

Study Title:
Electricity-free Infant Warmer for Newborn Thermoregulation

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Summary of Study (Synopsis)

Hypothermia contributes to a significant portion of neonatal deaths. Kangaroo mother care is a safe and effective method of warming; however, it is not always feasible, and not possible in settings such as resuscitation or clinical instability. Electric warmers are the standard of care in developed countries, but are extremely costly, complicated with risk of causing both hypo and hyperthermia with misuse, and often not feasible in settings without stable electricity. Through a multi-institutional collaboration, we have developed an electricity-free infant warmer. After laboratory based prototype testing for safety and efficacy, we aim to study the supervised use of the warmer under routine implementation conditions in a resource-limited setting. The primary aim of Phase 1 is to determine if the infant warmer is a safe, effective, usable and functional addition to KMC. This is planned in a convenience sample of patients in two district hospitals, one in a relatively warm environment, and one in a colder setting using quantitative methods and observer audits of usability and functionality. After determination of safety and effectiveness and making any necessary modifications to the warmer, Phase 2 aims to study the warmer in rural health centers and transport, as this is where we ultimately aim to use the electricity free devices due to the limited access to functioning and stable electricity in these settings. The primary aims are to assess the safety, efficacy, usability and functionality of the infant warmer in rural health centers during post-partum care, resuscitation/stabilization and on transport using the same methods as Phase 1. The second aim is to assess the perceived usability, functionality, and acceptability of the infant warmer as an addition to KMC in the health center setting from the perspectives of caregivers and health care providers using qualitative methods. The overall goal of the project is dissemination of the study results, and ultimately the infant warmer to the district and national level for key policy makers and stakeholders, as well as globally via publication.

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1. Background: Reaching Millennium Development Goal 4 is proving elusive in many countries, primarily due to lack of progress in decreasing neonatal mortality. Of the 2.9 million infants who die in the first month of life, 1 million die in their first day.¹ Reductions in the neonatal mortality must address this high proportion of early deaths. Thermoregulation is a critical component of the care of all newborn infants after birth, and is especially challenging in those born preterm, growth restricted, or ill. Ability to provide a warm environment through immediate drying and wrapping and prompt recognition and treatment of hypothermia is estimated to avert up to 40% of neonatal deaths.² Beyond survival, providing adequate warmth to infants decreases metabolic demand, with a 22% reduction in oxygen consumption in warmed term infants compared to controls.³ Therefore supporting thermoregulation also promotes nutrition and weight gain.

The current recommended method of providing ongoing thermoregulation for low birth weight (LBW) newborns in resource-limited settings is Kangaroo Mother Care (KMC). This entails placing an infant on the mother's chest for continuous skin-to-skin contact until the infant is mature enough to maintain a stable, normal temperature. KMC is a proven method of thermoregulation that saves infants' lives, and has been reported to be as efficacious as an incubator to provide thermoregulation for infants ≥ 28 weeks gestation.⁴ However KMC has important limitations: when an infant is ill, the position on the mother's chest is not conducive to providing medical assessments and interventions. If the mother dies during childbirth or is too ill post-partum, she is unable to provide KMC. If there are multiple gestations the mother cannot provide KMC for all of her newborns. Finally, many mothers have other responsibilities that prevent them from being able to provide continuous KMC, and some local customs and cultures create a barrier to effective promotion of KMC. Therefore, there is a need for a safe and affordable alternative to supplement KMC in these conditions.

The non-electric infant warmer proposed for study has been developed by the Institute for Transformative Technologies (ITT), one of the world's leading academic non-profit research institutions, with field-based input by clinical partners at Boston Children's Hospital, Partners In Health, and the Rwanda Ministry of Health to ensure that the developed product is informed by input from intended end-users. Members of the study team have no financial interest in the ultimate success or failure of the proposed product.

The only other currently available low-cost warmer that we know of, "Embrace," has a few notable differences from the proposed warmer. It uses similar phase-change material but covers the infant entirely, limiting exposure of the infant if unstable for resuscitation/stabilization. Additional disadvantages are that it costs approximately 10 times more than the device that we are developing (around \$200 vs. \$20 USD). Embrace has European Inspection (EI) approval. To test the proposed device, the laboratory used similar EI protocols to that used by "Embrace" for safety and performance assessment whenever possible. When no standard existed, a protocol was created with guidance from technical experts with experience in medical product design. Prior to conducting this clinical study, the proposed infant warmer has been extensively tested for safety, thermal performance, and durability by ITT, to ensure that it is safe for patient use (See Section 3 and Appendix A). Importantly, a focus has been maintained on ensuring rigorous laboratory testing protocols prior to study with human infants to minimize any potential harm to patients. However, no "infant" laboratory model will be able to replicate the living system in which the warmer studied is studied in relationship to real infants whose metabolism generates heat (as opposed to non-living objects that can only lose heat). Furthermore, given the variations in usability and functionality that are introduced when placed in a routine environment, study in infants when used in a setting where this technology is aimed for ultimate use is necessary.

The infant warmer is modeled on a heating pad, filled with a phase change material that changes from liquid to solid at skin temperature (approximately 37°C). It is heated by immersion in hot water. Once it cools to the phase change temperature between 37-38°C, it stays at this temperature for many hours. It is equipped with a color indicator that provides the user with a simple and clear means of knowing when it

has adequately cooled to a temperature in which it is safe to begin use. The safe/effective use zone is from 38 degrees down to 35 degrees (8), with the goal of providing similar warmth to that provided by KMC.

Each conceptual component of the safety and efficacy of this proposed system has been tested in a controlled setting. Placing premature infants on a heating pad in the delivery room has become an approved, recommended option to maximize thermoregulation prior to admission to a Neonatal Intensive Care Unit (NICU). Combining the rigorous safety and efficacy testing of the approved delivery room pads⁵ with the knowledge that long-term use continues to be safe and efficacious in the smaller sample size of those exposed to the water-heated mattress pad,⁶ as well as the proven benefits of KMC strongly supports the overall concept of using heating pads for thermoregulation in neonatal care.⁷

This simple, water-heated thermoregulation device has the potential to overcome many of the limitations encountered by current thermoregulation alternatives. It will be simple and reliable to heat even in remote settings, needing only on hot water instead of electrical or solar power. It is made out of sturdy material that can be cleaned and re-used many times. The cost of the heating pad is anticipated to be approximately US\$20 per pad, making it less expensive than options currently available. Basic newborn care and infant warmer instructions will be printed on the device in simple language with illustrations. The use of widely available, nontoxic materials allows the heating pad to be fully manufactured locally.

We propose to conduct a two-phase study. Phase 1 will assess the safety, efficacy, usability and functionality of the infant warmer in the hospital setting. If Phase 1 results demonstrate sufficient safety, efficacy, usability, and functionality and results are approved by the RNEC committee, we will proceed with Phase 2 of the study. The second phase will assess safety and efficacy in the health center setting and in transport, and usability, functionality, and acceptability in the health center setting.

PHASE 1 STUDY

2. Aims and Objectives: To determine if the infant warmer is a safe, effective, usable and functional addition to KMC. Our primary hypothesis is that the infant warmer is a safe, effective, usable and functional means to achieve and maintain eutheria when KMC is not possible or inadequate.

3. Methods

3.1.1 Study description: Intervention study using clinical observation to assess safety, efficacy, usability and functionality.

3.1.2 Study design: Prospective study in hospital setting assessing safety and efficacy of infant warmer based on clinical observation, and usability and functionality based on observer audits.

3.1.3 Study materials safety: The newly developed infant warmer has been extensively assessed for safety, thermal performance and durability prior to use with humans. US Food and Drug Administration (FDA) guidance was used as a gold standard when guidance existed. All products sold in the US must adhere to industry standards for safety, determined by the FDA. Per FDA guidelines for testing biocompatibility of pre-market medical devices, the materials used in the manufactured device will be tested according to International Standard ISO-10993, 116 "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing."⁸ The study device's biological safety has been ensured by selecting materials that are either FDA approved or have been previously been tested and certified safe (tested negative).

3.1.4 Study site: We will partner with PIH-IMB supported District Hospitals in Rwanda. The study will take place in the neonatal and maternity wards at these hospitals. Study sites will include a district hospital in a relatively cold region and one in a relatively warmer region of the country.

This will likely include Butaro and Kirehe District Hospitals. Preliminary conversations with hospital leadership regarding their willingness to host these studies has been encouraged, however, the formal request for hospital participation will come from the MCH Director upon protocol finalization. PIH-IMB has strong partnerships with the participating hospitals and sufficient research infrastructure to assist in data collection, entry and analysis.

3.1.5 Study population: The target study population is infants who meet criteria for KMC (particularly preterm and LBW infants at risk for hypothermia) for whom KMC is not able to be provided or is inadequate. Inclusion and exclusion criteria have been designed to identify this population. We aim to enroll all infants during the data collection period scheduled hours who meet inclusion criteria and have no exclusion criteria (see sections 4.1 and 4.2).

3.1.6 Proposed Intervention and Safety Considerations: In line with current recommended practice, the mother will be encouraged to provide KMC whenever possible. If the infant's temperature is not rising by ½ degree per hour with KMC alone, the infant warmer will be offered as an addition by the study staff. Heat can be provided by placing the infant on the infant warmer as it lies flat or by placing it over the infant's back while the mother provide KMC. These two options allow the degree of heat provision to be modified based on the degree of prematurity, low birth weight and hypothermia. If the mother is not available for KMC at any time, the infant will be warmed exclusively with the infant warmer. Bundling with clothes will only be added in addition to the warmer per caregiver/provider preference, as it is not medically necessary but often a parental desire. Because this would be expected to alter the effect of the infant warmer, bundling will be recorded on the data collection sheet. Temperature measurement of the infant, warmer, and ambient air will be measured every 15 minutes for the first hour, and then hourly and as needed for the remainder of use or until warmer endpoint is reached (warmer temperature below 36 degrees or phase-change material hardens [soft, semisoft, or hardened]).

If an appropriate electric warming source (warming table or incubator) is available and an infant is determined to meet the inclusion criteria for the study on the basis of hypothermia with failure of or unavailable KMC, heat should be provided by the electric warming source until consent can be obtained for the study and the infant warmer can be prepared for use. Infants, including stable preterm infants as outlined by inclusion and exclusion criteria, are eligible for use of the infant warmer every time they meet the inclusion criteria, which may be multiple times during their hospital stay. Each infant warmer unit will have an identification number assigned to it which will be clearly displayed on the unit. Each exposure of the infant to a warmer will be considered a separate exposure in the analysis. A warmer may be used on multiple infants. The infant warmer unit identification number will be tracked on the data collection form so that sub-analysis of patients using a specific infant warmer unit may be done.

Once the infant is receiving warmth from the non-electric infant warmer, if an electric heat source is available and the infant meets any of the stop criteria outlined below in section 4.2, the infant will be taken off of the non-electric infant warmer, and given heat via the electric heat source. If the infant is ever considered to be too severely ill by the medical team to be safely cared for in the non-electric infant warmer, the infant should be transferred to the electric warming table.

Though the duration of heat provision by the warmer will vary based both on the ambient temperature, and that of the infant, it would not be expected to stay within usable range for more than six hours. Therefore, it is expected that there will be not more than 4 measurements in hour 1 and 5 additional temperature measurements of the infant, the warmer, and the ambient air. The warmer will be removed once its temperature drops below 36 degrees, and/or the

phase-change material begins to harden. The method of thermoregulation and the addition of KMC and or bundling will be noted on the data collection sheet whenever it is changed. Generally, all of the data will be collected by the study manager; however, if there are 2 or fewer hourly measurements left at the end of business hours, the study manager may ask the nurse to voluntarily take the remaining 2 measurements. New subject recruitment will end 4 hours prior to the end of the Study Manager work day so as to avoid incomplete data and unobserved use greater than 2 hours.

In addition to the specific measurements collected for infants enrolled in the study, the study manager will work with the nurse to assess baseline patient temperature monitoring is being performed on all neonates throughout the neonatal unit to promote basic quality of care for all sick infants. According to the Rwandan national protocol infants are to be assessed every 3 hours with documentation.

Consent procedures (see also section 6, Ethical Considerations section) and data collection will be performed by study managers. Consent will be obtained from the mother as highest priority. If the mother is not physically co-located with the baby (ie, in maternity, while the baby is in neonatal) consent will be obtained from that father. Consent will be read orally to the caregiver(s) and written signature or mark (Appendices D and E). It will be obtained at the time that the infant is identified for study eligibility. If eligibility is anticipated prenatally, the parents will only be consented if able (not in advanced stage of labor or critically ill).

If illiterate but cognitively competent, the informed consent will be read to the family, and the family is encouraged to ask questions. This process will occur with a witness present. In this case, the witness is to observe the entire process, not just the signature. The consenting parent will affix a signature to or make an "X" on the consent document. The witness will sign and date the consent document, and is to document, in writing, that the process took place and that the subject/family member voluntarily consents to participate.

A study manager, with A1 or A0 clinical training and proficiency in the Rwandan national neonatal care protocol, research and data management experience, and relevant training in research ethics and confidentiality will be hired to supervise the study in each district hospital. The study managers will work in close collaboration with the Ministry of Health staff in their respective maternity and neonatal units.

Nursing staff will be oriented to the study and trained in preparation and use of the warmer during appointed meeting times assigned by the hospital leadership. These sessions will include familiarizing and training nurses on proper and safe preparation and application of the warmer, including when to remove the warmer, and proper cleaning and storage. Training will include nurses demonstrating their competencies, under direct observation, prior to use in the neonatal unit to the study manager. The study manager will be available to answer any questions about usage.

