A Randomised Community Interventional Control Pilot Study Demonstrating the Potential to Save Newborn lives in Zambia

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ABSTRACT

Background: Newborn care is an emerging priority in children’s health. A pilot community based, continuum of mother-neonatal care was delivered by trained rural community health workers and traditional birth attendants. They provided appropriate care to the mother. They also instituted early breast feeding, kept the infant warm, cared for birth asphyxia, sepsis and postnatal care, up to 28 days of life. Methods: A baseline knowledge attitude and practice survey (KAP) and Randomised Control Trial (RCT) were conducted sequentially, 2007 to 2013. The KAP provided baseline information. The RCT recruited 3846 pregnant women in Mpongwe and Chongwe, following them to postnatal care. Training was conducted for all community based agents in control and intervention sites. Intervention agents were equipped, supervised, and retrained every four months. Control sites provided MOH standard care. 2000 infants were delivered in the year of follow up. Findings: An algorithm to prioritise interventions was designed. CBAs implemented the COC and were able to save 20 per 1000 newborns, or 58.8 % of all newborns who should have died without the interventions. They identified danger signs, implemented specific care and reduce morbidity, while saving lives, of mothers and babies. Interpretation: Trained, equipped and supervised CBAs, are capable of saving infant’s life. 58.8 % newborns were saved by implementing a continuum of care. Our Government adopted these results for the Newborn Framework in 2013. Our work thus informs the newborn agenda and policy on rural maternal newborn care.

Keywords: Cluster Randomised Trial, community based care for newborn babies, Zambia
1. INTRODUCTION

Newborn health deserves its newfound recognition in developing countries. The Lancet series on Neonatal Survival, reported that almost 4 million babies died annually during the first 28 days of life, with an estimated 99% deaths occurring in the world’s most poverty stricken populations of Africa and Asia. The rural and remote areas of Zambia are the hardest hit by the dwindling numbers of health care providers and have the highest neonatal mortality rates. The newborn experiences the multiple burden of social-economic, cultural and poor health care provision including the devastating burden of HIV and AIDS. There is need therefore, for global, national and local communities to commit to reduce neonatal illnesses and deaths and to improve their survival.

More disconcerting is that 2.8 million lives could be saved each year if simple interventions were implemented. That 70% of these deaths could be averted with readily available low tech and low cost in at adequate coverages.(6,7,8).

Globally thirty six - thirty eight percent (36-38%) of all childhood deaths occur in the neonatal period. Additionally, a substantial proportion of these neonatal deaths occur in the first week with the highest risk of death soon after birth(6,7,8) and 25-45% occur within the first 24 hours of birth. The commonest causes’ of death include: birth asphyxia (23%), severe infections, including sepsis or pneumonia (25%). Prematurity and Low Birth Weight (LBW) (31%) alone account for almost 80% of all neonatal deaths. Other leading causes include tetanus (3%), diarrhoea (3%), congenital abnormalities (7%) and other causes (9%). Neonatal deaths worldwide are double that of HIV/AIDS. The Lancet article urges that adequate resources be invested into proven, low-tech and low-cost interventions designed to address the needs of the newborn(8).

Progressive works by Bang et al in Gadchiroli, Maharashtra State in India, provided among the earliest evidence that reduction in neonatal mortality is achievable. There is paucity of studies in Africa and our work contributes to the body of growing knowledge in the continuum of care from pregnancy to newborn and early infancy(6). Sixty three percent (63%) of all deliveries in developing countries take place at home and usually in suboptimal conditions(15) in limited care from few trained health personnel(9). For this reason neonatal mortality remains difficult to monitor and prevent as most neonatal deaths are unseen and undocumented. Worse still is the fact that most parents are unwilling to take neonates to hospitals; neonates are therefore confined in the house at a critical time when they need medical attention most(15).

The aim of the study was to pilot a community based continuum of neonatal care package, delivered by trained rural community health workers and traditional birth attendants in order to determine whether outcomes in morbidity and mortality in the newborn will improve by identifying pregnant women and tracking them to delivery and 28 days of the newborn period. Specifically we wished to determine the impact of the interventions on the neonatal morbidity and mortality rates in control and intervention sites.

2. METHODS

Definitions used in this study

Community Based Agents(CBAs): community volunteers, selected by the community, to function as traditional birth attendants (all female) or community health workers (often male) recommended to the Neighborhood Health Committee, trained and equipped to provide healthcare within the community and in homes and reporting to the nearest health centre.

Community Health Worker(CHW): Can be male or female and in our study there were more male volunteers, selected by the community, trained and equipped to provide appropriate health interventions to the community in which he or she lives.

