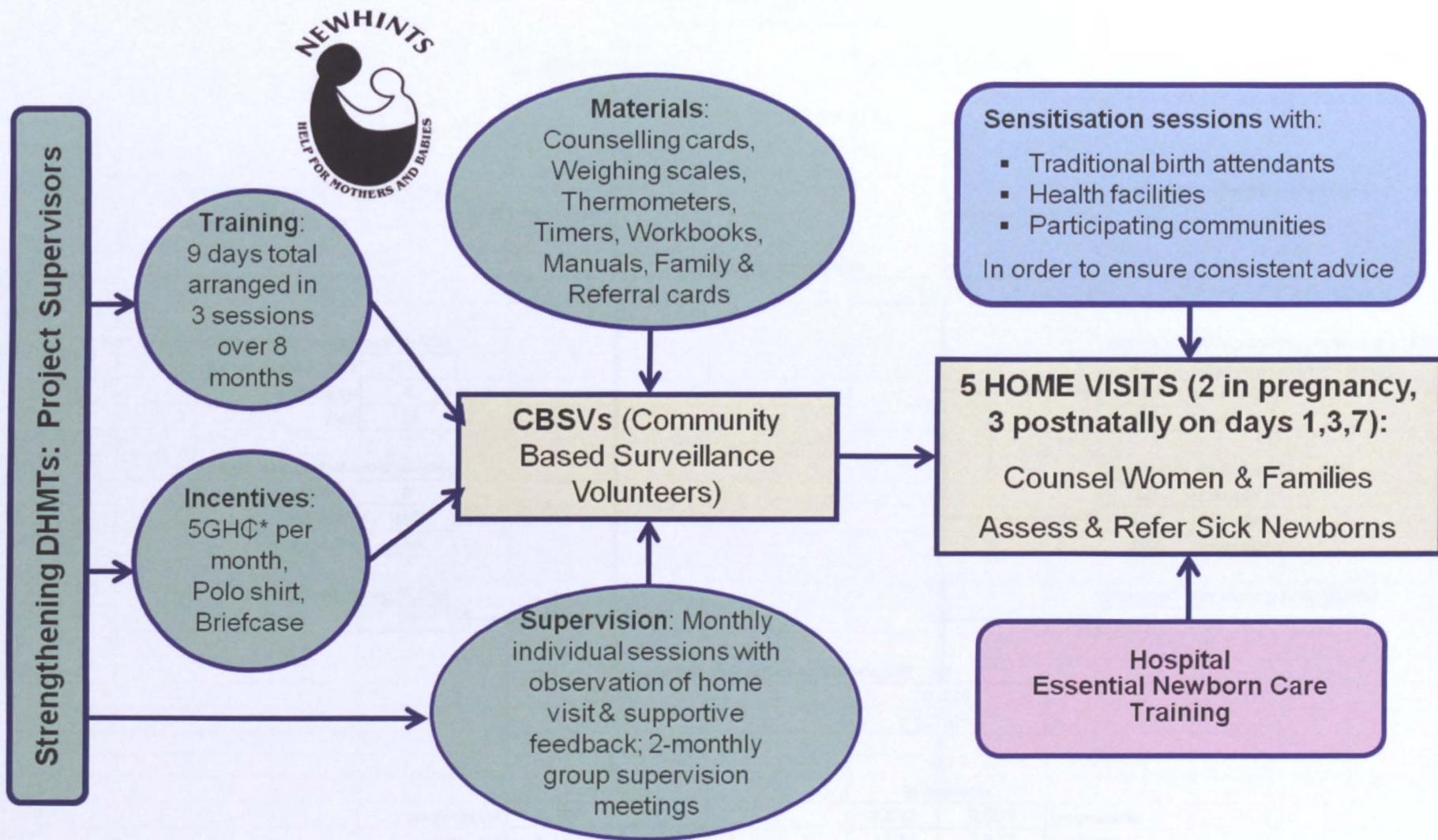


Figure 2: Newhints Integrated Intervention Package

*Ghana cedis (1 GH¢ approximately equal to 1 US\$ during trial)

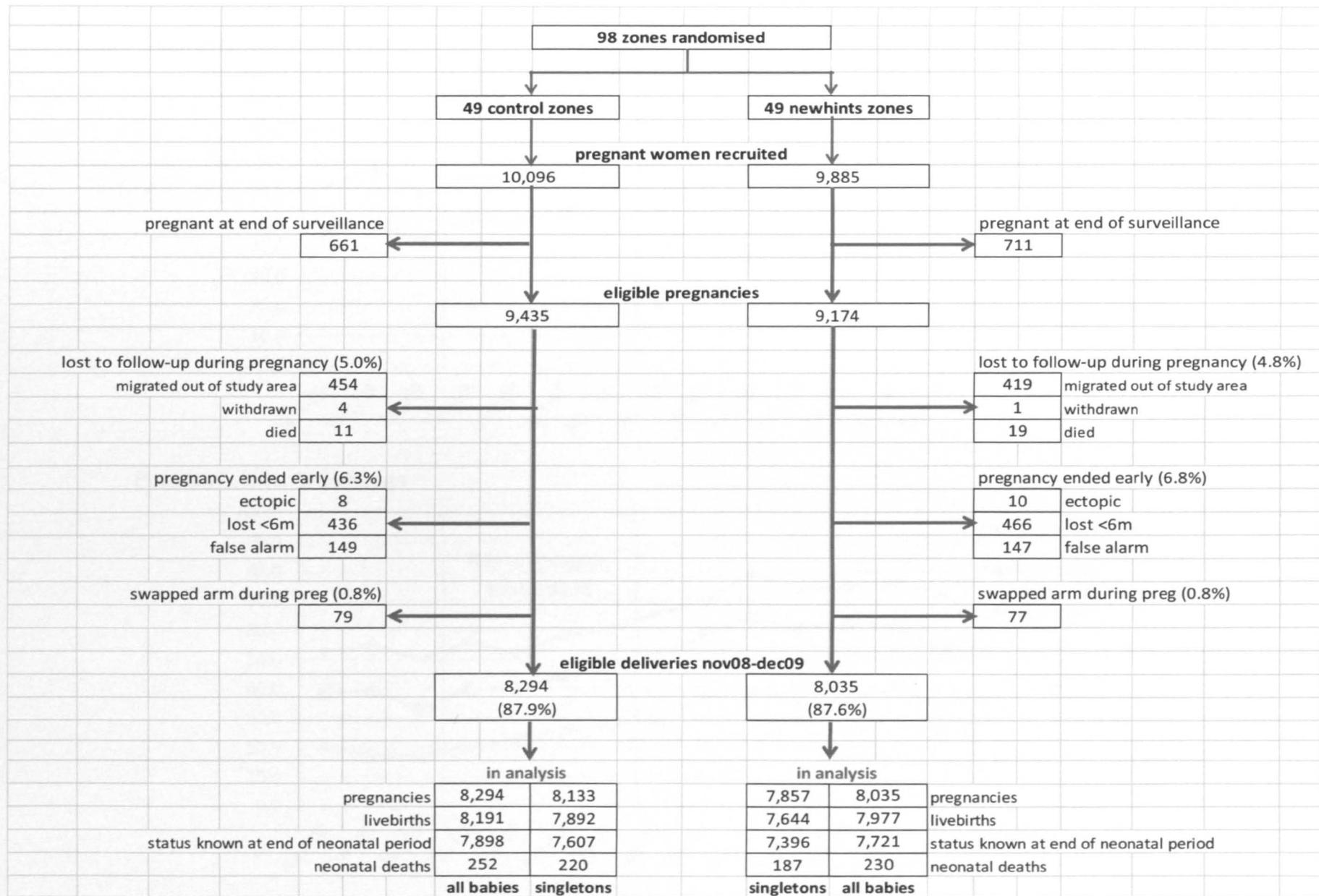


Figure 3: Trial profile

Pregnancy visits: % coverage



Postnatal visits: % coverage

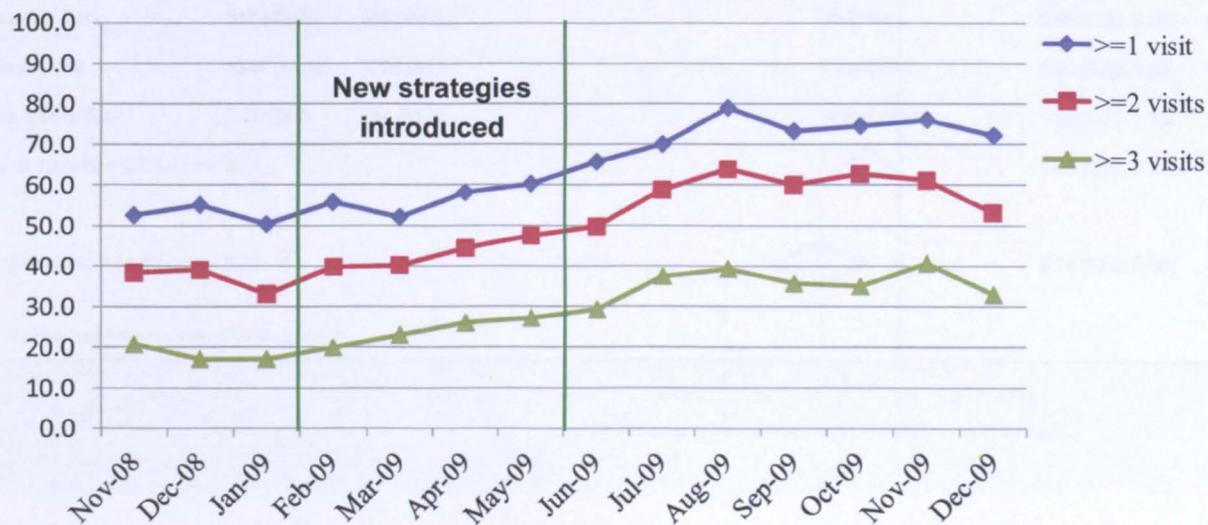


Figure 4: Coverage of home visits achieved in Newhints zones

(based on 6029 women who had their post birth surveillance visit at least 10 days after delivery and whose babies were still alive)

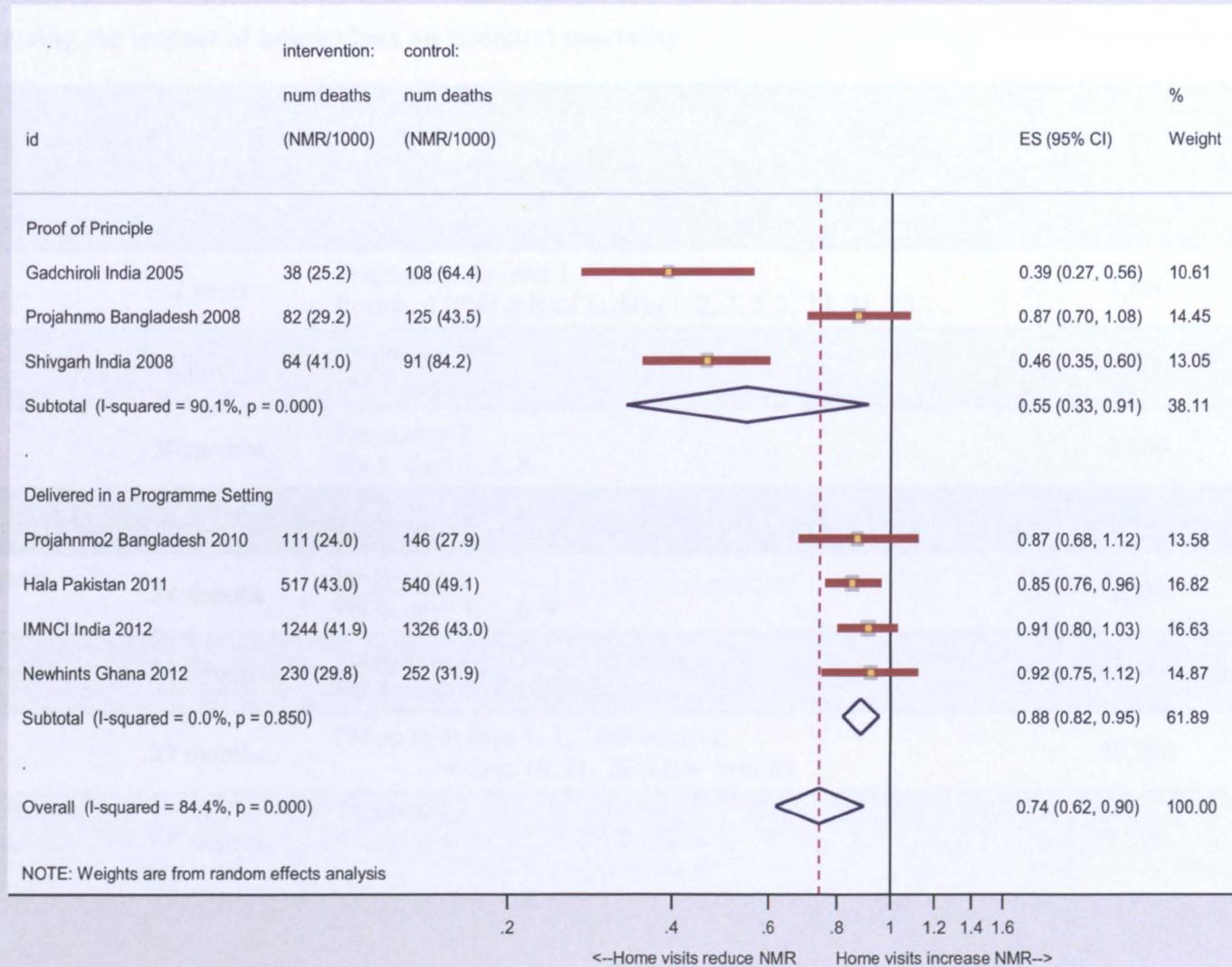


Figure 5: Impact of Home Visits on Neonatal Mortality - Meta-analysis

Table 1: Trials assessing the impact of home visits on neonatal mortality

Study	Evaluation period	Number & timing of home visits (Day 1 = day of birth)	Average number of livebirths/group (approx)	NMR in control group
Proof of Principle Trials				
Gadchiroli, India ⁷	7 years	Pregnancy: At least 1 Postnatal (PN) at least 8: days 1, 2, 3, 5, 7, 14, 21, 28	1,600	64.4
Shivgarh, India ⁸	16 months	Pregnancy 2 PN 2: days 1, 4	1,300	84.2
Projahnmo (Sylhet), Bangladesh ⁹	30 months	Pregnancy 2 PN 3: days 1, 4, 8	2,800	43.5
Trials with intervention delivered in a programme setting				
Projahnmo2 (Mirzapur), Bangladesh ¹¹	24 months	Pregnancy 2 PN 4: days 1, 3, 6, 9	5,000	27.9
Hala+Matiari, Pakistan ¹²	24 months	Pregnancy 2 PN 4: days 3, 7, 14, 28	11,500	49.1
Haryana, India ¹³	27 months	PN up to 6: days 1, 3, 7 (all babies); + days 14, 21, 28 (LBW babies)	30,200	43.0
Newhints, Ghana ¹⁴	14 months	Pregnancy 2 PN up to 4: days 1, 3, 7 (all babies); + day 14 (LBW babies)	8,000	31.9

Table 2: Newhints: CBSV Training Schedule

Phase 1: Mar 2008 – 3 days
<ul style="list-style-type: none">➤ Newhints rationale➤ Identifying pregnant women & newborns➤ Key behaviours➤ Counselling/problem-solving skills
Phase 2: June/July 2008 – 4 days
<ul style="list-style-type: none">➤ Weighing babies➤ Assessment for danger signs➤ Practical sessions with babies
Refresher training: Oct 2008 – 2 days

Table 3: Baseline comparability of key outcomes: 2005-2007

Events & Outcomes	Control zones	Newhints zones
Pregnancies	22,436	22,732
Births	22,963	23,221
Facility deliveries	58.3%	57.2%
Livebirths	22,211	22,491
Livebirths with status known on day 29	22,008 (99.1%)	22,276 (99.0%)
Neonatal deaths (days 1-28)	720	719
Neonatal mortality/1000 livebirths	32.7	32.3
Babies reported as severely ill in 1st 2 months:	315	280
Careseeking to hospital or clinic	168 (53.3%)	147 (52.5%)
Initiation of breastfeeding within 1st hour¹	41.6%	41.9%
Exclusive breastfeeding @ 1 month²	74.7%	71.5%

1. Restricted to babies who survived the first day.
2. Based on breastfeeding status of babies whose mothers were interviewed between days 26 & 32.

Table 4: Sociodemographic characteristics of trial participants in evaluation cohort

Characteristic	Control zones	Newhints zones
Pregnancies with full sociodemographic data (% all pregnancies)	8,172 (98.5%)	7,911 (98.5%)
Age group at start of pregnancy		
<20	10.8%	12.1%
20-29	53.5%	52.4%
30+	35.7%	35.5%
Parity		
0	23.0%	24.1%
1-2	37.9%	37.2%
3-4	23.8%	23.6%
5	15.3%	15.2%
Highest educational level		
None	36.4%	33.2%
Primary school	20.3%	21.9%
Junior/Middle secondary school	36.4%	38.2%
Senior secondary school or above	6.9%	6.7%
Marital Status		
Married	59.0%	56.1%
Living together	31.0%	35.0%
Widow or divorced	2.5%	2.9%
Single, unmarried	7.5%	6.0%
Religion		
Christian	66.8%	69.0%
Muslim	25.8%	23.1%
Traditional African/Other	7.4%	7.9%
Ethnic group		
Akan	42.0%	42.9%
Dagarti/Frafra/Sisala/Wala	24.3%	23.7%
Mo/Gonja/Dagomba	11.7%	10.1%
Bimoda/Ga/Ewe/Konkomba	7.8%	4.8%
Banda/Pantra	5.3%	6.8%
Fulani/Other	8.9%	11.8%

Table 5: Impact on key behaviours: Denominators

Behaviours	Denominator	Control zones (n)	Newhints zones (n)
Pregnancy behaviours	Pregnant women *	8121	7859
Birth preparations	Pregnant women who delivered after Feb 2009	6941	6681
Birth assistant hygiene behaviours	Home deliveries with birth assistant	2091	1992
Day one newborn behaviours	Babies surviving 1 st day	8047	7838
Newborn bednet use	Visits between 8-56 days: Babies alive at visit	5846	5756
Exclusive breastfeeding	Visits between 26-32 days: Babies alive at visit	1371	1414
Care-seeking	Visits between 1- 56 days: Babies alive with perceived severe illness reported	139	132

* Excludes 171 women in control & 174 in newhints zones who were unable to report their number of ANC visits, plus 2 women in each group with missing information on other pregnancy behaviours.

Table 6: Impact of Newhints on increasing coverage of key behaviours, and on reducing coverage gaps

BEHAVIOUR	COVERAGE: % CARRYING OUT BEHAVIOUR					COVERAGE GAP: % NOT CARRYING OUT BEHAVIOUR				P**
	Control Zones	Newhints Zones	Increase	RR*	(95% CI)	Control Zones	Newhints Zones	Reduction in gap	(95% CI)	
4+ ANC visits	73.7%	76.0%	2.3%	1.02	(0.96-1.09)	26.3%	24.0%	0.94	(0.78-1.14)	0.52
Bednet in pregnancy (always or sometimes)	63.2%	68.7%	5.5%	1.12	(1.03-1.21)	36.8%	31.3%	0.77	(0.64-0.92)	0.005
Saved money for delivery or emergency	79.6%	85.8%	6.2%	1.09	(1.05-1.12)	20.4%	14.2%	0.65	(0.56-0.76)	<0.001
Arranged transport for facility (in advance)	29.7%	37.4%	7.7%	1.30	(1.12-1.49)	70.3%	62.6%	0.88	(0.82-0.95)	<0.001
Delivered in a facility	68.4%	68.7%	0.3%	0.97	(0.81-1.14)	31.6%	31.3%	1.08	(0.75-1.57)	0.69
Birth assistant washed hands with soap (home delivery)	86.9%	93.0%	6.1%	1.05	(1.02-1.09)	13.1%	7.0%	0.57	(0.42-0.79)	0.001
Early initiation of breastfeeding (<1 hour)	41.1%	48.3%	7.2%	1.22	(1.07-1.40)	59.0%	51.7%	0.85	(0.76-0.95)	0.004
Skin to skin contact (any)	24.2%	43.4%	19.2%	2.30	(1.85-2.87)	75.8%	56.6%	0.70	(0.63-0.78)	<0.001
Delayed 1st bath (>6hrs)	28.2%	40.0%	11.8%	1.64	(1.26-2.14)	71.8%	60.1%	0.80	(0.71-0.91)	<0.001
Exclusive breastfeeding (26-32 days)	79.6%	86.1%	6.5%	1.10	(1.04-1.16)	20.4%	13.9%	0.59	(0.44-0.80)	0.001
Baby sleeping under bednet (8-56 days)	73.4%	79.0%	5.6%	1.09	(1.03-1.15)	26.6%	21.0%	0.71	(0.58-0.88)	0.002
Careseeking: sick babies taken to hospital or clinic	55.4%	77.3%	21.9%	1.43	(1.17-1.76)	44.6%	22.7%	0.45	(0.28-0.73)	0.001

* Relative risk, adjusted for clustering

** The P value applies to both the coverage and the coverage gap analyses

Table 7: Impact of Newhints on neonatal mortality rates

(a) From end of CBSV training; (b) After new implementation strategies introduced.