If the study manager observes any deviation from recommended infant warmer use that raises a safety concern, the study manager will intervene to discuss this with the nurse and prevent unsafe use of the warmer. For example if the nurse is preparing to put the infant on the warmer before the color indicator shows that the warmer is at a safe temperature to begin use, the study manager will alert the nurse to this safety concern. In this circumstance, the study manager would note on the data collection form that improper use of the infant warmer was attempted, so that the study will be able to calculate the frequency of usage mistakes.

3.1.7. Main exposures, outcomes and confounders to be measured

Exposures: The exposure is the method of thermoregulation: infant warmer with KMC or alone. Maximum exposure from here on out will be defined as the infant warmer plus KMC, if KMC is available. We will also document bundling of the infant. During an observed clinical encounter, it is possible for a infant to have multiple exposures.(i.e., using the infant warmer at multiple independent occurrences).

Outcomes:

a) Efficacy:

- Minimum patient temperature achieved during use
 - Target: at least 90% of encounters will have patient temperature $\geq 36.0^{\circ}\text{C}$ for all measurements during encounter. If the infant's initial temperature is below 36.0°C , one hour on the infant warmer will be allowed for every half degree below 36.0°C before categorizing temperature as below minimum acceptable value. Patient temperature will be measured with a standard thermometer taken in the patient's axilla.
- Duration that temperature of infant warmer is within the goal
 - Target: With at least 95% of encounters, infant warmer maintains temperature between 35 and 38 degrees for 4 hours or more. Arrival at 38 degrees will be determined by a color indicator. Once the warmer has cooled to 38 degrees, the temperature of the warmer will be determined every 15 minutes for the first hour, then hourly by the study manager with the use of a digital thermometer with a thermistor probe.

b) Safety:

- Maximum patient temperature achieved during use
 - Target: at least 95% of encounters will have all measurements of patient temperature $\leq 37.5^{\circ}\text{C}$. In order to protect patient safety, if infant's temperature is $> 37.5^{\circ}\text{C}$, infant will be taken off of warmer.
- Presence of skin irritation (abrasion, burns). Of note, it would be extremely unlikely for a burn to occur, as the infant warmer has a built-in color indicator to clarify when the warmer has cooled adequately for safe use. A primary purpose of the infant warmer is to avoid the burns that can occur with the current practice (though not officially endorsed) option of placing heated objects such as water bottles or water filled gloves in direct contact with the infants' skin, or improperly managed electric warmers and incubators.
 - Target: Fewer than 5% of infants with presence of skin irritation

c) Usability:

- Observer audit of usability:

The Study Manager will assess for correct application of warmer. This will be assessed by a yes/no questionnaire with list of qualitative findings of any incorrect applications (see questionnaire tool in Appendix). These will include assessment of the time taken for preparation of the warmer, whether the infant is placed in the warmer and removed from the warmer at the indicated temperatures, and whether the warmer is appropriately cleaned with soap and water.

Of note, safety of the patient will be protected by the Study Manager who will intervene prior to any unsafe use of the warmer that is observed (see section 3.1.5).

d) Functionality:

- Observer audit of functionality:

- The Study Manager will assess if the warmer material demonstrates any breakdown or other change

Confounders: Infant's degree of hypothermia, gestational age and weight, ambient temperature (relevant for infant warmer efficacy), bundling of infant, and use of KMC.

4. Selection of study population

4.1 Inclusion criteria: Any infant with the following criteria for whom caregiver not available for KMC, or KMC is not adequate (less than ½ degree Celsius per hour rise in temperature).

1) axillary temperature < 36°C and ≥35°C

1a) If an electric warmer is available and the infant's temperature is < 35 °C, then the infant would start by being warmed on the electric warmer until the infant's temperature reaches 36 °C, then can start non-electric infant warmer use

2) Infants at-risk for hypothermia (criteria: estimated post-menstrual age of < 35 weeks or current body weight of < 2.5 kg)

4.2 Exclusion Criteria:

1) Any infant whose family is unwilling to consent to study.

2) Mothers who are critically ill at the time of infant eligibility or deemed not medically stable by nursing staff to be approached for consent.

3) Any infant with a contraindication to KMC (medical instability) and electrical heating source available.

4) Any infant with initial temperature < 35°C and electrical heating source available.

5) Infants within the first hour of admission to neonatal unit or first hour of life in maternity.

6) Infants requiring phototherapy

7) Infants with significant skin condition

8) Infants with HIE

4.3 Stop Criteria: If an electric heating source is available, the infant will be taken off of the study and warmed with an appropriate source of electric heat if the infant:

1) Is hypothermic and temperature decreases on any measurement

2) Is hypothermic and temperature does not begin to rise within 30 minutes

3) Is hypothermic and not heating at a rate of > ½ °C per hour until temperature is >36.5°C

4) Has a temperature that falls below 36 °C despite maximum exposure to the heat source

5) Is ever considered to be too severely ill by the medical team to be safely cared for in the non-electric infant warmer.

6) The warmer will be removed once its temperature drops below 36 degrees, and/or the phase change material begins to harden.

4.4 Sampling: Continuous enrollment at PIH-IMB-supported district hospitals as described in section 3.1.5.

4.5 Recruitment Methods: Study manager will circulate between the neonatal and maternity units to identify eligible patients following the inclusion/exclusion criteria described above. Once a patient has been identified as eligible, the study manager will approach the caregiver for consent. If consent is given, the study manager will then consent the treating nurse and inform him/her to begin preparing the infant warmer for use.

4.6 Subject enrollment: All infants will be assigned a code by the order in which they are consented to participate. A password-protected file matching consent form code to

identification code will be kept on a password-protected computer equipped with antivirus software. The identification code will be marked on the patient's consent and data collection form. The completed consent and data collection forms will be locked in a filing cabinet in a locked room.

4.7 Randomization: None.

5. Study Procedures

5.1 Procedures at enrollment and data collection: Infants meeting criteria for KMC will be treated according to the thermoregulation chapter of the Rwanda MOH Neonatal Protocols, starting with initiation of KMC. Once KMC is initiated and if the patient meets inclusion criteria with no exclusion criteria, the caregiver will be approached for possible enrollment in study. If caregiver consents, data collection will commence by a data officer. If the infant's temperature with KMC alone does not rise by at least ½ degree per hour, addition of infant warmer will be offered. Whenever the consented mother is unavailable for KMC, the infant will be placed on the infant warmer exclusively. Temperature measurement of the infant, warmer, and ambient air will be measured every 15 minutes for the first hour, and then hourly and as needed for the remainder of use or until warmer endpoint is reached (warmer temperature below 36 degrees or phase-change material hardens). See also 3.1.6 for details of role of electric heat source for study patients and 4.3 for stopping procedures for study.

5.2 Follow-up: None

5.3 Measurement of exposures, outcomes and confounders: Exposure variable of infant warmer will be documented in the data collection form (see Appendix F). Whenever the mode of thermoregulation changes, the mode and time of change will be documented on the data collection form. Data regarding potential confounders (see section 3.1.7) will also be collected on the data collection form.

Infant's temperature, warmer temperature, and ambient temperature will be documented per protocol. The study manager will document at every application whether the infant warmer was applied correctly. The study manager will document at the end of every infant encounter whether the warmer is properly cleaned and assessed for any visible signs of material breakdown or change.

5.4 Study Limitations: This is not a randomized-controlled trial, and does not aim to prove that this method is more effective than KMC. Rather, this is a safety and efficacy trial and we aim to measure the safety and efficacy of the device when used to complement KMC through an observational study. Potential confounders may affect the generalizability of the results. Expectation bias may be of issue in that the study managers could opt to document the observer audit favorably under the non-electric infant warmer because they know that the warmer is something that PIH-IMB is involved in developing. Training will be specifically conducted with the study manager to minimize this potential bias.

5.5 Lab measures: none

5.6 Sample Size: We will power our study for the primary efficacy outcome, minimum temperature achieved. We aim for 90% of infants exposed to the infant warmer to achieve a temperature of at least 36.0°C. We aim to have 90% power to detect if the percent achieving the minimum temperature is 80% or less. For this one-sided test at the $\alpha=0.05$, a sample size of 102 infants is sufficient.

5.7 Data Management: A Rwanda-based study manager will be hired and trained to recruit patients, consent families (see Ethical Considerations section for details), collect data, enter data, and assist with data analysis. Study supervisors will audit 10% of data transcribed from paper forms to an electronic Excel database to assure data quality (e.g., completeness and concordance between paper forms and electronic database). If the completeness and concordance is less than 95% in the database, then the data from paper forms will be double-entered into the database. The completed consent and data collection forms will be locked in a filing cabinet in a locked room. All infants will be assigned a participant identification number by the order in which they are consented to participate. This participant ID will be on data collection forms and consent forms. De-identified data will be entered into an excel password-protected database for analysis. A separate password-protected linking file matching this ID to identifiers on the data collection forms (facility ID and date of birth) will be kept on a password-protected computer equipped with antivirus software for a total period of 2 years after the end of study completion. At that time the linking file and data collection forms will be destroyed. There will be no contact with families outside of the hospital stay.

5.8 Proposed analysis: We will estimate the proportion of exposures to the infant warmer in which:

- Minimum desired temperature of the infant is achieved (allowing one hour on infant warmer for every half degree below 36.0°C before categorizing temperature as below minimum temperature).
- The maximum desired temperature of infant is not exceeded.
- Infant skin has no visible skin irritation.
- The warmer is applied to the infant correctly.

Each use of the infant warmer will be included in the analysis. Because it is possible that an infant have multiple exposures to the infant warmer during an encounter, we will estimate the variance of these measures accounting for clustering on this level and adjust the confidence intervals accordingly. The estimates above will be compared to the goals described in section 3.1.6.

We will estimate the proportion of infant encounters where:

- The warmer maintains temperature in desired range of 36 – 40 degrees for 4 hours or more.
- The warmer is properly cleaned.
- The warmer shows no visible signs of deterioration.

We will conduct a secondary analysis of the subgroup that received both KMC and infant warmer thermoregulation to compare the efficacy of these alternatives to each other.

PHASE 2 STUDY

If the Phase 1 study in the hospital setting shows that the infant warmer is a safe, effective, usable and functional addition to KMC, we would then move to Phase 2 of our study in which we will assess the safety and efficacy in the health center and transport settings and the usability, functionality and the acceptability in the health center setting using quantitative and qualitative methods. Phase 1 results will be presented to RNEC for approval prior to proceeding to Phase 2.

2. Aim and Objectives:

1) To assess the safety, efficacy, usability and functionality of the infant warmer in rural health centers during post-partum care, resuscitation/stabilization and on transport (the target settings for ultimate use) using the same methods as Phase 1.

2) To assess the perceived usability, functionality, and acceptability of the infant warmer as an addition to KMC in the health center setting from the perspectives of caregivers and health care providers using qualitative methods.

Aim 1

3. Methods

3.1.1 Study description: Intervention study using clinical observation to assess safety, efficacy, usability and functionality.

3.1.2 Study design: Prospective study in health center and transport settings assessing safety and efficacy of infant warmer based on clinical observation, usability and functionality based on observer audits.

3.1.3 Study materials safety: The newly developed infant warmer has been extensively assessed for safety, thermal performance and durability prior to use with humans. US Food and Drug Administration (FDA) guidance was used as a gold standard when guidance existed. All products sold in the US must adhere to industry standards for safety, determined by the FDA. Per FDA guidelines for testing biocompatibility of pre-market medical devices, the materials used in the manufactured device will be tested according to International Standard ISO-10993, 116 "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing."⁸ The study device's biological safety has been ensured by selecting materials that have been previously been tested and certified safe (tested negative).

3.1.4 Study site: We will partner with PIH-IMB-supported District health centers in Rwanda for the testing sites (as described in Phase 1). We plan to sample two health centers in Burera district and two from Kirehe District after discussions with District leadership and determination of their interest in participation and authorization.

Including two districts allows for the inclusion of sites with varying ambient temperatures (colder district and warmer district). Using two sites per district allows us to sample a site with electricity and ideally one without electricity readily available.

3.1.5 Study population: The target study population is infants who meet criteria for KMC (particularly preterm and LBW infants at risk for hypothermia), not able to be provided or is inadequate. In Phase 2, we also include infants for whom KMC is contraindicated, such as those requiring resuscitation after delivery. Infants requiring transport will also be eligible. Inclusion and exclusion criteria have been designed to identify this population. We aim to enroll all infants who meet inclusion and with no exclusion criteria for study (see sections 4.1 and 4.2).

3.1.6 Proposed Intervention and Safety Considerations: In line with current recommended practice, the mother will be encouraged to provide KMC whenever possible. If the infant's temperature is not rising by ½ degree per hour with KMC alone, the infant warmer will be offered as an addition by the study staff. Heat can be provided by placing the infant on the infant warmer as it lies flat or by placing it over the infant's back while the mother provide KMC. These two options allow the degree of heat provision to be modified based on the degree

of prematurity, low birth weight and hypothermia. If the mother is not available for KMC at any time, the infant will be warmed exclusively with the infant warmer. Bundling with clothes will only be added in addition to the warmer per caregiver/provider preference, as it is not medically necessary but often a parental desire. Because this would be expected to alter the effect of the infant warmer, bundling will be recorded on the data collection sheet. Temperature measurement of the infant, warmer, and ambient air will be measured every 15 minutes for the first hour, and then hourly and as needed for the remainder of use or until warmer endpoint is reached (warmer temperature below 36 degrees or phase-change material hardens [soft, semisoft, or hardened]).

