

## REVIEW

## How did formative research inform the development of a home-based neonatal care intervention in rural Ghana?

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Formative research is often used to inform intervention design, but the design process is rarely reported. This study describes how an integrated home visit intervention for newborns in Ghana was designed. As a first step in the design process, the known intervention parameters were listed, information required to refine the intervention was then identified and a formative research strategy designed. The strategy included synthesizing available data, collecting data on newborn care practices in homes and facilities, on barriers and facilitators to adopting desired behaviors and on practical issues such as whom to include in the intervention. The data were used to develop an intervention plan through workshops with national and international stakeholders and experts. The intervention plan was operationalized by district level committees. This included developing work plans, a creative brief for the materials and completing a community volunteer inventory. The intervention was then piloted and the intervention materials were finalized. The design process took over a year and was iterative. Throughout the process, literature was reviewed to identify the best practice. The intervention focuses on birth preparedness, using treated bednets in pregnancy, early and exclusive breastfeeding, thermal care, special care for small babies and prompt care seeking for newborns with danger signs. The need for a problem-solving approach was identified to help ensure behavior change. A subset of behaviors were already being performed adequately, or were the focus of other interventions, but were important to reinforce in the visits. These include attending antenatal care and care seeking for danger signs in pregnancy. On the basis of the intervention content, the timing of newborn deaths and the acceptability of visits, two antenatal and three visits in the first week of life (days 1, 3 and 7) were planned. Several household members were identified to include in the visits as they were involved in newborn care or they made financial decisions. Birth attendants and health workers were often the locus of control for immediate newborn care, and sensitization activities were designed to improve their practices and to help ensure that families received consistent messages. An existing cadre of community volunteers was

identified to deliver the intervention—these volunteers were already trusted and accepted by the community, already visited pregnant women at home and had the time and commitment to deliver the intervention.

A supervision and remuneration system was developed through discussions with the volunteers and at the planning workshops. The need for community entry activities was identified to garner community support for the intervention, to encourage self-identification of pregnant and delivered women and to motivate the volunteer through community recognition.

Formative research is an essential step in helping to ensure the development of an effective, appropriate and sustainable intervention.

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### Introduction

The Lancet neonatal health series suggests that 15 to 32% of neonatal deaths can be prevented through the promotion of a few key practices: clean home delivery, hygienic cord care, thermal care, early and exclusive breastfeeding, community-based care for low birth weight and care seeking for illness.<sup>1</sup> Trained community workers are considered by many to be pivotal for newborn care in the community,<sup>2–4</sup> and results from Asia suggest that they could have a significant impact on neonatal mortality.<sup>5,6</sup> The United Nations Children's Fund is therefore working with several African countries to introduce large scale newborn care interventions with a home visit component.<sup>7</sup> However, there is currently no evidence of the effectiveness of such interventions in an African setting or from interventions conducted at scale, or on how such interventions can best be designed to be feasible and sustainable. The evaluation of the Newhints intervention, the design of which is described in this study, aims to address this gap.

The Lancet series stresses the importance of systematic data-driven decision making and prioritization when scaling up newborn care interventions.<sup>8</sup> Although much has been written

about designing interventions,<sup>9–12</sup> there are few published examples. This study therefore aims to provide information on intervention design by describing the process and information used to design a large scale community-based newborn intervention in Ghana (called Newhints); its impact on neonatal mortality and newborn care practices is being evaluated using a cluster randomized control design.

## Study design

### *Aim*

The overall aim was to develop a feasible and sustainable community-based approach to improve key maternal and newborn care practices and by so doing reduce neonatal mortality.

### *Intervention approach*

The first step in designing the Newhints intervention was to identify the predefined intervention parameters. As one of the objectives of the intervention was to test the SEARCH Asian home visit model<sup>5</sup> in an African setting, it was given that the intervention would be delivered through home visits in pregnancy and in the first week of life, and would consist of promoting a package of behaviors. Unlike the Asian model, the visits would not include community treatment of illness as this would be against the current Ghana Health Service policy. It was also known that, as families cannot change too many practices at once, priority practices would need to be selected from a list of practices of known or probable efficacy.<sup>13–14</sup>

The team already knew that, as we needed to develop and test an intervention that could be delivered at scale in a resource poor setting, we would work at scale in six districts in the Brong–Ahafo region of Ghana; use community ‘volunteers’ to make home visits; would not use expensive equipment or involve lengthy training; and would design and implement the intervention in partnership with the district health management teams (DHMTs).