	(a) Nov 2008 – Dec 2009				(b) June – Dec 2009			
	Control zones	Newhints zones	Adjusted RR* (95% CI)	P value	Control zones	Newhints zones	Adjusted RR* (95% CI)	P value
ALL BABIES: Neonatal mortality rate (NMR)/1000 livebirths								
Livebirths	7898	7721			3521	3423		
Neonatal deaths (days 1-28)	252	230			113	101		
NMR/1000 livebirths	31.9	29.8	0.92 (0.75-1.13)	0.405	32.1	29.5	0.91 (0.67-1.22)	0.528
ALL BABIES: Post day 1 NMR								
>1d Neonatal deaths (days 2-28)	122	103			62	45		
>1d NMR/1000 livebirths	15.4	13.3	0.85 (0.64-1.13)	0.268	17.6	13.1	0.74 (0.47-1.17)	0.204
SINGLETONS: NMR								
Livebirths	7607	7396			3389	3258		
Neonatal deaths (days 1-28)	220	187			105	80		
NMR/1000 livebirths	28.9	25.3	0.86 (0.69-1.08)	0.202	31.0	24.6	0.78 (0.56-1.08)	0.135
SINGLETONS: Post day 1 NMR								
>1d Neonatal deaths (days 2-28)	109	82			58	33		
>1d NMR/1000 livebirths	14.3	11.1	0.77 (0.57-1.04)	0.085	17.1	10.1	0.59 (0.35-0.98)	0.042

* Relative risk, adjusted for clustering

References

1. Oestergaard MZ, Inoue M, Yoshida S, Mahanani WR, Gore FM, Cousens S, et al. Neonatal Mortality Levels for 193 Countries in 2009 with Trends since 1990: A Systematic Analysis of Progress, Projections, and Priorities. *PLoS Med.* 2011;8(8):e1001080.
2. Black RE, Cousens S, Johnson HL, Lawn JE, Rudan I, Bassani DG, et al. Global, regional, and national causes of child mortality in 2008: a systematic analysis. *Lancet.* 2010 Jun 5;375(9730):1969-87.
3. Lawn JE, Yakoob MY, Haws RA, Soomro T, Darmstadt GL, Bhutta ZA. 3.2 million stillbirths: epidemiology and overview of the evidence review. *BMC Pregnancy Childbirth.* 2009;9 Suppl 1:S2.
4. Darmstadt GL, Bhutta ZA, Cousens S, Adam T, Walker N, de Bernis L. Evidence-based, cost-effective interventions: how many newborn babies can we save? *Lancet.* 2005 Mar 12-18;365(9463):977-88.
5. WHO & UNICEF. Home visits for the newborn child: a strategy to improve survival; 2009.
6. Bang AT, Bang RA, Baitule SB, Reddy MH, Deshmukh MD. Effect of home-based neonatal care and management of sepsis on neonatal mortality: field trial in rural India. *Lancet.* 1999 Dec 4;354(9194):1955-61.
7. Bang AT, Reddy HM, Deshmukh MD, Baitule SB, Bang RA. Neonatal and infant mortality in the ten years (1993 to 2003) of the Gadchiroli field trial: effect of home-based neonatal care. *J Perinatol.* 2005 Mar;25 Suppl 1:S92-107.
8. Kumar V, Mohanty S, Kumar A, Misra RP, Santosham M, Awasthi S, et al. Effect of community-based behaviour change management on neonatal mortality in Shivgarh, Uttar Pradesh, India: a cluster-randomised controlled trial. *Lancet.* 2008 Sep 27;372(9644):1151-62.
9. Baqui AH, El-Arifeen S, Darmstadt GL, Ahmed S, Williams EK, Seraji HR, et al. Effect of community-based newborn-care intervention package implemented through two service-delivery strategies in Sylhet district, Bangladesh: a cluster-randomised controlled trial. *Lancet.* 2008 Jun 7;371(9628):1936-44.
10. Bhutta ZA, Memon ZA, Soofi S, Salat MS, Cousens S, Martines J. Implementing community-based perinatal care: results from a pilot study in rural Pakistan. *Bull World Health Organ.* 2008 Jun;86(6):452-9.
11. Darmstadt GL, Choi Y, Arifeen SE, Bari S, Rahman SM, Mannan I, et al. Evaluation of a cluster-randomized controlled trial of a package of community-based maternal and newborn interventions in Mirzapur, Bangladesh. *PLoS One.* 2010;5(3):e9696.
12. Bhutta ZA, Soofi S, Cousens S, Mohammad S, Memon ZA, Ali I, et al. Improvement of perinatal and newborn care in rural Pakistan through community-

based strategies: a cluster-randomised effectiveness trial. *Lancet*. 2011 Jan 29;377(9763):403-12.

13. Bhandari N, Mazumder S, Taneja S, Sommerfelt H, Strand TA, Group IES. Effect of implementation of Integrated Management of Neonatal and Childhood Illness (IMNCI) programme on neonatal and infant mortality: cluster randomised controlled trial. *BMJ*. 2012;344:e1634.

14. Kirkwood BR, Manu A, Tawiah-Agyemang C, ten Asbroek G, Gyan T, Weobong B, et al. NEWHINTS cluster randomised trial to evaluate the impact on neonatal mortality in rural Ghana of routine home visits to provide a package of essential newborn care interventions in the third trimester of pregnancy and the first week of life: trial protocol. *Trials*. 2010;11:58.

15. Hill Z, Manu A, Tawiah-Agyemang C, Gyan T, Turner K, Weobong B, et al. How did formative research inform the development of a home-based neonatal care intervention in rural Ghana? *J Perinatol*. 2008 Dec;28 Suppl 2:S38-45.

16. Kirkwood BR, Hurt L, Amenga-Etego S, Tawiah C, Zandoh C, Danso S, et al. Effect of vitamin A supplementation in women of reproductive age on maternal survival in Ghana (ObaapaVita): a cluster-randomised, placebo-controlled trial. *Lancet*. 2010 May 8;375(9726):1640-9.

17. Smits J, Monden C. Twinning across the Developing World. *PLoS One*. 2011;6(9):e25239.

18. Boerma JT, Bryce J, Kinfu Y, Axelson H, Victora CG. Mind the gap: equity and trends in coverage of maternal, newborn, and child health services in 54 Countdown countries. *Lancet*. 2008 Apr 12;371(9620):1259-67.

19. Kirkwood BR, Sterne JAC. *Essential medical statistics*. 2nd ed. Malden, Mass.: Blackwell Science; 2003.

20. Localio AR, Margolis DJ, Berlin JA. Relative risks and confidence intervals were easily computed indirectly from multivariable logistic regression. *J Clin Epidemiol*. 2007 Sep;60(9):874-82.

21. Statcorp. *Stata Statistical Software: Release 11*: College Station, TX: StataCorp LP; 2009.

22. Gogia S, Sachdev HS. Home visits by community health workers to prevent neonatal deaths in developing countries: a systematic review. *Bull World Health Organ*. 2010 Sep 1;88(9):658-66B.

23. Sterne JA, editor. *Meta analysis in Stata: An Updated Collection from the Stata Journal*. : Stata Press (StataCorp LP, Texas); 2009.

24. Manu A, ten Asbroek G, Soremekun S, Weobong B, Gyan T, Tawiah-Agyemang C, et al. Increasing access to facility care for sick newborns: evidence from the Ghana Newhints trial. submitted. 2012.

25. Vesel L, Manu A, Lohela TJ, Gabrysch S, Okyere E, Owusu-Agyei S, et al. Quality of Newborn Care: A Health Facility Assessment in Rural Ghana Using Survey, Vignette and Surveillance Data. submitted. 2012.

Appendix 3: Forms & Interview guides

Newhints Women's IDI Guide: Referral practice, compliance, constraints and facilitators

1. Instructions

Data will be collected from all 7 Newhints districts on referral practices, compliance, constraints and facilitators to adherence or non-adherence. It will involve both CBSVs and women in the study area and will collect information on their experiences with referral in their Newhints work. The women will be selected from the surveillance database, the CBSV and DiPS workbooks. A random sample of CBSVs will also be selected for this exercise. This guide will elicit women's experiences and perceptions on the series of events that take place between the time the CBSV presents at home and assessed the baby till the time they and their babies have been seen in the hospital with treatment.

You will be provided with a list of the required age, ethnicity place of residence (rural/urban), parity, place of delivery of the baby and district characteristics of the respondents.

District: _____

Community: _____

Compound number: _____/

Date of interview: ___/___/___

Interviewer code: _____

Time start: _____ : _____ *m*

Time end: _____

**Information sheet to explain participation in an evaluation of an intervention to
reduce neonatal mortality (to be read)**

1. Hello my name is _____
and I am from Kintampo Health Research Centre. I would like to invite you to take part in an interview about a study we are conducting in the district. Before you decide if you want to be interviewed or not, I want to provide you with some information about the interview to help your decision.
2. As I explain the interview please ask me any questions that come to mind as I want to make sure you have all the information you need to decide whether to take part or not.
3. **For mother:** During your pregnancy and after the birth you have been visited by the volunteer in this community who helps the nurses during weighing (the CBSV). The Kintampo Health Research Centre, together with the health authorities in the district (DHMT), is carrying out a study to find out if these visits are helping reduce newborn deaths. One of the specific training the CBSVs received is for them to help families recognize and seek care for their very small or sick babies. He is expected to advice families on what to do when their babies have been found to be sick or very small in the first week of life of the baby.
4. If you agree to participate, you will be interviewed by me. The interview will take between 1- 1 3/4 hours and I will write some notes and tape record the interview to help me remember all that was discussed. Are you happy for me to tape record the interview? If you prefer me to just take notes, it is Ok just let me know.
5. When I conduct the interview we will find a private place and I will do everything possible to protect your confidentiality: Your name, my notes and the tape recording will be stored under lock and key at the study office. We will not disclose any information about you or the interview to anyone apart from us.
6. Taking part may not benefit you directly, but may benefit your community in the future as your opinions will help us improve this programme.
7. Taking part in the interview is voluntary. You can refuse to answer any question I ask or stop the interview at any time. Your participation in the programme or any community or health services received will not be affected.
8. Now I would like to formally ask you to participate. If you have any questions please ask me.
9. I want to be sure you are taking part because you want to, so I am going to ask you to sign or thumbprint a form that says you agree to take part. I will read you the form and then ask you to sign or thumbprint. If you do not want to participate that is OK, just let me know.

Consent form

Title of research: Evaluation of an intervention to reduce neonatal mortality

Investigator: Alexander Manu (Dr)

Contact details: Kintampo Health Research Centre

I have understood the verbal explanation about this study and I understand what will be required of me and what will happen to me if I take part in it. My questions concerning this study have been answered by

_____. I also understand that my responses will be kept private and that I can stop this interview at any time without giving any reason and without affecting my participation in the Newhints study/programme or any community or health services received.

I agree to be interviewed in this study: 1=Yes 2=No

Name of subject:

Village & Compound Number:

Date

Signature or Thumb Print

Fieldworker statement: *I, the undersigned, have explained to the respondent in a language she/he understands, the procedures to be followed in the study and risks and benefits involved.*

Date

Name & Signature of interviewer

(NOTE TO INTERVIEWER: Text in *italics* is NOT to be read out to the mother)

Purpose of this interview: We are conducting this interview to evaluate the ability of mothers of very small babies (RED) or sick babies to comply with referral advice given them by the Newhints CBSV. We want to know what makes women and their families comply with the referral advice, what minimum support women and their families require to be able to carry out the referral advice, who are the key stakeholders in careseeking for the newborn at the time of illness and whether families are able to carry out appropriate care practices related to sick newborns. We want to know what are the constraints and facilitators that made it (im)possible for women to comply with the referral (or not). We also want to explore women and their families' perceptions about the CBSVs' and other stakeholders' roles in the Newhints referral system from the recognition of the sick newborn through to the care given to them in the hospital. We would also want to explore what support families and communities provide to women to enable them seek care for their sick newborns. This information will help us to know whether Newhints led to a change in care-seeking behaviours for the most vulnerable infants or not.

IF THE RESPONDENT CAN'T ANSWER ANY OF THE QUESTIONS ASK WHO WOULD KNOW AND ARRANGE TO INTERVIEW THAT PERSON.

Make sure you note down how this person is related to the mother and why you felt the mother could not answer the questions.

2. Background Information

Say: I would like to ask you a few questions about yourself and your baby before we start the interview.

ObaapaVitA ID:

Name of respondent: (*This should be the first name only and only ask so you can politely address respondent by name during the interview.*)

Age:

Occupation:

Ethnicity:

Number of children: (Status of children and how many are below 10 years)

Marital status: (*If they are married include whether they are in a monogamous or polygamous marriage.*)

Education:

Socio-economic status: (*Record your opinion of whether the household is poor, average, or wealthy compared to others in the study area. You may also want to record your reasons for thinking this.*)

3. Interviewer comments:

- Record where (what place) you actually did the interview (eg their house, under a tree, in the yard).
 - What the respondent physically looked like or dressed like.
 - How their mood was during the interview (eg. did they get bored, tired, look worried sometimes or all the time).
 - Any other information such as interruptions that will help understand the context of the interview.
-

About the Baby:

Ask: "How is your baby doing?"

- a. Name of baby: _____
- b. Age of baby (in days on day of assessment): *If the baby is dead, how old was he/she when he died?* _____
- c. Sex of baby:
- d. Where was the baby born? (Home OR Health Facility)

If baby is still sick, continue the interview and at the end remind the family about the advice the CBSV gave about careseeking and encourage them to take the baby to the hospital.

If baby died, console the mother and ask if you can continue the interview. If not, end the interview and inform her that a supervisor may come later to interview her. Thank them and ask to leave the family.

A. Family recognition of sick newborns

- Our records show that when (*baby name if told*) was born, the CBSV came to visit you and said you should take him/her to the hospital. What happened before the CBSV came in to tell you this?

Purpose of this question: *This is to ascertain whether the families recognise sick newborns by themselves and what care they give to sick newborns even before the CBSV comes in.*

If not mentioned spontaneously, probe for the following:

- ***Whether family knew that the baby was ill and what they did***
- ***What care they sought elsewhere (where, why or who advised that and what was done for the baby) before the CBSV came to refer the baby.***
- ***Since when has the baby has been ill, if they knew.***

B. CBSV assessment before referral

- Could you please tell me in detail how the CBSV got to know about your baby and all what he/she did when he/she came to your house till he/she asked you to take the baby to the hospital?

Purpose of this question: *This is to ascertain whether the families actively demand CBSV visits for assessment and whether they understand what the CBSV found for which they are being referred to hospital.*

Probe for the following (if not mentioned in the narrative):

- ***Whether the family called the CBSV or the CBSV came on their own;***
- ***What checks the CBSV did on the baby;***
- ***What he/she told them about what he found;***

- **What advice he/she gave about going to the hospital (reason, where to go, speed or how quickly);**
 - **What they felt about the advice?**
 - **Whether they were given a Newhints referral card.**
 - **Whether pictures on the referral card were discussed.**
 - **Whether referral card was given to the Dr. And if it was given back to the woman and placed in her folders.**
-

C. Decision-making with regards to the referral compliance and actual compliance or non-compliance

- **Could you please tell me, in detail, what happened after you were advised to take the baby to the hospital?**

Purpose of this question: This is to know who were involved in the decision to send the baby to the hospital and what role they played; whether families were able to comply with instructions given on what to be doing for the baby even before they get to the facility; what were the constraints and the facilitators to compliance with the referral as well as the instructions and how they resolved these.

Probe for the following if not mentioned in the narrative:

- **Who was involved in the decision making (husband, mother-in-law, TBA, other health worker, friends, etc)?**
- **What exactly transpired during the discussion of the decision (did they discuss money, transport and what decision they made about these)**
- **How easy/difficult it was for them to decide to send the baby to the hospital and why?**
- **How long it took to decide that?**
- **What influenced their decision making:**
 - **ask about adequate savings and preparation during pregnancy, availability of transport, proximity to the facility, severity of illness, support from CBSV, previous experience at the facility, availability of helper to take care of other children, etc**
- **To what facilities the baby was sent before finally coming to the hospital and why they went there;**
- **Who advised they go there**
- **What was done for the baby at each of these (drug stores, herbalist, traditional practitioners including TBAs and other health facilities)?**
- **How long were you at each facility for and why they decided to leave one facility for another (poor care, worsening condition of baby, cost/demands, etc)?**
- **What they thought about being asked to and going to the hospital rather than health centre/post**

Record when the baby was referred and when they eventually got to the facility (Use time probes eg when children leave for school in the morning or meal preparation time in the evening and record date eg. from the referral card, if given).

- Could you please tell me, in detail, what instructions the CBSV gave you about how to care for the baby before you get to the hospital and what you actually did?

Probe for the following if not mentioned in the narrative:

- **Whether they were able to comply with the CBSVs advice** (Skin-to-skin care, frequent breastfeeding and exclusively) **and what made it difficult/ easy to comply.**
- **Ask whether the ease/difficulty applies to all the advice given or just some (specify)**
- **What support they needed (or had) to have been able to comply fully with the advice.**
- **What additional care they themselves were giving to the baby in the interval before arrival at the hospital).**

>>>>>>>> Skip and continue from section F if they were unable to go and go to section G

D. Experiences at the facility

- Could you please tell me, in detail, all what happened to you and the baby from the time you got to the facility till when you eventually came back home.

Purpose of this question: This is to know how women got to the facility, who were involved in the management of the newborn, whether there were delays in attending to the baby in the facility and whether the facilities had requisite "personpower", drugs and supplies for the management of the newborn.

Probe for following if not mentioned in the narrative:

- **How and when they got to the facility** (means of transport and)
- **Ask whether the means will be the same at all times** (or it might have been easier/more difficult at other times)
- **How long they delayed at the facility before being seen for the first time;**
- **Who saw the baby and whether this calibre of health worker met their expectations of who should take care of the baby;**
- **What assessments were done for the baby?; were breaths counted, temperature, weight etc.**

Purpose of this question: This is to know what the reasons are why women are not able to comply with referral advice and instructions and what they think will make it easier for them to comply in the future

Probe for the following if not mentioned in the narrative:

- **Whether it was a family decision (and why that) or a key person in the decision making was not available (and who that was)**
- **Was it based on beliefs about the baby's sickness (and what sickness was it) or**
- **Did it stem from their previous experience with the hospital**
- **Other issues like money and transport difficulties;**

What could have been done to make it possible for her to be able to take the baby to the hospital in the future.