Traditional Birth Attendant(TBA): Usually female volunteer, selected by the community, trained and equipped to attend to deliveries and provide perinatal care to the mother, within the community in which she lives.
Figure 1: Conceptual Framework and Flow of the Community Based Newborn Care Study

Two districts selected, each district was randomly assigned control and intervention sites, with mapping of NHC

KAP Baseline

Measure
- Outcomes: glossary, health seeking behavior & algorithm of priorities
- Inform RCT on feasibility & priority interventions

Train TBAs and CHW

Recruited and tracked pregnant women with usual referral for ANC, PMTCT birth and PNC

Identified and Referred to health center:
- Birth Asphyxia
- Neonatal sepsis
- Hypothermia & Hypoglycemia
- Under 5 pneumonia (separate paper)

Refresher Training

Data Collection at monthly intervals, up to end of the study

Measure and compared changes before and after study 2011 -2014 and report

KAP Baseline

Measure
- Outcomes: glossary, health seeking behavior & algorithm of priorities
- Inform RCT on feasibility & priority interventions

Train TBAs and CHW

Practical Sessions of skills at Health center

- Recruited and tracked pregnant women ANC, PMTCT &birth and PNC

Identified and Managed Newborn & Infant for:
- Birth Asphyxia
- Neonatal sepsis
- Hypothermia & Hypoglycemia
- Under 5 pneumonia (separate paper)

Refresher Training

Data Collection at monthly intervals, up to end of the study

Measure and compared changes before and after study 2011 -2014 and report

Study population and location
Two linked studies were planned. The first was the baseline knowledge, attitude and practice, KAP study in 2007, to ascertain community knowledge and practices as well as sociocultural leanings affecting pregnancy and newborn health. Products of the KAP study informed the subsequent randomized control interventions from 2008 -2013, in Chongwe and Mpongwe.

Participant profile
This paper focuses on the 2000 deliveries within the 11 month follow up period. All women and newborn babies up to 28 days postnatally, are reported in this article as indicated in the flow chart.

Table 1: Community based agents allocation

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<tr>
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<th>Chongwe District</th>
<th>Mpongwe District</th>
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<tbody>
<tr>
<td></td>
<td>Control</td>
<td>Interven.</td>
</tr>
<tr>
<td>Number NHC study Sites</td>
<td>8</td>
<td>12</td>
</tr>
<tr>
<td>Number TBAs trained</td>
<td>2</td>
<td>9</td>
</tr>
<tr>
<td>Number of CHWs</td>
<td>8</td>
<td>5</td>
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Randomization
The unit of randomization was defined by the Neighborhood Health Committee (NHC). This is the basic level of organization for health interventions within the community. Central Statistical Office has no maps of NHCs and so the study physically mapped these in each of the two districts, with the help of the district data focal point, the Environmental Health Technician (EHT). Randomization offered the power of comparison and enabled us calculate the lives saved by the intervention arm.

Training of Community Based Agents
The training was based on the MOH/ UNICEF ESARO material, supervisory checklist and monitoring and evaluation tools. Field effectiveness was assured by training, retraining, supportive supervision by health centre, district teams and national team.

Clearance and permission in writing were obtained from the community, district, provincial and national levels as well as the University of Zambia BioMedical Research and Ethics Committee, clearance number FWA00000338.

The injection sites were those deliberately nearest to the national team. Chongwe CBA’s only were trained and allowed to give injections for that reason. The national team conducted regular supportive visits in view of possible adverse events. The Community based newborn care strategy largely depends on attending to the needs of the mother and baby at home as follows:

- Identifying and tracking pregnancy.
- Identifying danger signs and encouraging antenatal care.
- Birth attendants to manage safe and clean delivery of baby (to prevent or treat birth asphyxia with bag and mask)
- Keeping the baby warm, and or with Kangaroo method of care, early breast feeding within the first hour and continued breast feeding
- Health education of mother and family of critical danger signs, these being: reduced sucking, drowsy or unconscious, weak cry, baby cold or hot to touch, fast breathing or chest in drawing or others locally adapted by the community themselves.
- Simple criteria for the diagnosis of sepsis by community health workers, using two or more signs to diagnose sepsis and high-risk newborns.
- Antibiotic treatment of sepsis, oral or injectable by community health worker Gentamycin in the antero-lateral aspect of thigh for 10 days (Chongwe) and cotrimoxazole 1.25ml for 7 days or Amoxycilin 2.5 ml three times per day (Mpongwe)
- Timely referral to next level after the first 24 hours.
- Home visits; 3 for normal newborn and 8 for sick newborn in the first month to record presence or absence of danger signs and ongoing education and communication.
- Keeping baby warm/maintaining normal body temperature (no bath for premature and low birth weight infants).
- Breast-feeding soon after birth and regularly thereafter.

