Study Title: Design, implementation and assessment of a comprehensive community neonatal heath package utilising medical and social interventions

Short title: Saving Babies Lives

Date and Version No: 11th July 2022, Version 6.0

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Confidentiality Statement

This document contains confidential information that must not be disclosed to anyone other than the authorised individuals from the University of Oxford, the Investigator Team and members of the Oxford Tropical Research Ethics Committee (OxTREC), unless authorised to do so.

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1. SYNOPSIS

Study Title	Design, implementation and assessment of a comprehensive community neonatal heath package utilising medical and social interventions
Internal ref. no.	N/A
Study Design	Cluster randomised control trial
Study Participants	The population of Preah Vihear (PVH) province, Cambodia
Planned Sample Size	• 293 villages with 586 Village Health Support Group Workers (VHSG) • 26,500 children born in Preah Vihear over the study period and their parents (5,300 deliveries a year) • 306 health centre nurses and midwives from 28 health centres and 17 health posts in Preah Vihear • 30 nurses, 27 midwives and 18 doctors from Preah Vihear Referral Hospital
Planned Study Period	5 years

	Objectives	**Outcome Measures**
Primary	The design, implementation and assessment of a comprehensive community neonatal heath package utilising medical and social interventions	A comprehensive community neonatal heath package utilising medical and social interventions
Secondary	Reduction of perinatal mortality in PVH province, Cambodia	A one third reduction in perinatal mortality in PVH province, Cambodia
Tertiary	To describe the characteristics of neonates, born in PVH province, Cambodia over a five-year time period	A document that describes the characteristics of neonates, born in PVH province, Cambodia over a five-year time period
	To develop a tool to undertake a full review of neonatal services and capabilities in PVH province, Cambodia	A user-friendly tool to assess neonatal healthcare services A report detailing neonatal services and capabilities in PVH province, Cambodia
	Design a fully comprehensive neonatal healthcare training and implementation package adapted to local need	A locally appropriate neonatal healthcare training and implementation package
	Establish regular VHSG meetings to address areas of concern for the local community with respect to childbirth and the neonatal period	Frequency and attendance rate of participants at the programmes VHSG group meetings

	With the Kingdom of Cambodia, Ministry of Health and the Provincial Health Director of PVH province develop a programme blueprint and implementation strategy for introduction of the developed programme into other locations within Cambodia	A programme and implementation plan for the reduction of neonatal mortality that can be used throughout Cambodia
	To calculate the cost-effectiveness of a neonatal community health programme and the resulting changes in care, as compared to the existing care given in the region	A cost effectiveness analysis

2. ABBREVIATIONS

AHC	Angkor Hospital for Children
CI	Chief Investigator
COMRU	Cambodia Oxford Medical Research Unit
CRF	Case Report Form
GCP	Good Clinical Practice
HC	Health Centre
HP	Health Post
KAP	Knowledge, Attitudes and Practice
KAPES	Knowledge, Attitudes, Practice, Equipment and Staff
NMR	Neonatal mortality rate
OxTREC	Oxford Tropical Research Ethics Committee
PAR	Participatory Action Research
PI	Principal Investigator
PIS	Participant Information Sheet
PVH	Preah Vihear
SBLP	Saving Babies Lives Programme
SBLT	Saving Babies Lives Team
VHSG	Village Health Support Group

3. BACKGROUND AND RATIONALE

Globally the proportion of childhood deaths that occur in the neonatal period is increasing [1]. Since 1990 there has been a 47% reduction in deaths in children less than five years of age [2]. However, this rate of reduction has not been seen in infants four weeks of age or younger (neonates). It is estimated that 2.9 million neonates die each year, with one million of these occurring on the first day of life [3]. Neonatal mortality now makes up 44% of all deaths in children younger than five years [3]. The reasons why the fall in neonatal mortality has not mirrored that seen in children mortality, is complex and one that is not well explored in the literature.

Cambodia has met most targets of the 4th and 5th Millennium Development Goals, reducing child mortality and improving maternal health by investing in health systems [4, 5]. However, the Sustainable Development Goals call for further improvements and Cambodia continues to fall behind its neighbouring countries in reducing neonatal mortality [6].