If an appropriate electric warming source (warming table or incubator) is available and an infant is determined to meet the inclusion criteria for the study on the basis of hypothermia with failure of or unavailable KMC, heat should be provided by the electric warming source until consent can be obtained for the study and the infant warmer can be prepared for use. Infants, including stable preterm infants as outlined by inclusion and exclusion criteria, are eligible for use of the infant warmer every time they meet the inclusion criteria, which may be multiple times during their hospital stay. Each infant warmer unit will have an identification number assigned to it which will be clearly displayed on the unit. Each exposure of the infant to a warmer will be considered a separate exposure in the analysis. A warmer may be used on multiple infants. The infant warmer unit identification number will be tracked on the data collection form so that sub-analysis of patients using a specific infant warmer unit may be done.

Ideally, consent for study participation would be obtained and the non-electric infant warmer will be being warming in the thermos of hot water while the mother is in labor. The infant warmer would then be taken out of the thermos to begin cooling about one hour prior to anticipated delivery in order to adequately cool for use immediately after delivery. However, if an appropriate electric warming source (warming table or incubator) is available and an infant is determined to meet the inclusion criteria for the study but the non-electric infant warmer is not available or consent has not been obtained, then heat should be provided by the electric warming source until the infant warmer can be prepared for use and consent can be obtained.

Once the infant is receiving warmth from the non-electric infant warmer, if an electric heat source is available and the infant meets any of the stop criteria outlined below in section 4.2, the infant will be taken off of the non-electric infant warmer, and given heat via the electric heat source. If the infant is ever considered to be too severely ill by the medical team to be safely cared for in the non-electric infant warmer, the infant should be transferred to the electric warming table.

Though the duration of heat provision by the warmer will vary based both on the ambient temperature, and that of the infant, it would not be expected to stay within usable range for more than six hours. Therefore, it is expected that there will be not more than 4 measurements in hour 1 and 5 additional temperature measurements of the infant, the warmer, and the ambient air. The warmer will be removed once its temperature drops below 35 degrees, indicated by a change in the temperature indicator. The method of thermoregulation and the addition of KMC and or bundling will be noted on the data collection sheet whenever it is changed.

Generally, all of the data will be collected by the study manager; however, if there are 2 or fewer hourly measurements left at the end of business hours, the study manager may ask the nurse to voluntarily take the remaining 2 measurements. New subject recruitment will end 4 hours prior to the end of the Study Manager work day so as to avoid incomplete data and unobserved use greater than 2 hours.

Additional use relevant to the health center setting includes use of the infant warmer when KMC is contraindicated or not feasible, in particular during neonatal resuscitation/stabilization and patient transport when an electric warmer is unavailable. Therefore, there are three main clinical settings in which we would like to assess the warmer performance: routine post-partum care, resuscitation/stabilization, and patient transport.

As in Phase I, consent and data collection will be performed by the study manager. Since the infant warmer will be studied during neonatal resuscitation and transfer as well as routine post-partum care, potentially eligible mothers will be approached upon admission to the health center for possible enrollment in study. Study managers will work with the nurse to identify women for potential enrollment (ie, anyone admitted to maternity at the health center). Once a patient has been identified as eligible, the study manager will approach the caregiver for consent. As in Phase I, consent will be obtained from the mother as highest priority.

Consent will be read orally to the caregiver(s) and written signature or mark (Appendices D and E). It will be obtained at the time that the infant is identified for study eligibility. If eligibility is anticipated prenatally, the parents will only be consented if able (not in advanced stage of labor or critically ill). If illiterate but cognitively competent, the informed consent will be read to the family, and the family is encouraged to ask questions. This process will occur with a witness present. In this case, the witness is to observe the entire process, not just the signature. The consenting parent will affix a signature to or make an "X" on the consent document. The witness will sign and date the consent document, and is to document, in writing, that the process took place and that the subject/family member voluntarily consents to participate.

If consent is given, the study manager will then consent the treating nurse and inform him/her to begin preparing the infant warmer for use. Data collection will commence by a study manager if patient ultimately meets eligibility requirements.

Generally, all of the data will be collected by the study manager; however, if there are 2 or fewer hourly measurements left at the end of business hours, the study manager may ask the nurse to voluntarily take the remaining 2 measurements. New subject recruitment will end 4 hours prior to the end of the Study Manager work day so as not to avoid incomplete data and unobserved use greater than 2 hours.

Actual preparation and application of the warmer will be performed by the nurse in order to assess usability. Nursing staff will be oriented to the study and trained in preparation and use of the warmer during morning staff meetings. The study manager will observe all usage of the warmer and be available to answer any questions about usage.

If the study manager observes any deviation from recommended infant warmer use that raises a safety concern, the study manager will intervene to discuss this with the nurse and prevent unsafe use of the warmer. For example if the nurse is preparing to put the infant on the warmer before the color indicator shows that the warmer is at a safe temperature to begin use, the study manager will alert the nurse to this safety concern. In this circumstance, the study manager would note on the data collection form that improper use of the infant warmer was attempted, so that the study will be able to calculate the frequency of usage mistakes.

In line with current recommended practice, the mother will be encouraged to provide KMC whenever possible. If the infant's temperature is not rising by $\frac{1}{2}$ degree per hour with KMC alone, the infant warmer will be offered as an addition by the study staff. If the mother is not

available for KMC at any time, the infant will be warmed exclusively with the infant warmer. Infants' temperature will be measured every hour and as needed.

3.1.7. Main exposures, outcomes and confounders to be measured

Exposures: The exposure is the method of thermoregulation: infant warmer with KMC or alone. Maximum exposure from here on out will be defined as the infant warmer plus KMC, if KMC is available. We will also document bundling of the infant. During an observed clinical encounter, it is possible for an infant to have multiple exposures. (i.e., using the infant warmer at multiple independent occurrences).

Outcomes: This phase of the study will assess the same outcomes in safety, efficacy, usability and functionality as described previously in Phase 1. This will be assessed in the health center and transport settings where we anticipate the infant warmer will ultimately serve the greatest need.

Confounders: Infant's severity of illness, gestational age and weight, ambient temperature (relevant for infant warmer efficacy), bundling of infant, use of KMC, and distance from clinic to hospital (relevant for infant warmer use on transport).

4. Selection of study population

Inclusion, exclusion, and sampling procedures are the same as described above in Phase 1. They will simply occur in the health center setting during routine post-partum care, resuscitation/stabilization, and transport settings.

4.1 Inclusion criteria: Any infant with the following criteria for whom caregiver not available for KMC, or KMC is not adequate (less than ½ degree Celsius per hour rise in temperature).

- 1) axillary temperature < 36°C and ≥35°C
 - 1a) If an electric warmer is available and the infant's temperature is < 35 °C, then the infant would start by being warmed on the electric warmer until the infant's temperature reaches 36 °C, then can start non-electric infant warmer use
 - 2) Infants at-risk for hypothermia (criteria: estimated post-menstrual age of < 35 weeks or current body weight of < 2.5 kg)
 - 3) Any infant requiring neonatal resuscitation or patient transfer.

4.2 Exclusion Criteria:

- 1) Any infant whose family is unwilling or unable (due to advanced stage of labor) to consent to study.
- 2) Mothers who are critically ill at the time of infant eligibility or deemed not medically stable by nursing staff to be approached for consent.
- 3) Any infant with initial temperature < 35°C and electrical heating source available.

4.3 Stop Criteria:

- 1) If an electric heating source is available, the infant will be taken off of the study and warmed with an appropriate source of electric heat if the infant:
 - a) Is hypothermic and temperature decreases on any measurement
 - b) Is hypothermic and temperature does not begin to rise within 30 minutes
 - c) Is hypothermic and not heating at a rate of > ½ °C per hour until temperature is >36.5°C
 - d) Has a temperature that falls below 36 °C despite maximum exposure to the heat source
 - e) Is ever considered to be too severely ill by the medical team to be safely cared for in the non-electric infant warmer.

2) The warmer will be removed once its temperature drops below 36 degrees, and/or the phase change material begins to harden.

4.4 Sampling: Continuous enrollment at PIH-supported district health centers as described in section 3.1.5.

4.5 Recruitment Methods: Study managers will be present at the health centers to identify eligible patients in maternity. Once a patient has been identified as eligible, the study manager will approach the caregiver for consent. If consent is given, the study manager will then consent the treating nurse and inform him/her to begin preparing the infant warmer for use.

4.6 Subject enrollment: All infants will be assigned a code by the order in which they are consented to participate. A password-protected file matching consent form code to identification code will be kept on a password-protected computer equipped with antivirus software. The identification code will be marked on the patient's consent and data collection form. The completed consent and data collection forms will be locked in a filing cabinet in a locked room.

4.7 Randomization: None.

5. Study Procedures

Aim 1 study procedures are similar to those described in Phase 1, but assessed at the health center level during post-partum care, resuscitation/stabilization, and patient transport.

5.1 Procedures at enrollment and Data Collection. Since the infant warmer will be studied during neonatal resuscitation and transfer as well as routine post-partum care, potentially eligible mothers will be approached upon admission to the health center for possible enrollment in study. If consent is given, data collection will commence by a study manager if patient ultimately meets eligibility requirements.

For usage during routine post-partum care and patient transport, thermoregulation protocol will be followed per routine. If the infant's temperature with KMC alone does not rise by at least ½ degree per hour, addition of infant warmer will be offered. Whenever mother is unavailable for KMC, the infant will be placed on the infant warmer exclusively. Temperature measurement of the infant, warmer, and ambient air will be measured every 15 minutes for the first hour, and then hourly and as needed for the remainder of use or until warmer endpoint is reached (phase-change material hardens or warmer temperature below 36 degrees). See also 3.1.5 for details of warmer positioning, role of electric heat source for study patients, and 4.2 for stop procedures for study.

For usage during resuscitation, the temperature will be measured after initial stabilization (as would be on an electric warmer). No additional measurements will be taken that could interfere with patient resuscitation procedures.

User audit for usability and functionality will be identical to Phase 1.

5.2 Follow-up. None

5.3 Measurement of exposures, outcomes and confounders. Exposure variable of KMC, usage setting, and infant warmer will be documented in data collection form (see Appendix E). Whenever the mode of thermoregulation and/or warmer position changes the change and time

of change will be documented on the data collection form. Data regarding potential confounders will also be collected on the data collection form.

Infant's temperature will be documented on a data collection form per protocol when used during routine post-partum care. Measurements will be immediately after infant stabilization if used during resuscitation, and hourly during patient transport. Infant warmer temperature will be documented on a data collection form every hour during post-partum care and transport. The study manager will document at every application whether the infant warmer was prepared and used correctly with the infant. The study manager will document at the end of every infant encounter whether the warmer is properly cleaned and assessed for any visible signs of material breakdown or change.

5.4 Study limitations: Limitations are as described in Phase 1.

5.5 Lab measures: none

5.6 Sample Size: As described in Phase I, we will use the calculations for sample size of 102. We will conduct the study at four health centers to explore the potential variability of safety and efficacy across health centers. Because of feasibility issues, we aim to enroll a minimum of 25 patients per health center to reach this total sample size. This assumes that there is no clustering of outcomes by health centers. Having enough health centers to account for potential clustering in our study design is not feasible at this stage. If clustering is high or if sample size is unable to be reached within 3 months per health center, then this data will be used to inform a larger study to better estimate the properties of the infant warmer.

5.7 Data Management: Study supervisors will audit 10% of data transcribed from paper forms to an electronic Excel database to assure data quality (e.g., completeness and concordance between paper forms and electronic database). If the completeness and concordance is less than 95% in the database, then the data from paper forms will be double-entered into the database. The completed consent and data collection forms will be locked in a filing cabinet in a locked room.

5.8 Proposed analysis: Analysis for Aim 1 will be as described for Phase 1.

Aim 2

3. Methods

3.1.1 Study description: Qualitative assessment of perceived usability, functionality and acceptability. Because the infant warmers are intended for use at health care centers, it is important to use qualitative methods to understand the user experience with the warmers in greater depth than the quantitative data alone will provide.

3.1.2 Study design: Perceived usability, functionality and acceptability will be assessed through semi-structured interviews with infant caregivers who were present during use of the warmer (e.g. the mother or accompanying family member) and health care providers. The interviews will be tape-recorded.

3.1.3 Study site: We will partner with PIH-IMB-supported health centers in Rwanda for the testing sites as described in Aim 1.

3.1.4 Study population: Health care providers; caregivers of infants exposed to infant warmer in the health care setting.

3.1.5 Proposed Intervention: Use of infant warmer when KMC is contraindicated, not available or not adequate, as described in Aim 1.

3.1.6. Main exposures, outcomes and confounders to be measured.

Outcomes: Perceived usability, functionality and acceptability of the infant warmer will be assessed through semi-structured interviews with caregivers and health center nurses.

4. Selection of study population

4.1 Inclusion criteria: Any nurse or family member who has been involved in the care of an infant who has used the infant warmer for thermoregulation.

4.2 Exclusion criteria: Caretaker of infants unwilling to consent to interview participation. Caregivers will not be approached for interview consent if the infant died during the encounter (for example, if the infant did not survive resuscitation or died during transport).