G. CBSV follow up visit

- **Could you please tell me, in detail, whether the volunteer came back to you after that day and what exactly (s)he came to do and what the families did about his coming the 2nd time?**

Purpose of this question: This is to know whether the CBSV conducted a follow-up visit after the referral and what they did to the baby

Probe for the following if not mentioned in the narrative:

- **What (s)he said or did about their (in)ability to comply with the referral**
- **Whether it (s)he was called by the family or (s)he came on his own.**
- **What assessments (s)he did and what (s)he found**
- **Whether (s)he communicated the findings to them**
- **What they felt about the CBSV coming the 2nd time**
- **What they did about the instructions the CBSV gave on this occasion.**

H. General impressions about the referral experience

- **What do you think about the whole Newhints referral experience from the role of the CBSV to the treatment received at the facility (if you went)? How do you think it could be improved further?**

Purpose of this question: This is to get women/families' impressions on the Newhints referral. It will help understand what women thought was good or bad about it and to obtain suggestions on how things can be improved in the referral system. It will also be to obtain information on women's perception and beliefs about certain ailments, the quality of care available in hospitals for newborn illnesses and how this affects their

Ghana Newhints CBSVs' Referral IDI Guide

1. Introduction

This guide is for collecting data from CBSVs in all 7 Newhints districts on referral experiences with families, community members and health service providers. The selection of CBSVs will be purposive so that it will be administratively, ethnically, gender and geographically representative. This guide will focus on CBSVs' experiences and perceptions on the referral process from the home of the visited woman, through the community's reactions to the referral process and then the health facilities and staff's reception of the referral system, the challenges involved/success stories in working with the health system regarding Newhints referral.

District: _____ Community: _____
 Compound number: _____/_____ Newhints zone _____
 Date of interview: ___/___/___ Interviewer code: _____
 Time start: _____ : _____ m Time end: _____ : _____ m
 Duration _____

2. CBSV characteristics:

<ul style="list-style-type: none"> • Name: (This should be the first name only) • CBSV ID number: • Age: • Sex: • Occupation: • Ethnicity: • Number of own biological children: 	<ul style="list-style-type: none"> • Marital status: • Education: • Number in community: (specify number of Males & Female colleagues) • Socio-economic status: (<i>Record your opinion of whether the household is poor, average, or wealthy compared to others in the study area. You may also want to record your reasons for thinking this.</i>) • Number of babies referred and their ages: • Duration of engagement as a <u>health volunteer</u> & then in <u>Newhints</u>
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3. Interviewer comments:

- Record where (what place) you actually did the interview (eg their house, under a tree, in the yard).
- What the respondent physically looked like or dressed like.
- How their mood was during the interview (eg. did they get bored, tired, look worried sometimes or all the time).
- Any other information such as interruptions that will help understand the context of the interview

4. Assessment experiences.

a. Tell me about your experiences checking/assessing the health of newborn babies?

Probe for the following if not mentioned spontaneously

- How willing are families to have their babies examined; is it the same even on the 1st day?
- Have you ever been refused and what happened?
- How you felt about touching and checking the newborn babies and on the 1st day.

5. Decision-making around referral

a. How did you arrive at the decision to refer?

Probe for the following if not mentioned spontaneously

- What danger signs did you find in the babies? (Let him cite instances)
- *How the feeling was, having to tell families to send their newborn babies to a health facility?*
- *Have you always been confident to refer?*
- *Have you ever had to talk to somebody else to be sure of whether you needed to refer? And who?*
- *Have you ever found a danger sign in a baby but thought baby looked so well and did not need referral and what did you do?*

6. Families' reaction and referral compliance

a. How do families react when you tell them you are referring their baby to the hospital?

Probe for the following if not mentioned spontaneously

- *Do some families react differently? Why do you think that is?*
- *Who are involved in the families' decisions?*
- *Did you need to convince the women to take their babies to the hospital? Anyone else?*
- *Have you put some arrangements in place to make women able to go and what these are?*
- *Are some sorts of families likely to go? Does Age, Marital status, Education, Parity, Health insurance enrolment status, Proximity to hospital matter?*
- *Which danger signs families readily accept? Why? (Discuss top 3)*
- *For which danger signs don't families accept and are UNLIKELY to comply with referral? (Discuss 2 of these)*
- *What women did for the babies if they do not go?*
- *How you felt about families who are unable to go (Indifferent, frustrated, annoyed or empathetic)?*

7. Health worker attitudes

7.1. What have been the experiences of mothers/families at health facilities when they take their referred babies for care and how did this affect your work (assessment and referral) in the community?

Probe for following if not mentioned spontaneously:

- *Any good or bad experiences they received at the health facility?*
- *Which health facility, by whom and why you thought they were treated that way?*
- *How did you feel when you heard about these experiences?*
- *How women's experiences affect CBSV's/Newhints work?*
- *What could have been or should be put in place to make women's experiences in the facilities better?*
-

8. Follow-up visits for referred babies

8.1. Have you been able to make follow-up visits for your referred babies and what happened?

Probe for the following if not mentioned spontaneously

- *Timing of the follow-ups and challenges with timing of visits*
- *What you usually do at these visits*
- *How families reacted to the follow-up visits - a bother or acceptable?*
- *Do families who comply with referral act differently from those who did not and how?*
- *Any bad experiences you had*

9. Supervision

9.1. Did supervisors' visits help you with the assessment and referral of sick babies?

Probe for the following if not mentioned spontaneously

- *Which type of supervisors were most useful*
- *How did these visits affect their confidence at assessment and referral?*
- *Did supervisory visits affect families' compliance with referral advice and how?*
- *How did community leadership help you regarding assessment and referral*

10. Improving the assessment & referral system in Newhints

10.1. In your own view, how do you think the assessment and referral system in Newhints could be further improved over what it is now?

Probe for the following if not mentioned spontaneously

- *What should be done differently about assessments, facility experiences, follow-ups, etc?*
- *What could make women more willing to comply?*

11. "Not-for-hospital" diseases

11.1. Have you had any experience with babies who have a disease which is said to be "not-for-hospital" and what happened?

Probe for the following if not mentioned spontaneously:

- *What the family said was wrong with the baby.*
- *Were you allowed to check the baby?*
- *What was wrong with the baby? Any danger signs you got upon checking?*
- *Why the family/community members thought the disease was not meant for hospital*
- *What was done for these babies?*

12. "Asram" and impact on Newhints work

12.1. What do you know about Asram and how has it (Asram) affected on your Newhints referral experiences in the community?

Probe for the following if not mentioned spontaneously:

- *What you knew about the cause, how it is acquired, signs and symptoms and treatment-before and after Newhints training?*
 - *What has changed since onset of Newhints?*
 - *How the families' beliefs around Asram affected their (CBSVs) work and which aspect- Assessment or referral compliance? How can this be changed?*
 - *Would you refer a baby said to have Asram to the hospital now and why?*
-

Thank the respondent

Newhints Referral IDI Guide: Prescriber's experiences & perceptions of impact on facility work

1. Introduction

One of the core interventions in the Newhints trial is the assessment and referral of sick newborns to health facilities within the study area for care. The success of future replication and scaling up efforts will require health worker input on their experiences with babies referred in the Newhints trial.

This guide therefore is aimed at eliciting health workers' experiences with mothers and their babies referred as a result of the Newhints volunteer visits and assessments in the homes. It will explore their perceptions on the validity of volunteer assessments and referrals, the impact of the CBSV referrals on Health workload at the facility, challenges posed by the referral system to their facility and on themselves and their perceptions on the support that need to be provided for health systems to cope with similar interventions at scale.

Data will be collected from purposively selected facilities (based on facility being recommended as a Newhints referral destination, number of babies seen, etc.) within the Newhints study districts. Health workers (Matrons, one nurse on duty, one auxiliary nurse, one frontline staff at the OPD and one Health insurance agent) will be interviewed for 45mins to 1hr in this evaluation study.

Responses from participants will be treated with all confidentiality and only the researcher and the core research team will have access to the data. Even then, respondents will only be identified with an alphanumeric code generated to identify the type of facility and the district but not the individual respondent. Respondents will be free to withdraw from this interview at the start, during the process or even at the end of the interview without any adverse effect on their position in the facility or district or indeed the Ghana Health Service.

District: _____

Facility name: _____

Date of interview: ___/___/___

Interviewer code: _____

Time start: _____ : _____ m

Time end: _____

2. Health worker characteristics:

- **Name of respondent(s):** (This should be the first name only)
 - **Rank (professional qualification):**
 - **Position in facility (present designation):**
 - **Age:**
 - **Sex:**
 - **Number of years of work in facility:**
 - **Number of years of work at present post:**
-

3. Interviewer comments

- Record where (what place) you actually did the interview (eg their house, under a tree, in the yard).
 - What the respondent physically looked like or dressed like.
 - How their mood was during the interview (eg. did they get bored, tired, look worried sometimes or all the time).
 - Any other information such as interruptions that will help understand the context of the interview
-

4. WHAT DO YOU KNOW ABOUT THE NEWHINTS INTERVENTION AND WHAT THE ROLES OF THE CBSVS ARE?

Purpose: The purpose of this question is to elicit the prescriber's general views on the work of the CBSV in Newhints.

Probe for the following If not mentioned but they know about Newhints.

- How did you hear about it?

NB: If they do not know anything about Newhints, show the referral card but if it still does not remind them of anything, only ask questions 5 and end the interview

5. ARE THERE CHALLENGES TAKING CARE OF SICK NEWBORNS REFERRED TO THIS FACILITY? IF YES, WHICH WERE THE MAJOR ONES? WHAT SUPPORT AND PREPARATIONS HAVE YOU RECEIVED IN MANAGING SICK NEWBORNS?

Purpose: The purpose of this question is to elicit responses on whether HWs who manage newborns identify any challenges doing this and what support, if any, they have received to equip them to render these services?

Probe for the following If not mentioned

- Are the challenges related to **skill, manpower availability, equipment or supplies?**
- How did you **cope with these challenges?**
- **What training** did you receive- Clinical, use of equipment to help you and who did the training?
- Did you **participate** in the **Newhints training for health workers?** If yes **how did it help; if no, why not?**

6. WHAT HAVE BEEN YOUR EXPERIENCES WITH NEWBORN BABIES REFERRED TO THIS FACILITY BY A NEWHINTS CBSV?

Show the referral card if necessary

||||

Purpose: The purpose of this question is to ascertain whether HWs could identify babies referred in the Newhints intervention by CBSVs, their perceptions on the validity of CBSV reasons for referral and their mode of confirmation and the care given to them.

Probe for the following If not mentioned

- How did you know they were referred by the Newhints CBSV? And why did they refer them?
- What did you do for the babies-history, examination, diagnosis?
- Are there special procedures for managing Newhints babies specifically?

7. HAVE YOU HAD TO ADMIT ANY OF THE BABIES REFERRED TO YOU BY THE CBSVS? WHAT HAPPENED?

Probe for the following:

- **Why** did you admit them?
- For **how long?**
- **What** were you doing for them **during** the admission?
- **Why** did you finally **discharge** them?

8. HAS ANY CBSV REFERRED A BABY TO THIS FACILITY WHICH YOU FOUND NOT TO BE SICK? IF YES, CAN YOU PLEASE NARRATE WHAT HAPPENED?

(if the health worker says no to the above question, ask what he would have done if that scenario occurs).

||||

Purpose: The purpose of this question is to ascertain how HWs treat mothers who comply with CBSV referrals but are found to be having a healthy baby.

Probe for the following If not mentioned (if respondent said yes to the above):

- **How** did you **conclude** that the baby was not sick?
- **How often** did you see this happen?
- **How do you feel** when you see these "well babies"? How do you think this affected care for babies they referred subsequently?

- **What you do for such babies and mothers?**
- What have been the mothers' reactions?

9. HAS THE WORK OF THE CBSVs CHANGED THINGS IN THIS FACILITY IN ANY WAY? WHAT WAYS?

Probe for:

- positive and negative influences including:
 - o Change in **numbers of women and babies seen**
 - o Changes in **behaviors,**
 - o Changes in **work load.**
 - o Changes in **women's expectation of care given?**

10. WHAT ARE YOUR IMPRESSIONS ABOUT THE NEWHINTS REFERRAL BY CBSVs?

Purpose: The purpose of this question is to find out what HWs think about the referral in general? How they see the CBSVs work-whether they see it as a good support for the health system and should be encouraged or they that it's of no use and so should be cancelled.

Probe for the following If not mentioned:

- **Are the CBSVs any good?**
- **What are they doing well or not?**
- Is it **possible health facility contacts** can have an **effect on CBSVs' work** in the community **and how?**

11. IN YOUR OPINION, HOW DO YOU THINK THE NEWHINTS REFERRAL COULD BE IMPROVED FURTHER?

Purpose: The purpose of this question is to find out about health workers opinion on how they think the Newhints referral could be improved?

Probe for the following If not mentioned (if respondent said yes to the above):

- What would you **have wanted the CBSVs do** which they do not do now?
- What do the CBSVs do now which **you think they should not** be doing?
- **What support** would a facility like this **need to cope with the Newhints referrals?**
- **Who** could best provide that support?

12. WOULD YOU RECOMMEND THAT OTHER DISTRICTS ADOPT THE NEWHINTS APPROACH AND WHY?

Thank the respondent

Newhints Referral IDI Guide: Matron of Paedics/maternity's experiences & perceptions on impact on facility work

1. Introduction

One of the core interventions in the Newhints trial is the assessment and referral of sick newborns to health facilities within the study area for care. The success of future replication and scaling up efforts will require health worker input on their experiences with babies referred in the Newhints trial.

This guide therefore is aimed at eliciting health workers' experiences with mothers and their babies referred as a result of the Newhints volunteer visits and assessments in the homes. It will explore their perceptions on the validity of volunteer assessments and referrals, the impact of the CBSV referrals on Health workload at the facility, challenges posed by the referral system to their facility and on themselves and their perceptions on the support that need to be provided for health systems to cope with similar interventions at scale.

Data will be collected from purposively selected facilities (based on facility being recommended as a Newhints referral destination, number of babies seen, etc.) within the Newhints study districts. Health workers (Matrons, one nurse on duty, one auxiliary nurse, one frontline staff at the OPD and one Health insurance agent) will be interviewed for 45mins to 1hr in this evaluation study.

Responses from participants will be treated with all confidentiality and only the researcher and the core research team will have access to the data. Even then, respondents will only be identified with an alphanumeric code generated to identify the type of facility and the district but not the individual respondent. Respondents will be free to withdraw from this interview at the start, during the process or even at the end of the interview without any adverse effect on their position in the facility or district or indeed the Ghana Health Service.

District: _____

Facility name: _____

Date of interview: ___/___/___

Interviewer code: _____

Time start: ____ : ____ m

Time end: _____

2. Health worker characteristics:

- Name of respondent(s): (This should be the first name only)
 - Rank (professional qualification):
 - Position in facility (present designation):
 - Age:
 - Sex:
 - Number of years of work in facility:
 - Number of years of work at present post:
-

3. Interviewer comments

- Record where (what place) you actually did the interview (eg their house, under a tree, in the yard).
- What the respondent physically looked like or dressed like.
- How their mood was during the interview (eg. did they get bored, tired, look worried sometimes or all the time).
- Any other information such as interruptions that will help understand the context of the interview

4. WHAT HAPPENS WHEN A SICK NEWBORN (UNDER 1 MONTH) IS BROUGHT TO THIS FACILITY?

Purpose: The purpose of this question is to elicit responses on whether there are existing protocols for the management of sick newborns in the facility. The protocols could be anything from who manages them, written procedure for their management, triaging, their admissions, what happens to the mother (provided lodging, food, etc. or not) all the way through to discharge procedures.

Probe for the following If not mentioned

- Who sees them? When? What happens if that person is not around?
- Where in the facility are they seen and/or admitted if required?
- Are there special protocols for managing these sick newborns and what are they? Where did they come from?
- Is it different if the baby is just 1 week old?
- What if they are carrying Newhints referral card (show the Newhints referral card)?



5. ARE THERE CHALLENGES TAKING CARE OF NEWBORNS REFERRED TO THIS FACILITY? IF YES, WHICH WERE THE MAJOR ONES? WHAT SUPPORT AND PREPARATIONS HAVE YOU RECEIVED IN MANAGING SICK NEWBORNS?

Purpose: The purpose of this question is to elicit responses on whether HWs who manage newborns received any training to equip them to render these services?

Probe for the following If not mentioned

- Are the challenges related to skill, manpower availability, equipment or supplies?
- How did you cope with these challenges?
- What training did you receive- Clinical, use of equipment to help you and who did the training?
- Did you participate in the Newhints training for health workers? If yes how did it help; if no, why not?

6. WHAT HAVE BEEN YOUR EXPERIENCES WITH NEWBORN BABIES REFERRED TO THIS FACILITY BY A NEWHINTS CBSV?

Show the referral card if necessary



Purpose: The purpose of this question is to ascertain whether HWs could identify babies referred in the Newhints intervention by CBSVs, their perceptions on the validity of CBSV reasons for referral and their mode of confirmation and the care given to them.

Probe for the following If not mentioned

- How did you know they were referred by the Newhints CBSV? And why did they refer them?
- What did you do for the babies-history, examination, diagnosis?
- Do you know if there are special procedures for managing Newhints babies?

7. HAVE YOU HAD TO ADMIT/TAKE CARE OF ANY BABY REFERRED TO YOU BY THE CBSVS? WHAT HAPPENED?

Probe for the following:

- Why did you admit them/why were they admitted?
- For how long?
- What were you doing for them during the admission?
- Why did you finally discharge them/were they finally discharged?

8. HAS ANY CBSV REFERRED A BABY TO THIS FACILITY WHICH YOU FOUND NOT TO BE SICK? IF YES, CAN YOU PLEASE NARRATE WHAT HAPPENED?

(if the health worker says no to the above question, ask what he would have done if that scenario occurs).



Purpose: The purpose of this question is to ascertain how HWs treat mothers who comply with CBSV referrals but are found to be having a healthy baby.

Probe for the following if not mentioned (if respondent said yes to the above):

- **Who decided** that the baby was not sick and how?
- **How often** did you see this happen?
- **How do you feel** when you see these “well babies”? How could this affect care for babies they refer subsequently?
- **What you do** for such **babies and mothers?**
- What have been the mothers’ reactions?

9. HAS THE REFERRAL OF SICK BABIES TO THIS FACILITY BY CBSVS HAD ANY IMPACT ON YOUR WORK (PERSONALLY AND COLLECTIVELY)? IF YES HOW? IF NO WHY NOT?

Purpose: The purpose of this question is to explore HW perceptions on impact of the Newhints referrals on their work.

Probe for the following if not mentioned

- Are there changes in your workload and how?
- Do you think the work of the CBSVs has helped your work in anyway?
- What are the negative effects on your work, if any?

10. DO YOU THINK THERE HAS BEEN ANY CHANGES IN THE MOTHERS’/CARETAKERS’ EXPECTATIONS OF WHAT HAPPENS IN THIS FACILITY WHEN THEY BRING THEIR SICK NEWBORNS FOR CARE? WHAT ARE THESE CHANGES AND WHY?

11. HOW DO YOU THINK THE NEWHINTS ASSESSMENT AND REFERRAL BY CBSVS COULD BE IMPROVED FURTHER?

Probe for the following if not mentioned

Probe for the following if not mentioned (if respondent said yes to the above):

- What would you **have wanted the CBSVs do** which they do not do now?
- What do the CBSVs do now which **you think they should not** be doing?
- **What support** would a facility like this **need to cope with the Newhints referrals?**
- **Who** could best provide that support?

12. WOULD YOU RECOMMEND THAT OTHER DISTRICTS TO ADOPT THE NEWHINTS APPROACH TO NEWBORN CARE? AND WHY?

13. ANY other thing you want to discuss which I did not mention in this interview?

Thank the respondent

Newhints Referral IDI Guide: Front desk health workers' experiences & perceptions

1. Introduction

One of the core interventions in the Newhints trial is the assessment and referral of sick newborns to health facilities within the study area for care. The success of future replication and scaling up efforts will require health worker input on their experiences with babies referred in the Newhints trial.

This guide therefore is aimed at eliciting health workers' experiences with mothers and their babies referred as a result of the Newhints volunteer visits and assessments in the homes. It will explore their perceptions on the validity of volunteer assessments and referrals, the impact of the CBSV referrals on Health workload at the facility, challenges posed by the referral system to their facility and on themselves and their perceptions on the support that need to be provided for health systems to cope with similar interventions at scale.