The CBAs visited the sick newborns and infants on average 3 times to treat and assess whether their health conditions had improved, remained the same or deteriorated.
Newborn Essential Care: immediate breastfeeding and keeping baby warm with the Kangaroo Method of Care

CBAs provided essential newborn care inclusive of keeping low birth weight babies warm using Kangaroo Method of care, drying and wrapping older babies, avoiding cold baths, breastfeeding soon after birth, suction, bag and mask for asphyxia and identify, monitor for signs and symptoms of sepsis and morbidity in the newborn and treatment of sepsis with antibiotics.
antibiotic and or timely referral to the next level of care.

The CBAs measured baby weights correctly with 1210 of 1260 in intervention sites (96.03%) and 526 of 567 (92.76%) in the control sites. By the fourth postnatal visit, they measured less baby weights, 636/934 (68%) in the intervention sites and 222/348 (63%) in control sites.

First baby examination: A total of 1870 newborns were examined of these 1314 were in the intervention site and 556 control sites. Examinations were conducted in first week of life by traditional birth attendants. There was no significant difference in feeding in the first hour in both the control and intervention arms (p=0.711). A total of 1831 newborns fed well out of which 6 of the newborns were bottle fed while 2 were given water. Complications of breast feeding were significant in both arms (p=0.07) while complications in the mother were more significant in the control arm (p=0.03).

Thermal care: was good in both intervention and control arms. Dried after birth, Z =3.796, Baby was kept warm, 96% Chongwe, 94% Mpongwe. Kangaroo care method (KMC) was used with 51% of the newborns in the intervention site, KMC, Z-score of 2.245. Bathing in warm water happened in 36% Chongwe and 25% Mpongwe. Keeping the newborns room warm occurred in 6% in both districts. Respondents noted that a newborn should not be bathed when it is very sick or when it is premature (59% and 42%) respectively, as is not safe for the baby (64%) and or the baby might die (17%). Delayed bath had a Z-score of 2.135.

Birth asphyxia
Out of 1996 births 96% of newborns were observed for asphyxia. Birth asphyxia was defined by weak cry, no cry, gasp, weak breathing or no breathing. There were more cases of asphyxia identified in the intervention, 59% (114/1925), compared to the control (p=0.0002). There were also milder cases of birth asphyxia in the intervention with 12.3% deaths in the intervention compared to41.2% in the control (p=0.009). Among babies born with asphyxia, 72.2% (n=88) were born at home. Out of these 44 were delivered by skilled TBA and 34 by unskilled TBA. Mortality was 2.3% for skilled TBA, 14.7% for unskilled TBAs and 31.5% for HC staff.

Infections
Based on their training CHWs and TBAs identified and managed newborn local infections or possible severe bacterial infections with amoxyllin or gentamycin injections (Chongwe only) The CBAs identified 280 infants with local infection and possible severe bacterial infection. More infants, 68.9% (n=205), received oral antibiotic than injection, 31.1% (n=87). Approximately 43% of the infections were in the neonatal period, (n=135). Perinatal infection accounted for 33% of these infections.

Calculating the number of newborn lives saved in intervention sites
The climax of our RCT, was in the calculation of newborn lives saved. The study design made it possible to compare results between the control arm and the intervention arm. The calculation demonstrates how it was possible to save a large percentage of infants that would have otherwise died. This is the evidence that community based agents when trained, equipped and supported, can deliver maternal newborn interventions successfully.

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<th>Table 2: Evidence for the Success (in absolute numbers) of the Implementation of the Continuum of Care</th>
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<td>Births(2000)</td>
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<tr>
<td>Births(2000)</td>
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<td>Still births</td>
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<td>Deaths</td>
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<tr>
<td>Neonatal mortality rate per 1000 LB</td>
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<td>Number of Lives saved</td>
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The table above demonstrates the strength of our methodology, randomised study design. Taking into account gross fertility rate of 214/1000, National NMR=34/1000, the death rate of 34 per 1000 live births among 1,101, 672 annual births (MOH) we could save 20 /1000 x 1,101,672 = 22,033 newborn lives per year in Zambia, utilizing all interventions in the continuum of care. This number of newborns would constitute 22,033 / 37,456 of annual deaths or 58.8 % of newborns that would have died without the interventions from the community based agents.
4. DISCUSSION

Over the last 10 years tremendous advances have been made in the provision of health care for children under-five years of age, as mirrored in the child health indicators. The under 5 mortality rate (U5MR) has dropped remarkably from 191 in 1992 to 119 in 2007 and 75 in 2013, with comparable drop in infant mortality to 45 per 1000 live births ZDHS, 2007& 2013. Though the neonatal (NMR) has equally decreased, the magnitude of the change is not as significant as the other groups. Herein the challenge of today’s health care.