One proposed explanation is that interventions that have been successfully employed to reduce childhood death do not reach the community and it is in the community where most neonates die [7, 8]. Another pervasive perceived barrier to providing neonatal care, particularly in remote and rural areas, is the misconception that neonatal care is difficult and expensive [9].

During the neonatal period, perhaps more than at any other time, there are deep rooted health practices and beliefs. These differ in different communities but often share common themes. Hot bed use, food avoidance in the mother postpartum, discarding colostrum and application of various substances to the umbilical cord (such as cow dung, petrol and ash) are examples of widely held practices [10-12]. Many of these practices are potentially harmful to the neonate and need to be addressed in the communities where they occur by community engagement and education.

Community

Many health problems are rooted in powerlessness. Health education that involves community involvement: dialogue and problem solving, rather than just message giving, is more empowering. Addressing social needs and empowering communities to make decisions about health care needs allows for the design of programmes that account for local practices and beliefs [13, 14]. In participatory action research (PAR) communities identify and prioritise problems, develop action plans, implement these plans and assess them [15-18]. Community assessment of health problems and barriers increases the awareness of those problems; it has been shown to increase social support and participation in problem solving [13]. PAR uses facilitation rather than teaching to increase knowledge in community groups.

Health Care facilities

Up to two-thirds of neonatal deaths could be prevented if neonates were given proper care during and immediately after birth, because the majority of neonatal deaths occur around the time of delivery [19]. Training primary level health care workers to deal with emergency situations that occur around the time of delivery, such as ante-partum and post-partum haemorrhage, umbilical cord prolapse and shoulder dystocia, has been shown to decrease maternal mortality and neonatal mortality [20]. Similarly, a model for neonatal care in low-resource settings, special baby care areas, has been proven to significantly reduce neonatal mortality over a period of a few years [9].

It is reported that 79% of deliveries in Cambodia occur in healthcare facilities [21]. The majority of these will occur at primary healthcare facilities (health centres (HC) or health Posts (HP)). Babies born in HCs or

HPs who require further care are referred to the referral hospital. The majority of referral hospitals in Cambodia do not have the resources or skills to effectively deal with neonatal complications for babies born either in health centres or in their on-site maternity wards.

The Saving Babies Lives Programme will be developed in partnership with the Kingdom of Cambodia Ministry of Health (MoH). The programme will be approved by the MoH and a memorandum of understanding signed with the provincial health director of Preah Vihear (PVH) province. The major objective of this project is to develop a programme blueprint and implementation strategy for introduction of the developed programme into other locations within Cambodia. Data will be collected and used to assess the impact of the programme, its perceived facilitators and barriers and its successes and failures. This information will be used to iterate the programme content and structure in order to improve it.

3.1. Research Question

The central hypothesis of this study is that a neonatal healthcare programme that has a significant impact on neonatal mortality and which spans the healthcare journey from village to referral hospital can be developed and implemented in low resource rural setting

Aim of the study

The design, implementation and assessment of a comprehensive community neonatal heath package utilising medical and social interventions

3.2. Intervention

The study has four components

1. Design and implementation of a locally appropriate comprehensive neonatal healthcare package – Saving Babies Lives Programme (SBLP)
2. Establishment of baby health meetings for VHSGs
3. Measurement of perinatal mortality in PVH province
4. Economic evaluation of the programme and its implementation

Saving Babies Lives Programme

A comprehensive, contextual and adaptive neonatal healthcare package will be developed using the Kingdom of Cambodia national guidelines on neonatal and maternal health, WHO maternal and child health guidelines and results from the pre-implementation assessment [24-26]. Course-based training will be combined with continuous in-situ mentoring to support doctors, nurses and midwives and other health worker cadres in order to improve their practical daily skills in emergency and clinical neonatal care. Essential equipment will be identified and included in the package. The neonatal healthcare package will be developed by the Saving Babies Lives team which consists of experienced nursing and medical staff working at the Angkor Hospital for Children (AHC), Cambodia. AHC is a non-governmental teaching hospital that has been in operation since 1999. Each year it provides approximately 180,000 free treatments to neonates and children and has a dedicated neonatal care programme.

