A Cluster Randomized Controlled Community Based Trial Utilizing a Continuum of Care Among Pregnant Women: Outcomes in the Women

Mary Shilalukey Ngoma¹, Tepa Nkumbula², Wilbroad Mutale³, Rodgers Mwale⁴, Tesfaye Shiferaw⁵, Chabala Chishala¹, Anitha Menon⁶, Maria Nsowa¹, Godfrey Biemba⁷,⁸,⁹ and David Hamer⁷,⁸,⁹

¹University of Zambia School of Medicine, University Teaching Hospital, Associate Professor of Pediatrics and Child Health, Neonatologist, Lusaka, Zambia
²Program Manager, the University Response to HIV, University of Zambia
³Public Health Physician, Department of Community Medicine, School of Medicine, University of Zambia
⁴Ministry of Health, Zambia
⁵UNICEF Zambia and ESARO Nairobi.
⁶Department of Psychology, University of Zambia,
⁷Zambia Centre for Applied Health Research and Development (ZCAHRD), Lusaka, Zambia
⁸Center for Global Health and Development, Boston University, Boston, MA, USA
⁹Department of Global Health, Boston University School of Public Health

Corresponding Author: Mary Shilalukey Ngoma
profngoma09@gmail.com

ABSTRACT

Objective: To assess a home based continuum of pregnancy and neonatal care package, delivered by community based agents (CBAs), to improve maternal and neonatal outcomes. Method: The package was developed and tested in a randomized controlled trial conducted from 2009 to 2013. The unit of randomization was the Neighborhood Health Committee (NHC), within one hour from the client, and serving 150-200 households with 900 to 1200 persons. The 48 CBAs in 10 RHCs, made up 40 clusters. 3846 pregnant women were enrolled and tracked for one year. The intervention group received care from trained, equipped and supported CBAs while the control group received the Standard national health care. Results: The 3486 pregnant women were tracked, 2767 in the intervention group and 1079 in the control group. By the 12th month, 2000 women had delivered, with 1282 (33%) completing 28 days postnatal care, 934 in the intervention and 348 in the control group. A total of 673 (66%) women in the intervention group and 236 (58%) women in the control group were identified with danger signs, among whom 49.3% had institutional deliveries, availing newborn care in addition. The 2013 New Born Framework of the Ministry of Health utilised findings for policy. Conclusion: evidence shows that when trained, equipped and supported, community based caregivers are effective during pregnancy and early newborn care. Geographically disadvantaged populations can benefit from adopting the continuum of care as standard practice to improve maternal and newborn outcomes, within the community.

Keywords: Cluster Randomised Trial, continuum of care in pregnant women, Zambia
1. INTRODUCTION

The appreciable change in mortality of pregnant women in resource-challenged countries\(^{(5,7,9)}\) is a good progress, but the proportion of neonatal deaths has increased in all regions of the world.\(^6\) Sub-Saharan Africa carries the second largest burden of neonatal mortality in the world, against a backdrop of the high HIV/AIDS rates, civil unrest, extreme poverty and weak health systems.\(^8\) Underlying causes of death relate to the high number of deliveries that take place without skilled attendance due to geographic distance, together with lack of adequate transportation.\(^{(5,7,9)}\) More newborn deaths occur at home among the rural poor. Consistent with global trends almost 50% of all deliveries in Zambia take place at home or rely on traditional birth attendants as the nearest available source of maternity and delivery healthcare.\(^{(4,7,9,10)}\) History has taught us that we do not need expensive technologies to facilitate the reductions of either maternal or newborn deaths.\(^{(10)}\)

Community based effectiveness trials of maternal and neonatal packages\(^{(23,24,25)}\) indicate however that not many have tested strategies to deliver neonatal interventions in existing infrastructures with neonatal mortality as an outcome, in low resource settings.\(^{(14,15,16,17,18,19)}\)

The role of community health workers in child survival is under debate as to the acceptability, level, function, type of incentives.\(^{(12,13)}\) Traditional birth attendants and other CBAs continue to be the nearest source of care within the community.\(^{(4,7,9,10,14,15,16,17,18,19)}\)

This article describes cluster randomized community based trial in Zambia, with deliberate interventions in the pregnant mother. The primary intention is to save the endangered newborn, in rural areas, where access to the formal health system remains a challenge.

Our aim was to develop and implement a community based continuum of neonatal care package, from identifying pregnant women and tracking them to delivery and 28 days of the newborn period. Inspired by a visit to India, Gadchiroli “SEARCH” project, we studied the role of trained CBAs in delivering a continuum of care, in order to establish outcomes in morbidity and mortality, primarily in the newborn and secondarily in the pregnant woman.