4.3 Sampling: Caregivers of infants who received the warming intervention will be purposively selected to be invited to participate in interviews. The purposive selection process will aim to maximize the diversity of the interviewees in terms of the following key characteristics expected to influence their experience with/perceptions of the infant warmer (see Appendix for the purposive sampling matrix tool that the Study Manager will use to keep track of the number of interviewees falling into each category):

- Mode of thermoregulation (including caregivers of infants who experienced IW alone, and infants who experienced IW plus KMC and, IW plus bundling)
- Setting of use (routine post-partum care, resuscitation, or transport).
- Observer audit results (including caregivers of infants where the observer recorded optimal application of the warmer, and infants where the observer recorded sub-optimal application of the warmer)

Among caregivers who consent to interview (see Ethical Considerations section for details on the recruitment and consent process), the interviews will be conducted until saturation has been reached: in other words, new interview participants will be sought until the interview responses are producing no new major themes or ideas.

Additionally, 1-3 nurses will be interviewed per health center, prioritizing those nurses who have had the largest number of encounters with the warmer in the following settings: routine post-partum care, resuscitation, and transport (see Ethical Considerations section for details on recruitment and consent).

4.4 Recruitment Methods: Study managers will approach for consent caregivers and health care providers who are eligible for the Aim 2 portion of the study on the basis of having participated in the Aim 1 portion of the study. They will be informed that they may participate in Aim 1 without consenting to participate in Aim 2. If consent is given to participate in Aim 2, the study manager will arrange a time that is convenient for the participant to answer a series of interview questions.

4.5 Subject enrollment: All participants will be assigned a code by the order in which they are consented to participate. The code will be linked to the code of the infant whose participation in

Aim 1 prompted the caregivers and health care providers' eligibility for Aim 2. A password protected file matching consent form code to identification code will be kept on a password protected computer equipped with antivirus software. The identification code will be marked on the participants consent and data collection form. The completed consent and data collection forms will be locked in a filing cabinet in a locked room.

4.6 Randomization: None.

5. Study Procedures

5.1 Procedures at enrollment: Nurses and family member who have been involved in the care of an infant who has used the infant warmer will be approached regarding willingness to participate in qualitative interviews as well as direct observation of infant warmer use. Nurses and family members will be formally consented to participate in study. While they will be consented for Aim 1 prior to use of the warmer, Aim 2 consent will happen prior to patient discharge for those using the warmer in routine post-partum care, or soon after stabilization or patient transport.

Nurses, family members and caregivers will receive qualitative, semi-structured interviews in Kinyarwanda. Interview guides will be developed to assess perceived usability, functionality, and acceptability of the infant warmer (see Appendix for the interview guide for caregivers and the interview guide for nurses).

5.2 Follow-up. None

5.3 Measurement of exposures and confounders. None

5.4 Measurement of outcome: None

5.5 Lab measures: none

5.6 Sample Size: 10-15 caregivers and 1-3 nurses per health center. This is based on numbers typically needed in qualitative assessment before a theme is saturated. Goal will be to capture at least 3-5 encounters in each of the following settings: routine post-partum care, resuscitation, and transport.

5.7 Data Management. Rwandan-based study manager to recruit patients, consent families, collect data, and conduct semi-structured interviews. The study manager will then translate and transcribe interviews into English for analysis prior to data analysis. An independent translator will back-translate 10% of interviews into Kinyarwanda and compare to original transcripts for validation.

All caregivers and nurses participating in the qualitative interview will be assigned a code by the order in which they are consented to participate. A password-protected file matching consent form code to identification code will be kept on a password-protected computer equipped with antivirus software. The identification code will be marked on the patient's consent and data collection form. The completed consent and data collection forms will be locked in a filing cabinet in a locked room. Interviews are estimated to take 1 hour maximum. Destruction of audio recording will be the same as destruction of the linking file, 2 years after data collection.

5.8 Proposed analysis. Transcripts will be analyzed for emerging themes, and a codebook will be created to assist with data analysis

PHASES 1 AND 2

6. Ethical considerations

6.1 Risks and discomforts: We did extensive safety, durability and performance testing as described in Appendices A & B; however, the potential for misuse by nurse providers remains. Therefore, we plan to do training for all providers in the use of the warmer and all study use will be supervised by the study staff.

There is a minor risk of skin irritation due to contact with infant warmer. There is theoretically a risk of burn due to excessive heat exposure if an infant were to be placed on the warmer before the color indicator showed temperature to be < 40 degrees. However, a primary purpose of the infant warmer is to avoid the burns that can occur with the currently practiced (though not officially endorsed) option of placing heated water bottles in direct contact with the infants' skin: thus, the anticipated risks from the study are not expected to be greater, and may be less than the current standards. Additionally, the risk of burning or skin irritation will be mitigated by the presence of study staff during the use of the warmer, who will be instructed to intervene if a nurse attempts to place an infant on a warmer that is too hot.

For patients enrolled with hypothermia and/or failure of KMC alone, another risk could be potential delay of warming if an electrical warmer is deferred in favor of study participation. However, per study protocol, patients will be placed on an electric warmer while the non-electric warmer is being prepared so as not to delay thermoregulation. Furthermore, if the warmer is prepared ahead of time, the infant will be monitored every 15 minutes to allow for early detection of thermoregulation failure and transfer to electric warmer if appropriate. Given our inclusion criteria of stable infants appropriate for KMC (particularly for Phase 1), we believe this potential 15-minute delay is within the bounds of ethical and safe practice. In Phase 2 the warmer will be introduced to the resuscitation setting (with potentially unstable term and preterm infants), which we believe to be appropriate with informed consent even in the setting of an electric warmer after demonstrating safety and efficacy in Phase 1.

A third risk is breach of confidentiality for data collected that includes identifying information. Any health records that include patient level identification will be stored in a secure database if electronic or in a locked secure cabinet if not. Transcripts will be wiped of identifying information and instead marked with identification codes. Computers containing study data will be password protected and installed with anti-virus software, and all filing cabinets will be kept in locked offices. Any information will be de-identified before any reports or manuscripts are issued. All staff handling data will receive training in confidentiality and data security. Any gaps in security identified during the study will be communicated immediately to the principal investigators.

6.2 Potential benefits: The infant could potentially benefit from participating in this study by having more normal and stable thermoregulation. This would have multiple health advantages regarding cardiorespiratory function, growth and nutrition.

6.3 Confidentiality: Patient confidentiality will be protected in the manners described above in section 6.1.

6.4 Informed consent: Informed consent will be obtained from all nurses and caregivers participating in Phase 1 or 2. A small incentive of 5000 RWF airtime will be offered to nurses who participate in the study as appreciation for the extra work done related to the study, particularly in preparation and application of the infant warmer. An incentive will also be given to caregivers and nurses who participate in the qualitative assessment (Phase 2, Aim 2) as an appreciation for their time (2000 RWF airtime).

6.5 Ethical approval: Ethical approval will be obtained from the Rwanda National Ethics Committee and Boston Children's Hospital (BCH). Approval will also be sought from Harvard Medical School (HMS), either through ceded review to BCH or directly if the institution will not cede review. Technical approval has been received by the IMB Research Committee and National Health Research Committee.

7. Logistics

7.1 Distribution of responsibilities

Evrard Nahimana MD: Field-based input on study design, determination of study design, data collection oversight, data analysis and interpretation, manuscript preparation. Partners in Health, 10% time.

Hema Magge MD: Field-based input on study design, determination of study design, data collection oversight, data analysis and interpretation, manuscript preparation. Partners in Health, Boston Children's Hospital, Brigham and Women's Hospital, 10% time.

Leana May DO: Field-based input on study design, determination of study design, data collection oversight, data analysis and interpretation, manuscript preparation. Partners In Health, 15% time.

Anne Hansen MD: Technical input on product design, determination of study design, data interpretation, and manuscript preparation. Boston Children's Hospital, 5% time.

Bethany Hedt-Gauthier PhD: Determination of study design, data analysis and interpretation, manuscript preparation. National University of Rwanda School of Public Health, Harvard Medical School, 2.5% time.

Annie Michaelis (PhD): Determination of study design, data analysis, interpretation and manuscript preparation for Phase II Aim 2 (qualitative study). Partners in Health, 2.5% time.

Shashi Buluswar PhD: Product development and design, data interpretation. Institute for Transformative Technologies (ITT), 2.5% time.

Victor Mivumbi, MD: Field-based input on product development, data interpretation and manuscript preparation. Rwanda Ministry of Health, 2.5% time.

Peter Drobac MD: Study design, data interpretation and manuscript preparation. Partners in Health, Brigham and Women's Hospital, 2.5% time.

Fidele Ngabo MD: MOH study supervisor, field-based input on product development, study design, data interpretation and manuscript preparation. Rwanda Ministry of Health, 2.5% time.

Rwandan-based study manager: Study oversight, patient recruitment and consent, data collection, user audits, qualitative data collection.

7.2 Timetable: November 2014- Fall 2016

Goal: November 2014– Fall 2015: The study has been approved by the Partners In Health Research Committee. When the prototype has been approved by the Ministry of Health and Bureau of Standards and the study has been approved by NHRC, RNEC, Harvard Medical School and Boston Children’s Hospital, with approval from the district hospital directors, we will start enrollment in Phase 1. Will continue enrollment until sample size achieved. Anticipate enrolling patients in Phase 1 for approximately 3 months per district.

Goal: January 2016- July 2016: When data from phase 1 has been collected and analyzed, if infant warmer is determined to be a safe, efficacious, usable and functional alternative or addition to KMC, the data will then be shared with RNEC for approval of Phase 2. Infant warmers, with training to health centers, will be provided to begin Phase 2 safety/efficacy and feasibility (usability, functionality and acceptability) study. Phase 2 will take approximately 3 months per health center depending on volume seen and feasibility of study manager staying on-site continuously versus daily visits. Total time anticipated is 3-6 months per district.

Goal Fall 2016: Publish results of both phases and consider next steps regarding manufacturing and plan for scale and distribution.

Appendix A: Infant Warming Blanket Durability, Performance and Safety Testing

Component technical specifications, safety information, and certifications/approvals

The warming mat has an external cover made of nylon (with the brand name PolyNylon), made by the company ULine (of Wisconsin, USA). It is certified compliant with both FDA and USDA. It is a strong material designed to hold air, fluids or vacuum, and withstand very high temperatures. It is easily heat-sealed, and the seals are designed to withstand significant weight and pressure. The warming pad has two layers of ULine PolyNylon. The inner layer is in the form of tubes filled with the 37°C phase-change material (PCM). The PCM, made under the brand name PureTemp 37 by Entropy Solutions (of Minnesota, USA) is a mix of USDA-certified vegetable oils. It has been tested on animals and found to be non-hazardous, with the animal tests showing no eye or skin irritation. Being a vegetable-based product, it is also readily biodegradable. It is also certified to be safe for transport. It has been tested to stabilize at 37°C for 10,000 cycles, with a maximum stabilizing temperature of 38.1°C. However, the manufacturer recommends against consumption, eye contact and prolonged exposure, and provides instructions for handling and medical attention if necessary. The Appendix contains technical and safety data sheets for PureTemp 37, and a certificate of USDA/FDA compliance for ULine-PolyNylon.

The temperature indicator is inserted between the inner and outer PolyNylon layers. It is made by TipTemp Products (of New Jersey, USA), and is made with another phase-change material. This material is non-toxic, and does not come into contact with either the user or the infant because it is inside the outer PolyNylon layer. Exposure to very high temperatures (above 120°C, which can happen if water is boiled in a pressure cooker) is known to damage the material and adversely affect its accuracy; extended exposure to direct sunlight and UV can also damage the material and impact accuracy.

The flask is a standard off-the-shelf product made by Coleman (USA) and is normally used for storing food, with one modification: we have inserted a custom-built lining made with an inert plastic in order to change the flask's dimensions to fit our purpose.

The insulating pad is made with two materials, both of which are non-toxic. The outer layer (manufactured by Coastal Films (of Florida, USA) is made of a linear low-density product (LLDPE) which is certified by both USDA and FDA. The inner foam pad, made with a non-toxic material (EVA/PE foam), has been manufactured by DerTex Corporation (of Maine, USA). The relevant certifications are attached in the Appendix.

Product thermal performance and durability tests conducted

In addition to the above certifications of the various components for toxicity, irritation and skin sensitization, the following performance and durability tests were successfully conducted on the product as a whole.

Thermal performance

The Thermal Performance tests were conducted in order to determine how long the mat retains its heat, and how long it can keep the infant warm. Three tests were conducted, each measuring how long the mat stayed between 35°C and 38°C. In each case, the heated pad was placed on a Styrofoam board, in an environmental chamber simulating room temperature (about 22°C)

1. *No insulation*: This test measures the time the mat retains the 35°C and 38°C temperature range, with nothing placed on it. A minimum threshold of 30 minutes was used to determine if this test had been successful.
2. *Estimated use*: This test simulates conditions of the pad in use, with a surrogate infant (1.5 kg water bags that were heated to approximately 37°C in an oven before testing), small (3.8 W) light bulbs to simulate an infant's metabolism, and two light cotton towels (to simulate the weight of a light blanket commonly used in hospitals). A minimum threshold of 120 minutes (2 hours) was

used to determine if this test had been successful. Please note that the expected use of the mat is 6-8 hours or longer, even though a minimum threshold of 2 hours was used for this test.

3. *Maximum insulation:* This test determines the maximum time the pad retains the target 35°C-38°C temperature range, with a heated 1.5 kg water bag as a surrogate infant, and levels of insulation comparable to other products on the market. A minimum threshold of 180 minutes (3 hours) was used to determine if this test had been successful. Please note that under these conditions, the mat consistently retained the desired temperature range for more than 12 hours, even though the minimum threshold for this test is 3 hours.