Data will be collected from purposively selected facilities (based on facility being recommended as a Newhints referral destination, number of babies seen, etc.) within the Newhints study districts. Health workers (Matrons, one nurse on duty, one auxiliary nurse, one frontline staff at the OPD and one Health insurance agent) will be interviewed for 45mins to 1hr in this evaluation study.

Responses from participants will be treated with all confidentiality and only the researcher and the core research team will have access to the data. Even then, respondents will only be identified with an alphanumeric code generated to identify the type of facility and the district but not the individual respondent. Respondents will be free to withdraw from this interview at the start, during the process or even at the end of the interview without any adverse effect on their position in the facility or district or indeed the Ghana Health Service.

District: _____

Facility name: _____

Date of interview: ___/___/___

Interviewer code: _____

Time start: _____ : _____ m

Time end: _____

2. Health worker characteristics:

- **Name of respondent(s):** (This should be the first name only)
 - **Rank (professional qualifications; include educational attainment):**
 - **Position in facility (present designation):**
 - **Age:**
 - **Sex:**
 - **Number of years of work in facility:**
 - **Number of years of work at present post:**
-

3. Interviewer comments

- *Record where (what place) you actually did the interview (eg their house, under a tree, in the yard).*
 - *What the respondent physically looked like or dressed like.*
 - *How their mood was during the interview (eg. did they get bored, tired, look worried sometimes or all the time).*
 - *Any other information such as interruptions that will help understand the context of the interview*
-

4. COULD YOU PLEASE TELL ME IN DETAIL WHAT YOU DO IF A MOTHER PRESENTS HERE WITH BABY WHO IS LESS THAN A MONTH OLD BUT SICK?

Purpose: The purpose of this question is to explore whether frontdesk staff of the hospital are aware of how to help mothers of sick newborns find their way around facilities to which babies are referred.

Probe for the following If not mentioned

- What **special considerations**, if any, are they given?
- Are **you expected** to do anything for them? If yes, **what** and **who told you** what to do?

(inspect and record the details; if possible take a photocopy or sketch if algorithms on wall)



- Approximately how long (**and why?**) will it take a mother from the time she enters this facility till they get to
 - o You?
 - o The doctor/one who takes definitive care of them?
 - o Leave the facility?
- And does it differ for **time of day, particular days** (which days), **weekends?**

5. WHAT DO YOU KNOW ABOUT THE WORK OF THE CBSVS' IN THE COMMUNITY (BY NEWHINTS)?

Probe about:

- Visits to pregnant and delivered women,
- What they actually do?
- When **baby is sick-how** do they know and **what do** they do?
- Who **trains** them and for how long,
- Whether they get **paid**, why not?

Purpose: The purpose of this question is to assess front desk staff knowledge about CBSV roles and especially referrals since they are the first potential point of contact with the facility and play roles in the triaging.

6. WHAT HAVE BEEN YOUR EXPERIENCES WITH BABIES REFERRED HERE FROM NEWHINTS? **Show the referral card if they do not know fully about Newhints.**

Purpose: The purpose of this question is to collate information on frontdesk staff of facilities' interactions with women referred from Newhints.

Probe for the following If not mentioned

- **Who** usually **accompanies** these babies when they come here?
- **What** do the people accompanying them do?
- Have **any CBSVs or men (husbands)** accompanied any newborn here for care? **What happened?**
- Do you think **their expectations** of how they are treated is different; **how** different and **why?**

7. HAS THE WORK OF THE CBSVS CHANGED THINGS IN THIS FACILITY IN ANYWAY? HOW?

Probe for:

- positive and negative influences including:
 - o Change in **numbers of women and babies seen**
 - o Changes in **behaviors**,
 - o Changes in **work load**.
 - o Changes in **women's expectation of care given?**

8. IN YOUR OPINION, HOW DO YOU THINK THE NEWHINTS CBSVS' REFERRAL WORK COULD BE IMPROVED FURTHER?

Purpose: The purpose of this question is to find out about health workers opinion on how they think the Newhints referral could be improved in the community?

Probe for the following If not mentioned (if respondent said yes to the above):

- What would you **have wanted the CBSVs do** which they do not do now?
- What do the CBSVs do now which **you think they should not** be doing?

9. FROM YOUR EXPERIENCES, HOW COULD CARE FOR BABIES REFERRED FROM NEWHINTS BE IMPROVED IN THIS FACILITY?

Purpose: The purpose of this question is to explore respondents views on how to improve referral in Newhints

Probe for the following If not mentioned

- **What support** would a facility like this need to cope with the Newhints referrals?
 - **Who** could best provide that support?
-

10. IS THERE ANYTHING YOU WOULD HAVE WANTED ME TO DISCUSS WHICH I DID NOT ABOUT THE NEWHINTS REFERRAL?

THANK THE RESPONDENT

2. FACILITY'S ACCESSIBILITY TO THE CATCHMENT POPULATION:

2.1 Does this facility offer 24hr services?.....	1. Yes	2. No	24HRS			
2.2 Is this facility open to offer services on all weekdays?.....	1. Yes	2. No	WEEKDAYS			
2.3 Is this facility open to offer services on all weekends?.....	1. Yes	2. No	WEEKENDS			
2.4 Do you offer ANC care to pregnant women in this facility?.....	1. Yes	2. No	ANC			
2.5 How many days of the week do you offer ANC services?.....	1. 1 day	2. 2 days	3. 3-5 days	4. Everyday	9. NA	ANCDAYS
2.6 Can a woman come to deliver in this facility?.....	1. Yes	2. No	DELIVERY			
2.7 How many days of the week are delivery services given?.....	1. 1 day	2. 2 days	3. 3-5 days	4. Everyday	9. NA	DELIVDAYS
2.8 Are delivery services available for 24 hrs in a day?.....	1. Yes	2. No	DELIV24HRS			
2.9 Does this facility offer immunization (EPI vaccines) to children?.....	1. Yes	2. No	EPI			
2.10 Days of EPI services to children per week in facility?.....	1. 1 day	2. 2 days	3. 3-5 days	4. Everyday	9. NA	EPIDAYS
2.11 Does this facility operate a static CWC?.....	1. Yes	2. No	CWCSTATIC			
2.12 How many days of the week do you offer CWC services?.....	2. 1 day	2. 2 days	3. 3-5 days	4. Everyday	9. NA	CWCDAYS
2.13 Does this facility offer PNC services?.....	1. Yes	2. No	PNC			
2.14 How many days of the week do you offer PNC services?.....	3. 1 day	2. 2 days	3. 3-5 days	4. Everyday	9. NA	PNCDAYS
2.15 Does this facility offer laboratory services?.....	1. Yes	2. No	LABHERE			
2.16 Are patients admitted to this facility overnight?.....	1. Yes	2. No	ADMITHERE			
2.17 Does this facility also admit pregnant women who come here and are considered not fit to go home?.....	1. Yes	2. No	PREGADMIT			
2.18 Do you provide accommodation for staff of this facility on the premises?.....	1. Yes	2. No	HOUSESTAFF			

Summary of days of service:

Can you briefly tell me on what days this facility operates.

Opening days/times:
ANC days (any special arrangement for the market days?):
CWC days:
Immunization days: <i>For pregnant women</i> <i>For children</i>

3. **STAFFING: (for pregnancy and newborn care):** TELL RESPONDENT YOU WANT TO KNOW ABOUT THE NUMBERS OF ALL HEALTH PROVIDERS AND ESPECIALLY THOSE WHO TAKE CARE OF NEWBORNS AND PREGNANT WOMEN IN THE FACILITY.

Category	No who work in facility	No present today	No who conduct deliveries	No trained to manage delivery complications	No able to do C-Sections	No who manage sick newborns	No trained in Newborn resuscitation	No on duty last night
Doctors								
Med. Assts.								
Midwives								
PH Nurses								
Staff nurses								
CHNs								
ENs								
HEWs								
WARD ASST								
Other1, specify								
Other2, specify								

4. ANTENATAL CARE SERVICES (If no ANC is offered at this facility, cross out this section)

4.1 What happens if a pregnant woman comes to this facility and has not had Tetanus toxoid immunization?	1.Treated	2. Referred	9. Nothing, no ANC	TTANC
4.2 If you have a woman with high-risk/complicated pregnancy, do you manage her here?	1.Yes	2. No	9. NA, No ANC	COMPLICATE
4.3 Do you do ultrasound scan for pregnant women in this facility?	1.Yes	2. No	9. NA, No ANC	USGSCAN
4.4 If a woman came here with premature rupture of membranes, what do you do for her?	1.Treated	2. Referred	9. NA, No ANC	PROM
4.5 Do you routinely measure the blood pressure(s) of pregnant women when they come to the ANC clinic?	1. Yes	2. No	9. NA, No ANC	BP
4.6 Do you offer haemoglobin testing at your ANC?.....	1. Yes	2. No	9. NA, No ANC	HBTEST
4.7 Is your facility able to conduct urine protein testing for pregnant women at ANC?...	1. Yes	2. No	9. NA, No ANC	URINPROT
4.8 Is Sickle Cell screening part of antenatal care in this facility?	1. Yes	2. No	9. NA, No ANC	SSDSCREEN
4.9 Do you also give Intermittent preventive treatment for malaria (IPT)?.....	1. Yes	2. No	9. NA, No ANC	IPT

5. LABOUR, DELIVERY AND IMMEDIATE POSTPARTUM CARE (If no Delivery Care is offered at this facility, cross out this section)

5.1 Number of babies delivered in 2009.....						NUMDEL	
5.2 Number of neonatal sick admissions in 2009.....						NEOADMIT	
5.3 How many babies were delivered in this facility over the past year?	1. 1- 49	2. 50-249	3.250-499	4. 500-999	5. 1000+	9. NA, No delivery care	TOTDELIV
5.4 Is there a lying-in ward for women who have just delivered?.....	1. Yes	2. No	9. NA, No delivery care				WARD
5.5 Must a woman have a GHS maternity card to deliver in this facility?....	1. Yes	2. No	9. NA, No delivery care				GHSCARD
5.6 Does this facility provide emergency obstetric care (EmOC) to women?:	1. Yes	2. No	9. NA, No delivery care				EMOC

Which of the following signal EmOC functions does this facility provide and which of these was done in the past 6 months?

5.7 Injectable antibiotics administration?.....	1. Yes, done in past 6 months	2. Yes, not done in past 6 months	3. Not done	9. NA, No delivery care	IVATB
5.8 Injectable oxytocic (Synto/Ergot) drugs administration?..	1. Yes, done in past 6 months	2. Yes, not done in past 6 months	3. Not done	9. NA, No delivery care	IMOXYTOC
5.9 Injectable anticonvulsant administration?..	1. Yes, done in past 6 months	2. Yes, not done in past 6 months	3. Not done	9. NA, No delivery care	IVANTICONV
5.10 Manual removal of retained placenta?.....	1. Yes, done in past 6 months	2. Yes, not done in past 6 months	3. Not done	9. NA, No delivery care	PLACENTA
5.11 Manual removal of retained products of conception?.....	1. Yes, done in past 6 months	2. Yes, not done in past 6 months	3. Not done	9. NA, No delivery care	RPOC

5.12 Assisted vaginal/instrumental (Vacuum or forceps) delivery?.....	1. Yes, done in past 6 months	2. Yes, not done in past 6 months	3. Not done	9. NA, No delivery care	INSTRDELIV
5.13 Blood transfusion services?.....	1. Yes, done in past 6 months	2. Yes, not done in past 6 months	3. Not done	9. A, No delivery care	BLOODTRANS
5.14 Caesarean delivery?.....	1. Yes, done in past 6 months	2. Yes, not done in past 6 months	3. Not done	9. NA, No delivery care	CS
5.15 Do you routinely monitor labour with a partograph in this facility?.....	1. Yes	2. No	9. NA, No delivery care		PARTOGRAPH
5.16 Are women's husbands/family/friends allowed in the delivery suite/labour ward when women come to deliver in this facility?.....	1. Yes	2. No	9. NA, No delivery care		COMPANY

6. IMMEDIATE POSTPARTUM CARE: Ask the respondent(s) to describe what happens to a woman and her baby immediately a baby is delivered. Prompt them for all the topics below if they do not voluntarily cite specifics.

Management of the 3rd stage of labour:

6.1 Controlled cord traction?.....	1. Yes	2. No	9. NA, No delivery care		CCT	
6.2 Injection oxytocin on the thigh within 1 minute after the delivery of the baby?.....	1. Yes	2. No	9. NA, No delivery care		IMSYNTO	
6.3 Uterine massage after the delivery?.....	1. Yes	2. No	9. NA, No delivery care		UTMASSAGE	
6.4 How long after delivery is the woman discharged home if mother and baby are well?..	1. < 6hrs	2. 6-12hrs	3. 12-24hrs.	4. 24+ hrs	9. NA, No delivery care	DURPOSTDEL

Handling of the baby:

6.5 Once the baby is delivered in this facility, where is (s)he placed?.....	1. Mother's abdomen	2. Clean mat or bed in ward	3. Other, specify	9. NA, No delivery care	SURFACE	
6.6 How soon after delivery is the baby dried?.....	1. Immediately after delivery	2. Not immediately; between 1-5mins	3. Between 5-10mins	4. After placenta delivery	9. NA, No delivery care	DRYBABY
6.7 What is done to the cord after it is cut?	1. Spirit / tincture applied	2. Nothing applied	3. Other, specify	9. NA, No delivery care	CORDRESS	
6.8 How long after delivery is baby first put to the breast?	1. Immediately, before placental delivery	2. After placental delivery	3. When the mother has rested and is ready to	9. NA, No delivery care	BFINITIATE	
6.9 Is the baby weighed in this facility?.....	1. Yes	2. No	9. NA, No delivery care		WEIGH	
6.10 Is the temperature of a newborn taken after birth in this facility?.....	1. Yes	2. No	9. NA, No delivery care		TEMP	
6.11 What is done to the eyes of the baby after delivery?.....	1. Antibiotic eye drop /ointment applied	2. Wiped with plain cloth/gauze alone.	3. Other, specify	9. NA, No delivery care	EYECARE	
6.12 How soon after delivery is the baby 1 st bathed, if normal weight?.....	1. Immediately after delivery	2. After delivery but before 6 hours	3. After at least 6 hours	9. NA, Not done /No delivery care	BATH	
6.13 Are babies routinely examined after delivery and by whom?.....	1. Yes, by midwife/Dr	2. Yes, but not by midwife/Dr	9. NA, No delivery care		EXAMINEBABY	

If yes, at what time(s) do they get this thorough medical exam after delivery?

6.14 Immediately after delivery?.....	1. Yes	2. No	9. NA, No delivery care		EXAIMM	
6.15 Just before discharge home?.....	1. Yes	2. No	9. NA, No delivery care		EXAMDC	
6.16 Is there a checklist to follow for this examination?.....	1. Yes and used all the time	2. Yes but only used sometimes	3. Yes but not used.	4. No checklist	9. NA, No delivery care(No exam)	EXAMLIST

7. NEWBORN EMERGENCY CARE: Ask these specific questions on newborn resuscitation.

7.1 Are newborns resuscitated in this facility?.....

1. Yes	2. No	9. NA, No delivery care
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 RESUS

How is the resuscitation of newborns carried out in this facility?

7.2 Vigorous wiping	1. Yes	2. No	WIPING
7.3 Suctioning using machine or syringe.....	1. Yes	2. No	SUCTION
7.4 Bag and mask with air.....	1. Yes	2. No	BAGMASK
7.5 Bag and mask with oxygen.....	1. Yes	2. No	OXYGEN
7.6 Bag and mask plus cardiac massage.....	1. Yes	2. No	HTMASSAGE

7.7 How long will you attempt to resuscitate a baby before you declare death?.....

1. For the first 5 minutes	2. Between 5-20 mins	3. After 20mins	9. NA, Not done/ No delivery care
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 RESUSTIME

Does this facility provide the following newborn emergency care functions, and were they performed in the past 6 months?

7.8 Newborn resuscitation with bag and mask?.....	1. Yes, done in past 6 months	2. Yes, but not done in past 6 months	3. No	9. NA, No newborn care	NEORESUS
7.9 Newborn resuscitation with bag and mask using oxygen?.....	1. Yes, done in past 6 months	2. Yes, but not done in past 6 months	3. No	9. NA, No newborn care	OXYGEN
7.10 Intravenous antibiotics for babies?.....	1. Yes, done in past 6 months	2. Yes, but not done in past 6 months	3. No	9. NA, No newborn care	NEOABX
7.11 Intravenous fluids for babies?.....	1. Yes, done in past 6 months	2. Yes, but not done in past 6 months	3. No	9. NA, No newborn care	NEOIV
7.12 Teach mother skin-to-skin / Kangaroo Mother Care for premature and very small babies?.....	1. Yes, done in past 6 months	2. Yes, but not done in past 6 months	3. No	9. NA, No newborn care	KMC
7.13 Teaching mother to express breast milk and feed with small cup if unable to breastfeed.....	1. Yes, done in past 6 months	2. Yes, but not done in past 6 months	3. No	9. NA, No newborn care	ALTFEED
7.14 Dexamethasone to the mother if you anticipate the baby is going to be born prematurely?.....	1. Yes, done in past 6 months	2. Yes, but not done in past 6 months	3. No	9. NA, No newborn care	PRECORT

8. Discharge procedures in facilities.

8.1 Is there a checklist of things that must be fulfilled before discharge?

1. Yes and used all the time	2. Yes but only used sometimes	3. Yes but not used.	4. No checklist	9. NA, No delivery care
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 DISCHECKLIST

8.2 Can a baby be kept in for longer than usual after delivery?.....

1. Yes	2. No	9. NA, No delivery care
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 STAYLONG

Under what circumstances will a baby be (have been) kept for longer than usual?

(Circle as many as they cite but don't prompt. Encourage them to add anything they remember even when on another question)

8.3 Baby not breastfeeding or stopped breastfeeding completely.....	1. Mentioned	2. Not mentioned	STOPBF
8.4 Baby having fits or convulsed since birth.....	1. Mentioned	2. Not mentioned	CONVULSED
8.5 Baby lethargic or unconscious.....	1. Mentioned	2. Not mentioned	LETHARGY
8.6 Baby jaundiced.....	1. Mentioned	2. Not mentioned	JAUNDICE
8.7 Baby having difficulty breathing (respiration rate \geq 60/min).....	1. Mentioned	2. Not mentioned	DYSPNOEA

8.8 Baby having grunting respiration.....	1. Mentioned	2. Not mentioned	GRUNTING
8.9 Baby having lower chest indrawing.....	1. Mentioned	2. Not mentioned	INDRAWING
8.10Baby having hypothermia (axillary temperature<35.4°C).....	1. Mentioned	2. Not mentioned	HYPOTHERM
8.11Baby having fever (axillary temperature≥37. 5°C).....	1. Mentioned	2. Not mentioned	FEVER
8.12Baby having 10 or more skin pustules.....	1. Mentioned	2. Not mentioned	PUSTULES
8.13Baby having eye infection.....	1. Mentioned	2. Not mentioned	EYEINFECT
8.14Baby is sick.....	1. Mentioned	2. Not mentioned	SICK
8.15Baby very small.....	1. Mentioned	2. Not mentioned	VSMALLDSCH
8.16Other, specify.....	1. Mentioned	2. Not mentioned	DSCHOTHER

9. Care for very small babies born in health facilities. Tell the respondent you want to talk more about what is done for very small babies born in this facility. Cross out if no deliveries are conducted in the facility.

9.1 What is done if a baby born/referred here is very small (<1.5kg)?	1. Sent home	2. Referred to another facility	3. Detained & treated on OPD and send home	3. Baby is admitted	VLBW
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9.2 Are there any special procedures done for these very small babies if admitted?	1. Yes	2 No	10. NA, No admissions	CAREVLBW
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10.1Have you received any special training in the care for very small babies?	1. Yes	2 No	TRGVLBW
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What are these special procedures done for very small babies in this facility?