The paper limits itself to findings in the women, with a second paper on the outcomes in the newborn.

Definitions used in this study

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

**Community Health worker (CHW):** Male or female, 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.

2. METHODS

**Study design and location**

The community based clustered randomized control trial was conducted in 2009 - 2013, in the rural districts of Chongwe and Mpongwe which share similar health and demographic profiles. Chongwe is nearer urban activity, being 50 km outside the capital city, with a population of 196,999 of which 22% are women in the child bearing age, 15-49 years. Mpongwe is 300 kilometres from Lusaka with a population of 93,258, and nearer Zambia’s second city, Ndola.

Based on the crude birth rate and sample size calculated for the preceding KAP baseline survey, an estimated sample size, of 3,000 and 4000 pregnant women aged 15-49 was made for the Randomized Control Trial.

We assumed the unmet need for care occurs in neonates aged 0-7 days and 8-28 days and underfive children with Acute Respiratory Infections. We assumed each contributes equally to morbidity. The study was unblinded and CBAs were randomized to intervention or control groups.\(^{(1,2,3)}\)
Figure 1: Study profile

Randomization and Masking
The basic unit of randomization was the Neighbourhood Health Committee (NHC). Central Statistical Office has no maps of NHCs. The study team mapped these in each of the two districts, with the help of the district data focal point, the Environmental Health Technician (EHT). Each cluster comprised a NHC within the community, serving 150-200 households or a population of 900 to 1200 persons. NHCs where assigned to Health Centres to supervise them.

Table 1: Allocation of NHCs and CBAs into Control and Intervention sites

<table>
<thead>
<tr>
<th></th>
<th>Chongwe District</th>
<th>Mpongwe District</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Number NHC study Sites</strong></td>
<td>8</td>
<td>12</td>
</tr>
<tr>
<td><strong>Number TBAs trained</strong></td>
<td>2</td>
<td>9</td>
</tr>
<tr>
<td><strong>Number CHWs</strong></td>
<td>8</td>
<td>5</td>
</tr>
</tbody>
</table>

The epidemiologist in the study team listed all the RHCs in each district by name and placed the names in a closed box. Each district representative randomly selected a total of 5 RHCs. A second list of NHCs was produced, separated by a minimum geographic distance of 10 km between sites. Approximately 3-5 NHCs were allocated to each RHC, conscious of the need to minimize or avoid cross contamination between control and intervention sites.

**Training**

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. Total training was 10 weeks, spread over one year and included clinical care, data and record keeping. It entailed 7-day participatory, one month practicum, 5-day refresher and regular supportive on site visits by clinical and data supervisors.

Community based agents were equipped, supervised and retrained every four months. A methodological paper is available and describes in detail our approach. All CBAs were supplied with questionnaires, bags and kits including raincoats and boots.

The control site, were trained together with the intervention group, but were urged to practice routine “business as usual” care, while intervention teams implemented new activities. The Health Centre provided supportive supervision to the Neighborhood Health Committee, while the study team visited the districts on a monthly basis.

Recruitment fatigue occurred when 80% of our sample size had been reached. The additional incentive of 60 cents per pregnant woman recruited helped to complete the remaining 20% of the sample. Data was collected in the two sites using self-administered questionnaires and through focus group discussions in three sites per district. The questionnaire was semi-structured and was developed on the basis of the study objectives and the common illnesses in newborn babies, pregnant women, health seeking behaviour and knowledge attitudes and practices for newborn care.

Focus group discussions (FGDs) were conducted with TBAs and other community based health agents both men and women in groups of 12 participants. These were conducted by trained moderators. The first part highlighted knowledge and attitudes in the community regarding newborn illnesses such as sepsis or infection. The rest of the discussion brought out the types of actions taken by the community to deal with newborn illnesses which could be either useful or harmful. Each discussion lasted a maximum of one hour.

**Statistics**

Questionnaires were checked by the district data manager for completeness and couriered to national level by the data manager or the forms were handed to the national team during monitoring visits to the district. These were collated and data entered by data entry clerks at national level. Data cleaning was done at national level. Quality assurance was provided by a mathematician and statistician from the University of Zambia. Data collected was entered in EPI software data base, cleaned and exported to statistical pack hard copies. Original questionnaires are on the institutional website. Hard copies have been stored in a locked cupboard. This trial is registered with the University of Zambia BioMedical Research and Ethics Committee, clearance number FWA00000338.