### *Formative research strategy*

Once the known intervention parameters were identified, a list of desired behaviors and a set of research questions (Table 1) that would help define the intervention content and structure were developed through a literature review and discussions with experts. A formative research strategy was designed to answer the research questions. The strategy started with a literature review to determine the mortality risk associated with each behavior<sup>13</sup> and to identify the best practice for material design, motivating, training and supervising community volunteers.<sup>9–22</sup> The literature review was followed by a synthesis of available data from the study area to determine whether any of the research questions had already been answered. Any knowledge gaps were then filled through primary data collection. A quantitative survey was conducted with the 635 women who delivered in the study districts in December 2006 to measure the prevalence of the desired behaviors. This was

**Table 1** Questions to be answered by the formative research

*Which behaviors should be included in the intervention package?*

- Is the behavior associated with mortality?
- Does the behavior need improving?
- Is behavior change likely?

*How can behavior change be achieved?*

- What are the constraints and facilitating factors for adopting optimal care practices?
- What visit schedule will be most effective in terms of the epidemiology of newborn health and in terms of community acceptance?
- Who should be the target of the visits and how can they be identified and visited in a timely manner?
- What other activities need to be conducted in the community and in the health facility to facilitate the adoption of the care practices and to ensure newborns receive adequate care in the facilities?

*Who should make the home visits and what support will they need?*

- Are there existing community workers who are acceptable and able to deliver the intervention?
- What workload can the community health workers effectively manage?
- What payment/remuneration/incentives are required to ensure the community health workers carry out the intervention, and are sustainable?
- What training, job aids and supervisory structures do the community health workers require to support their activities?

followed by a survey of seven health facilities, selected to represent the range of facilities in the study area. The facility survey aimed to identify whether facility practices and messages were consistent with the desired behaviors and whether the quality of care needed to be improved.

Qualitative data were collected from villages selected to reflect the districts diversity and aimed to provide a broad understanding of the barriers and facilitators for behavior change from a wide range of respondents. Several data collection methods were used:

- Home birth narratives (25 with recently delivered women) and in-depth interviews (30 with recently delivered or pregnant women, 20 with birth attendants and grandmothers, 12 with husbands, 16 with current community health workers and six with those responsible for supervising community health workers) were used to collect information that related to personal experiences and beliefs.
- Focus group discussions (two with recently delivered or pregnant women, six with birth attendants and grandmothers and two with husbands) were used to collect information that required more discussion.
- Nine observations of current community volunteers and three observations of current supervisors at work were used to

collect information related to current volunteer practices and workloads.

The quantitative data were analyzed using SPSS, and the qualitative data was systematically coded using Nud\*ist with key themes identified.

#### *Intervention development workshops*

The formative research findings were presented at a planning workshop in Accra in February 2007 with the aim of making decisions in a way that would encourage local ownership, ensure that the intervention was consistent with national policy, would be feasible and sustainable, and that would be supported by evidence. We, therefore, invited to the workshop representatives from national (the key neonatal policy makers and program coordinators) and regional levels of the Ghana Health Service, the six DHMTs and nongovernmental organization and United Nations agencies as well as experts in neonatal health, behavior change communication and working with community volunteers. Plenary discussions and group work were used as an arena for building consensus on key decisions and for identifying the next steps in the intervention design process. Further planning workshops were held at key points in the intervention design process.

#### *Conceptual framework*

The planning workshops resulted in the development of a plan of the content and structure of the intervention. The plan was used to develop a conceptual framework, which showed how the intervention activities contribute to the behavior change outcomes. The framework was used to check that the intervention was fully thought through, and to help design the monitoring and evaluation plan.