10.2Observation for at least a day.....	1. Yes	2. No	OBSERVE
10.3Skin-to-skin/kangaroo mother care.....	1. Yes	2. No	SSCNKMC
10.4Incubator nursing.....	1. Yes	2. No	INCUBATOR
10.5Alternate feeding if unable to breastfeed.....	1. Yes	2. No	ALTFEED
10.6Delayed first bath for at least 24hrs	1. Yes	2. No	DELAYBATH
10.7Other1, specify.....	1. Yes	2. No	OTHERVLBW

11. POSTPARTUM AND NEONATAL CARE FOR SICK BABIES

11.1 When are women expected to bring their babies for review here after discharge home if the mother and baby are well?.	1. Before 2 weeks of birth	2. At exactly 2 weeks	3. After (over) 2 weeks	9. NA, No PNC/CWC	PNCWC
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11.2 What is the first option given to women who report their babies are not able to suckle at the breast?.....	1. Expressed breast milk with cup (and spoon)	2. Infant formula	3. Other, specify	ALTERNATEBF
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What would be done for a baby who presents in this facility with the following signs and symptoms?

11.3Baby not breastfeeding or stopped breastfeeding completely.....	1. Admitted for treatment	2. Treated on OPD basis	3. Referred	3. Reassured and sent home	BFRX
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10.5 Baby having fitted or convulsed since birth.....	1. Admitted for treatment	2. Treated on OPD basis	3. Referred	4. Reassured and sent home	CONVULSRX
10.6 Baby lethargic or unconscious.....	1. Admitted for treatment	2. Treated on OPD basis	3. Referred	4. Reassured and sent home	LETHARGYRX
10.7 Baby jaundiced.....	1. Admitted for treatment	2. Treated on OPD basis	3. Referred	11 Reassured and sent home	JAUNDICERX
10.8 Baby having difficulty in breathing (respiration rate \geq 60/min).....	1. Admitted for treatment	2. Treated on OPD basis	3. Referred	4. Reassured and sent home	DYSPNOEARX
10.9 Baby having grunting respiration.....	1. Admitted for treatment	2. Treated on OPD basis	3. Referred	4. Reassured and sent home	GRUNTINGRX
10.10 Baby having lower chest indrawing.....	1. Admitted for treatment	2. Treated on OPD basis	3. Referred	4. Reassured and sent home	INDRAWINGRX
10.11 Baby having hypothermia (axillary temp $< 35.4^{\circ}\text{C}$)	1. Admitted for treatment	2. Treated on OPD basis	3. Referred	4. Reassured and sent home	HYPOTHERMRX
10.12 Baby having fever (axillary temperature $\geq 37.5^{\circ}\text{C}$)	1. Admitted for treatment	2. Treated on OPD basis	3. Referred	4. Reassured and sent home	FEVERRX
10.13 Baby having 10 or more skin pustule.....	1. Admitted for treatment	2. Treated on OPD basis	3. Referred	4. Reassured and sent home	PUSTULESRX
10.14 Baby having conjunctivitis.....	1. Admitted for treatment	2. Treated on OPD basis	3. Referred	4. Reassured and sent home	EYEINFECTRX
10.15 Baby having apnoeic spells.....	1. Admitted for treatment	2. Treated on OPD basis	3. Referred	4. Reassured and sent home	APNOEARX

11. (PRE-) REFERRAL CARE

11.1 To which facility do you refer severely ill neonates from this facility? <i>WRITE CODE (99=NA, no referral)</i>	<input type="text"/>	<input type="text"/>	REFERBABY				
11.2 To which facility do you refer women with complications of pregnancy or delivery from this facility? <i>WRITE CODE (99=NA, no referral)</i>	<input type="text"/>	<input type="text"/>	REFERWOMAN				
11.3 How long (estimate to the nearest half hour) will it take to get the baby to this referral facility? <i>Every 30mins = 0.5HRS</i>	<input type="text"/>	<input type="text"/>	99. NA, No referral	TRAVELTIME			
11.4 Do you provide means of transport from here to the facility?	1. Yes, with ambulance	2. Yes, with locally arranged transport	2. No	9. NA, No referral	AMBULANCE		
11.4 Does this facility have a functioning motorised vehicle on site for such an emergency transfers? Is fuel available?	1. Yes, functioning with fuel	2. Yes, but not functioning or no fuel	3. No vehicle available	9. NA, No referral	REFVEHIC		
11.5 Who apart from the driver usually accompanies such an emergency referral patients to the hospital?	1. Nobody, only driver	2. Nurse /midwife	3. dr/MA	4. Family members	5. Other, HWs	9. NA, No referral	REFACCOM

12. ADMINISTRATIVE SUPPORT FOR MATERNAL AND NEWBORN CARE

12.1 Does this facility routinely conduct audit for maternal deaths?	1. Yes	2. No	9.NA	MMRAUDIT
12.2 Does this facility routinely conduct audit for early neonatal deaths?	1. Yes	2. No	9.NA	ENDAUDIT

12.3 Does this facility routinely conduct audit for stillbirths?

1. Yes	2. No	9. NA
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SBAUDIT

12.4 Does this facility routinely monitor equipment and supplies status for repair/replacement?

1. Yes, with timely repair/replacement	2. Yes, but no repair/replacement	2. No
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EQUIPAUDIT

12.5 When was the last time a bag-and-mask resuscitation was attempted here? **RECORD DAYS** 999=NA

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LASTRESUS

12.6 When was the last time a fresh stillbirth was delivered here? **RECORD DAYS** 999=NA

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LASTFSB

12.7 Was resuscitation attempted for this stillbirth?

1. Yes	2. No	9. NA, no delivery care
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LASTSBRESUS

CLINICAL VIGNETTES

13. ECLAMPSIA CASE

A 26-year-old woman who is 7 months pregnant comes in complaining of headaches, blurred vision and epigastric pain and her face looks swollen. In this facility, what would you usually do to establish a diagnosis? *DON'T PROMPT!*

13.1 Measure the woman's blood pressure

1. Mentioned	2. Not mentioned	9. NA, no delivery care	ECBP
1. Mentioned	2. Not mentioned	9. NA, no delivery care	ECPROT
1. Mentioned	2. Not mentioned	9. NA, no delivery care	ECREFL
1. Mentioned	2. Not mentioned	9. NA, no delivery care	ECFHR
1. Mentioned	2. Not mentioned	9. NA, no delivery care	ECREFIM

13.2 Check her urine for protein

13.3 Check her reflexes

13.4 Check fetal heart rate

13.5 Refer to other health facility immediately

Upon examination she had a blood pressure of 170/120, 3+ protein in her urine and brisk reflexes. How would she be managed at this facility? *DON'T PROMPT!*

13.6 Giving antihypertensive drug, e.g. hydralazine, labetalol or nifedipine

13.7 Give Magnesium sulfate or, if not available, diazepam

13.8 Give diuretics

13.9 Have somebody stay with her all the time in case she starts having seizures

13.10 Plan for delivery within the next 24 hours

13.11 Refer to other health facility immediately

1. Mentioned	2. Not mentioned	9. NA, no delivery care	ECHTN
1. Mentioned	2. Not mentioned	9. NA, no delivery care	ECMGS
1. Mentioned	2. Not mentioned	9. NA, no delivery care	ECDIUR
1. Mentioned	2. Not mentioned	9. NA, no delivery care	ECACCOM
1. Mentioned	2. Not mentioned	9. NA, no delivery care	ECDELIV
1. Mentioned	2. Not mentioned	9. NA, no delivery care	ECREFER

14. APH CASE

A 35-year old woman who is 8 months pregnant comes to this facility because she has started to bleed heavily vaginally. She has no contractions and does not complain of any pain. In this facility, what would you usually do to establish a diagnosis? *DON'T PROMPT!*

14.1 Check the woman's vital signs

14.2 Check fetal heart rate

14.3 Perform abdominal examination

14.4 Will not perform vaginal examination

1. Mentioned	2. Not mentioned	9. NA, no delivery care	APHVIT
1. Mentioned	2. Not mentioned	9. NA, no delivery care	APHFHR
1. Mentioned	2. Not mentioned	9. NA, no delivery care	APHABD
1. Mentioned	2. Not mentioned	9. NA, no delivery care	APHVAG

The woman has a feeble pulse at 120/min, her systolic blood pressure is 85 and she is pale, sweating and breathing rapidly at 30 breaths per minute. Foetal heart sound is normal. There is no tenderness on abdominal examination. She is still bleeding vaginally, bright red blood. You suspect **placenta praevia** and therefore do not perform a vaginal examination. How would such a patient be managed now? **DON'T PROMPT!**

14.5 Elevate legs to increase return of blood to the heart	1. Mentioned	2. Not mentioned	9. NA, no delivery care	APHLEGS
14.6 Give IV fluids rapidly	1. Mentioned	2. Not mentioned	9. NA, no delivery care	APHFLUID
14.7 Give oxygen by mask or nasal cannulae	1. Mentioned	2. Not mentioned	9. NA, no delivery care	APHOXY
14.8 Do ultrasound to confirm diagnosis	1. Mentioned	2. Not mentioned	9. NA, no delivery care	APHULTRA
14.9 Prepare for Caesarian section	1. Mentioned	2. Not mentioned	9. NA, no delivery care	APHCS
14.10 Give blood transfusion	1. Mentioned	2. Not mentioned	9. NA, no delivery care	APHBLOOD
14.11 Refer to hospital where Caesarean section can be done	1. Mentioned	2. Not mentioned	9. NA, no delivery care	APHREFER

15. VBWI CARE

Newhints is a study which is training CBSVs in the communities to help mothers and families to recognise babies who might probably be sick and refer them to health facility for care. A 17 yr-old woman pregnant for 8 months delivered a baby at home. A CBSV weighed the baby and found it to be 1.4kg. As a result, she referred the baby to your facility.

a. What would be your first line of action?	1. Admit her for immediate care	2. (Ensure baby's stable and) refer immediately	3. Reassure her and send home	8. Don't know	LBW1STLINE
b. What would you do for this baby?					
i. Detain for thorough examination	1. Mentioned	2. Not mentioned	9. NA, no delivery care		DETAIN
ii. Ensure breastfeeding is established and provide support if necessary	1. Mentioned	2. Not mentioned	9. NA, no delivery care		BFSUPPORT
iii. Put the baby in an incubator	1. Mentioned	2. Not mentioned	9. NA, no delivery care		LBWINCUBATE
iv. Teach the mother to keep baby Skin-to-skin or KMC	1. Mentioned	2. Not mentioned	9. NA, no delivery care		LBWSSC
v. Check cord dressing and other potential sources of infection...	1. Mentioned	2. Not mentioned	9. NA, no delivery care		LBWCORD
vi. Encourage and ensure hygiene in care	1. Mentioned	2. Not mentioned	9. NA, no delivery care		LBWHYGIENE
vii. Refer to a hospital/another facility	1. Mentioned	2. Not mentioned	9. NA, no delivery care		LBWREFER
viii. Other, specify.....	1. Mentioned	2. Not mentioned	9. NA, no delivery care		LBWOTHER
c. Mother says the baby is not breastfeeding and was contemplating giving glucose solution. What would you do?					
i. Watch her breastfeed her baby and teach her good positioning and attachment	1. Mentioned	2. Not mentioned	9. NA, no delivery care		LBWPOSITION

- ii. Examine the baby's mouth to ensure there are no anatomical deformities
- iii. If baby not breast feeding, teach her to express the milk and feed with a clean cup
- iv. Encourage infant formula only if EBM is not possible and mother can afford
- v. Educate her and encourage her to practice exclusive breastfeeding for the 1st 6 months of the baby's life
- vi. Other, specify.....

1. Mentioned	2. Not mentioned	9. NA, no delivery care	LBWMOUTH
1. Mentioned	2. Not mentioned	9. NA, no delivery care	LBWEBM
1. Mentioned	2. Not mentioned	9. NA, no delivery care	LBWFORMULA
1. Mentioned	2. Not mentioned	9. NA, no delivery care	LBWXCLUSIVE
1. Mentioned	2. Not mentioned	9. NA, no delivery care	OTHERCONT

16. NEWBORN RESUSCITATION

A woman presented here in labour. The FHR is more than 160bpm. On examination, her cervix was fully dilated and the baby had the head in the perineum.

a. How would you first manage her?

- i. Prepare her for immediate delivery
- ii. Prepare to resuscitate the baby

1. Mentioned	2. Not mentioned	9. NA, no delivery care	OLDPRIMIP
1. Mentioned	2. Not mentioned	9. NA, no delivery care	SMALLSFH

b. Baby was normal weight but did not cry after delivery; what would you do for this baby?

- i. Dry quickly and vigorously
- ii. Examine and suction the mouth
- iii. Ensure extra warmth for the baby
- iv. Use bag and mask to ventilate if baby does not cry after suctioning
- v. Apply cardiac massage if ventilation alone does not help....
- vi. Refer to another facility/hospital.....

1. Mentioned	2. Not mentioned	9. NA, no delivery care	BABYDRY
1. Mentioned	2. Not mentioned	9. NA, no delivery care	BABYSUCTION
1. Mentioned	2. Not mentioned	9. NA, no delivery care	BABYWARMTH
1. Mentioned	2. Not mentioned	9. NA, no delivery care	BABYVENTIL
1. Mentioned	2. Not mentioned	9. NA, no delivery care	BABYHEART
1. Mentioned	2. Not mentioned	9. NA, no delivery care	BABYHEART

c. Supposing the resuscitation was successful, what would you do next?

- i. Initiate breastfeeding immediately
- ii. Keep in skin-to-skin contact with the mother
- iii. Ensure and encourage hygiene
- iv. Other, specify.....

1. Mentioned	2. Not mentioned	9. NA, no delivery care	ACTIONBFINI
1. Mentioned	2. Not mentioned	9. NA, no delivery care	ACTIONSSC
1. Mentioned	2. Not mentioned	9. NA, no delivery care	ACTIONHYGIN
1. Mentioned	2. Not mentioned	9. NA, no delivery care	ACTIONOTHER

d. During routine checking on the baby after about 2 hrs, you saw the baby sleeping alone and the mother is sleeping but not in touch with baby. There was no covering on the baby since it wriggled out of the mother's cloth. What would you do?

- i. Feel if baby is too cold

1. Mentioned	2. Not mentioned	9. NA, no delivery care	FEELBABY
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ii.	Take the temperature with a thermometer	1. Mentioned	2. Not mentioned	9. NA, no delivery care	COLDTEMP
iii.	Give SSC/KMC by mother or put in incubator for rewarming	1. Mentioned	2. Not mentioned	9. NA, no delivery care	REWARM
iv.	Check the ward to see if windows are open and close them all as well as any fans on the ward to prevent draught..	1. Mentioned	2. Not mentioned	9. NA, no delivery care	DRAUGHT
v.	Breastfeed the baby immediately	1. Mentioned	2. Not mentioned	9. NA, no delivery care	COLDBF

EQUIPMENT SUPPLIES AND DRUGS INVENTORY

THANK THE RESPONDENT AND ASK HER NOW TO TAKE YOU ROUND THE FACILITY TO LOOK AT THEIR EQUIPMENT, DRUGS STOCK AND SUPPLIES AND EMPHASIZE ONLY THE LABOUR, DELIVERY AND NEWBORN CARE ASSOCIATED EQUIPMENT ARE NEEDED. Go round with her as she shows you the equipment and probe if there is any missing and ask about the status of the equipment.

Equipment, drug or supplies	Status		Number, if applicable	
	1. Available	2. Not available		
17.1 Landline/Mobile phone/Radio phones	1. Available	2. Not available		PHONE
17.2 Electricity/power supply	1. Available	2. Not available		ELECTRIC
17.3 Vehicle for referral	1. Available	2. Not available		VEHICLE
17.4 Sink with soap for hand washing	1. Available	2. Not available		SOAP
17.5 Source of clean water	1. Available	2. Not available		WATER
17.6 Freezer / fridge for storage	1. Available	2. Not available		FRIDGE
17.7 Sterilizer/autoclave machine	1. Available	2. Not available		AUTOCLAV
17.8 Oxygen cylinder	1. Available	2. Not available		OXYCYL
17.9 Thermometer	1. Available	2. Not available		THERMO
17.10 Adult weighing scale	1. Available	2. Not available		ADSCALE
17.11 Baby weighing scale	1. Available	2. Not available		BABYSCALE
17.12 Bag and mask for adult	1. Available	2. Not available		ADMASK
17.13 Bag and mask for baby	1. Available	2. Not available		BABYMASK
17.14 Suction machine / nasal aspirator	1. Available	2. Not available		SUCTION
17.15 Stethoscope	1. Available	2. Not available		STETHOS
17.16 Fetoscope	1. Available	2. Not available		FETOSCOPE
17.17 Electronic FH monitor (Tocometer)	1. Available	2. Not available		TOCOMETER
17.18 Incubator	1. Available	2. Not available		INCUBATOR
17.19 Sphygmomanometer (to measure blood pressure)	1. Available	2. Not available		SPHYG
17.20 Shadowless lamp	1. Available	2. Not available		LAMP
17.21 Wall thermometer in delivery suite	1. Available	2. Not available		WALLTHERM
17.22 Heating device in delivery suite	1. Available	2. Not available		HEATING
17.23 Graduated cup to measure expressed breast milk	1. Available	2. Not available		CUPMEAS
17.24 Small cup for feeding expressed breast milk	1. Available	2. Not available		CUPFEED
17.25 Delivery forceps	1. Available	2. Not available		FORCEPS
17.26 Vacuum aspirator	1. Available	2. Not available		VACUUM
17.27 IV Infusion sets	1. Available	2. Not available		IVSET
17.28 Small syringes for baby drug dosing	1. Available	2. Not available		SMALLSYR
17.29 Sterile blade	1. Available	2. Not available		BLADE
17.30 Sterile gauze	1. Available	2. Not available		GAUZE
17.31 Cord clamp	1. Available	2. Not available		CLAMP

17.32	Gloves (sterile)	1. Available	2. Not available		GLOVESTER
17.33	Gloves (non-sterile)	1. Available	2. Not available		GLOVES
17.34	Apron	1. Available	2. Not available		APRON
17.35	Clock with second hand in delivery room	1. Available	2. Not available		CLOCK
17.36	IV fluids	1. Available	2. Not available		IVFLUID
17.37	Chlorhexidine/other antiseptics	1. Available	2. Not available		ANTISEPT
17.38	IV antibiotics	1. Available	2. Not available		ABXIV
17.39	Magnesium sulphate (MgSO ₄)	1. Available	2. Not available		MGSULF
17.40	IV Diazepam	1. Available	2. Not available		DIAZEPAM
17.41	Oxytocics (syntometrine/Ergot)	1. Available	2. Not available		OXYTOCIN
17.42	Dexamethasone (parenteral)	1. Available	2. Not available		DEXAMET
17.43	IV Hydralazine / SL Nifedipine	1. Available	2. Not available		HYDRALAZIN

PROTOCOLS & GUIDELINES AVAILABLE

PROTOCOL/SOP/DOCUMENT	STATUS		REMARKS/SITING
	1. Available	2. Not available	
Partograph	1. Available	2. Not available	
Referral form	1. Available	2. Not available	
Newborn baby examination checklist	1. Available	2. Not available	
Discharge protocol/checklist	1. Available	2. Not available	
Child Health Records	1. Available	2. Not available	
Protocol for reporting adverse events	1. Available	2. Not available	
Breastfeeding attachment guidelines	1. Available	2. Not available	
Breastfeeding positioning guidelines	1. Available	2. Not available	
Resuscitation guidelines	1. Available	2. Not available	
Shock treatment guidelines	1. Available	2. Not available	
KMC guidelines	1. Available	2. Not available	
Breastfeeding policy	1. Available	2. Not available	
Baby friendly policy	1. Available	2. Not available	
Other1,	1. Available	2. Not available	

Notes on plans for consent

Ghana Newborn Home Intervention (Newhints) Trial: Health facility quality of maternal and newborn care assessment survey

- Clearance for the survey will be obtained from the district and municipal health management teams (DHMTs) as well as the medical directors/administrators of all health facilities to be involved in the survey.
- In the health facilities, 2 sets of informed consent will be obtained from staff on duty; one will be from the matron/in-charge of the maternity and/or newborn care unit of the facility who will be the target respondent for the entire assessment. The 2nd will be an extension of the primary consent obtained from the matron/in-charge and be to consent any other staff of the facility who will be invited by the matron/in-charge to participate in the assessment.
- Agreement to participate will be indicated by signature on prepared consent forms.
- The individual's right to refuse consent or to stop the interview at any time after consent has been given will be preserved without prejudice to their position in the hospital or Ghana Health Service. Individuals will not be required to provide explanation for such decisions.