A neonatal healthcare assessment tool will be developed that is quantitative and qualitative in nature. It will be based on the KAP survey method of analysing Knowledge, Attitudes and Practice. KAP involves a representative survey on a specific topic, of a particular population, by using predefined questions in standardised questionnaires, to produce data which may be quantitative, qualitative, or a mixture of the

two [27, 28]. In addition, two further domains will be added, equipment and staffing, leading to a "KAPES" model of assessment. Before the neonatal healthcare package is introduced into a HC or HP the KAPES assessment will be carried out. It will also be performed after the initial training period and then annually until the end of the study. The information gathered using this tool will further inform the content of the neonatal health care package.

VHSG Baby Health Meetings

Baby Health meetings (BHM) will be conducted at each HC. Each BHM will be attended by two VHSG from each of the villages served by the HC. The purpose of the BHM is to identify problems and concerns around neonatal health care in their own village. Monthly meetings will take place at the HC in order for the group to discuss problems, attempt to arrive at solutions, and share learning. These meetings will be facilitated by the SBL team who will use a Participatory Action Research (PAR) methodology to:

1. Identify problems with provision of, and barriers to seeking, neonatal health care
2. Develop interventions to improve care
3. Implement these interventions
4. Assess the group's perception of the effectiveness of interventions (Figure 1).

Specific questions and prompts will be devised by the SBLT prior to the meeting and will be based on experiences gained from previous meetings. The use of storytelling will be used to simulate discussion [22].
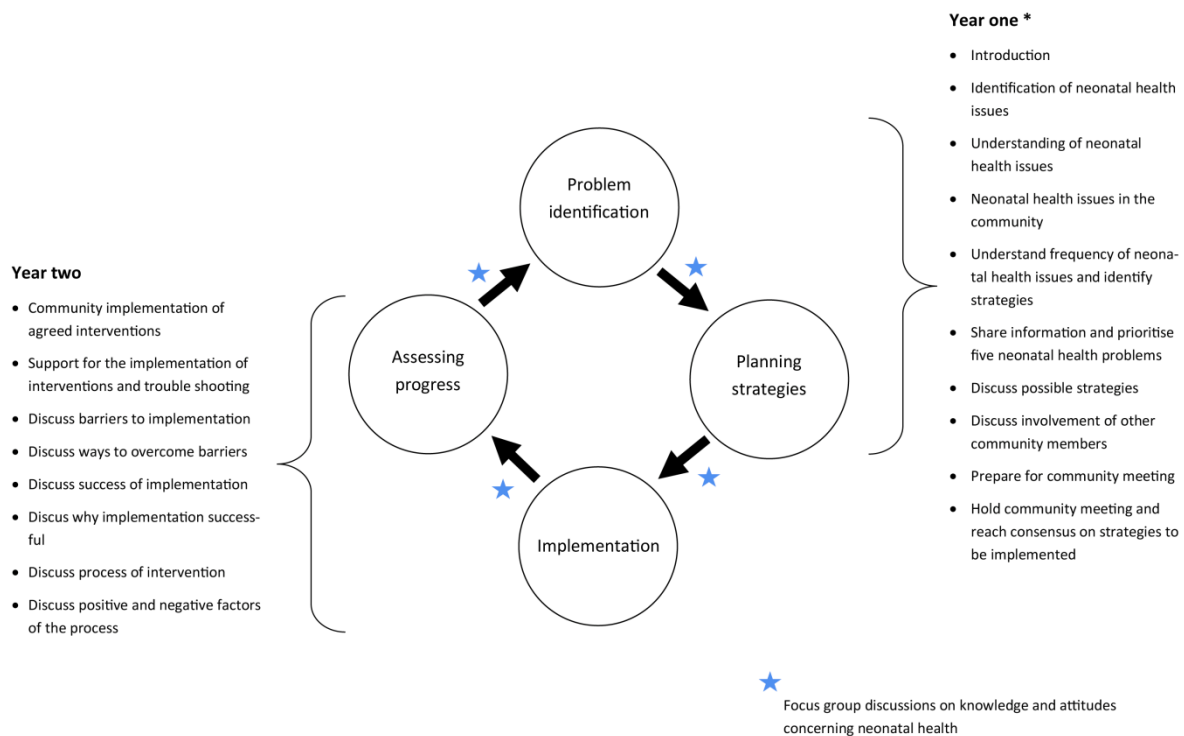