#### *Creative brief*

A creative brief was developed to guide the content, design and production of the materials needed to support the intervention. During the development of the creative brief, additional focus group discussions were conducted to determine how best to illustrate the desired messages through pictures. The creative briefs were discussed with local artists and printers who produced drafts of the materials. The drafts were presented at a workshop and revised based on the workshop recommendations.

#### *Pilot*

The content, training, materials and supervisory structure were piloted with 30 community volunteers for several months. The pilot was evaluated through observing visits and conducting qualitative interviews with the volunteers and the families they had visited. In addition, trials of improved practices<sup>23</sup> relating to special care for small babies were conducted with five mothers of low birth weight babies who were identified at the district hospital.

#### *Newhints management committee*

A management committee consisting of representatives of the six DHMTs and the research team met regularly throughout the design and piloting of the intervention to make operational plans about community entry, training, supervision, the incentive system for volunteers and other intervention activities. This included conducting an inventory of community-based surveillance volunteers (CBSVs), the group selected to deliver the intervention, to determine whether their coverage was adequate and the proposed workloads were feasible.

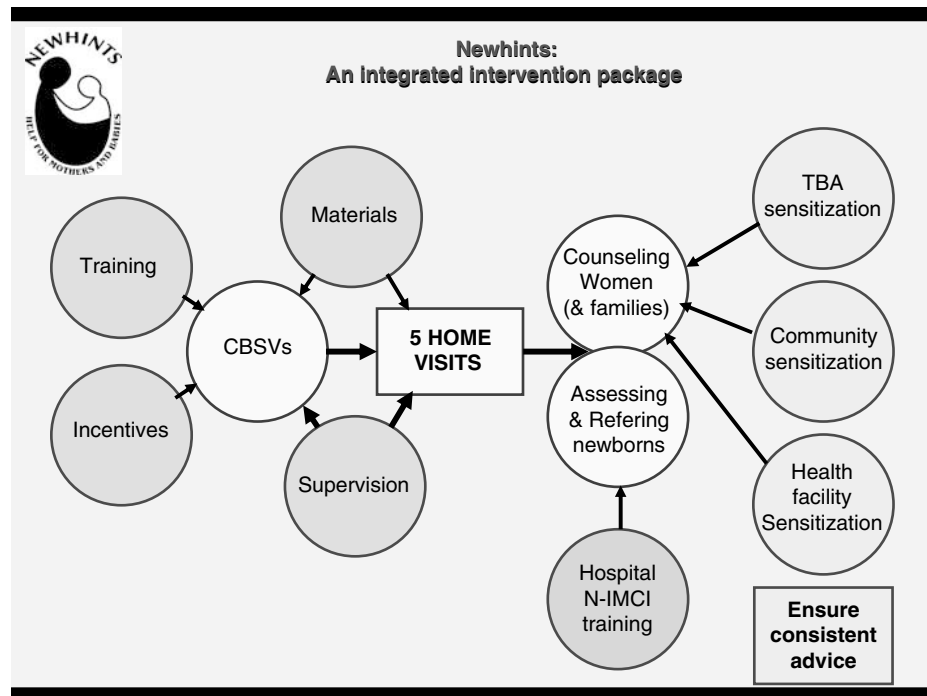
## **Results**

The formative research strategy and intervention design process were iterative, and as planning progressed, new questions were identified and unforeseen complexities and problems arose. The intervention content and structure was redesigned several times. Figure 1 shows the resulting integrated package.

### **Home visits**

At the core of the integrated intervention strategy are five home visits to be carried out by CBSVs, an existing cadre of community volunteers. The timing and content of the home visits are shown in Table 2.