Interventions in communities in India, Nepal, Bangladesh including the African continent in Ethiopia, Malawi, Uganda and South Africa, demonstrate positive outcomes for mothers and babies. Zambia conducted two randomized studies on maternal newborn health 2005 to 2013. These works provide comparable local evidence between Chongwe, Mpongwe and Lufwanyama. The Gadchiroli work 6 inspired the conceptual development of the Zambian studies. Trained community based health agents reduced mortality by 58.8% among newborns in our study and in Lufwanyama by 45% at day 28. Our work adds to the current body of knowledge, by engaging a continuum of care from pregnancy to newborn and early infancy, with positive primary outcomes for the newborn and the mother.

The Zambian newborn, without a doubt, faces a fraught struggle for survival in a health system with inadequate health personnel and only recently recognised newborn health as a priority. Culturally, Zambia, like many African countries does not regard the neonate as an individual until it is a couple of weeks old. Kaseba et al and Bang et al demonstrate the high cultural acceptance of neonatal mortality. The neonate remain unnamed during the neonatal period and in the event of death are unmourned and soon forgotten.

The Zambia National Position Paper estimated that 77,300 children under the age of five years in Zambia die annually and of these, about 17,000 babies die within the first 28 days of life, the neonatal period. About 3,000 Zambian mothers also die every year due to pregnancy and childbirth related illness. The suggested continuum of care answers to this situation. Global evidence shows that half of these mothers and a quarter of the newborns die within 24 hours of giving birth or being born, respectively. To the newly born baby, the death of the mother is a double tragedy of surviving the critical first 28 days of life and of being orphaned without the nurturing care of a mother. Simple lifesaving techniques are available in the community as Bang et al demonstrated in India. The India, Nepal experiences motivated the Zambian studies in Lufwanyama, Chongwe and Mpongwe. Results from Lufwanyama, an observational study and ours show a high potential to save newborns 4, 45% and 58% respectively.

Birth asphyxia, is the third major cause of death in newborns. Approximately 3% of all births in developing countries develop birth asphyxia and require resuscitation. In the absence of intervention roughly one quarter of these newborns perish or develop other complication every year. Up to 75% of these deaths could be prevented if basic resuscitation is correctly conducted using simple inexpensive tools and techniques. World Health Organization. Basic Newborn Resuscitation: A practical guide supports these basic interventions, as part of the strategy to reduce the Neonatal Mortality Rates (NMR). The Lancet series on neonatal health also include neonatal resuscitation as one of their 16 evidence based, effective and life saving interventions. What does it take? Understanding to prevent birth asphyxia, quick action with suction, bag and mask and a life is saved. Initiatives such as “Helping Babies Breathe” support communities with this.

Neonatal Sepsis: pneumonia, meningitis and septicemia are all collectively referred to as sepsis. These diseases attribute to 23% of all neonatal deaths, and can in the case of meningitis result in long term neurological and developmental disorders. Difficulty in diagnosing neonatal sepsis has been contributing to the persistent paradigm of neonatal deaths. A very large proportion of remote and rural areas in developing countries lack laboratory diagnostic tools used to identify sepsis. In light of this the WHO and many other practitioners have settled to treat sepsis using simple clinical criteria. In hospital settings this has proved efficient as 89.1% of cases presenting clinical signs result in positive laboratory results. It also resulted in a reduction of mortality and morbidity in the SEARCH, India field trail and Nepal. Treatment in both these field trails was of basic and inexpensive antibiotics provided by local community health workers. In our work CBAs coped better with Amoxicillin, though they liked the idea of injection better.

Low Birth Weight (LBW) and Preterm Infants: LBW and preterm babies need additional special care as they are particularly at high risk of infections and
hypothermia. Thirty one percent (31%) of all neonatal deaths are directly linked to prematurity and LBWs. LBWs also underlie 40-80% of all neonatal deaths\(^4,7,8,9,10,11,12,13,14,15,16,17\). LBWs and preterm deliveries are often the result of poor maternal health, nutrition, social status and low birth intervals. This one cause of mortality highlights the importance on the continuum of care, to eliminate LBWs and preterm babies intervention have to be put in place before the child is even born via the mother\(^4,11\). CBAs managed hypothermia well in both control and intervention sites. 

The Ministry of Health (MOH) and various NGOs efforts in recent years have included segregated attempts on the management of birth asphyxia, thermal care and neonatal sepsis. Evidence from these studies indicate that this form of care for new born can be effective, acceptable and is necessary given adequate resources, supervision and support. The successes of these efforts need to progress from being isolated with limited coverages and be pulled into a comprehensive consortium inclusive of a complete newborn community based care package. The 2013 National Framework for Newborn care is based on local evidence generated by the Lufwanyama study and our work\(^19\).

5. CONCLUSION

Based on the effectively implemented interventions by trained CBAs, there is compelling evidence to support community based newborn care in rural and difficult to access areas of Zambia. We urge government and partner agencies to adapt interventions that made significant contribution in intervention sites for Home Based Newborn Care in communities, to counter neonatal deaths.

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REFERENCES