Figure 1. Overview of the baby health meetings

Set-up

The BHM will be conducted in the HCs chosen to be in the intervention group. Both prior to the meeting and after it refreshments will be served. The group will decide whether they want to sit on chairs or the floor. At the start of the first meeting ground rules will be discussed and agreed upon; these will be written in Khmer and displayed at each subsequent meeting. Flip charts, post it notes and pens will available during each session to help clarify points and to reach consensus about topics. These charts will be photographed at the end of each meeting. All participants will receive their travel costs, calculated by distance travelled and at a fixed rate and paid at the end of the meeting.

Conducting the Meetings

The meetings will be conducted in Khmer by one of the SBLT. A focus group discussion like method will be used, with the SBLT member encouraging discussion and interaction in the group. A meeting topic guide will be used for each meeting (Appendix 1. Baby Health Meeting topic guide

Recording the Meetings

An observer will be present to take notes on nonverbal communication and interactions using a meeting observation form (Appendix 1. Baby Health Meeting topic guide

Baby Health Meetings for Saving Babies Lives

Meeting topic guide

HC code: |__|__|__|__| Facilitator Initials: |__|__|__| Note-taker Initials: |__|__|__|

Date: |__|__|/|__|__|/|__|__|

Meeting number: |__|__|

Introduction

I am _____ from _____ (Facilitator)

I am _____ from _____ (note-taker)

⇒   Ask group to introduce themselves using first names

⇒   Todays topic for discussion (check meeting time table and use specific guide)

⇒   Aims of the discussion and expected duration (1 hour)

⇒   Remind the group of the ground rules

⇒   Any questions

⇒   Check position of the tape recorder

⇒   Check for everyone's consent to participate and be recorded

⇒   Refreshments will be served before and after the discussion

⇒   Travel reimbursement will be given after the meeting

Questions	Prompts

Meeting topic guide	Version 2.0	1st August 2018

Appendix 2). Each participant will be given an ID number and these will be used so that the note taker can draw a map of where people were sitting and attribute contributions to specific people.

Contact Summary Forms

At the end of each meeting the SBLT will meet and complete a contact summary form, documenting the meeting process (Appendix).

Perinatal Mortality

The expected outcome of the SBLP is a reduction in perinatal mortality (PMR). In order to assess the effectiveness of the SBLP an accurate measure of PMR is needed. Although births and deaths are required to be registered in Cambodia, often the births and deaths of young infants, particularly those born at home, are not registered. To accurately determine the perinatal mortality rate (PMR) in PVH province, government village health support groups (VHSG) will be asked to record details of all births and neonatal deaths in their villages. The data collected will include:

1. Village name
2. Estimated Date of Delivery
3. Date of delivery
4. Gender
5. Prematurity
6. Place of delivery
7. Birth weight
8. Alive at 28 days

The data will be brought to monthly VHSG meeting and entered in to a database by a member of the SBLT. Each VHSG will receive a $2 phone credit card for each completed birth data collected. If a neonate dies, a verbal autopsy will be performed by one of the Saving Babies Lives team using the WHO Verbal autopsy tool [23].

Economic Evaluation

A detailed cost analysis will be carried out to estimate the added resources that are required for the SBLP as compared with standard care. These costs will be combined with estimates for the incremental cost of caring for children at AHC, and HCs if attendance is found to increase, and by modelling the subsequent survival benefits in terms of incremental disability adjusted life years averted. This will indicate whether the SBLP is as cost-effective as compared to the existing standard of care (control arm).

At the time of the newborn health questionnaire, the mother will be asked about any health seeking costs the family incurred for their infant in the first four weeks of life.

3.3. Study Site

Preah Vihear is one of the most remote and isolated provinces in Cambodia. The province has a population of around 172,000 people spread out through 293 villages in eight districts. The mainly rural population survive on sustenance farming. Within the province there are 28 government HC, 17 HP, and one referral hospitals. Each HC and HP serves a number of villages and is the first point of access for health care. There are approximately 5,300 recorded deliveries in the province per year (data obtained from PVH provincial health offices).