*Selection of behaviors.* Each of the focus behaviors in Table 2 were carefully selected based on their mortality risk, prevalence and the likelihood of behavior change. This led to an intervention being designed where CBSVs carry out two main activities: counseling women and their families about birth preparedness and early newborn care and assessing and referring babies identified as having danger signs. The home visit strategy also includes extra visits for babies identified as having danger signs and for low birth weight infants. Behaviors that were already being performed adequately were either simply reinforced (for example, attending antenatal care) or were omitted (for example, hygienic cord cutting). An example of a behavior that was omitted from the intervention, because behavior change was deemed unlikely and the mortality risk was considered low, is not putting anything on the umbilicus. Shea butter or alcohol was applied to the cord of 70% of babies and hot water was dripped to help ensure that the cord did not become dry. All respondents felt that applying nothing to the cord would have negative consequences including discomfort and the potential death of the baby: 'if it is not carried out (applying something to the cord) the baby cannot sleep and there will be sickness in his stomach... the sore would go into the stomach and this could kill' [27-year-old pregnant woman]. Questions such as whether people in the community would change their behavior were often met with disbelief: 'Eh... Do you want to kill us, if we don't drip water how can the sore heal?'



**Figure 1** Strengthening DHMT: DiPS; CBSV supervision structure; M&E capacity.

**Table 2** Timing and content of five home visits

1. Early pregnancy	Birth preparedness: promote facility delivery, plan for delivery, save for emergencies, sleep under bednets. Reinforce antenatal care
2. Third trimester	Dry, wrap and breastfeed immediately after delivery. Encourage second assistant during delivery
3. Day of birth	Weigh and assess the baby for danger signs Refer very low birth weight and sick babies to hospital Encourage exclusive breastfeeding; reduce bathing Special care for low birth weight babies
4. Day 3	Assess baby for danger signs and refer sick babies Problem solve Reinforce exclusive breastfeeding Encourage illness recognition and prompt care seeking
5. Day 7	Assess baby for danger signs and refer sick babies Problem solve Reinforce exclusive breastfeeding and prompt care seeking Encourage bednet use and immunizations

(40-year-old recently delivered woman) . . . ‘If you say it (put nothing on the cord) people may agree in your presence but in actual fact they will never do it’ (35-year-old recently delivered woman).

*Timing of visits.* Families and community volunteers reported that too many visits in pregnancy would be a burden, so two visits

in pregnancy were deemed appropriate. The findings of the formative research suggested that the first home visit should be as early in pregnancy as possible to give families sufficient time to prepare for the delivery and the second visit should be in the third trimester to check on the preparations and to counsel on immediate care of the newborn. As the first week of life is particularly risky for the newborn, the intervention includes three visits in the first week of life (on days 1, 3 and 7). Some respondents reported that women may not want to be visited on the day of delivery as they would want to rest, and a strategy was developed to discuss the importance of a day 1 visit in community entry activities. Including an assessment of the baby on the day of delivery was identified as increasing the acceptability to the family of the day 1 visit. Extra visits were developed for babies with danger signs (follow-up visits on the next day to check on referral, and a reassessment of babies who were not taken to the facility to check if they still required referral), and for low birth weight infants (two extra visits in the first week of life and one on day 14 to assess for danger signs and check on special care).

*Home visit messages and approach.* Messages for each of the focus behavior were carefully developed to overcome the main behavior change barriers that were identified in the formative research. For example, immediate drying and wrapping of the baby after delivery was selected as a focus behavior because immediately after birth, a wet newborn is at particular risk of hypothermia, and because the formative research found a wide gap between desired and

actual behaviors (37% of babies were left wet with birth fluids and 42% of babies were unwrapped for more than 15 min after delivery). The main reason babies were left wet and unwrapped was because the birth attendant focuses on the mother until the placenta is delivered: 'If the afterbirth is not delivered, then the baby is not a human being... all the attention is on the mother because they want to save her life' (35-year-old recently delivered woman), or because the consequences of leaving the baby unattended were considered less serious than the consequences of leaving the woman unattended: 'Since the newborn is stronger it should be left alone after delivery and the mother attended to' (34-year-old recently delivered woman). A facilitator to the baby being immediately dried and wrapped after delivery was having two people present at the birth 'Since two people assist during delivery the baby is always wiped immediately it is born and then wrapped with samboto (flour sack) to keep warm' (pregnant woman of unknown age). Sixty-two percent of women who delivered at home reported that there were two or more people present at the delivery, but the second person often ran errands or helped support the delivering woman in the squatting position: 'her aunt fetched water for the grandmother and her mother held her waist to deliver. The other family members present did not do anything' (recently delivered woman of unknown age). Organizing an extra person/utilizing the people already present at a home birth was developed into a key intervention message. Some women did not want others present at delivery because of shyness, fear of the evil eye or because they may need to confess secrets to ease a difficult delivery, so a compromise behavior of calling the extra person immediately the baby was born was developed for such women. The need to target traditional birth attendants (TBAs) to ensure that the role of this extra person was known and accepted was stressed by respondents.