**Role of Funding**

UNICEF Country Office Zambia and ESARO provided funds and equipment. The corresponding author had full access to all the data in the study and had final responsibility for the decision to submit for publication.

**Study limitations**

The study should have been 18 months long, to allow all women identified to deliver their babies.
3. RESULTS

Participants and interventions
Community Based Agents were able to reduce morbidity and prevent death, with the continuum of care in pregnant women and the newborn. The NHCs identified 4682 pregnant women of child bearing age, 15-49 years of age, among whom 3846 were eligible for enrolment. The 48 CBAs served 40 clusters which were allotted as 25:15 intervention and control sites, respectively 2767 and 1079 pregnant women.

Intervention sites registered higher participation for all services, starting with pregnancy tracking, antenatal care HIV screening, Prevention of Mother to Child Transmission, identification of danger signs, deliveries, perinatal and postnatal care. All the participants were local women that lived in the selected NHC and could be tracked during their pregnancy through to the neonatal period. The mean age of the participants was 26.22 (I=26.32, C=25.97). Majority of the participants had one or more pregnancies, it was the first pregnancy for 6.8%
(n=263) participants. Number of previous pregnancies ranged from 1 to 13 pregnancies, with 1 to 11 live children. 12.1% of the participants reported experiencing 1-5 miscarriages and 11.8% reported up to 4 still births. Prolonged labor in previous pregnancies was experienced by 12.8% of the participants.

By the close of the study 2000 women had delivered, of which 1282 (33%) 934 intervention and 348 control were followed up through delivery up to the end of the neonatal period (28 days).

**Pregnancy tracking**

CBAs identified pregnant women of child bearing age, They tracked pregnant women among 3846 pregnant women who had been recruited. Intervention sites in both districts recruited over twice (n=2762) the recruitment in the control sites (n=1079) (p-value 0.0001). The participants were tracked for two scheduled visit, one early and the second visit before delivery. All 3846 had the initial home based antenatal visit. However out of these, only 69% n=2676, received a second visit before delivery. By the close of the study 2000 women had delivered of which 1282 (33%) comprising 934 pregnant from the intervention site and 348 from the control site, were followed up from pregnancy, delivery through to the neonatal period. Tracking provided assurance that care was retained placenta, severe vaginal bleeding, prolonged labour, hypertension, high fever and complications of the cord. The role of community based agents is equally highlighted during perinatal care.

**Antenatal Care**

Attendance to antenatal care was stable in the intervention arm, 85% of the pregnant women received essential care with at least two scheduled visits before delivery. CBAs were trained successfully to identify danger signs in pregnant women. Most danger signs such as hypertension, bleeding, anaemia, malaria were recognized at the first visit. From the danger signs identified 79.6% were referred and encouraged to have institutional deliveries. Out of these 49.3% delivered at health facilities. CBAs also conducted health education, birth preparedness and counselling.

All (3846) participants received the initial home based antenatal visit by the CBAs after recruitment. However only 2676 (69%) of the participant received a second home visit before delivery. Ninety five percent (95%, n=313) of the participants that did not receive a second antenatal visit were recruited in the second (40.7%) or third (54.4%) trimester of pregnancy. There was a decline after the third antenatal visits, in both intervention and control sites. The decline was more noticeable between second and third antenatal visits, underscoring the need for focused antenatal care with 2 visits, before delivery.

**Perinatal Care**

By the end of the study 52%, namely 2000/ 3846 pregnant women had delivered. In Chongwe, of the total recruited in the intervention site n=1256, 595 had delivered while in Mpongwe, out of the 1511 recruited in the intervention site, 811 delivered at the time of analysis (figure 3). Results also show that 74% were delivered by a skilled birth attendant. During the perinatal period CBAs identified and recorded danger signs during delivery and referred pregnant women for delivery at the health centre and or larger health institutions. CBAs also recorded danger signs such as retained placenta, severe vaginal bleeding, prolonged labour, hypertension, high fever and complications of the cord. The role of community based agents is equally highlighted during perinatal care.

<table>
<thead>
<tr>
<th></th>
<th>INTERVENTION</th>
<th>CONTROL</th>
<th>P-VALUES</th>
</tr>
</thead>
<tbody>
<tr>
<td>ANC1-ANC2</td>
<td>875(31%)</td>
<td>299(27.7%)</td>
<td>0.008</td>
</tr>
<tr>
<td>ANC2-Deliv</td>
<td>486(26%)</td>
<td>186(24%)</td>
<td>0.343</td>
</tr>
<tr>
<td>Deliv-PNV1</td>
<td>147(10%)</td>
<td>27(4%)</td>
<td>0.0001</td>
</tr>
<tr>
<td>PNV1-PNV2</td>
<td>837(7%)</td>
<td>82(14%)</td>
<td>0.0001</td>
</tr>
<tr>
<td>PNV2-PNV3</td>
<td>746(6%)</td>
<td>58(12%)</td>
<td>0.0002</td>
</tr>
<tr>
<td>PNV3-PNV4</td>
<td>167(15%)</td>
<td>80(19%)</td>
<td>0.0009</td>
</tr>
</tbody>
</table>

Deliv = abbreviation for delivery, note that the intervention group have significantly more clients after delivery.