4. OBJECTIVES AND OUTCOME MEASURES

Objectives	Outcome Measures	Time point(s) of evaluation of this outcome measure (if applicable)
Primary Objective The design, implementation and assessment of a comprehensive community neonatal heath package utilising medical and social interventions	A comprehensive community neonatal heath package utilising medical and social interventions	Study end
Secondary Objective Reduction of perinatal mortality in PVH province, Cambodia	A one third reduction in perinatal mortality in PVH province, Cambodia	Study end
Tertiary Objectives: To describe the characteristics of neonates born in PVH province, Cambodia over a five-year time period	A document that describes characteristics of neonates, born in PVH province, Cambodia over a five-year time period	Study end
To develop a tool to undertake a full review of neonatal services and capabilities in PVH province, Cambodia a. Assess the level of knowledge possessed by health care workers with respect to fundamental areas of care surrounding delivery and the neonatal period b. Evaluate current practice regarding delivery and neonatal care c. Undertake a review of health centre facilities and resources d. Record the staff composition and working patterns e. Detect commonalties as well as differences between facilities f. Assess the local community service provision, including the activity of the VHSGs as well as any other community health projects and initiatives	A user-friendly tool to assess neonatal healthcare services A report detailing neonatal services and capabilities in PVH province, Cambodia	Study end

g. Identify factors that may be functioning as barriers and facilitators to improvements in the delivery of care		
Design a fully comprehensive neonatal healthcare and implementation package adapted to local need a. Provide health workers with essential knowledge with respect the neonatal period. b. Design a programme to teach that is acceptable and feasible for government health workers c. Empower healthcare providers to make positive changes in order to overcome any barrier to improvement. d. Equip each facility with the resources required to safely resuscitate a neonate and provide ongoing neonatal care as required.	A locally appropriate neonatal healthcare training and implementation package	Study end
Establish VHSG groups to address areas of concern for the local community with respect to childbirth and the neonatal period a. To identify issues communities, have in relation to neonatal health, and which interventions are seen as priorities to improve neonatal health care	Frequency and attendance rate of participants at the programmes meetings	Study end
With the Kingdom of Cambodia, Ministry of Health and the Provincial Health Director of PVH province develop a programme blueprint and implementation strategy for introduction of the developed programme into other locations within Cambodia	A programme and implementation plan for the reduction of neonatal mortality that can be used throughout Cambodia	Study end

To calculate the cost-effectiveness of a neonatal community health programme and the resulting changes in care, as compared to the existing care given in the region.		

5. STUDY DESIGN

A cluster randomised study design will be used, with a cluster being defined as a HC administrative group, as defined by the PVH Provincial Health Department. This includes all HC, HP, villages, and villagers in that group.

Pilot: to begin in July 2018, consisting of 4 clusters.

Intervention arm: to begin October 2019, consisting of 10 clusters.

Control arm: all remaining clusters.

Completion: December 2022.

The SBLP will be introduced into the provincial referral hospital during 2018.

The SBLP will be introduced into the new referral hospital during 2022.

The choice of which health centres will be included at each time point will be made using purposive sampling to ensure a mix of health centre characteristics. Characteristics that will be taken into account are the distance from the health centre to the referral hospital and number of villages the HC serves.

6. PARTICIPANT IDENTIFICATION AND RECRUITMENT

6.1. Saving Babies Lives Training Programme
6.2. Study Participants

The Saving Babies Lives Programme will be aimed at government health care staff working in the community (VHSG), at HC (nurses and midwives) and at the referral hospital (doctors and nurses)

6.3. Inclusion Criteria
- Staff members chosen by the Provincial Health Director to attend the programme

6.4. Exclusion Criteria
- Not applicable

6.5. VHSG Baby Health Meetings
6.6. Study Participants
- Two VHSG from villages served by each HC cluster
- Adults (aged 18 years or older)

6.7. Inclusion Criteria

- Work as a VHSG
- Live in a village served by a chosen HC
- Are able to commit to attend meetings regularly
- Give consent to participate in the meetings

6.8. Exclusion Criteria

- Refusal to participate
- Be from a village where two members have already been chosen

7. STUDY PROCEDURES

7.1. Saving Babies Lives Programme

7.2. Recruitment

Not applicable

7.3. Screening and Eligibility Assessment

Not applicable

7.4. Informed Consent

Not applicable

7.5. Discontinuation/Withdrawal of Participants from Study

- Each participant has the right to withdraw from the SBLP at any time.
- The reason for withdrawal will be recorded in the teaching attendance log book.