The FACILITY ASSESSMENT survey

- This is an addition to the on-going Ghana Newborn Home Intervention Study (Newhints) being carried out by the Kintampo Health Research Centre (KHRC) and the London School of Hygiene and Tropical Medicine with close collaboration from the Ghana Health Service (headquarters, region and 7 DHMTs in Nkoranza North and South, Kintampo North and South, Techiman, Wenchi and Tain).
 - The Newhints intervention is using home visits by community-based surveillance volunteers to pregnant women and their families in pregnancy and the first week of life of the baby. In all 5 visits will be made. The 2 pregnancy visits will be to encourage pregnant women to attend antenatal clinics (ANC) during pregnancy for routine medical examinations and reviews and to encourage them to deliver in health facilities. In the 3 postnatal visits, they will assess newborns for 'neonatal danger signs' and to refer them to the hospitals appropriately. These are aimed to improve the survival of these babies. The trial has therefore sensitized all health facilities in the study area on the tenets of the intervention and to prepare for a likely increase in workload and higher demand for quality care. To understand how the trial works or does not, this assessment will add to knowledge about accessibility of obstetric and newborn care to pregnant and delivered women in health facilities within the Newhints study area.
 - Agreement or clearance for this assessment will be given by the directors of the District Health Management Teams and the medical administrators of all the health facilities to be covered. No written informed consent will be obtained by interviewer from the DHMTs or the administrators except verbal clearance to undertake the assessment.
-

II. Information sheet to explain participation in the FACILITY ASSESSMENT survey for all health facilities in the Newhints study area

1. Hello my name is Dr. Alexander Manu. I am from Kintampo Health Research Centre (Ghana Health Service) and studying at the London School of Hygiene and Tropical Medicine. I would like to invite you to take part in an interview and assessment on the care available to pregnant women and their newly delivered babies in this facility.
 2. Before you decide if you want to be interviewed or not, I want you to read the following information about the interview to help your decision. Please ask me any questions that you may have as you read through this document.
-

3. **Information on survey:** As you may be aware, the Kintampo Health Research Centre (KHRC) and the London School of Hygiene and Tropical Medicine together with the DHMTs are currently conducting a trial called the Newhints trial to reduce neonatal mortality through home visits by community based surveillance volunteers. In the trial, community-based surveillance volunteers (CBSVs) have been trained to visit, dialogue and counsel pregnant about the need to attend ANC and deliver in the facility among other things. In the postnatal period, they also help families identify 'danger signs' in the newborn and to seek prompt care in a hospital. In checking whether the intervention is successful, we want to know how easy it is for women to access these services when they need them. This survey is therefore looking at what services are available or provided at all the health facilities in the study area.

The whole assessment will last for a maximum 3 hours and will comprise of an interview session where I will want to ask you a series of questions about what services you provide to clientele in this facility and when. The 2nd part will involve me taking inventory of equipment you have for the resuscitation and management of pregnant women and newborns and their functional status as at today. The third part will require you (and any member of your staff that you will want to support you) to provide answers to a set of clinical scenarios that you are likely to have in this facility. It is not a test of your performance but just an assessment of your current practice here. Lastly, if during the period of my stay in this facility you happen to get any case of labour and delivery or a sick newborn brought to this facility, I will take the opportunity to observe how you care for them.

4. If you agree to participate, you will be interviewed by me. The interview and assessment will take between 2-3 hours and I will take down some notes and record the conversations to help me remember all that was discussed.
5. I will like us to sit in a private place of your choice for the conduct of this assessment and I will do everything possible to protect your confidentiality: Your name will be written on my notes but only so that if we do not complete or if I need some more clarifications later, I could contact you again but no direct link will be made between you and the information you provide when the report is being made. The notes will be stored under lock and key at the trial office. If the trial team reports your responses or practices in this facility, your name and the name of your facility will not appear and we will make sure that no individual can be identified.

6. Taking part in the interview may not benefit you directly, but may input into what services need to be put in place should Newhints be rolled out nationwide.
7. Taking part in this interview/assessment is voluntary. You can refuse to answer any question I ask or stop the interview at any time. You do not have to give a reason to refuse to take part or to stop the interview and your participation and your position in the Ghana Health Service and in this facility will not be affected.
8. Now I would like to formally ask you to participate. If you have any questions please ask me or if you do not want to ask me please contact Dr. Guus ten Asbroek at Kintampo Health Research Centre.
9. I want to be sure you are taking part because you want to, so I am going to ask you to sign a form that says you agree to take part. If you do not want to participate that is OK, just let me know.

Thank you very much.

III. Consent form for the matron of the maternal/newborn care unit of the facility.

Title of research: Ghana Newborn Home Intervention (Newhints) Trial: Health facility quality of maternal and newborn care assessment survey

Investigator: Alexander Ansah Manu

Contact details: Kintampo Health Research Centre

I have understood the information I read about this survey and I understand what will be required of me and what will happen to me if I take part in it. My questions concerning this survey have been answered by Alexander Manu. I also understand that my responses will be kept private and that I can leave the survey at any time without giving a reason and without affecting my position in this facility or the Ghana Health Service.

I agree to participate in this assessment survey and to be interviewed: 1=Yes 2=No

Name of respondent:

Facility:

District:

Date

Signature

Interviewer statement: I, the undersigned, have given out the information sheet on this survey to the respondent in English on the procedures to be followed in the survey and risks and benefits involved as well as answering all questions she has about the survey and she agrees to participate in the survey.

Date

Name & Signature of interviewer

IV. Information sheet to explain participation in the FACILITY ASSESSMENT survey for all other health staff who are invited by matron (or primary respondent) to participate in the assessment in health facilities in the Newhints study area

1. Hello my name is Dr. Alexander Manu and I am from Kintampo Health Research Centre (Ghana Health Service) and studying at the London School of Hygiene and Tropical Medicine. As per directive from matron/in-charge of this ward, I would like to invite you to take part in an assessment of the care available to pregnant women and their newly delivered babies in this facility.
2. Before you decide if you want to take part or not, I want you to read the following information about the assessment to help your decision. Please ask me any questions that you may have as you read through this document.
3. **Information on survey:** As you may be aware, the Kintampo Health Research Centre (KHRC) and the London School of Hygiene and Tropical Medicine together with the DHMTs are currently conducting a trial called the Newhints trial to reduce neonatal mortality through home visits by community based surveillance volunteers. In the trial, community-based surveillance volunteers (CBSVs) have been trained to visit, dialogue and counsel pregnant about the need to attend ANC and deliver in the facility among other things. In the postnatal period, they also help families identify 'danger signs' in the newborn and to seek prompt care in a hospital. In checking whether the intervention is successful, we want to know how easy it is for women to access these services when they need them. This survey is therefore looking at what services are available or provided at all the health facilities in the study area.

Most part of the survey has been answered by matron/in-charge of the ward but at this stage, we are now looking at a set of clinical scenarios that you are likely to have in facilities like this. It is not an examination but just an assessment of your current practice here. Lastly, if during the period of my stay in this facility, I have the opportunity, I will observe how you care for any case of labour and delivery or a sick newborn brought to this facility.

4. If you agree to participate, I will take down some notes and record the conversations to help me remember all that was discussed and this will last just under an hour.
5. I will like us to sit in this private place of chosen by matron/in-charge for the conduct of this assessment and I will do everything possible to protect your confidentiality: Your name will be written on my notes but only so that if we do not complete or if I need some more clarifications later, I could contact you again but no direct link will be made between you and the information you provide when the report is being made. The notes will be stored under lock and key at the trial office. If the trial team reports your responses or practices in this facility, your name and the name of your facility will not appear and we will make sure that no individual can be identified.
6. Taking part in the interview may not benefit you directly, but may input into what services need to be put in place should Newhints be rolled out nationwide.

7. Taking part in this interview/assessment is voluntary. You can refuse to answer any question I ask or stop the interview at any time. You do not have to give a reason to refuse to take part or to stop the interview and your participation and your position in the Ghana Health Service and in this facility will not be affected.
8. Now I would like to formally ask you to participate. If you have any questions please ask me or if you do not want to ask me please contact Dr. Guus ten Asbroek at Kintampo Health Research Centre.
9. I want to be sure you are taking part because you want to, so I am going to ask you to sign a form that says you agree to take part. If you do not want to participate that is OK, just let me know.

Thank you very much.

V. Consent form for other staff of the maternal/newborn care unit of the facility.

Title of research: Ghana Newborn Home Intervention (Newhints) Trial: Health facility quality of maternal and newborn care assessment survey

Investigator: Alexander Ansah Manu

Contact details: Kintampo Health Research Centre

I have understood the information I read about this survey and I understand what will be required of me and what will happen to me if I take part in it. My questions concerning this survey have been answered by Alexander Manu. I also understand that my responses will be kept private and that I can leave the survey at any time without giving a reason and without affecting my position in this facility or the Ghana Health Service.

I agree to participate in this assessment survey and to be interviewed: 1= Yes 2=No

Name of respondent:

Facility:

District:

Date

Signature

Interviewer statement: I, the undersigned, have given out the information sheet on this survey to the respondent in English on the procedures to be followed in the survey and risks and benefits involved as well as answering all questions she has about the survey and she agrees to participate in the survey.

Date

Name & Signature of interviewer

KINTAMPO HEALTH RESEARCH CENTER KIVAP NEWHINTS PROJECT PROCESS EVALUATION FORM ENG 18082009	PROCESS EVALUATION Form No.
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FORMNO

2. BACKGROUND and ID:

1.2 Cluster code:.....											CLUSTER
1.2 Woman's ID:.....											WOMANID
1.5. Woman's name.....											NAME
2.5 Date of visit:											DATEVISIT
2.6 Staff code:											FW

**RESCHEDULE VISIT LATER IN DAY OR WEEK IF MOTHER IS TEMPORARILY ABSENT ,
CONDUCT INTERVIEW WITH CARETAKER IN CASE MOTHER OR BABY DIED**

3. CBSV VISITS

READ OUT: I would like to ask you some questions about visits that CBSVs have been making.

3.1 Did you have any visits from a CBSV in which he discussed about your pregnancy, delivery and newborn baby?

1. Yes	2. No
--------	-------

 VISITANY

If Not , Why not? [PROMPT]

3.1.1 CBSV did not visit me	1. Yes	2. No	8. NK	9. NA	VISNOCBSV
3.1.2 I did not have time for these visits	1. Yes	2. No	8. NK	9. NA	VISNOTIME
3.1.3 I did not like/trust CBSV	1. Yes	2. No	8. NK	9. NA	VISNOTRUST
3.1.4 I did not think the visits were useful	1. Yes	2. No	8. NK	9. NA	VISNOUSEF
3.1.5 Other, specify: _____	1. Yes	2. No	8. NK	9. NA	VISNOOTHER

**IF ANSWER TO 3.1= "2, NO CBSV VISITS RECEIVED", END INTERVIEW HERE,
DRAW DOUBLE LINE THROUGH REST OF FORM**

3.2 Did the CBSV give you a card like this during any of the visits to keep home? [SHOW EXAMPLE OF NEWHINTS FAMILY CARD]

1. Yes	2. No	8. NK
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 CARDFAMILY

3.3 IF yes: Can you show me the card

1. Card presented	2. Card not presented	9. NA
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 CARDFAMSHW

IF A FAMILY CARD IS PRESENTED, USE IT ALSO TO COMPLETE SECTION 8 AT THE END OF THE INTERVIEW

4 CBSV VISITS DURING PREGNANCY

READ OUT: I would like to ask you about any visits the CBSV made DURING PREGNANCY.

4.1 Did you have visits from a CBSV during your pregnancy

1. Yes	2. No
--------	-------

VISPREGANY

4.1.1 If "No", why not?

1. The CBSV did not know that I was pregnant	2. The CBSV knew about my pregnancy but didn't visit me	3. I was too busy to receive any visits	4. I delivered before CBSV could make a visit
5. I Moved-In just before or after delivery	6. Other, specify: _____	8. NK.	9. NA, had visits

VISPREGNOY

4.2 How did the CBSV know about your pregnancy? [PROMPT]

1. I/my family informed the CBSV	2. CBSV asked me/my family	3. The Obaapa fieldworker informed the CBSV	4. Other source of information, Specify: _____	8. NK	9. NA, CBSV didn't know
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KNOWPREG

4.3 How old was your pregnancy when the CBSV came the first time to discuss the pregnancy or planning for the birth? [WRITE IN MONTHS. 88= NK, 99=NA, no visits received in pregnancy].

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VISPRGFRST

4.4 How old was your pregnancy when the CBSV came the last time before delivery to discuss the pregnancy or planning for the birth? [WRITE IN MONTHS. 00= NO SECOND VISIT in pregnancy, 88= NK, 99=NA, no visits received in pregnancy].

--	--

VISPRGLAST

5 CBSV VISITS AFTER DELIVERY

READ OUT: Now I would like to ask you about any visits the CBSV made AFTER DELIVERY.

5.1 Did you have any visits from a CBSV after delivery to assess the baby

1. Yes	2. No
--------	-------

VISDELANY

5.1.1 If "No", why not?

1. The CBSV did not know that I had delivered	2. The CBSV knew about my delivery but didn't visit me	3. I was too busy to receive any visits	4. I moved just after delivery
5. Other, specify: _____		8. NK.	9. NA, had visits

VISDELNOY

5.2 How did the CBSV know about your delivery? [PROMPT]

1. I/my family informed the CBSV	2. CBSV asked me/my family	3. The Obaapa fieldworker informed the CBSV	4. Other source of information, Specify: _____	8. NK	9. NA, CBSV didn't know
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KNOWDEL

IF ANSWER TO 5.1= "2, NO CBSV VISITS AFTER DELIVERY", DRAW DOUBLE LINE THROUGH REST OF SECTION 5 AND 6 AND CONTINUE WITH SECTION 7

VISIT SCHEDULE AFTER DELIVERY:

5.3 How soon after delivery did the CBSV make the first visit?

1. Within the first hour	2. After 1 hour but within three hours	3. More than 3 hours but less than 6 hours	4. More than 6 hours after delivery but within a day
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VISDELDAY

5. on the 2 nd day	6. On the 3rd day	7. After 3rd day	8. NK
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5.3.1 CODE NUMBER OF DAYS OF FIRST VISIT AFTER DELIVERY:

IF ANSWER TO 5.3 WAS 1-4 ENTER 01,

IF ANSWER WAS 5 ENTER 02,

IF ANSWER WAS 6 ENTER 03,

IF ANSWER WAS 7 ASK HOW MANY DAYS AFTER DELIVERY. (88=NK)

		VISDEL1
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FOR QUESTION 5.4 to 5.9 USE "88" IF VISIT WAS MADE BUT DAYS SINCE DELIVERY OR PREVIOUS VISIT ARE NOT KNOWN; USE "99" IF NO VISIT WAS MADE

5.4 How many days later did the CBSV make the next (second) visit?

		VISDEL2
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5.5 How many days later did the CBSV make the next (third) visit?.

		VISDEL3
--	--	---------

5.6 How many days later did the CBSV make the next (fourth) visit?

		VISDEL4
--	--	---------

5.7 How many days later did the CBSV make the next (fifth) visit?

		VISDEL5
--	--	---------

5.8 How many days later did the CBSV make the next (sixth) visit?

		VISDEL6
--	--	---------

5.9 How many days later did the CBSV make the next (seventh) visit?

		VISDEL7
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READ OUT: Now I would like to ask you some questions about what the CBSV did:

5.10 Did the CBSV weigh the baby on the first visit after delivery?.....

1. Yes	2. No	8. NK	WEIGHTDAY1
1. Yes	2. No	8. NK	WEIGHTOTH

5.11 Did the CBSV weigh the baby on any other visit?

5.12 Did the CBSV tell you anything about the weight of your baby?

1. Yes	2. No	8. NK	9. NA, Not weighed	WEIGHTTELL
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5.12.1 If yes, what did the CBSV tell you?

1. The baby was small or very small	2. The baby's weight was okay	3. Other, specify _____	9. NA: Not weighed	WEIGHTINFO
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5.13 Did the CBSV take the baby's temperature?

1. Yes, on all visits	2. Yes, on some visits	3 No, not at all	8. NK	CHKTEMP
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5.14 Did the CSBV count the baby's breaths?

1. Yes, on all visits	2. Yes, on some visits	3 No, not at all	8. NK	CHKBREATH
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6 REFERRALS

6.1 At any of the visits, After the CBSV checked your baby, did they tell you that you needed to take your baby to get treatment at a health facility?

1. Yes	2. No
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 REFCSBV

6.1.1 If Yes, what was the reason for this?

1. Baby sick	2. Baby very small	8. NK	9. NA
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 REFWHY

IF NO REFERRAL, DRAW DOUBLE LINE THROUGH REST OF SECTION 6 AND CONTINUE WITH SECTION 7

6.2 Did the CBSV give you a referral slip like this? **[SHOW EXAMPLE OF REFERRAL SLIP]**

1. Yes	2. No	8. NK
--------	-------	-------

 REFSLIP

6.2.1 If yes, can you show it to me?

1. Referral slip shown	2. Referral slip not shown
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 REFSLIPSHW

IF A REFERRAL SLIP IS PRESENTED, USE IT ALSO TO COMPLETE SECTION 9 AT THE END OF THE INTERVIEW

Did the CBSV discuss any of the following ways of caring for your baby on the way to the facility?:

6.2.2 Keeping the baby skin to skin.....

1. Yes	2. No	8.NK
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 REFDISSSC

6.2.3 Keeping the baby well wrapped (if skin to skin not done)

1. Yes	2. No	8.NK
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 REFDISWRAP

6.2.4 Breastfeeding continuously

1. Yes	2. No	8.NK
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 REFDISBF

6.3 Did you take the baby to the facility?.....

1. Yes	2. No
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 REFTAKE

If "No", why not?

CIRCLE ALL THOSE MENTIONED. DO NOT PROMPT

6.3.1 Financial constraints	1. Mentioned	2. Not Mentioned	9. NA	REFNOFINAN
6.3.2 Transport constraints	1. Mentioned	2. Not Mentioned	9. NA	REFNOTRANS
6.3.3 Husband did not allow	1. Mentioned	2. Not Mentioned	9. NA	REFNOALLOW
6.3.4 Husband not at home	1. Mentioned	2. Not Mentioned	9. NA	REFNOHUSBA
6.3.5 Waiting to see if baby improved	1. Mentioned	2. Not Mentioned	9. NA	REFNOWAIT
6.3.6 Used herbal or home treatment/ visited trad. healer first	1. Mentioned	2. Not Mentioned	9. NA	REFNOHERB
6.3.7 Thought baby was okay	1. Mentioned	2. Not Mentioned	9. NA	REFNOOKAY
6.3.8 Other, specify: _____	1. Mentioned	2. Not Mentioned	9. NA	REFNOOTHER

IF THEY DID NOT TAKE THE BABY, DRAW DOUBLE LINE THROUGH REST OF SECTION 6 AND CONTINUE WITH SECTION 7

6.4 How soon were you able to take the baby to the facility?

1. Within 1 hour	2. After 1 hour but within 3 hours	3. More than 3 hrs but within a day
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 REFWHEN

4. Next day	5. Two (2) or more days later	8. NK
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If you did not take the baby to the facility on the same day , why not?