The example presented above shows the type of information collected in the formative research and how this information was used to inform decisions about the intervention message approach. A more detailed example showing the depth of the data collected by the formative research strategy is given in a companion paper in this supplement.<sup>24</sup>

The need for compromise behaviors, such as calling the extra person immediately the baby is delivered, illustrates why a problem solving approach was selected for the intervention. The formative research suggested that information alone would not be sufficient for behavior change, so the community health worker training was designed to include behavior change communication based on the stages of behavior change model<sup>25</sup> and to discuss potential problems that the families may have adopting each focus behavior and possible solutions (see Table 3 for an example of the problems and solutions discussed).

**Involvement of family members.** The formative research identified that several family members help care for the newborn or influence decision making and should thus be included in the home visit. For example, the formative research found that

**Table 3** Examples of the problems and potential solutions related to encouraging women to deliver at a facility discussed with community health workers during the training

<i>Problem</i>	<i>Potential solution</i>
<i>Cost of delivery</i>	Explain that saving a very small amount of money each week adds up to a significant amount over the pregnancy, especially if all the family is involved Stress that delivering in a health facility helps ensure a safer delivery and a healthy baby, which saves money in the long run
<i>Perception of home births as safe</i>	Explain that the health facility is the best place to deal with delivery complications Explain that complications such as prolonged labor, delayed placenta and bleeding after delivery can happen to any woman, even those who usually have safe deliveries.
<i>Lack of transport</i>	Help families identify a means of getting to the facility for either a day or night delivery If transport is not available at all times ensure the family also prepares for a home birth
<i>Fear of health facility procedures</i>	Educate families on the fact that the health facility procedures are always carried out to save lives. If these procedures are not conducted when they are required, it is likely that the woman will die

husbands are often key in financial decision making, and so are important to include in at least the first home visit where finances for delivery and emergencies are discussed.

**Care for sick babies.** Data from earlier research in the study area<sup>26</sup> found both poor recognition of danger signs such as fast breathing and no or delayed care seeking when illness was recognized. Mothers reported seeking care outside the home for only 36% of newborns reported as having had a serious illness and delays in care seeking were common. To improve care seeking, a strategy was designed to both train volunteers to assess the newborn for danger signs during the most risky time (first week of life and up to the second week of life for low birth weight babies) and to counsel families on the symptoms they should seek prompt care for. To help overcome common barriers to care seeking, the volunteers were trained to problem solve with families around issues such as transport and to counsel on care during the journey.

The assessment includes checking for the following: baby not able to feed since birth/stopped feeding well, baby convulsed or fitted since birth, fast breathing, chest in-drawing, high or low temperature, baby only moves when stimulated, baby has yellow soles, baby has red/pus from umbilicus, pus from the eyes or boils with pus. The assessment not only allows the volunteers to identify potentially sick newborns but may also provide families with the impetus of a formal referral to help overcome care seeking barriers such as the baby being diagnosed with a spiritual illness, such as 'Asram', which is usually treated with herbs at home.

*Care for low birthweight (LBW) babies.* Low birth weight babies are at high risk and need special care; however, there was poor recognition of low birth weight. Among women who delivered in hospital maternal perception of a small baby had a sensitivity of 73% for detecting birth weight less than 2000 g but only 30% sensitivity to detect babies from 2000 to 2500 g. It was thus decided that the volunteers should measure birth weight on the day of birth, or as soon as possible, to determine whether counseling on special care for small babies (skin to skin care, frequent feeding, delayed bathing and extra care with hygiene) was required. To facilitate use of the scale, a color coded scale was selected with red for very small babies who need referral to a facility, yellow for small babies who can be given special care at home and green for normal weight babies. Weighing was also identified as an incentive for families accepting the day 1 visit and the provision of 'medical equipment' as a motivator or the community health workers.