7.6. VHSG Baby Health Meetings

7.7. Recruitment

The Saving Babies Lives Team (SBLT) will visit all health centres and give a presentation about the project. All VHSGs will be invited to take part in the meetings

Each VHSG will be approached (face-face) and asked whether they give consent to be in the BHM.

Demographic data will be collected from all VHSG. A short questionnaire administered to assess knowledge on neonatal health, attitudes towards neonatal health and their practice as VHSG. This questionnaire will be repeated on an annual basis to observe changes in responses over time.

If a participant leaves the group, their replacement VHSG will be approached and asked to join the group.

7.8. Informed Consent

Formal written consent for the VHSG to participate in the BHM will not be taken. This decision has been made for the following reasons:

1. Consent will be inferred by the fact that the VHSG is attending the meeting. The individuals will only take an active role in the discussion if they wish to
2. The Provincial Health Director of PVH regards attendance at the BHMs as being part of the normal role of the VHSG and has requested that no special procedures be undertaken

7.9. Discontinuation/Withdrawal of Participants from Study

Each participant has the right to withdraw at any time. In addition, the Investigator may discontinue a participant from the study at any time if the Investigator considers it necessary for any reason including:

- Non-attendance at three or more meetings within one year
- Withdrawal of Consent

The reason for withdrawal will be recorded

8. STATISTICS AND ANALYSIS

8.1. Description of Statistical Methods

VHSG Baby Health Meetings

Summary forms from the BHM will be translated into English. Ten percent of data will be double translated and transcribed and the two versions compared for errors. The data will be exported into a qualitative software package (N-Vivo 10 (QSR International, Cambridge, MA). After data entry an analytical framework will be developed to identify common and emerging themes, which will then be coded. Once the codes have been developed they will be applied to the whole data set for interpretation of the data. Quantitative data will be used to contextualise the qualitative data [14-16]. Ethnographic and content thematic analysis will be performed on the data generated by the BHM. This will focus on process evaluation and outcome evaluation. The Medical Research Council guidelines for evaluating complex interventions will be used as a guide [24].

Primary Outcome:

- Factors associated with the success or failure of the engagement process
  - Factors to explore:
    - Involvement of group members in the meeting
    - Cohesiveness of the group
    - Taking message back to the community
    - Acceptability of the process
    - Appropriateness of group members
    - Factors influencing the ability / inability of the VHSG to implement suggested interventions

Secondary Outcomes:

- Changes in the VSHG's knowledge, attitudes and practices in neonatal health over time
- VHSG's perceptions of neonatal health issues in rural Cambodia

- Interventions suggested to improve neonatal care and reasons behind them
- Acceptability of the groups to the community / health providers / community leaders
- Acceptability to the group
- VHSG's perception of the effectiveness of interventions
- Involvement of community members with the program

Perinatal Mortality

The analysis will be performed by intention to treat; mothers and their infants who began the study as residents of one cluster will remain in that group even if they move to another cluster.

Primary Outcome:

1. Perinatal mortality rate will be described by hazard rate and 95% confidence interval (CI) separated by groups. Survival between groups will also be described using Kaplan-Meier plot. Log-rank test will be used for univariate comparison of survival. We will also describe median time to perinatal death with 95% CI in each group from Kaplan-Meier plot.

Secondary Outcomes:

1. Description of the cohort
    a. Prematurity
    b. Birth weight
    c. Sex
2. Facility based deliveries

Facility based deliveries prematurity, sex, will be described using percentage and compared between groups using Chi-square test or Fisher's exact test as appropriate. Number of ANC visits will be described using median with inter-quartile range (IQR) and compared between groups using Mann-Whitney U test. Birth weight will be described using mean with standard deviation and compared between groups using Student's t test or using median with inter-quartile range and compared between groups using Mann-Whitney U test if data have non-normal distribution.