Performance testing: Summary

Test type	Criteria for passing the test	Result
No insulation	30 minutes	Pass
Estimated Use	120 minutes	Pass
Maximum insulation	180 minutes	Pass

Durability

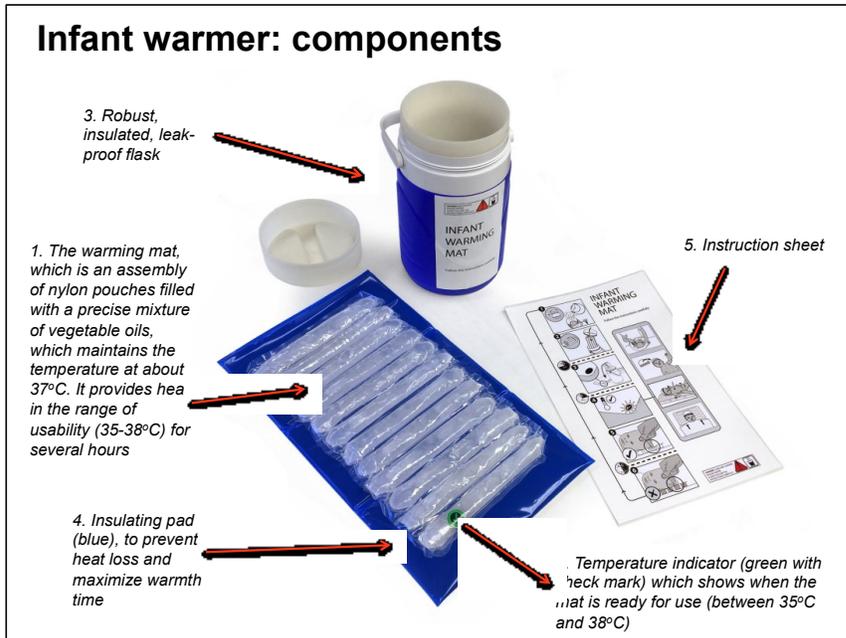
Durability tests were conducted on candles consisting of 4x26 cm rectangles of the material filled with PCM. After 10, 30, 50, 70, and 100 cycles of each test, the candles were placed in a jar with boiling water. The water was observed for evidence of PCM in the water. If PCM crystals were observed, it was deemed that the material had failed. The approximate number of cycles before failure were recorded. If the material did not fail after 100 cycles, it was deemed to be a durable material for that specific test.

1. *Bend test:* For liquid PCM, half of a candle was held over the lab bench while a 200g weight was attached to the end furthest away from the bench. The weighted end was then let go and allowed to hang for 30 seconds. This was defined as one cycle. For solid PCM, the candle was marked halfway and placed over a marker on a lab bench at the mark. The two ends of the candle were pushed downward toward the lab bench at the same time until both ends touch the lab bench. This caused the candles to crack, and was defined as 10 cycles.
2. *Functional test:* A 1kg weight was placed on top of the center of the candle for 5 min. This is equivalent to 1cycle. The weight was usually left for 10 cycles at a time (50 min). Often, the weight could not balance on the candle so it was tilted on a wall for additional support.
3. *Horizontal drop test:* The candle was dropped horizontally onto a smooth floor from roughly 1.5m above the ground. One drop was defined as 1 cycle.
4. *Vertical drop test:* The candle was dropped vertically onto a smooth floor from roughly 1.5m above the ground. One drop was defined as 1 cycle.
5. *Rapid cooling test:* The candle was placed in ice water for 15 minutes. The solid candle was originally at ambient temperature while the liquid candle was taken directly out of the hot water. Fifteen minutes of ice water exposure was defined as 1 cycle.
6. *Bleach test:* Two different bleach exposure tests were performed—one with a diluted bleach solution and one with pure bleach. The diluted bleach solution consisted of 3 cups of water mixed with 22mL of Clorox bleach (the standard recommended use by Clorox for disinfection). The pure bleach solution consisted of 1 cup of pure bleach. Candles were left to soak in the solution for approximately 24 hours.

Durability Testing: Summary

Test type	Criteria for passing the test	Result
Bend Test	30 cycles, no leak	Pass
Functional Test	30 cycles, no leak	Pass
Horizontal Drop Test	30 cycles, no leak	Pass
Vertical Drop Test	30 cycles, no leak	Pass
Rapid Cooling Test	30 cycles, no leak	Pass
Bleach Pure	No leak after 24 hours	Pass
Bleach Dilute	No leak after 24 hours	Pass

Appendix B: Infant Warmer Set-up



Appendix C: Budgets

Study funding Source: Rosenfeld Fund from Harvard Medical School

Phase 1 Budget:

Activity	Unit Cost	Unit Number	Total cost (USD=630 RWF)	Comment
RNEC application	1600	1	1600	
Yearly renewal	800	1	800	
NHRC application	300	1	300	
Staff				
Study Manager (1 per district) salaries	600USD/month	6	3600	Salary: 600USD/month/for 3months/2people
Nurse incentives	5000 RWF/month	60	500	Approximate 10 nurses involved per district per month x 3 months
Accommodations	100	6	600	1 study manager per district x 3 months each
Data collection				
tablet/laptop	800	2	1600	For study manager
laptop case	50	2	100	
external hard drive	100	2	200	
washing materials	100	1	100	Towels, soap
electric kettle	40	2	80	
Communication	30	6	180	Phone credits per study manager, 30USD/month
electronic thermometers	10	10	100	
training for study managers	100	1	100	
Orientation meeting for nurses	50	2	100	
Translation	500	1	500	back-translation, parent guides, consent, information sheets etc
Printing/binding	100	1	100	consent forms and other forms
Data analysis	190	1	190	programming software
TOTAL COST PHASE 1			10750	

Phase 2 Budget:

Activity	Unit Cost	Unit Number	Total cost (USD)	Comment
Staff				
Study Manager salaries (1 per district)	600USD/month	12	7200	Remuneration for study managers: 600USD/month/6months/2people
Accommodation and transport for study managers at the health center	100USD/month	12	1200	
Data Collection				
Communication for study managers	50USD/month	12	600	
Nurse incentives (Aim 1)	5000 RWF/month	120	950	
Incentive for qualitative participation	2000 RWF	72	250	15 caregivers and 3 nurses per 4 health centers
electric kettle	40	4	160	
Info meeting for HC team	50	4	200	On-site meetings
electronic thermometers	10	8	80	
Printing/binding	150	1	150	consent forms and data collection forms
Data analysis	150	1	150	qualitative software
TOTAL COST PHASE 2			10940	
STUDY GRAND TOTAL			21690	

Appendix D: Caregiver Consent Form for Warmer Use (Phases 1 and 2)

INSHUTI MU BUZIMA
PARTNERS IN HEALTH RWANDA
Electricity-free Infant Warmer for Newborn Thermoregulation

Consent Form

Instructions: To be read aloud to the participant

We are conducting a research study to understand the *effectiveness of an infant warmer that does not require electricity as a strategy to improve care for newborns in Rwanda by keeping babies warm*. The information we gather through this study will help us understand if and how this infant warmer can help prevent illness and death of newborns in Rwanda.

If you and your treating nurse agree to participate in this study, the Study Manager will supervise the nurse preparing the infant warmer and ensure that it is properly and safely used on your baby to prevent or treat being cold. It should not interfere with skin-to-skin warming and is intended as an alternative if you are not present or if skin-to-skin is insufficient. In hospitals, it may be used during routine care. In health centers, it may also be used in the case of resuscitation or transport. If it is not keeping your baby warm enough, we will move you to an electric warmer, if an electric warmer is available. Your baby's health and safety is the number one priority. You can choose to stop use of the infant warmer at any time. Your baby's temperature will be monitored frequently to make sure the baby is safely warm. You and your baby's information will be kept confidential, which means we will never tell anyone outside of the study your name, age, or the village where you live. All data collection forms will be kept in a locked file. Only the members of our study team will have access to them. At the end of the assessment, these forms will all be destroyed. You are asked to participate for the length of your child's hospital stay, which means that the infant warmer could be used on your child multiple times, but you may stop participation at any time with no negative consequences to you or your child's care.

If you choose not to participate in this study, there will be no negative consequences to your care in the hospital or health center. You will be treated just as if the non-electric infant warmer did not exist and use skin-to-skin or an electric warmer to keep your baby warm. Your doctors and nurses will not treat you any differently.

There is a small risk that your baby might experience skin irritation if the infant warmer is used when it is too hot, or that your baby may be warmed more slowly if the warmer is too cold. To keep this risk very low, the Study Manager will closely supervise the nurses using the infant warmer and will stop them from putting the baby into the infant warmer if it is not the right temperature and will monitor the baby's temperature very closely to keep your baby healthy. There is also a risk of your private study information being shared. To prevent this, your personal information will be kept in a locked cabinet that only the study manager and primary investigators can locate, and will be destroyed 2 years after the end of the study.

Benefits of the study could be closer temperature monitoring for your baby. It is also possible that the infant warmer will keep your baby's temperature more normal and stable than other options for warming. If you participate in the study, you will also help us to learn if this blanket is a good way to prevent cold temperature in newborns in Rwanda.

If you have any questions about the study you can contact one of the following persons:

1) Dr Evrard Nahimana, Study Manager, 07 88 89 77 34 or enahiman@pih.org

2) Ancille Musabende, Pediatric Program Coordinator, [07 88 42 27 94](tel:0788422794) or amusabende@pih.org If there are any questions related to participant rights, please contact the Rwandan National Ethics Committee chair, Dr. Jean-Baptiste Mazarati 0788309807 or secretary Dr. Laetitia Nyirazinyoye 0738683209.

Do you have any questions?

Do you agree to be in this study?

Yes (PROCEED) No (STOP)

Caregiver Signature/Mark

Date

I attest that as a witness I was present throughout the entire consent process. The mother/father voluntary consents to participate in the above research statement.

Witness Signature

Date

INSHUTI MU BUZIMA

PARTNERS IN HEALTH RWANDA

Uburyo bwo kongerera ubushyuhe umwana ukivuka hadakoreshejwe amashanyarazi

Ururupapuro rutanga uburenganzira bwo kubazwa

Amabwiriza: Bigomba gusomerwa ubazwa mu Kinyarwanda kandi mu ijwi ryigiye ejuru

Turimo gukora ubushakashatsi bugamije kumva no gusobanukirwa uburyo buboneye bwo kongerera ubushyuhe abana bakivuka budasaba gukoresha amashanyarazi nk'ingamba yo kunoza imivurire y'abana bakivuka mu Rwanda dufureba impinja. Amakuru tuzakusanya muri ubu bushakashatsi burebana no gukoresha uburyo bwo kongerera ubushyuhe umwana ukivuka azafashe mu kumva ndetse no gusobanukirwa uko iki kiringiti cyafasha mu kurinda indwara ndetse n'imfu z'abana bakivuka mu Rwanda.

Niba wowe hamwe n'umuforomo ukuvura mwemeye kwitabira ubu bushakashatsi, umuyobozi w'ubu bushakashatsi azaganzira ko umuforomo ategura neza ikiringiti cyongerera ubushyuhe kandi ko anagukoresha mu buryo buboneye ku mwana wawe kugira ngo kimurinde ubukonje cyangwa se kimuvure gukonja. Ubu buryo bw'ikiringiti ntibugomba kubangamira uburyo busanzwe bwo gushyushya umwana umushyira mu gituzza, ahubwo bwashyirweho nk'ubwa kwifashishwa mu gihe umubyeyi adahari cyangwa mu gihe byaragaragaye ko uburyo bwo gushyushya umwana mu gituzza budahagije. Mu bitaro ubu buryo bushobora gukoreshwa mu bikorwa by'ubuvuzi bya buri munsu. Mu bigo nderabuzima, ubu buryo bushobora gukoreshwa mu gihe bari kongerera amahirwe yo kubaho (kuzanzamura) umwana cyangwa se mu gihe bamutwaye ku bitaro. Mu gihe bigaragaye ko icyo kiringiti kitarimo guha ubushyuhe buhagije umwana wawe, tuzamwimurira kuri rya tara ritanga ubushyuhe rikoreshejwe n'amashanyarazi niba hari irihari. Ubuzima ndetse n'ubusugire by'umwana wawe nibyo bishyirwa imbere kandi bihabwa agaciro. Ufite uburenganzira bwo guhitamo igihe icyo aricyo cyose guhagarika gukoresha ikiringiti cyongerera ubushyuhe umwana ukivuka. Ibipimo by'ubushyuhe bw'umubiri by'umwana wawe bizaganzurwa buri saha kugira ngo hakurikiranwe ku buryo bwizewe ko umwana wawe afite ibipimo by'ubushyuhe biboneye. Amakuru arebana nawe ndetse n'amakuru yose arebana n'umwana wawe bizagirwa ibanga, bisobanuye ko nta muntu tuzabwira amazina yawe cyangwa imyaka yawe ndetse n'izina ry'umudugudu utuyemo. Amakuru yose azakusanywa kuri iyi fishi azabikwa ahantu habugenewe hafungwa neza. Abantu bemerewe kugera kuri ayo makuru ni abakozi bo muri ubu bushakashatsi. Nibamara gukorera isuzuma sesengura ayo makuru, aya mafishi yose azatwikwa. Turagusaba kwitabira iki gikorwa cy'ubushakashatsi mu gihe cyose umwana wawe azamara arwariye muri ibi bitaro, bivuze ko ubu buryo bw'ikiringiti cyongerera ubushyuhe umwana ukivuka gishobora gukoreshwa ku mwana wawe inshuro nyinshi, ariko igihe icyo aricyo cyose ufite uburenganzira bwo kuba wahagarika ubwitabire bwawe muri ubu bushakashatsi ariko nta ngaruka bizakugiraho cyangwa se ku buvuzi buhabwa umwana wawe.