CIRCLE ALL THOSE MENTIONED. DO NOT PROMPT

6.4.1 Financial constraints	1. Mentioned	2. Not Mentioned	9. NA	REFDLFINAN
6.4.2 Transport constraints	1. Mentioned	2. Not Mentioned	9. NA	REFDLTRANS
6.4.3 Husband did not allow	1. Mentioned	2. Not Mentioned	9. NA	REFDLALLOW
6.4.4 Husband not at home	1. Mentioned	2. Not Mentioned	9. NA	REFDLHUSBA
6.4.5 Waiting to see if baby improved	1. Mentioned	2. Not Mentioned	9. NA	REFDLWAIT
6.4.6 Used herbal or home treatment/ visited trad. healer first	1. Mentioned	2. Not Mentioned	9. NA	REFDLHERB
6.4.7 Other, specify: _____	1. Mentioned	2. Not Mentioned	9. NA	REFDLOTHER

FOR THE FOLLOWING QUESTION EXPLORE HOW MANY FACILITIES THE MOTHER TOOK THE BABY TO FOLLOWING THE REFERRAL BY THE CBSV (Either because she chose to consult more than one or because she was referred on)

6.5 To how many facilities in total did you end up taking your baby to after the CBSV told you to?	1. One	2. Two	3. Three	4. More than three	9. NA	REFFACNR
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Ask the following questions 6.6 to 6.12 only for the **FIRST** facility they took the baby to:

6.6 To which facility did you take your baby FIRST ?...	Facility Name= _____				
6.7 WRITE FACILITY CODE FIRST FACILITY:					REF1CODE

6.8 How did you get to this (first) facility? [RECORD MAIN WAY ONLY]	1. Walked	2. Bicycle	3. Motorbike	4. Tro-Tro / Bus	REF1TRANS
	5. Taxi	6. Private car	7. Other, specify: _____		

6.9 Did you do any of the following on the way to the FIRST facility?			
6.9.1 Keeping the baby skin to skin.....	1. Yes	2. No	REF1SSC
6.9.2 Keeping the baby well wrapped (if skin to skin not done)...	1. Yes	2. No	REF1WRAP
6.9.3 Breastfeeding continuously	1. Yes	2. No	REF1BF

6.10 In this (first) facility, how quickly were you seen by a health worker?	1. Less than 30 minutes	2. More than 30 minutes but less than 1 hour	3. More than 1 hour but less than 3 hours	4. More than 3 hours	REF1WAIT
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6.11	Was your baby admitted in this (first) facility you went to?	1. Yes, admitted	2. NO, referred to another facility	3. Treated at facility and sent home	REF1ADMIT
		4 Sent home with treatment to give	5. Sent home, no treatment		

6.12	Did you go to a second facility? And why?	1. Yes, because the baby was referred	2. Yes, not referred but went on our own initiative	3. No	REF2TAKE
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IF ONLY ONE FACILITY WAS VISITED , DRAW DOUBLE LINE THROUGH QUESTIONS 6.13 to 6.25

Ask the following questions 6.13 to 6.19 only for the SECOND facility they took the baby to:

6.13	What was the name of this (second) facility?	Facility Name= _____
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6.14	WRITE FACILITY CODE SECOND FACILITY:			REF2CODE
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6.15	Did you go straight away to this (second) facility	1. Yes	2. No, went home first	3. No, other	REF2STRAIT
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6.16	How did you get to this (second) facility? [RECORD MAIN WAY ONLY]	1. Walked	2. Bicycle	3. Motorbike	4. Tro-Tro / Bus	REF2TRANS
		5. Taxi	6. Private car	7. Other, specify: _____		

6.17	In this (second) facility, how quickly were you seen by a health worker?	1. Less than 30 minutes	2. More than 30 minutes but less than 1 hour	3. More than 1 hour but less than 3 hours	4. More than 3 hours	REF2WAIT
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6.18	Was your baby admitted in this (second) facility you went to?	1. Yes, admitted	2. NO, referred to another facility	3. Treated at facility and sent home	REF2ADMIT
		4 Sent home with treatment to give	5. Sent home, no treatment		

6.19	Did you go to a third facility? And why?	1. Yes, because the baby was referred	2. Yes, not referred but went on our own initiative	3 No	REF3TAKE
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IF ONLY TWO FACILITIES WERE VISITED , DRAW DOUBLE LINE THROUGH QUESTIONS 6.20 to 6.25

Ask the following questions 6.20 to 6.25 only for the THIRD facility they took the baby to:

6.20	What was the name of this (third) facility??	Facility Name= _____
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6.21	WRITE FACILITY CODE THIRD FACILITY:			REF3CODE
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6.22	Did you go straight away to this (third) facility	1. Yes	2. No, went home first	3. No, other	REF3STRAIT
------	---	--------	------------------------	--------------	------------

6.23 How did you get to this (third) facility?
[RECORD MAIN WAY ONLY]

1. Walked	2. Bicycle	3. Motorbike	4. Tro-Tro / Bus	REF3TRANS
5. Taxi	6. Private car	7. Other, specify: _____		

6.24 In this (third) facility, how quickly were you seen by a health worker?

1. Less than 30 minutes	2. More than 30 minutes but less than 1 hour	3. More than 1 hour but less than 3 hours	4. More than 3 hours	REF3WAIT
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6.25 Was your baby admitted in this (third) facility you went to?

1. Yes, admitted	2. NO, referred to another facility	3. Treated at facility and sent home	REF3ADMIT
4 Sent home with treatment to give		5. Sent home, no treatment	

7 GENERAL QUESTIONS ABOUT THE VISITS

READ OUT: Now, I would like to ask you some general questions about all the visits that you received from the CBSV, both in pregnancy and after delivery.

7.1 Apart from you and the CBSV, who participated in the visits? [PROMPT]

7.1.1 Mother or mother-in-law.....	1. Yes	2. No	VISPRESMOT
7.1.2 Husband/father of the baby.....	1. Yes	2. No	VISPRESHUS
7.1.3 Sister/sister in law.....	1. Yes	2. No	VISPRESSIS
7.1.4 TBA.....	1. Yes	2. No	VISPRESTBA
7.1.5 Other. Specify: _____	1. Yes	2. No	VISPRESOTH

7.2 Was your CBSV male or female?.....

1. Male	2. Female	CBSVSEX
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7.3 Did the gender of the CBSV matter to you?

1. Yes	2. No	CBSVSEXMAT
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7.4 Did the CBSV have the same ethnicity as you?..

1. Yes	2. No	8.NK	CBSVETHNIC
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7.5 If 7.4= "2, No" : Did it matter to you that the CBSV had a different ethnicity?.....

1. Yes	2. No	9. NA: CBSV same ethnicity	CBSVETHMAT
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7.6 IF 7.5= "1, Yes", can you explain why? [WRITE IN CAPITALS] :

CBSVETHWHY

7.7 If you become pregnant again, would you like the CBSV to come and visit you again

1. Yes	2. No	8. NK	CBSVFUTURE
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7.8 Would you recommend the CBSV visits to other women in the community?

1. Yes	2. No	8. NK	CBSVRECOM
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8 IF FAMILY CARD WAS PRESENTED EARLIER EXPLAIN THAT YOU WOULD NOW LIKE TO COPY INFORMATION FROM THE CARD

OTHERWISE DRAW DOUBLE LINE THROUGH SECTION 8 AND GO TO SECTION 9

8.1 CBSV Name: (WRITE "BLANK" IF NAME NOT FILLED) _____

8.1.1 CBSV ID [TO BE ENTERED BY NEWHINTS TEAM]

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CBSVID

COPY FROM APPOINTMENTS TABLE ON "NEWHINTS FAMILY CARD"

USE "77 77 77" IF "DAY OF DELIVERY" IS WRITTEN

USE "99 99 99" IF DATES LEFT BLANK

8.2 Date of next visit

Date of next visit :1

Date of next visit :2

Date of next visit :3

Date of next visit :4

Date of next visit :5

Date of next visit :6

Date of next visit :7

Date of next visit :8

Date of next visit :9

CARDVIS1

CARDVIS2

CARDVIS3

CARDVIS4

CARDVIS5

CARDVIS6

CARDVIS7

CARDVIS8

CARDVIS9

8.3 Date of delivery:

CARDATEDEL

8.4 First visit after delivery on (circle)

1. Day of delivery	2. 1 day after delivery	3. 2 or more days after delivery	9. Not Filled
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CARDELVIS1

8.5 BIRTH WEIGHT: COPY INFO FROM CARD. IF COLOUR IS LEFT BLANK USE "9", NOT FILLED" IF WEIGHT IS LEFT BLANK, USE "9.9"

circle box for colour code

8.5.1 Baby 1

1. R	2. Y	3. G	9, Not Filled
------	------	------	---------------

Weight in kg

	.		Kg
--	---	--	----

WEIGHTCOL1
WEIGHTKG1

8.5.2 Baby 2

1. R	2. Y	3. G	9, Not Filled
------	------	------	---------------

Weight in kg

	.		Kg
--	---	--	----

WEIGHTCOL2
WEIGHTKG2

8.5.3 Baby 3

1. R	2. Y	3. G	9, Not Filled
------	------	------	---------------

Weight in kg

	.		Kg
--	---	--	----

WEIGHTCOL3
WEIGHTKG3

IF "REFERRALS" SECTION ON FAMILY CARD IS LEFT COMPLETELY BLANK: DRAW DOUBLE LINE ACROSS 8.6 AND 8.7

8.6 DATE REFERRED : COPY INFO FROM CARD. USE "99 99 99" IF LEFT BLANK

8.6.1 Date referred :

CARDATREF1

8.6.2 Date referred :

CARDATREF2

8.6.3 Date referred :

CARDATREF3

8.7 REASON REFERRED : COPY INFO FROM CARD. USE "9, NA or Not Filled" IF LEFT BLANK

8.7.1	Reason referred :	1. Very small	2. Sick	9. NA, or Not Filled	CARWHYREF1
8.7.2	Reason referred :	1. Very small	2. Sick	9. NA, or Not Filled	CARWHYREF2
8.7.3	Reason referred :	1. Very small	2. Sick	9. NA, or Not Filled	CARWHYREF3

9 IF REFERRAL SLIP WAS PRESENTED EARLIER , EXPLAIN THAT YOU WOULD NOW LIKE TO COPY INFORMATION FROM THE REFERRAL SLIP OTHERWISE DRAW DOUBLE LINE THROUGH SECTION 9, THANK THE MOTHER, END INTERVIEW

COPY FROM REFERRAL SLIP:

9.1	Age of baby (in days)							REFSLPAGE
9.2	Date referred :							REFSLPDATE
9.3	Seen at facility by	1. Filled		2. Not filled				REFSEENFAC
9.4	Date (seen)							REFSEENDTE

THANK THE MOTHER. TO END THE INTERVIEW EPLAIN THE FOLLOWING:

IN CASE THE BABY IS YOUNGER THAN 29 DAYS ON DAY OF VISIT (TODAY):

**EXPLAIN THAT WE WILL VISIT THE FAMILY AGAIN IN 8 WEEKS TIME
INDICATE THE DATE OF THAT VISIT**

IN CASE THE BABY IS OLDER THAN 28 DAYS ON DAY OF VISIT (TODAY):

**YOU MAY BE VISITED AGAIN WHEN THE BABY IS OLDER THAN 6
MONTHS OF AGE.**

**THANK THE MOTHER AND FAMILY FOR ALL THEIR HELP IN CONDUCTING
THIS WORK**

2.8. What is your religion?

1. Catholic	2. Protestant	3. Pentecostal	4. Muslim	5. Traditional African	6. Other:	RELIGION
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2.9. What ethnic group do you belong to?

11. Akan: e.g. Bono, Ashanti, Fanti.etc.	12. Bimoda, Chokosi	13. Dagarti, Frafra, Kusasi	14. Fulani	ETHNIC
15. Ga, Adangbe, Ewe	16. Gonja, Dagomba, Mamprusi	17. Konkomba, Basare	18. Mo	
19. Sisala, Wala	20. Zambraba	21. Banda/Pantra	22. Other:	

2.10. Do you own any land?.....

1. Yes	2. No	WOWNLAND
--------	-------	----------

2.11. Do you have land on which you farm?

1. Yes, my own	2. Yes, part of family land	3. Yes part of husband's	4. Yes, rented land	5. No	OWNLAND
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2.12. What do you grow (on your land)?

1. Food items, mainly for home consumption	2. Food items, mainly for sale on the market	3. Cash crops: tobacco, cashew, cocoa, etc.	9. NA, no farm	CROPS
--	--	---	----------------	-------

2.13. Do you have a regular cash income/are you a salaried worker?

1. Yes, professional – teacher, nurse, accounts, administrative	2. Yes, clerical/secretarial	3. Yes, seamstress, hairdresser etc.	SALARY
4. Yes, trader/food seller	5. Yes, labourer/domestic worker/farmer	6. Other:	7. No

SAY NOW YOU ARE GOING TO ASK ABOUT THE 'HOUSEHOLD' AND EXPLAIN WHAT A HOUSEHOLD IS

2.14. Who is the household head?

1. You	2. Your husband	3. Your father	4. Your mother	5. Other:	8. NK	HOUSEHEAD
--------	-----------------	----------------	----------------	-----------	-------	-----------

2.15. In what year was the household head born? [1908 = NK].....

1	9			HHYOB
---	---	--	--	-------

2.16. How old is the household head now (in years)? [88 = NK].....

		HHAGE
--	--	-------

2.17. What was the household head's highest educational level reached?

1. None	2. Primary school	3. Middle, continuation school, JSS	4. Technical, commercial, SSS, Secondary school	HHMEDLEV
5. Post-middle college, teacher training, secretarial	6. Post secondary, nursing, teacher, polytechnic	7. University	8. Not known	

2.18. What was the number of years that the household head completed at the highest level reached? [88 = NK, 00 = no education].....

		HHNUMYRS
--	--	----------

2.19. Does the household head have a regular cash income or salaried job?

1. Professional – teacher, nurse, accounts, administrator etc.	2. Clerical / secretarial	3. Trader / businessman / driver with own car etc.	4. Employed tradesman, driver without own car, builder, etc.	HHSALARY
5. Farmer/labourer/domestic worker	6. Other:	7. No	8. NK	

2.20. Do members of the household do any farming?.....

1. Yes	2. No	HHFARMING
--------	-------	-----------

2.21. Does anyone in the household own any land?.....

1. Yes	2. No	HHOWNLAND
--------	-------	-----------

2.22. Does anyone in the household own their own farm?.....

1. Yes	2. No
--------	-------

 HHOWNFARM

2.23. What do they grow?

1. Food items, mainly for home consumption	2. Food items, mainly for sale on the market	3. Cash crops – tobacco, cashew, cocoa, etc.	9. NA, no farm	HHCROP
--	--	--	----------------	--------

2.24. Does anyone in the household own:

Chickens or ducks?.....		1. Yes	2. No	CHICKEN
Sheep or goats?.....		1. Yes	2. No	SHEEP
Other animals?.....		1. Yes	2. No	OTHANIM
Table?.....		1. Yes	2. No	TABLE
Sleeping mattress?.....		1. Yes	2. No	MATTRESS
Cupboard, wardrobe, room divider?.....		1. Yes	2. No	DIVIDER
Mosquito net?.....		1. Yes	2. No	MOSNET
Sewing machine?.....		1. Yes	2. No	MACHINE
Bicycle?.....		1. Yes	2. No	BICYCLE
Radio?.....		1. Yes	2. No	RADIO
TV?.....		1. Yes	2. No	TV
Gas or electric cooker?.....		1. Yes	2. No	COOKER
Fridge or freezer?.....		1. Yes	2. No	FRIDGE
Motorcycle?.....		1. Yes	2. No	MOTORCYCLE
Car?.....		1. Yes	2. No	CAR

2.25. Does your household have electricity?.....

1. Yes	2. No
--------	-------

 ELECTRIC

2.26. What is the main source of drinking water for members of your household?

11. Piped into dwelling/yard/plot	12. Public tap	13. Handpump / closed bore hole	14. Closed well	15. Open well	WATER
16. Stream / river	17. Lake / dam /pond	18. Water trucks	19. Rain water	20. Other	

2.27. How long does it take for you to go there, get water and come back?

1. Less than 15 minutes	2. 15 minutes- less than 30 minutes	3. 30 minutes – less than 60 minutes		REACH
4. 60 minutes or more	9. NA / drinking water source is in compound			

2.28. What kind of toilet facility does your household have?

1. Flush latrine / WC	2. Ventilated improved pit /VIP /KVIP	3. Other pit latrine	4. Open fields	DEFAEC
5. Defaecate in house, faeces transferred elsewhere / bucket latrine		6. Other:		

2.29. What are the total number of rooms in the household used for sleeping? 88 = NK.....

--	--

 ROOMS

2.30. What are the total number of people that slept in the household last night? 88 = NK.....

--	--

 RESIDENT

2.31. Do you own or rent the house you live in, or do you have another type of arrangement, such as "perching"?

1. Sole Ownership	2. Joint Ownership	3. Renting	4. Family/relation's house	OWNHOUSE
5. House provided rent free	6. Perching	7. Other:	8. NK	

MATERIALS USED IN THE CONSTRUCTION OF THE HOUSE [OBSERVE]

2.32. Floor of sleeping room	1. Cement	2. Mud/clay	3. Other:	8. NK	FLOOR
2.33. Roofing	1. Metal/asbestos	2. Thatch/mud	3. Other:		ROOF
2.34. Wall	1. Cement	2. Mud	3. Other:		WALL

2.35. Does the household have a separate room with a roof just for cooking?

1. Yes	2. No	8. NK
--------	-------	-------

 KITCHEN

2.36. Does the household have a separate sleeping room for children?

1. Yes	2. No	8. NK
--------	-------	-------

 SHARERM

2.37. Does the household have a domestic worker not related to the household head?

1. Yes	2. No	8. NK
--------	-------	-------

 DOMESTIC

3. FERTILITY AND OBSTETRIC HISTORY

Now, I would like to ask you some questions about any pregnancies and children that you have had.

3.1 How many male children of your own are living with you right now? [00 = NONE].....

--	--

 BOYALIV1

3.2 How many male children of your own are living elsewhere? [00 = NONE].....

--	--

 BOYALIV2

3.3 How many female children of your own are living with you right now? [00 = NONE].....

--	--

 GIRLALIV1

3.4 How many female children of your own are living elsewhere? [00 = NONE].....

--	--

 GIRLALIV2

3.5 Do you have any children who were born alive but died later? How many? [0 = NONE].....

--

 DEADCHN

3.6. Have you ever lost a pregnancy? How many? [0 = NONE]

--

 ABORT

3.7. Have you ever had a stillbirth? How many? [0 = NONE].....

--

 STILLBIRTH

3.8. Have you ever had an ectopic pregnancy? How many? [0 = NONE]...

--

 ECTOPIC

3.9. CALCULATE THE TOTAL NUMBER OF PREGNANCIES SHE HAS HAD, THAT IS THE SUM FOR 3.1 – 3.8 [DO NOT INCLUDE THE CURRENT PREGNANCY].....

--	--

CHECK THIS NUMBER WITH HER AS FOLLOWS:

3.9.1. I would like to check with you the total number of pregnancies you have had. From what you have told me, you have had a total of [SUM] pregnancies. Is this correct?

1. Yes	2. No
--------	-------

 CORRECT

IF THE ANSWER IS NO, REPEAT QUESTIONS 3.1 TO 3.8 UNTIL YOU HAVE AGREEMENT. NOTE THAT THIS NUMBER SHOULD NOT INCLUDE THE CURRENT PREGNANCY IF SHE IS PREGNANT. NOTE ALSO THAT IN OUR DEFINITION TWINS COUNT AS TWO PREGNANCIES AND TRIPLETS AS THREE.

3.10. Have you ever had a Caesarean Section?.....

1. Yes	2. No
--------	-------

 CS

3.11. Have you ever had a delivery where the baby had to be pulled out with an instrument?

1. Yes	2. No
--------	-------

 VACUUM

3.12. DATE OF BIRTH OF LAST CHILD [THE ONE BEFORE THIS PREGNANCY OR THE ONE BEFORE THE CHILD JUST BORN; 080808 = Not known; 090909 = No child].....