**Danger Signs**

The CBAs identified danger signs in the whole continuum of care, antenatal, delivery and postnatal periods 34%, n=1332 of the women experienced danger signs during the antenatal period, recognized and recorded by the CBAs. 99% of the danger signs were seen at the first ANC visit. More were recorded in the intervention sites.

The danger signs included severe vaginal bleeding ante partum haemorrhage, I=6%; C= 4% control,
hypertension/ Pre-eclampsia I=47%; C=45%, fever/ malaria I= 18%; C= 14%, bad obstetric history I= 15%; C=13% and other complications I=5%; C= 9%. Additionally CBAs collected information on HIV status, teenage pregnancies, older pregnant woman, previous still births, history previous caesarian section, five or more previous pregnancies, diabetes mellitus, multiple pregnancies, breech position and no movement by the baby.

Of note, is the woman who died among the 2000 deliveries. A CBA recruited a 16 year old mother who had swollen hands and feet during a supervisory visit. She was referred to the health centre where she fainted and fitted. She was urgently transferred to the University Teaching Hospital where she unfortunately died soon after delivering a fresh still born infant. Double tragedy.

4. DISCUSSION

Zambia conducted two separate randomized studies on maternal newborn health 2005 to 2013. These works provide local evidence from Chongwe, Mpongwe and Lufwanyama(4). The Gadchiroli India(10), work inspired the conceptual development of the Zambian studies. Trained community based health agents reduced morbidity and mortality by 58.8% among newborns in our study and in Lufwanyama to 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.

A preliminary baseline survey provided ethnographic information on socioeconomic, cultural, health seeking and health status of our study communities(8). It also provided indicators of morbidity and therefore enabled the study prioritise conditions that were of relevance to pregnant women and newborn babies.

Community participation is advocated to build links between primary services and their users and improve service quality(4,5,7,8,9,10). According to Lewyca(7), the rationale for using community based interventions is based on the fact that many maternal and neonatal deaths occur at home and could potentially be avoided by changes in antenatal or newborn care practice and better understanding of health problems. Hence, involving local community workers may ensure higher and more equitable coverage, improve care seeking, be more cost effective and have greater acceptability in the community(6,12,13). Health research therefore has to increasingly adopt a participatory approach if to be accepted and implemented meaningfully by the same community.

Long distances to health facilities in both rural communities hinder access to health care resulting in the tendency towards home deliveries. In Chongwe 57% of deliveries happened at home and 29 % in Mpongwe. Given the current pervasiveness of deliveries in the home, the potential to work with TBAs to promote and provide available low-cost, low-tech and effective interventions that address immediate neonatal care should be further explored(7). According to Falle(7) CBAs could play an effective role in providing interim delivery care for rural pregnant women. Training TBAs to manage common perinatal conditions can significantly reduce neonatal mortality(4,5,9,10). In our work, 74% of the deliveries were attended to by trained CBAs. Furthermore, CBAs identified and recorded danger signs during delivery and referred pregnant women for delivery to the next level.

In deciding what interventions may make a difference to the pregnant woman the study noted the long distances to care, untrained caregivers in the communities and poor referral systems. It therefore makes sense that woman who are pregnant are offered oversight for their health within the community in which they live and most deliver at home. This decision to offer pregnancy tracking took into account the results of a preliminary baseline showing high levels of morbidity such as fever, 34-36% in Mpongwe and Chongwe respectively, hypertension and pre-eclampsia up to 22%, urinary and abdominal pains(8). A unique feature of the continuum of care was the identification of women of child bearing age and those who knew they were pregnant to enable tracking. This was guaranteed the earliest form of care that would improve access to healthcare. There was a significant preference to attend care when tracking was introduced. Tracking provided assurance that care was near and offered an opportunity for counselling within the home as well as timely referral to a health facility. This should improve the numbers of pregnant women accessing care, but also utilized as the opportunity for health education at each contact.