Mu gihe uhisemo kutagira uruhare muri ubu bushakashatsi, nta ngaruka mbi bizakugiraho ku birebana n'ubuvuzi uhabwa ku Bitaro no ku kigo nderabuzima. Bazakuvura nkaho buriya buryo bw'IKIRINGITI butigeze bubaho ahubwo bazakoresha uburyo busanzwe bwo gushyira umwana mu gituzza ndetse no kumushyira ku itara ryagenewe kongerera umwana ubushyuhe. Abaganga n'abaforomo ntabwo bazagufata bitandukanye nuko bagufataga mbere y'ubu bushakashatsi.

Gukoresha iki kiringiti cyongerera ubushyuhe abana bakivuka bishobora kugira ingaruka zidakomeye ku mwana wawe harimo ko gishobora kumutera ibibazo by'uruhu kubera ko icyo kiringiti kiba gishyushye cyane. Cyangwa umwana wawe ashobora kongerera ubushyuhe buhoro buhoro mu gihe icyo kiringiti gikonje cyane. Mu kugabanya ibibazo bishobora kuba kuri uwo mwana kubera gukoresha ubwo buringiti, ushinze ubu bushakashatsi azakurikiranira hafi abaforomo uko bakoresha icyo kiringiti ndetse ntazabemerera ko bashyira icyo kiringiti ku mwana mu gihe igipimo cy'ubushyuhe nyacyo gisabwa ndetse azakomeza kuzanzurira hafi igipimo cy'ubushyuhe bw'umubiri bw'umwana kugira ngo ubuzima bw'umwana wawe bubungwabungwe. Indi ngaruka ishobora gukomoka kuri ubu bushakashatsi nuko amakuru yawe bwite arebana nawe muri ubu bushakashatsi ashobora gusangirwa. Mu kwirinda ko haba

izo ngaruka, amakuru yawe bwite muri ubu bushakashatsi azabikwa mu kabati gafungwa neza, Umuyobozi w'ubu bushakashatsi hamwe n'abashakashati bo ku rwego rwa kabiri niba bazamenya aho ayo makuru ashyinguwe; izo mpapuro zibitseho ayo makuru zikaba zizatwikwa imyaka ibiri nyuma yaho ubwo bushakashatsi burangiriye.

Inyungu yo muri ubu bushakashatsi ni kugenzura ku buryo bwa hafi ibipimo by'ubushyuhe bw'umubiri w'umwana wawe. Birashoboka ko ubu buryo bw'ikiringiti cyongerera ubushyuhe abana bakivuka bushobora gutuma ubushyuhe bw'umubiri bw'umwana wawe buguma ku gipimo gisanzwe mu gihe bitari gushoboka mu gihe hakoreshejwe ubundi buryo bwo gufureba no kwongerera ubushyuhe abana bakivuka. Mu gihe witabiriye ubu bushakashatsi, uzadufasha kumenya niba iki kiringiti ari uburyo bwiza bwafasha mu kurinda ikibazo cy'ubukonje mu bana bakivuka mu Rwanda.

Ufite ikibazo cyangwa icyo ushaka gusobanuzwa kuri ubu bushakashatsi, wahamagara umwe muri bano bakozi b'umuryango inshuti Mu Buzima:

1) Dr Evrard Nahimana, ukurikirana ubushakashatsi, 07 88 89 77 34 cyangwa email: enahiman@pih.org

2) Musabende Ancille umuhuzabikorwa ushinze ubuzima bw'abana kuri telephone [07 88 42 27](tel:0788422794)

[94 cyangwa email: amusabende@pih.org](mailto:amusabende@pih.org)

Niba hari ibi bibazo birebana n'uburenganzira bw'abitabiriye ubu bushakashatsi, mwahamagara Umuyobozi Mukuru w' Ikigo Rwanda National Ethics Committee Dr Jean-Baptiste Mazarati 07 88 30 98 07 cyangwa Umunyamabanga Dr. Laetitia Nyirazinyoye 07 38 68 32 09.

Hari ibibazo waba ushaka kubaza?

Mwaba mwemeye kugira uruhare muri ubu bushakashatsi? **Yego** (Komeza) **Hoya** (Hagarara)

Umukono cyangwa igikimwe cy'umurwaza

Itariki

Ndemeza nk'umugabo w'igikorwa ko nari mpari mu gikorwa cyose cyigamije gutanga uburenganzira bwo kubazwa. Nyina/Ise bemeye ku bushake kugira uruhare mu bushakashatsi bwavuzwe haruguru.

Umukono w'umuforomo

Itariki

Appendix E: **Nurse Consent Form** for Warmer Use (Phases 1 and 2)

INSHUTI MU BUZIMA
PARTNERS IN HEALTH RWANDA

Comment [HA1]: Make sure signature line has "nurse" not "caregiver" in Ikenyarwanda version

Electricity-free Infant Warmer for Newborn Thermoregulation

Consent Form

Instructions: To be translated into ikinyarwanda and offered to read aloud to the participant.

We are conducting a research study to understand the **effectiveness of an infant warmer that does not require electricity as a strategy to improve care for newborns in Rwanda by keeping babies warm**. The information we gather through this study will help us understand if and how this infant warmer can help prevent illness and death of newborns in Rwanda.

If you agree to participate in this study, the Study Manager will supervise you in preparing the warming blanket for an eligible patient and ensure that it is properly and safely used on the baby. This consent will be valid for your participation in the duration of the study in your unit. It should not interfere with kangaroo mother care and is intended as an alternative if the caregiver is not present or if skin-to-skin is insufficient. In hospitals, it may be used during routine care. In health centers, it may also be used in the case of reanimation or transport. If it is not keeping the patient warm enough, we will move the baby to an electric warmer if available. The patient's health and safety is the number one priority. You can choose to stop use of the warming blanket at any time. The patient's temperature will be monitored every hour to make sure the baby is safely warm. Your will be kept anonymous, which means we will never tell your name to anyone. Data collection forms will be kept in a locked file. Only the members of our study team will have access to them. At the end of the assessment, these forms will be destroyed.

If you choose to participate in the study, you will be given 5000 RWF airtime per month, in order to facilitate your work and communication required by participation in this study.

If you do not choose to participate in this study, or at any point, decide you no longer want to be apart of the study, there will be no negative consequences to you or your job position in the hospital or health center. Your supervisors will not punish you in any way.

There are no direct benefits to you from participating in the study. You will be helping us to learn if this blanket can help prevent cold temperature in babies that can cause death in newborns in Rwanda and the rest of the world. There is a small risk that an infant placed in the warmer might experience skin irritation if it is used when it is too hot. To prevent this, your personal information will be kept in a locked cabinet that only the study manager and primary investigators can locate, and will be destroyed 2 years after the end of the study.

If you have any questions about the study you can contact one of the following persons:

- 1) Dr Evrard Nahimana, Study Manager, 07 88 89 77 34 or enahiman@pih.org
- 2) Ancille Musabende, Pediatric Program Coordinator, [07 88 42 27 94](tel:0788422794) or amusabende@pih.org

If there are any questions related to participants rights, please contact the Rwandan National Ethics Committee chair, Dr. Jean-Baptiste Mazarati 0788309807 or secretary Dr. Laetitia Nyirazinyoye 0738683209.

Do you have any questions?

Do you agree to be in this study?

Yes (PROCEED) No (STOP)

Nurse Signature

Date

INSHUTI MU BUZIMA
PARTNERS IN HEALTH RWANDA

Uburyo bwo kongerera ubushyuhe umwana ukivuka hadakoreshejwe amashanyarazi

Ururupapuro rutanga uburenganzira bwo kubazwa

Amabwiriza: Bigomba gusomerwa ubazwa mu Kinyarwanda kandi mu ijwi ryigiye ejuru

Turimo gukora ubushakashatsi bugamije kumva no gusobanukirwa **uburyo** bwo kongerera ubushyuhu abana bakivuka budasaba gukoresha amashanyarazi nk'ingamba yo kunoza imivurire y'abana bakivuka mu Rwanda dufureba impinja. Amakuru tuzakusanya muri ubu bushakashatsi burebana no gukoresha uburyo bwo kongerera ubushyuhu umwana ukivuka azadufasha mu kumva ndetse no gusobanukirwa uko iki kiringiti cyafasha mu kurinda indwara ndetse n'imfu z'abana bakivuka mu Rwanda.

Niba wemeye kugira uruhare muri ubu bushakashatsi, Umuyobozi w'ubu bushakashatsi azakugenzura urimo gutegurira umurwayi wujuje ibisabwa mu guhabwa ikiringiti cyongerera ubushyuhu abana bakivuka kugira ngo yizere neza ko gikoreshwa neza mu buryo butanga umutekano ku mwana. Ubu ururupapuro rutanga uburenganzira bwo kubazwa buzakoreshwa ku birebana n'ubwitabire bwawe mu gihe cy'ubushakashatsi mu gashami ukoreramo. Ubu buryo bw'ikiringiti cyongerera ubushyuhu abana bakivuka ntibugomba kubangamira uburyo busanzwe bwo gushyushya umwana umushyira mu gituzi (uburyo bwa kangaroo), ahubwo bwashyiriweho nk'ubwa kwifashishwa mu gihe umubyeyi cyangwa umurwaza adahari cyangwa mu gihe byaragaragaye ko uburyo bwo gushyushya umwana mu gituzi budahagije. Mu bitaro ubu buryo bushobora gukoreshwa mu bikorwa by'ubuvuzi bya buri muni. Mu bigo nderabuzima, ubu buryo bushobora gukoreshwa mu gihe bari kongerera amahirwe yo kubaho (kuzanzamura) umwana cyangwa se mu gihe bamutwaye ku bitaro. Mu gihe bigaragaye ko icyo kiringiti kitarimo guha ubushyuhu buhagije umurwayi, tuzamurira umwana kuri rya tara ritanga ubushyuhu rikoreshe n'amashanyarazi niba hari irihari. Ubuzima ndetse n'ubusugire by'umwana nibyo bishyirwa imbere kandi bihabwa agaciro. Ufite uburenganzira bwo guhitamo igihe icyo aricyo guhagarika gukoresha uburingiti bwongerera ubushyuhu umwana. Ibipimo by'ubushyuhu by'umubiri w'umurwayi bizagenzurwa buri saha kugira ngo hakurikiranwe ku buryo bwizewe ko umwana afite ibipimo by'ubushyuhu biboneye. Amakuru arebana nawe ndetse n'amakuru yose akwerekeye azagirwa ibanga, bisobanuye ko nta muntu tuzabwira amazina yawe. Amakuru yose azakusanywa kuri iyi fishi azabikwa ahantu habugenewe hafungwa neza. Abantu bemerewe kugera kuri ayo makuru ni abakozi bo muri ubu bushakashatsi. Nibamara gukorera isuzuma ayo makuru, aya mafishi yose bazayatikwa.

Niba wemeye kugira uruhare muri ubu bushakashatsi, uzahabwa ikarita yo guhamagara buri kwezi ingana n'amafaranga 5000 mu rwego rwo kugira ngo bigufashe mu kazi kawe ndetse izanagufasha mu birebana n'itumanaho mu rwego rwo kwitabira ubu bushakashatsi.

Mu gihe utemeye kwitabira muri ubu bushakashatsi, cyangwa se hari aho ugeze ukumva utagishatse gukomeza kugira uruhare muri ubu bushakashatsi, nta ngaruka mbi zizakugera mu birebana n'akazi kawe mu bitaro cyangwa mu kigo nderabuzima. Nta bihano umuyobozi wawe azakugenera.

Nta nyungu yako kanya uzabona zikomoka mu kugira uruhare muri ubu bushakashatsi. Uzaba udufasha mu kumenya niba ubu burungiti bushobora kurinda ubukonje bushobora guhitana impinja zikivuka mu Rwanda ndetse no ku isi hose. Gukoresha iki kiringiti cyongerera ubushyuhu abana bakivuka bishobora kugira ingaruka zitaremeye ku mwana wawe harimo ko gishobora kumutera ibibazo by'uruho kubera ko icyo kiringiti kiba gishyushye cyane. Kubyirinda, amakuru yawe azabikwa mu kabati gafungwa neza, umuyobozi w'ubu bushakashatsi ndetse n'abamwunganira bo ku rwego rwa kabiri nibo bonyine bashobora kumenya aho ayo makuru ashyinguye, ikindi nuko impapuro zibitseho ayo makuru zizatwikwa imyaka ibiri nyuma yuko ubu bushakashatsi bushojwe.

Ufite ikibazo cyangwa icyo ushaka gusobanuzwa kuri ubu bushakashatsi, wahamagara umwe muri bano bakozi b'umuryango inshuti Mu Buzima:

1) Dr Evrard Nahimana, ukurikirana ubushakashatsi, 07 88 89 77 34 cyangwa email: enahiman@pih.org

2) Musabende Ancille umuhuzabikorwa ushinze ubuzima bw'abana kuri telephone [07 88 42 27](tel:0788422794)

[94 cyangwa email: amusabende@pih.org](mailto:amusabende@pih.org)

Niba hari ibi bibazo birebana n'uburenganzira bw'abitabiriye ubu bushakashatsi, mwahamagara Umuyobozi Mukuru w' Ikigo Rwanda National Ethics Committee Dr Jean-Baptiste Mazarati 07 88 30 98 07 cyangwa Umunyamabanga Dr. Laetitia Nyirazinyoye 07 38 68 32 09.