### Community-based volunteers

*Selection of CBSVs.* The formative research identified an existing cadre of community volunteers, CBSVs, to make the home visits. These CBSVs were mostly men and trusted and accepted by the community, 'There would be no need to look for other people who do not know anything about health' (29-year-old recently delivered woman), they already visit pregnant women at home and have the time and commitment to deliver the intervention 'It would be no problem... after all it is the same women I already visit' (CBSV of unknown age). Although families reported a preference for female home visitors the high status of CBSVs outweighed this desire 'They have proven to the community that they have a good character' (22-year-old pregnant woman). The decision to use predominantly male volunteers limited the scope of the intervention as families may not want the CBSVs to physically help put a small baby in the skin to skin position or help with breastfeeding attachment.

*Training and materials.* A competency based training plan was devised which, to not overburden the CBSVs, consisted of two training blocks and periodic refresher trainings. The first 4 day block covers identifying pregnant women, who to include in the visits, counseling methods and behavior change messages. Three months later, the second 4-day block, covers assessment, weighing and special care for small babies. During the training, CBSVs are given opportunities to practice the skills they learn and to use the intervention materials. The materials consist of:

- A set of counseling/instruction cards with pictures on the front to engage the family and help them remember the message and simple CBSV instructions on the back to guide the visits.

- A family card with pictorial reminders of the main messages and a space to record the date of the next visit and the CBSVs contact details.
- A referral card to encourage prompt care seeking with instructions on keeping babies with danger signs (without a fever) in the skin to skin position on the journey to the facility and a space to record the reason referred to assist the health worker.
- A CBSV workbook to help the CBSV manage their work by keeping track of appointments and referrals.
- A CBSV manual to be used during the training/supervision and to motivate CBSVs
- For the assessment, the following basic equipment is provided: digital thermometer, color coded scale and respiratory timer.

*Supervision and incentives.* A remuneration and supervision subgroup discussed the implications of the findings of the formative research at the intervention-planning workshop. On the basis of the findings of the formative research and the group's experience working with volunteers, the group decided that providing a monthly monetary incentive linked to a supervisory visit would be key in keeping CBSVs active and supervision regular. An amount of \$5 per month was determined by the government representatives to be sustainable and sufficient to motivate the CBSVs. The importance of developing an accountable and functioning system were recognized as broken promises were reported as de-motivating CBSVs, 'sometimes they promise them so many incentives and they never honor them' (47-year-old CBSV). Other incentives that were identified as motivational from the interviews with CBSVs and deemed feasible and sustainable by the DHMTs were an ID card, a bag and a T-shirt.

The supervision was designed to include a monthly visit where CBSVs are either directly observed visiting families or an individual discussion session is held. At 2 to 3 monthly intervals, group meetings where CBSVs can share experiences and discuss problems are held. Lessons learnt from the formative research related to the supervision included the need for a session in the supervisors training on giving feedback, as CBSVs reported that feedback was rarely given or was carried out so through shouting 'They (current supervisors) seem to forget that the work is a voluntary one and as such we should be treated well and encouraged' (50-year-old CBSV).

The CBSVs identified the need for good quality supervision to increase retention 'Even if there is no money in it you would feel that you are being supervised and that would motivate you to do the work well' (47-year-old CBSV). It was thus decided that the first few months of the intervention implementation supervision would be provided by experienced supervisors who would be paid a salary. Several CBSVs (with a much lower workload than the paid supervisors) would then be promoted into supervisory positions, would be given a bicycle and would receive an allowance of \$10 a

month. The promoted CBSVs would shadow the experienced supervisors to help them gain supervisory skills. This system aims to ensure that the CBSVs receive intensive and high quality supervision in the first months of the intervention, when they may need support applying what they learnt during the training. It also allows CBSVs with supervisory skills to be identified and to get on the job training.