Registration forms an essential part of maternal and foetal surveillance. With early registration it is possible to avert poor birth outcomes such as stillbirths, abortions and neonatal deaths(14). The first visits involve the confirmation of the pregnancy and also for the assessment of the wellbeing of the mother and the unborn child. Dating of the pregnancy is also performed, either using the last normal menstrual

To Cite This Article: Mary Shilaluke Nyoma, Tępa Nkumbula, Wilbrod Mutale, Rodgers Mwale, Tesfaye Shiferaw, Chabala Chishala, Anitha Menon, Maria Nsowa, Godfrey Biemba and David Hamer. A Cluster Randomized Controlled Community Based Trial Utilizing a Continuum of care Among Pregnant Women : Outcomes in the Women. International Annals of Medicine. 2017;1(11).  
https://doi.org/10.24087/IAM.2017.1.11.348
period (LMNP), or ultrasound scan in the first or early second trimester. This allows for the determination of the estimated date of delivery (EDD)\(^{(14)}\). By dating the pregnancy it provides a framework on which various aspects of antenatal care can be implemented as well as providing a timeline of the pregnancy allowing for the approximate prediction of expected delivery that might require intervention if the need arises.

Antenatal care is one of the earliest Safe motherhood interventions which is well accepted across the health systems 95% attendance and above. (CBOH, WHO) Antenatal services have been in use for several years and are well accepted in Zambia\(^{(12)}\). Our baseline study recorded that more than 95% of the respondents or their partners had attended Antenatal clinic in their last pregnancy and 99% considered ANC as beneficial to both mother and baby in both districts antenatal\(^{(8)}\). The number of antenatal visits ranged from 1 to 8.

It was noted that attendance was impressive for the first visit but tapered off at three visits. In our RCT, attendance to antenatal care was stable in the intervention group, with at least two visits before delivery\(^{(19)}\). Based on their training CBAs were able provide appropriate antenatal care, critical for the reduction of neonatal deaths. It is interesting to note that antenatal care is a long standing health intervention, whose results did not differ significantly, between intervention and control sites.

The recommended frequency of antenatal visits differs from country to country and still remains a widely debated issue\(^{(17)}\). However, in advanced health systems like the National Health Service (NHS) of the UK, mothers that are expecting their first child must have up to 10 antenatal visits whilst mothers that have had more than one child before are expected to have up to 7 visits, the minimum number of visits being 5. A study led by the WHO showed that essential interventions can be provided over 4 visits at specific intervals in healthy women with no underlying medical problems\(^{(17)}\). For those that are at particularly high risk, more antenatal visits are advised. This model is termed as “focused antenatal care” and has been adopted by several countries, however the quality of antenatal care in Zambia despite the high attendance rates needs further definition.

Community based agents demonstrated ability to identify danger signs. Through the training, each danger sign was defined, allowing for the specific diagnosis and intervention. Danger signs were identified along the continuum of care, from tracking pregnancy, antenatal period to the postnatal period and for the newborn. The benefits of this continuum of care comes from individual interventions, but collectively, the benefit will be additive for both the mother and infant.

5. CONCLUSION

- Given the human resource, geographic, material and financial constraints, it seems inevitable that the present and immediate future of newborn survival in rural Zambia remains in the hands of the Community Based worker. Though CBAs represent the informal sector of the health sector, there is need to formally recognize them by training, equipping and supporting their work, to reduce morbidity and save life in pregnant women and newborn infants.
- Local evidence available from Mpongwe, Chongwe and Luwanyama sufficiently supports the use of community based continuum of care as appropriate technology. We therefore recommend the community based care package to the Ministry of Health.

ACKNOWLEDGEMENTS

The authors acknowledge the Ministry of Health Directorate of Research and Public Health, who commissioned this work. We also acknowledge Drs Luwei Pearson, Tesfay Shiferaw and Rodgers Mwale, UNICEF ESARO and Zambia country offices respectively, for financial, technical and logistic support. Dr Alasfrod Ngwengwe Mathematician, at the University of Zambia provided quality assurance, research assistants and all the participating communities of Mpongwe and Chongwe districts, to whom we are deeply indebted.

FUNDING

UNICEF, Zambia Country Office and ESARO.

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To Cite This Article: Mary Shilulukey Ngoma, Tepa Nkumbula, Rodgers Mwale, Tesfaye Shiferaw, Chabala Chishala, Anitha Menon, Maria Nsowa, Godfrey Biemba and David Hamer. A Cluster Randomized Controlled Community Based Trial Utilizing a Continuum of care Among Pregnant Women: Outcomes in the Women. International Annals of Medicine. 2017;1(1). https://doi.org/10.24087/IAM.2017.1.11.348