Haba hari ikibazo cyangwa ibisobanuzo ufite?

Wemeye kwitabira ubu bushakashatsi

Yego (Komeza) Hoya (Hagarara)

Umukono cyangwa igikimwe cy'umurwaza

Itariki

Appendix F: Qualitative Interview Consent Form for Nurses and Caregivers (Phase 2)

INSHUTI MU BUZIMA

PARTNERS IN HEALTH RWANDA
Electricity-free Infant Warmer for Newborn Thermoregulation

Consent Form

Instructions: To be translated into ikinyarwanda and offered to read aloud to the participant.

We are conducting a study in order to understand the experiences and opinions of caregivers and nurses who have participated in using the infant warming blanket. We plan to interview 10-15 caregivers & 1-3 nurses per health center. Our goal is to create a safe, simple, inexpensive way to keep babies warm and decrease newborn illness and death in Rwanda. If you agree to participate in this part of our study, you will be asked a series of questions to help us understand your views regarding the blanket. Information gathered from this assessment will help us improve or modify the blanket in order to be most useful to newborn health.

Your responses will not affect your access to services, your employment as a provider of services, or the employment of those who provide services to you. You are not required to participate. You get to choose whether or not you want to participate in this evaluation. If you decide to participate and find that some of the questions make you feel shy or uncomfortable, you do not have to answer them. You can also stop the interview at any time, without being punished in any way.

Your information will be kept anonymous, which means we will never tell your name, age, or the village where you live to anyone. With your permission, the interview will be audio-recorded. Only the members of our study team will have access to them. At the end of the assessment, these tapes will all be destroyed. There is a risk of your private study information being shared. To prevent this, your personal information will be kept in a locked cabinet that only the study manager and primary investigators can locate, and will be destroyed 2 years after the end of the study. If you do not wish to be tape-recorded, please inform the interviewer.

As a token of appreciation for your time, you will be given 2000 RWF airtime

If you have any questions about the study you can contact one of the following persons:

- 1) Dr Evrard Nahimana, Study Manager, 07 88 89 77 34 or enahiman@pih.org
- 2) Ancille Musabende, Pediatric Program Coordinator, [07 88 42 27 94](tel:0788422794) or amusabende@pih.org

If there are any questions related to participants rights, please contact the Rwandan National Ethics Committee chair, Dr. Jean-Baptiste Mazarati 0788309807 or secretary Dr. Laetitia Nyirazinyoye 0738683209.

Do you have any questions?

Do you agree to be in this study? **Yes (PROCEED) No (STOP)**

Participant Signature/mark

Date

For Caregiver participation:

I attest that as a witness I was present throughout the entire consent process. The mother/father voluntary consents to participate in the above research statement.

Witness Signature

Date

INSHUTI MU BUZIMA
PARTNERS IN HEALTH RWANDA

Uburyo bwo kongerera ubushyuhe umwana ukivuka hadakoreshejwe amashanyarazi

Urupapuro rutanga uburenganzira bwo kubazwa

Amabwiriza: Bigomba gusomerwa ubazwa mu Kinyarwanda kandi mu ijwi ryigiye ejuru

Turimo gukora ubushakashatsi bugamije kumva no gusobanukirwa ubunararibonye ndetse n'ibitekerezo by'abarwaza ndetse n'abaforomo bitabiriye mu ikoreshwa ry'ikiringiti cyongerera ubushyuhe abana bakivuka. Turateganya kugirana ibiganiro hagati y'abarwaza 10 na cumi na batanu ndetse n'abaforomo hagati ya 1 na 3 kuri buri kigo nderabuzima. icyo tugamije nu gushyiraho uburyo bwizewe kandi bworoshye ndetse budahenze bwo kongerera ubushyuhe/ gufureba abana bakivuka ndetse no kugabanya indwara ndetse n'impfu z'abana mu Rwanda. Mu gihe wemeye kugira uruhare muri iki cyiciro cy'ubushakashatsi, uzabazwa ibibazo bitandukanye bizadufasha kumva neza no gusobanukirwa ibitekerezo byawe ku birebana n'iki kiringiti. Amakuru yose azakusanywa muri ubu bushakashatsi azadufasha mu kunoza cyangwa guhindura iki kiringiti kugira ngo kirusheho gufasha mu kurengera ubuzima bw'abana bakivuka.

Ibisubizo byawe nta ngaruka bizakugiraho ku birebana no guhabwa serivisi cyangwa se ku kazi kawe nk'umwe mubatanga izo serivises, cyangwa se nanone akazi k'abagaha izo serivisi. Ntabwo usabwe

kugira uruhare muri ubu bushakashatsi. Ufite uburenganzira bwo guhitamo niba ushobora kwitabira iri suzuma sesengura cyangwa udashaka kugira uruhare muri iri suzuma sesengura. Mu gihe wiyemeje kwitabira iri suzuma ugasanga harimo ibibazo bituma wumva utamerewe neza cyangwa bigutera isoni, ubufite uburenganzira bwo kutabisubiza. Ufite uburenganzira kandi bwo guhagarika iki kiganiro igihe icyo aricyo cyose kandi nta ngaruka bizakugiraho.

Amakuru yose uzatagariza azagirwa ibanga, bisobanuye ko tutazagira undi muntu dutagariza amazina, imyaka yawe, cyangwa izina ry'umudugudu utuyemo. Mubiduhereye uruhushya, ikiganiro tuzagirana cyazafatwa ku byuma bifata amajwi. Abazagera kuri ayo makuru ni abagize gusa itsinda ry'ubushakashatsi. Nyuma y'ubu bushakashatsi aya makaseti azatwikwa. Hari n'impungenge yuko amakuru yawe bwite ashobora gusangirwa. Mu kwirinda ko ibyo byaba, amakuru yawe bwite akureba azabikrwa mu kabati gafunze neza aho umukuru w'ubu bushakashatsi ndetse n'abamwugirije bo ku rwego rwa mbere ari bonyine bashobora kumenya aho ayo makuru abitswe, mu gihe cy'imyaka ibiri nyuma y'ubu bushakashatsi nibwo ayo makuru azatwikwa.

Mu gihe waba utifuzwa ko ikiganiro tugirana gifatwa ku byuma bifata amajwi, bimenyeshe umuntu ushinze ibazwa muzaba mugiyeho kugirana icyo kiganiro.

Uzagenerwa agashimwe k'ikarita yo guhamagara ya telephone yi 2000 kuko waduhaye umwanya wawe

Ufite ikibazo cyangwa icyo ushaka gusobanuzwa kuri ubu bushakashatsi, wahamagara umwe muri bano bakozi b'umuryango inshuti Mu Buzima:

1) Dr Evrard Nahimana, ukurikirana ubushakashatsi, 07 88 89 77 34 cyangwa email: enahiman@pih.org

2) Musabende Ancille umuhuzabikorwa ushinze ubuzima bw'abana kuri telephone [07 88 42 27](tel:0788422794)

[94 cyangwa email: amusabende@pih.org](mailto:amusabende@pih.org)

Niba hari ibi bibazo birebana n'uburenganzira bw'abitabiriye ubu bushakashatsi, mwahamagara Umuyobozi Mukuru w' Ikigo Rwanda National Ethics Committee Dr Jean-Baptiste Mazarati 07 88 30 98 07 cyangwa Umunyamabanga Dr. Laetitia Nyirazinyoye 07 38 68 32 09.

Hari ibibazo ufite cyangwa ibyo waba ushaka gusobanuzwa?

Waba wemeje kwitabira ubu bushakashatsi? **yego** (Komeza) **Hoya** (Hagarara)

Umukono cyangwa igikumwe cy'uwitabiriye ikiganiro

Itarik

Ndemeza nk'umugabo w'igikorwa ko nari mpari mu gikorwa cyose cyigamije gutanga uburenganzira bwo kubazwa. Nyina/Ise bemeye ku bushake kugira uruhare mu bushakashatsi bwavuzwe haruguru.

Umukono w'umuforomo

Itariki

**Appendix G: Infant Warmer Data Collection Form
During Infant Warmer Use**

If at risk for hypothermia, follow thermoregulation per neonatal protocol. If temp < 36^oC, start thermoregulation with Kangaroo Mother Care (KMC) unless contraindicated.

Consider enrollment in Infant Warmer (IW) Study:

Inclusion Criteria (check all that apply)

- Temperature < 36^oC
- At risk for hypothermia
 - Estimated post menstrual age (PMA) < 35 weeks
(PMA = gestational age + chronologic age. A 7 day old 33 week gestation baby has a PMA of 34 weeks)
 - Current body weight < 2.5 kg

Exclusion criteria:

- Family unwilling to consent to study,
- Mother not medically stable enough to approach for consent, per nursing judgment.

- Consent obtained
- Consent denied

Participant ID Phase 1 (1- 102): _____

Participant ID Phase 2 (1- 40 per health center): _____

Date of Birth: _____

Today's Date: _____

Name of Hospital/Health Facility: _____

Birth weight: _____

Today's weight: _____

Gestational Age: _____

Severity of Illness (check all that apply)

- Vital Sign instability
(specify: _____)
- Other _____

Setting of Use (check all that apply):

- Hospital care of hypothermic and/or LBW/preterm infant
- Routine post-partum care
- Reanimation
- Transport (e.g. from health center to hospital)

Received electric heat source while infant warmer prepared and/or consent signed? yes no

Taken off study because hypothermic and not warming > 1/2 °C/hour? yes no

Taken off study because unable to maintain temp > 36 °C despite max exposure? yes no

Taken off study because determined to be too ill by medical team? yes no

Participant ID:		Date:		TIME BASED DATA FLOW SHEET	
	Temperature: Infant/Warmer/Air	Position of color change indicator	Mode of thermoregulation (check all that apply)		Comments
Start of study ____:____	/ /	<input type="checkbox"/> Hot frowny face <input type="checkbox"/> Warm smiley face <input type="checkbox"/> Cold frowny face	<input type="checkbox"/> IW <input type="checkbox"/> KMC <input type="checkbox"/> blanket <input type="checkbox"/> bundling <input type="checkbox"/> hat		
15 minutes ____:____	/ /	<input type="checkbox"/> Hot frowny face <input type="checkbox"/> Warm smiley face <input type="checkbox"/> Cold frowny face	<input type="checkbox"/> IW <input type="checkbox"/> KMC <input type="checkbox"/> blanket <input type="checkbox"/> bundling <input type="checkbox"/> hat		
30 minutes ____:____	/ /	<input type="checkbox"/> Hot frowny face <input type="checkbox"/> Warm smiley face <input type="checkbox"/> Cold frowny face	<input type="checkbox"/> IW <input type="checkbox"/> KMC <input type="checkbox"/> blanket <input type="checkbox"/> bundling <input type="checkbox"/> hat		
45 minutes ____:____	/ /	<input type="checkbox"/> Hot frowny face <input type="checkbox"/> Warm smiley face <input type="checkbox"/> Cold frowny face	<input type="checkbox"/> IW <input type="checkbox"/> KMC <input type="checkbox"/> blanket <input type="checkbox"/> bundling <input type="checkbox"/> hat		
1 hour ____:____	/ /	<input type="checkbox"/> Hot frowny face <input type="checkbox"/> Warm smiley face <input type="checkbox"/> Cold frowny face	<input type="checkbox"/> IW <input type="checkbox"/> KMC <input type="checkbox"/> blanket <input type="checkbox"/> bundling <input type="checkbox"/> hat		
2 hours ____:____	/ /	<input type="checkbox"/> Hot frowny face <input type="checkbox"/> Warm smiley face <input type="checkbox"/> Cold frowny face	<input type="checkbox"/> IW <input type="checkbox"/> KMC blanket <input type="checkbox"/> blanket <input type="checkbox"/> bundling <input type="checkbox"/> hat		
3 hours ____:____	/ /	<input type="checkbox"/> Hot frowny face <input type="checkbox"/> Warm smiley face <input type="checkbox"/> Cold frowny face	<input type="checkbox"/> IW <input type="checkbox"/> KMC <input type="checkbox"/> blanket <input type="checkbox"/> bundling <input type="checkbox"/> hat		
4 hours ____:____	/ /	<input type="checkbox"/> Hot frowny face <input type="checkbox"/> Warm smiley face <input type="checkbox"/> Cold frowny face	<input type="checkbox"/> IW <input type="checkbox"/> KMC <input type="checkbox"/> blanket <input type="checkbox"/> bundling <input type="checkbox"/> hat		
5 hours ____:____	/ /	<input type="checkbox"/> Hot frowny face <input type="checkbox"/> Warm smiley face <input type="checkbox"/> Cold frowny face	<input type="checkbox"/> IW <input type="checkbox"/> KMC <input type="checkbox"/> blanket <input type="checkbox"/> bundling <input type="checkbox"/> hat		
6 hours ____:____	/ /	<input type="checkbox"/> Hot frowny face <input type="checkbox"/> Warm smiley face <input type="checkbox"/> Cold frowny face	<input type="checkbox"/> IW <input type="checkbox"/> KMC <input type="checkbox"/> blanket <input type="checkbox"/> bundling <input type="checkbox"/> hat		

Infant Warmer Data Collection Form
Phase 1 study, Observer audit

Participant ID: _____
Infant Warmer ID: _____
Date: _____ Time: _____

- 1. a) Time Decision made to prepare warmer: _____
- b) Time warmer placed in boiling water: _____
- c) Time warmer removed: _____
- d) Time warmer safety color change indicator turns: _____
- e) Time of application of warmer to patient: _____

2. Did health care worker attempt to place infant on warmer before it has cooled adequately (before color indicator demonstrated safe temperature)? Yes No If yes, describe:

3. Was infant positioned on warmer correctly? Yes No If yes, describe:

4. Was there any other deviation or attempted deviation from recommended infant warmer use? Yes No If yes, describe:

5. If the warmer was inappropriately used, did it cause an adverse event? (See SoP page 7 for adverse event reporting) Yes No If yes, describe

6. Is there any evidence of skin irritation associated with use of the warmer? Yes No

If yes, describe:

Participant ID: _____

Infant Warmer ID: _____

Date: _____ Time: _____

7. Was warmer cleaned properly with 10% chlorhexidine or soap and water?: Yes No

If issues with cleaning, describe:

Not thoroughly cleaned?