### Strengthening DHMTs

The intervention was designed to be feasible and sustainable at scale, as the formative research process was time and skill intensive this was performed by the research team, the intervention was then designed through the workshops and through the intervention management committee. Initially, the research team will be responsible for the day-to-day running of the intervention, which is designed to be handed over for the DHMTs to manage in a phased way. To assist in this process, an extra member of staff was assigned to each DHMT to help with the intervention logistics and supervision.

### Supportive activities

The need for activities to support the home visits was identified from the formative research. This was because some newborn care behaviors were not under the families' control and because behavior change is enhanced when messages from different sources are consistent and when the community is supportive of the behavior. Activities in both communities and health facilities were developed.

*Community sensitization.* The formative research participants suggested that the newly trained CBSVs should be introduced during community entry activities to encourage the self identification of pregnant and delivered women and to motivate the CBSVs through community recognition, as this was reported by CBSVs as a reason for volunteering 'He believes that one day he could get a certificate so that his children can boast to the next generation that their father served the community' (48-year-old CBSV).

*TBA sensitization.* TBAs were identified as the locus of control for several immediate newborn care activities and their support was needed for behaviors such as having an extra person available during home deliveries to care for the baby immediately after delivery. Where the birth attendant is a family member, it was determined that they can be included in the home visit, but the formative research revealed that formalized TBAs may be unwilling to attend the home visit and would require separate sensitization activities. A half-day TBA sensitization was designed as part of the community entry to garner their support for behaviors, such as early breastfeeding, and to discuss behaviors under their control such as hand washing before delivery.

*Health facility sensitization.* The health facility survey identified that health worker sensitization was needed to ensure that health worker practices and messages were consistent with those promoted in the home visits. For example, bathing in the hospital soon after delivery (reported in five out of the seven facilities) was reported as being a potential barrier for behavior change in the home 'even in the hospitals babies are bathed immediately after delivery, so why do I (referring to interviewer) want them to delay the bathing?' (22-year-old pregnant woman). A half-day health worker sensitization was developed.

*Essential newborn care training.* It was decided during the intervention planning workshop that it was inappropriate to encourage care seeking for sick or very small babies without improving the quality of newborn care in the facilities, in response the Ghana Health Service requested that the World Health Organization conduct essential newborn care training in the main district hospitals in the study area. This was in line with the Ghana Health Service plans related to newborn care.

### Discussion

This paper reports the process taken in designing a community-based newborn care intervention in rural Ghana. Decisions were made using a data driven approach and involved key stakeholders. The DHMTs, who are often not involved in program design, proved keen and insightful members of the intervention design team and it is likely that their involvement will increase sustainability. Explicitly stating the remit of the intervention at the start of the design process allowed the formative research to be focused and ensured there was consensus among team members about the overall intervention design. Developing the formative research questions and designing the research strategy required an experienced researcher with both qualitative and quantitative skills. Using a mix of methods was important, the quantitative data helped in selecting the focus behaviors and the qualitative data helped in this selection and in developing the intervention messages and structure. The quantitative survey utilized a preexisting surveillance and data collection system, but could have been conducted using a simpler method such as that used in the United Nations Children's Fund's multiple cluster survey.<sup>27</sup> Presenting the results of the formative research at stake holder workshops and using these as an arena for decision making was useful to build country ownership and to garner expert opinion for areas in which the team had little experience (for example, designing incentive systems for volunteers). The decision making process was iterative with decisions being modified as new information emerged. As there is always room to improve an intervention, it was important to determine when to stop intervention development. The design process has resulted in an

intervention whose content and structure is determined by the local context and which builds on best practice, although the intervention may not be transferable to other contexts the design process is. The intervention is being evaluated using a randomized controlled design with mortality as an outcome. A process evaluation will allow the individual elements of the intervention, such as the families' reactions to the counseling cards to be assessed. This will help understand whether the design process has led to a sustainable and acceptable intervention.

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