Statistical analysis will be performed using STATA software package. Statistical significance will be considered if *p*-value < 0.05

Sample size Calculation

With perinatal mortality rate and a simple parallel cluster randomised trial design, the number of clusters are fixed to the intervention and control arm clusters and the time-frame is fixed to five years. The change in study design has been necessitated by logistical reasons and the post-study power calculations are not relevant. We will report limitations to the power in write-up.

The statistical analysis will remain broadly the same, with the main difference being that we will no longer adjust for the confounding effects of time. The primary analysis will exclude pilot cluster results, and will only be conducted on the intervention and control arm clusters.

Please see the study Statistical Analysis Plan for full details.

Economic Evaluation

A detailed cost analysis will be carried out to estimate the added resources that are required for the SBLP as compared with standard care. These costs will be combined with estimates for the incremental cost of caring for neonates at the referral hospital if attendance is found to increase, and by modelling the subsequent survival benefits in terms of incremental disability adjusted life years averted. This will indicate whether SBLP are cost-effective as compared to the normal standard of care (control arm).

9. DATA MANAGEMENT

9.1. Access to Data

Direct access will be granted to authorised representatives from the University of Oxford and any host institution for monitoring and/or audit of the study to ensure compliance with regulations.

9.2. Data sharing

Data collected for this study will be under the custodianship of AHC, will be de-identified and may be shared with other groups of researchers in accordance with the current MORU Data Sharing Policy. (http://www.tropmedres.ac/data-sharing-policy) All applications will be carefully reviewed by the MORU Data Access Committee before granting any approvals to access data. All researchers accessing the data need to adhere to a set of terms and conditions that aim to protect the interests of research participants and other relevant stakeholders.

9.3. Data Handling and Record Keeping

During Field Work

Notes will be kept with the SBLT at all times or in a locked vehicle to ensure confidentiality. Non SBLT members will not be permitted to look at the notes. Content of the discussions will not be revealed to anyone else.

After the Field Work

All notes will be taken to the SBL office at the end of the day. The paper notes will be stored in a locked filing cabinet prior to data entry. Following data entry, the files will be kept on a on a secure, password encrypted server. The server will be backed up to tape every day and the tapes kept in a secure off-site location.

10. QUALITY CONTROL AND QUALITY ASSURANCE PROCEDURES

Prior to commencement of programme the team will be trained in teaching and facilitation methods and techniques. In addition, they will be trained in the programme specific data collection and in GCP. The study will be conducted in accordance with relevant regulations and standard operating procedures.

11. ETHICAL AND REGULATORY CONSIDERATIONS

11.1. Declaration of Helsinki

The Investigator will ensure that this study is conducted in accordance with the principles of the Declaration of Helsinki.

11.2. Guidelines for Good Clinical Practice

The Investigator will ensure that this study is conducted in accordance with relevant regulations and with Good Clinical Practice.

11.3. Approvals

The protocol and any proposed advertising material will be submitted to OxTREC and the Cambodian National Ethics Committee for written approval.

Permission to introduce this programme will be sought from the Government of the Kingdom of Cambodia.

The Investigator will submit and, where necessary, obtain approval from the above parties for all amendments to the original approved documents.

11.4. Participant Confidentiality

The study staff will ensure that the participants' anonymity is maintained. The participants will be identified only by a participant ID number on all study documents and any electronic database, with the exception of the CRF, where participant initials may be added. All documents will be stored securely and only accessible by study staff and authorised personnel. The study will comply with the Data Protection Act, which requires data to be anonymised as soon as it is practical to do so.

11.5. Expenses and Benefits

Reasonable travel expenses for any visits additional to work will be reimbursed.

11.6. Reporting

The CI shall submit an Annual Progress Report to OxTREC on the anniversary of the date of approval of the study. In addition, the CI shall submit an End of Study Report to OxTREC within 12 months of completion of the study.

12. FINANCE AND INSURANCE

12.1. Funding

Funding is actively being sought

12.2. Insurance

The University has a specialist insurance policy in place which would operate in the event of any participant suffering harm as a result of their involvement in the research (Newline Underwriting Management Ltd, at Lloyd's of London).