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 DOBCHILD

3.13. Where did you deliver your last child?
[USE FACILITY KEY CODE; 99 = NA, No child or delivered at home]

--	--

 WHEREDEL

4. HEALTH HISTORY: Now I would like to ask some questions about your health

4.1. How would you describe your state of health in general?....

1. Excellent	2. Good,	3. Poor
--------------	----------	---------

 HEALTHY

4.2. Have you been admitted to hospital for more than 2 days in the past 12 months?

1. Yes, for illness during pregnancy	2. Yes, for other illness	3. Yes, for accident/injury	4. No
--------------------------------------	---------------------------	-----------------------------	-------

 ADMIT

4.3. Has a doctor ever told you if you have any of the following illnesses?

Heart disease or hypertension?.....	1. Yes	2 No	8. NK	HEARTDIS
Varicose veins?.....	1. Yes	2 No	8. NK	VEINS
Kidney disease?.....	1. Yes	2 No	8. NK	KIDNEY
Asthma?.....	1. Yes	2 No	8. NK	ASTHMA
TB?.....	1. Yes	2 No	8. NK	TB
Epilepsy?.....	1. Yes	2 No	8. NK	EPILEPSY
Diabetes?.....	1. Yes	2 No	8. NK	DIABETES
Jaundice or hepatitis.....	1. Yes	2 No	8. NK	JAUNDICE
Any other serious illness:	1. Yes	2 No	8. NK	OTHILL

4.4. Do you currently REGULARLY take any medicines for an illness or health condition?

1. Yes	2. No	8. NK
--------	-------	-------

 MEDICINE

4.5. Have you ever had any surgical operation on your womb?

1. Yes, C-section	2. Yes, fibroid	3. Yes, D&C	4. Yes, other:	5. No
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 WOMBOPS

4.6. Have you ever had any other surgical operation?

1. Yes (SPECIFY):	2. No
-------------------	-------

 OTHOPS

END OF PROFILE FORM. CHECK YOUR FORM AND THANK THE RESPONDENT

COMPLETE THIS FORM FOR ANY PREGNANCY ENDING AT SIX OR MORE MONTHS WHETHER SHE HAD A LIVE BIRTH OR STILLBIRTH.

6. BACKGROUND and ID:

1.3 Cluster code:					CLUSTER
1.2 Woman's ID :					WOMANID
1.6 Woman's name:					
6.5 Date of visit:					DATEVISIT
6.6 Staff code:					FW

2. END OF PREGNANCY

2.1 Date of delivery:.....						DATDELIV
2.2 How many babies did you have?						NUMBABY
2.3 Did this pregnancy end early, on time, or late?	1. Early	2. On time	3. Late	8. NK		PREMBAB
2.4 How many months pregnant were you with this child/children? (88 = NK).....						GESTATE

3. DURING PREGNANCY

3.1 How many times did you receive antenatal care from a doctor or nurse during pregnancy? [00 = NONE] [ASK TO SEE ANTENATAL CARE RECORD, EXCLUDE ILLNESS]					ANC
3.2 How many tetanus toxoid immunisations did you receive during pregnancy? [00 = NONE, 88 = NK, ASK TO SEE ANY MEDICAL RECORDS, YELLOW CARD]...					TETTOXD
3.3 How many tetanus toxoid immunisations had you ever received before this pregnancy? [00 = NONE, 88 = NK, ASK TO SEE ANY MEDICAL RECORDS, YELLOW CARD]					TETTOXB
3.4 WAS HAEMOGLOBIN< 10 EVER RECORDED DURING HER ANC ATTENDANCE? [CHECK FROM HER CARD; 8 = NO CARD]	1. Yes	2. No	8. NK		HAEMOG
3.5 During pregnancy did you sleep under a bed net?	1. Never	2. Sometimes	3. Always	8. NK	BEDNET
3.6 Did a doctor or a nurse ever say you had malaria during pregnancy?.....	1. Yes	2. No	8. NK		MALARIA
3.7 Are you currently registered with the new district mutual health insurance scheme?	1. Yes	2. No	8. NK		HEALTHINS

3.8 Is your baby/babies registered with the new health insurance scheme?

1. Yes	2. No	8. NK	9. NA, stillbirth
--------	-------	-------	-------------------

BABYINS

Have you had any visits from a CBSV?

3.9 During pregnancy?	0. No (No visits)	1. Yes (1 visit)	2. Yes (2 visits)	3. Yes (3 or more visits)	8. NK	CBSVPREG
3.10 Since delivery?	0. No (No visits)	1. Yes (1 visit)	2. Yes (2 visits)	3. Yes (3 or more visits)	8. NK	CBSVPP

4. LABOUR AND DELIVERY: Now I would like to ask you some questions about the labour and delivery.

4.1 Did you deliver in a health facility, on the way, or at home?

1. Clinic/hospital/ Private maternity home	2. At home	3. At the TBA's	4. On the way to the clinic/ hospital/ maternity home
5. On the way to the TBA's	6. Multiple births at different places, specify:...		7. Other (specify):

PLACEDELIV

Was the decision to go to the health facility [ASK IF ANSWER TO Q4.1="1" or "4", OTHERWISE CIRCLE "9. NA"]

4.2 Planned during pregnancy?	1. Yes	2. No	9. NA, did not deliver in a facility or on the way to one	PLANNEDHF
4.3 Taken because problems occurred in labour/delivery?	1. Yes	2. No	9. NA, did not deliver in a facility or on the way to one	EMERGENCY

4.4 Did the waters break before labour or during labour?

1. Before labour started	2. During labour or delivery	8. Don't know
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WATERBRK

4.5 How much time before you started labour did the waters break?

[ASK IF ANSWER TO Q4.4="1" or OTHERWISE CIRCLE "9. NA"]

1. Less than 4 hours	2. 4 to 23 hours	3. 24 hours or more	8. Don't know	9. NA, broke during labour
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TIMEBRK

4.6 Did the person assisting with delivery wash their hands before or during the delivery?

1. Yes, with soap	2. Yes, with water only	3. No	8. NK	9. NA, nobody assisted with delivery
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WASHHANDS

4.7 On what surface did you deliver? **PROMPT**

1. Indoors, uncovered floor	2. Indoors, floor covered with plastic sheet/mat/cloths/rags	3. Outdoors, inside of the compound
4. Outdoor outside of the compound	5. Other (specify)	8. NK

DELSURF

4.8 Did you have a Caesarean Section

1. Yes	2. No	8. NK
--------	-------	-------

CS

4.9 Did you know you were going to have a CS before you went into labour?

1. Yes	2. No	9. NA, no CS
--------	-------	-----------------

KNOWCS

Now, I would like to ask about **SERIOUS** problems you may have experienced during labour or soon after delivery.

Did you experience:

- 4.10 Surgery to repair or remove the womb?
- 4.11 Tear in the vagina
- 4.12 Heavy bleeding from vagina during labour, delivery or after delivery?
- 4.13 Convulsions during labour, delivery or after delivery?
- 4.14 Loss of consciousness during labour, delivery or after delivery?
- 4.15 Did somebody have to remove the placenta from inside the uterus?
- 4.16 Were you given an IV drip?
- 4.17 Were you given a blood transfusion?
- 4.18 The umbilical cord coming out before the baby?
- 4.19 Dark green fluid in the birth fluids?

1. Yes	2. No	8. NK	SURGERY
1. Yes	2. No	8. NK	VAGTEAR
1. Yes	2. No	8. NK	DBLEED
1. Yes	2. No	8. NK	DCONVUL
1. Yes	2. No	8. NK	LOSSCONC
1. Yes	2. No	8. NK	RETPLAC
1. Yes	2. No	8. NK	IVDRIP
1. Yes	2. No	8. NK	BLOODTR
1. Yes	2. No	8. NK	PROLAPSE
1. Yes	2. No	8. NK	MECONIUM

5. PROBLEMS SINCE THE BIRTH: Now I'd like to ask about problems you may have experienced since the birth.

Have you experienced any of the following?

- 5.1 Large clots and heavy bleeding from the vagina
- 5.2 Offensive or foul smelling vaginal discharge
- 5.3 Hot body
- 5.4 Leaking urine or faeces
- 5.5 Breast infection: swollen, painful, "pompo", discharge, etc.
- 5.6 Any other serious problem I have not mentioned [SPECIFY]

1. Yes	2. No	8. NK	PPCLOT
1. Yes	2. No	8. NK	PPDISCHARG
1. Yes	2. No	8. NK	PPFEVER
1. Yes	2. No	8. NK	PPLEAK
1. Yes	2. No	8. NK	PPMASTITIS
1. Yes	2. No	8. NK	PPOTHPROB

SAY THAT YOU WILL NOW LIKE TO ASK SOME QUESTIONS ABOUT THE BABY (BABIES).

6. FIRST BABY

C	1
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CHILD1ID

6.1 Where was this baby born?

1. Clinic/hospital	2. Private maternity home	3. At home/TBA	4. On the way to the clinic/hospital /TBA
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B1PLACEBIR

6.2 IF THE ANSWER TO 6.1 IS 1 OR 2, STATE WHERE. [USE CODE FROM FACILITY KEY]

--	--

B1HOSPITAL

6.3 Was this baby born via a normal delivery through the vagina?

1. Normally, through the vagina	2. Baby was pulled with an instrument	3. By caesarean section	4. Other. Specify.
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B1TYPDELIV

6.4 Who delivered this baby?

1. Doctor	2. Midwife	3. TBA	4. Other person/relative	5. Delivered myself	8. Don't know	B1WHODELIV
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6.5 Was the baby born alive ie. did it cry or move or breathe after birth?

1. Yes	2. No	B1ALIVE
--------	-------	---------

6.6 Is the baby still alive?

1. Yes	2. No, died within an hour of birth	3. No, died first day	4. No, died after 1 day	9. NA, stillbirth	B1STATUS
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6.7 If the baby died, how many days old was it when it died? (99= Still alive OR Stillbirth)

		B1AGEDIED
--	--	-----------

6.8 Is/was the baby a male or female?.....

1. Male	2. Female	8. NK	B1SEX
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6.9 Which part of the baby came out first?

1. Head	2. Feet/bottom	4. Hand/arm	5. Other . SPECIFY	8. NK	B1POSN
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6.10 Does the baby have any congenital abnormality?
[EXAMINE AND SPECIFY]:

1. Yes	2. No	8. NK	9. NA, baby dead	B1ANOMALY
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6.11 How big was the baby when he/she was born?
[PROMPT]

1. Very tiny	2. Smaller than average	3. Average size	B1SIZE
4. Larger than most babies	5. Very big baby	8. Don't know	

ASK TO SEE ANY HEALTH OR FAMILY CARDS FOR THE BABY.

6.12 Weighing Card/Discharge Slip

1. Seen	2. Not seen	B1HLTHCARD
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6.13 Family Card

1. Seen	2. Not seen	B1FAMCARD
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RECORD BIRTHWEIGHTS FROM CARDS (IN KILOGRAMS; 888 = NO RECORD)

6.14 FROM HEALTH CARD/DISCHARGE SLIP:

	•			B1BIRTHWT
	•			B1BIRWTFC

FROM FAMILY CARD:

6.15 BIRTHWEIGHT

6.16 COLOUR CODING OF WEIGHT

1. Red (<1.5Kg)	2. Yellow (1.5-2.49Kg)	3. Green (2.5+Kg)	9. NA, No card	B1LBWCODE
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IF RESPONSE TO Q6.6 IS "9" (STILL BIRTH) OR "2" (BABY DIED WITHIN AN HOUR OF BIRTH) PLEASE DRAW A DOUBLE LINE THROUGH THE REST OF THE QUESTIONS FOR THIS BABY, AND GO TO SECTION 7.

6.17 What was used to cut the umbilical cord?

1. Clinic/hospital instrument (scissors, razorblade, knife, etc)	2. New razorblade/knife (not from clinic/hospital)	B1CORDCUT
3. Old razorblade/knife (not from clinic/hospital)	4. Other: 8. NK	

6.18 What was used to tie the cord?

1. New thread	2. Used thread	3. Other:	8. NK	B1TIECORD
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6.19 Since birth, what has been applied to the baby's umbilical cord stump?

1. Nothing. Left it alone	2. Hospital clinic medicine	3. Shea butter	4. Leaves or herbs	5. Palm oil	B1CORDMED
6. Ground nut oil	7. Other:			8. NK	

6.20 Was the baby dried after delivery?

1. Yes, Before cord tied	2. Yes, After cord tied, Before placenta delivered	3. Yes, After placenta delivered	4. No, Not dried after birth	8. NK	B1DRIED
1. Yes, Before cord tied	2. Yes, After cord tied, Before placenta delivered	3. Yes, After placenta delivered	4. No, Not wrapped	8. NK	

6.21 Was the baby wrapped after delivery?

6.22 How soon after birth was the baby first put to the mother's breast?

1. Immediately	2. Within an hour of birth	3. After 1 hour but within first 12 hours	4. Between 12 & 24 hours	B1BFSTART
5. Day 2	6. Day 3	7. Day 4 or after	8. NK	

6.23 IF Q6.22 WAS "1", "2" OR "3" CIRCLE "99/NA", OTHERWISE ASK:

Why was the baby not put to the mother's breast in the first 12 hours after birth?

11. Mother ill / weak	12. Child ill / weak	13. Child died	B1DAYIREAS
14. Nipple / breast problem	15. Not enough milk	16. Mother working	
17. Child refused	19. Did not want to give colostrum	20. Mother died	
18. Other	99. NA, mother did breastfeed baby in first 12hrs		

In the first 24 hours after birth, Was the baby offered anything else: [PROMPT]:

- 6.24 Breastmilk from another woman?

1. Yes	2. No	8. NK
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 B1DAYWET
- 6.25 Other milk [PROMPT for: cow's milk, tinned milk, infant formula, Lactogen, SMA]?

1. Yes	2. No	8. NK
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 B1DAYOTH
- 6.26 Other fluids [PROMPT for: water, tea, traditional medicines]?

1. Yes	2. No	8. NK
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 B1DAYFLUID
- 6.27 Any foods [PROMPT for: any solid foods, gruels, porridge, bread, rice, cerelac, nutrimix]?

1. Yes	2. No	8. NK
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 B1DAYSOLID
- 6.28 Did you give colostrum to this baby?.....

1. Yes	2. No	8. NK
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 B1COLOSTRU
- 6.29 How soon after delivery was the baby bathed?
- | | | | | | |
|---------------------|--------------|---|-------------------|-------|------------|
| 1. Less than 1 hour | 2. 1-6 hours | 3. after 6 hours but less than 24 hours | 4. after 24 hours | 8. NK | B1FIRSBATH |
|---------------------|--------------|---|-------------------|-------|------------|
- 6.30 Was the water heated?

1. Yes	2. No	8. NK
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 B1HOTWATER
- 6.31 Was the baby well in the first 24 hours after birth?.....

1. Yes	2. No	8. NK
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 B1DAYWELL

6.32 Have you heard of SKIN-to-SKIN Contact between the mother and her baby as a way to take care of the new baby?	1. Yes	2. No	8. NK	B1HEARDSSC
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6.33 A. Was the baby placed in SKIN-to-SKIN contact in the first 24 hours after delivery?

1. Not at all	2. A little (up to 2 hours total)	3. Moderate amount (between 2 to 5 hours total)	4. A lot (more than 5 but less than 12 hours)	5. Most of the time (day & night, more than 12 hours)
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B1SKTOSKIN

**6.33 B. IF Q6.33 A, was "1. Not at all" then circle "9/NA". IF Q6.33 A. was "2", "3", "4" or "5" then ask:
How soon after delivery was the baby placed SKIN-to-SKIN for the first time?.**

1. Before the cord tied	2. After the cord tied, before the placenta delivered	3. After the placenta delivered, within the first hour after birth.	4. After one hour after delivery	8. NK	9. NA, baby was not put SKIN-to- SKIN at all.
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B1IMMSKIN

IF BABY HAS DIED PLEASE DRAW A DOUBLE LINE THROUGH THE REST OF THE QUESTIONS FOR THIS BABY, AND GO TO SECTION 7.

SAY THAT YOU WILL NOW ASK SOME QUESTIONS ABOUT THE LAST 24 HOURS

6.34 How many times did you bath your baby during the day yesterday? 88= NK

B1BATHE

6.35 How many times did you breastfeed your baby during the day yesterday? 88= NK

B1BFDAY

6.36 How many times did you breastfeed your baby during the night? 88= NK

B1BFNIGHT

6.37 Did the baby sleep under a bednet last night?

1. Yes	2. No	8. NK
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B1BEDNET

In the last 24 hours, was the baby offered anything else: [PROMPT]:

6.38 Breastmilk from another woman?

1. Yes	2. No	8. NK
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B1CURRWET

6.39 Other milk [PROMPT for: cow's milk, tinned milk, infant formula, Lactogen, SMA]?

1. Yes	2. No	8. NK
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B1CURROTH

6.40 Other fluids [PROMPT for: water, tea, traditional medicines]?

1. Yes	2. No	8. NK
--------	-------	-------

B1CURFLUID

6.41 Any foods [PROMPT for: any solid foods, gruels, porridge, bread, rice, cerelac, nutrimix]?

1. Yes	2. No	8. NK
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B1CURSOLID

SAY THAT YOU WILL NOW ASK SOME QUESTIONS ABOUT WHETHER THE BABY HAS BEEN WELL

6.42 Since birth, has the baby had any illness that you thought was serious or severe

1. Yes	2 No
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B1ILLNESS

IF ANSWER IS NO, DRAW A DOUBLE LINE THROUGH THE REST OF THE SECTION, AND GO TO SECTION 7.

What illness/illnesses did the baby have?

6.43 Weak, abnormal crying, or no crying

1. Yes	2. No	8. NK	9. NA
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B1ABNCRY

6.44 Unresponsive/Lethargic

1. Yes	2. No	8. NK	9. NA
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B1UNRESP

6.45 Too weak to feed or stopped feeding

1. Yes	2. No	8. NK	9. NA
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B1WEAK

6.46 Difficulty breathing

1. Yes	2. No	8. NK	9. NA
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B1DIFFBR

6.47	Fast breathing	1. Yes	2. No	8. NK	9. NA	BIFASTBR
6.48	Very hot body	1. Yes	2. No	8. NK	9. NA	BIHOTBODY
6.49	Very cold body	1. Yes	2. No	8. NK	9. NA	BICOLDBODY
6.50	Convulsions/shocks	1. Yes	2. No	8. NK	9. NA	BICONVULS
6.51	Jaundice	1. Yes	2. No	8. NK	9. NA	BIJAUNDICE
6.52	Vomits all feeds	1. Yes	2. No	8. NK	9. NA	BIVOMIT
6.53	Asram	1. Yes	2. No	8. NK	9. NA	BIASRAM
6.54	Puni	1. Yes	2. No	8. NK	9. NA	BIPUNI
6.55	Other serious illness, please specify:	1. Yes	2. No	8. NK	9. NA	B1OTHERILL

6.56 Was care sought outside the home for this illness/illnesses?

1. Yes	2 No	8. NK	9.NA	B1CARESEE
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Who was consulted?

6.57 Traditional healer?

1. Yes	2. No	8. NK	9.NA	B1TRADHEAL
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6.58 Druggist?

1. Yes	2 No	8. NK	9.NA	B1DRUGGIST
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6.59 CBSV?

1. Yes	2 No	8. NK	9.NA	B1CBSVCARE
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6.60 Doctor/nurse at a clinic?

1. Yes	2 No	8. NK	9.NA	B1CLINCARE
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6.61 Doctor/nurse at a hospital?

1. Yes	2 No	8. NK	9.NA	B1HOSPCARE
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6.62 Was he/she admitted to the hospital?.....

1. Yes	2. No	9. NA	B1ADMITTED
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6.63 Where was he/she admitted? [ENTER CODE FROM FACILITY KEY]
["88"=Not known, "99"=Not applicable]

		B1PLADM
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Did anyone advise you to take the baby to the clinic or hospital during this illness/ illnesses?

6.64 Family member?

1. Yes	2 No	8. NK	9.NA	B1FAMREFER
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6.65 Traditional healer?

1. Yes	2. No	8. NK	9.NA	B1THREFER
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6.66 Druggist?

1. Yes	2 No	8. NK	9.NA	B1DRGREFER
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6.67 CBSV?

1. Yes	2 No	8. NK	9.NA	B1CBSVREF
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6.68 TBA?

1. Yes	2 No	8. NK	9.NA	B1TBAREFER
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IF ONLY ONE BABY END FORM HERE, DRAW A DOUBLE LINE THROUGH THE REST OF THE FORM, THANK THE RESPONDENT, AND CHECK YOUR FORM.

Rest of form to be completed for any SECOND or THIRD baby is not reproduced here.

END OF BIRTH FORM. THANK THE RESPONDENT AND CHECK YOUR FORM.