13. PUBLICATION POLICY

The results of the evaluation of the programme will be shared with the Kingdom of Cambodian MoH, presented at relevant national and international meetings and submitted for publication in an international peer-reviewed journal.

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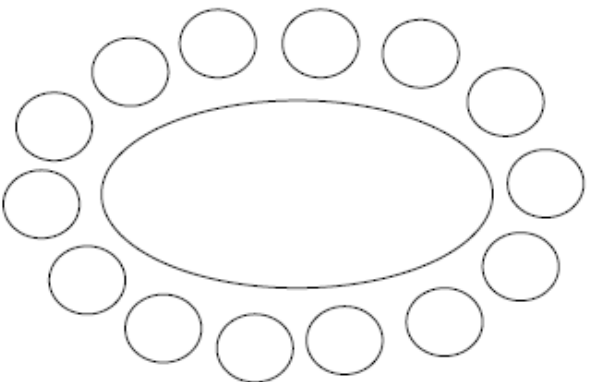
15. Appendices
Appendix 1. Baby Health Meeting topic guide

Baby Health Meetings for Saving Babies Lives

Meeting topic guide

HC code: |__|__|__|__| Facilitator Initials: |__|__|__| Note-taker Initials: |__|__|__|

Date: |__|__|/|__|__|/|__|__|

Meeting number: |__|__|

Introduction

I am _____ from _____ (Facilitator)

I am _____ from _____ (note-taker)

⇒   Ask group to introduce themselves using first names

⇒   Todays topic for discussion (check meeting time table and use specific guide)

⇒   Aims of the discussion and expected duration (1 hour)

⇒   Remind the group of the ground rules

⇒   Any questions

⇒   Check position of the tape recorder

⇒   Check for everyone's consent to participate and be recorded

⇒   Refreshments will be served before and after the discussion

⇒   Travel reimbursement will be given after the meeting

Questions	Prompts

Meeting topic guide	Version 2.0	1st August 2018

Appendix 2. Meeting observation form

Baby Health Meeting for Saving Babies Lives
Meeting observation and summary form

HC code: |__|__|__|__| Facilitator Initials: |__|__|__| Note-taker Initials: |__|__|__|

Date: |__|__|/|__|__|/|__|__| Time start ___:___ end ___:___

Meeting place description: *detail and description, e.g. size and accessibility, and how this could affect the discussion; interruptions during the discussion*

Participants: *any observations, anyone missing?*

Group dynamics: *general description – level of participation, dominant and passive participants, interest level, boredom, anxiety – and how these relate to the different topics discussed*

Impressions and observations:

Seating diagram:

Meeting notes and summary form   Version 2.0   1st August 2018

Running notes (detailed notes following the discussion, as near verbatim as possible, including identification of all contributors):

Meeting notes and summary form   Version 2.0   1st August 2018

Summary points made by group:

Do all the participants agree with this summary?   ◯ No   ◯ Yes

If no give more details:

Completed by: _____   Date: _____

Meeting notes and summary form   Version 2.0   1st August 2018

Appendix 3. VHSG meeting contact form

Baby Health Meetings for Saving Babies Lives

Meeting contact summary form (to be completed by facilitator in conjunction with note taker)

HC code: |__|__|__|__| Facilitator Initials: |__|__|__| Note-taker Initials: |__|__|__|

Date: |__|__|/|__|__|/|__|__|

What were the main issues or themes that struck you during this meeting?

What new information did you gain through this meeting compared to previous meetings ?

Was there anything surprising to you personally? Or that made you think differently ?

What messages did you take from this group?

How would you describe the general atmosphere and engagement of the group?

How would you describe the group dynamics? For example, were there dominant individuals?
Did all participants contribute? Did you feel there was pressure to adhere to dominant viewpoints (what topics)?

Meeting contact summary form   Version 2.0   1st August 2018

What else was important about this meeting

Were there any problems with the topic guide (e.g. wording, order of topics, missing topics) you experienced in this focus group?

Other observations of notes:

Completed by: _____ Date: _____

Meeting contact summary form   Version 2.0   1st August 2018

What else was important about this meeting