Water not available

Water available but not used?

Soap not available

Soap available but not used?

Other Concerns/Comment _____

8. Did warmer demonstrate any breakdown or other change? Yes No If yes, describe:

Other changes of warmer? Concern/Comment _____

9. Any other comments, concerns of observations:

**Appendix I: Infant Warmer Data Collection Form
Phase 2 Study
Qualitative Interview Questionnaire: Caregivers of Infants**

Name of researcher: _____
Date of interview: _____
Study code # for infant belonging to this caregiver: _____
Health Center name: _____

Introduction script:

As you know, your baby experienced the use of a new kind of warming blanket to help keep newborn babies warm. We are trying to understand if this new infant warmer is helpful, or how it could be improved for the future. As a caregiver of a baby who has used this new infant warmer, we are talking to you today to understand your opinions about the infant warmer. This is an anonymous study; your identity will not be shared with anyone. Your opinions are important to us, so please say what you think. There are no wrong answers, and we are especially interested to hear about any challenges or problems with the infant warmer that you might have experienced. I will be audio-recording our conversation, to make sure I remember everything that you say. Do you have any questions for me before we start the interview?

- 1) To start, I'm curious to hear how you would describe the infant warmer. What does it look like?
 - Do you like the way it looks? Why/why not?
 - Is the material soft?
 - Does it seem like a safe thing to put a new baby onto? Why/why not?
 - Did you have a chance to see the color indicator that shows whether the warmer is the right temperature?
 - If yes, did you understand what the color indicator was for?
 - Does it seem like something that helps nurses use the warmer correctly?

- 2) Please tell me about your experience seeing the infant warmer used with your baby: what happened?
 - When did the nurse first say that it was time to use the infant warmer?
 - Was the warmer used before or after the baby had been placed skin-to skin with you to warm?
 - Did you understand what the purpose of the infant warmer was?
 - What was it like to see the infant being put on or inside the warmer?
 - Did you have any fears or concerns about the warmer? How so?

- 3) Were there any difficulties with getting the infant positioned on the warmer?
- Did the nurse seem to have any trouble measuring the infant's temperature while the baby was on the warmer?
 - Did the warmer seem comfortable for the infant to be on?
- 4) How do you think this infant warmer compares to other ways you may have seen new babies kept warm?
- Have you ever seen new babies kept warm in a way other than the infant warmer?
 - Do you think the infant warmer is more helpful or less helpful, compared to other ways of keeping babies warm?
 - Have you ever seen new babies kept warm on an electric warming table?
 - If so, do you think the infant warmer is more helpful/safe or less helpful/safe than an electric warming table?
- 5) Did you [*or, for other caregivers: did the baby's mother*] have a chance to hold the baby close either before or after using the infant warmer?
- Were there any ways that it was difficult to have a normal interaction between you and baby because of the infant warmer?
- 6) Overall, what is your opinion of the infant warmer?
- Would you want the infant warmer to be used on another new baby in your family, if the baby had a similar need for warming up?
 - Why/why not?
 - Would you recommend to your friends that they should ask to use the infant warmer if their babies need warmth?
 - Why/why not?
- 7) Is there anything else you can tell me about your experience with the infant warmer before we finish our conversation?

Thanks so much for participating in this interview!

INSHUTI MU BUZIMA
PARTNERS IN HEALTH RWANDA

Uburyo bwo kongerera ubushyuhe umwana ukivuka hadakoreshejwe amashanyarazi

Umugereka wa J: Ifishi yo kwandimo amakuru arebana n'ikoreshwa ry'uburyo bushya bw'ikiringiti cyongerera ubushyuhe abana bakivuka

Icyiciro cya kabiri cy'ubushakashatsi

Ibibazo bigamije gucukumbura ireme bigenewe ababyeyi cyangwa abarwaza b'abana bakivuka

Amazina y'umushakashatsi: _____

Itariki ikiganiro cyabereyeho: _____

Umubare w'ibanga wahawe uyu mwana w'uyu mubyeyi muri ubu bushakashatsi: _____

Izina ry'ikigo nderabuzima: _____

Iriburiro:

Nkuko mubizi umwana wawe yagize uruhare mu bushakashatsi burebana no gukoresha uburyo bushya bw'ikiringiti cyongerera ubushyuhe abana bakivuka. Mu rwego rwo kumva no gusobanukirwa neza uko ubwo buryo bushya bw'ikiringiti cyongerera ubushyuhe abana bakivuka bwagufashije, cyangwa se ni mu buhe buryo bw'ikiringiti cyongerera ubushyuhe abana bakivuka bwarushwaho kunozwa ku buryo bwisumbuye mu gihe kizaza. Nk'umubyeyi cyangwa umurezi w'uyu mwana wakoresha ubu buryo bushya bw'ikiringiti cyongerera ubushyuhe umwana ukivuka. Uyu muni twaje kuganira nawe kugira ngo twumve ndetse tunasobanukirwe ibyiyumviro byawe ku birebana n'ubu buryo bushya bw'ikiringiti cyongerera ubushyuhe abana bakivuka. Ubu bushakashatsi ntabwo buzagaragaza umwirondoro wawe; nta wundi muntu tuzagaragariza umwirondoro wawe. Ibitekerezo byawe n'ingenzi kuri twebwe, mwisanzure mutubwire icyo mutekereza. Nta bisubizo bitari byo ndetse dushishikajwe by'umwihariko kumva imbogamizi n'ibibazo ushobora kuba waragize mu gukoresha ubu buryo bushya bw'ikiringiti cyongerera ubushyuhe abana bakivuka. Iki kiganiro turi bugirane ndagifata mu byuma bifata amajwi, ibi ni kugira ngo nzabashe kwibuka ibyo twaganiriye byose. Hari ikibazo mwaba mufite mbere yuko dutangira iki kiganiro?

1) Mu gutangira, mfite amatsiko yo kumva icyo watubwira mu buryo ranga shusho bw'ubu buryo bushya bw'ikiringiti cyongerera ubushyuhe abana bakivuka? Ese iki kiringiti kigaragara gute?

- Ese waba ukunda uburyo iki kiringiti giteye? Kubera iki/ kubera iki atariko bimeze?
- Iki kiringiti cyaba cyoroshye?
- Ese byaba byoroshye gushira umwana kuri kino gikoresho? Kubera ik/ kubera iki atariko bimeze?

- Wigeze ugira amahirwe yo kubona ibara ry'ikimenyetso ndangagikorwa ryerekana ko ikiringiti kiri ku gipimo nyacyo cy'ubushyuhe ?
 - Niba ari yego, waba warasobanukiwe nicyo iryo bara ry'ikimenyetso ndangagikorwa risobanura?
 - Byaba byarakugaragariye nkaho ari ikintu gifasha abaforomo gukoresha neza ubu buryo bushya bw' ikiringiti cyongerera ubushyuhe abana bakivuka?

2) Mwatubwira uko wabonye ubu buryo bushya bw'ikiringiti cyongerera ubushyuhe abana bakivuka cyakoreshejwe ku mwana wawe: byagenze gute?

- Niki umuforomo yakubwiye bwa mbere ubwo yakubwira ko hageze igihe cyo gukoresha ikiringiti cyongerera ubushyuhe abana bakivuka?
- Ese ubu buryo bushya bw'ikiringiti cyongerera ubushyuhe abana bakivuka bwaba bwarakoreshejwe mbere cyangwa nyuma yuko umwana yari yashyizwe mu gituzi cya mama we kugira ngo ashyuhe?
- Waba warasobanukiwe n' impamvu y' ikoreshwa ry'ubu buryo bushya bw' ikiringiti cyongerera ubushyuhe abana bakivuka?
- Ese wabyakiriye ute ubonye uruhinja rwawe barushyize kuri ikiringiti cyongerera ubushyuhe abana bakivuka?
- Hari ubwoba cyangwa impungenge wagize ku birebana n'ubu buryo bushya bw'ikiringiti cyongerera ubushyuhe abana bakivuka?

3) Hari ingorane wagize zo gushyira umwana neza kuri icyi kiringiti cyongerera ubushyuhe abana bakivuka?

- Hari ubwo umuforomo yagowe no gufata ibipimo by'ubushyuhe mu gihe umwana yari yashyizwe muri icyo kiringiti cyongerera ubushyuhe abana bakivuka?
- Wabonye ubu buryo bushya bw' ikiringiti cyongerera ubushyuhe abana bakivuka giha umudendezo umwana bagishyizemo?

4) Niki utekereza kuri ubu buryo bushya bw' ikiringiti cyongerera ubushyuhe abana bakivuka ugereranyije n'ubundi buryo bukoreshwa mu kongerera ubushyuhe abana waba warabonye?

- Hari ubwo wigeze ubona aho impinja zifurebwa mu bundi buryo butari ubu buryo bushya bw'ikiringiti cyongerera ubushyuhe abana bakivuka?
- Uratekereza ko ubu buryo bushya bw' iki kiringiti cyongerera ubushyuhe abana bakivuka gifasha cyangwa ntaho gifasha, ugereranyije n'ubundi buryo bukoreshwa mu kongerera ubushyuhe abana bakivuka?
- Waba warigeze ubona aho abana bakivuka bongererwa ubushyuhe hakoreshejwe itara rikoresha amashanyarazi ryongerera ubushyuhe abana bakivuka?
- Niba waragize kubona aho ubundi buryo bukoreshwa, utekereza ko ubu buryo bushya bw'ikiringiti cyongerera ubushyuhe abana bakivuka bufasha/bwizewe cyangwa budafasha/kandi butizewe ugereranyije n'itara rikoresha amashanyarazi ryongerera ubushyuhe abana bakivuka?

5) Waba [cyangwa abandi babyeyi]waragize amahirwe yo guterura umwana umwiyegerejeho mbere cyangwa nyuma yo gukoresha ubu buryo bushya bw'ikiringiti cyongerera ubushyuhe abana bakivuka?

- Haba hari igihe waba warabogamiwe mu guhuza urugwiro hagati y'umwana n'umubyeyi nkuko bisanzwe bitewe n'ubu buryo bushya bw'ikiringiti cyongerera ubushyuhe abana bakivuka?

6) Muri rusange, niki wavuga ku birebana n'ubu buryo bushya bw'ikiringiti cyongerera ubushyuhe abana bakivuka?

- Wakwifuzako ubu buryo bushya bw'iki kiringiti cyongerera ubushyuhe abana bakivuka ko cyakoreshwa ku wundi mwana ukivuka wo mu muryango wawe, mu gihe bigaragaye ko uwo mwana ukivuka akeneye kongerera ubushyuhe?
 - yego kubera iki/ kubera iki ataribyo?

- Wumva washishikariza inshuti zawe ko zasaba ko ubu buryo bushya bw'ikiringiti cyongerera ubushyuhe abana bakivuka bwakoreshwa mu gihe abana babo bakenewe kongererwa ubushyuhe? >yego kubera iki/ kubera iki ataribyoye?

7) Haba hari ikindi kintu mwifuzaga kumbwira mbere ku birebana n' uburyo mwabonye iki kiringiti cyongerera ubushyuhe abana bakivuka mbere yuko dusoza iki kiganiro?

Turagushimira kuba witabiriye iki kiganiro!

Appendix J: Infant Warmer Data Collection Form Phase 2 Study

Qualitative Interview Questionnaire: Health Center Nurses

Name of researcher: _____

Date of interview: _____

Study code # for nurse: _____

Health Center name: _____

Introduction script:

As you know, we are doing a trial of a new infant warmer, in order to understand how well it works, and how it is accepted by the people using it. As a nurse who has helped with this study, we are talking to you today about your experiences with the infant warmer. This is an anonymous study; your identity will not be shared with anyone. Your opinions are important to us, so please say what you think. There are no wrong answers, and we are especially interested to hear about any challenges or problems with the infant warmer that you might have experienced. I will be audio-recording our conversation, to make sure I remember everything that you say. Do you have any questions for me before we start the interview?

1) To start, I'm interested to hear what it was like for you to learn about how to use this new infant warmer?

- How do you remember when to put an infant on or take the infant off of the warmer?
- Was there anything that made it difficult to learn how to use the warmer properly?

2) What do you think about the instructions on the warmer (*show warmer instructions to participant*)?

- Did you usually look at the instructions when you were using the warmer? Why/why not?
- Are the instructions written in a way that they are easy to understand?
- Is there some way the instructions could be changed to make them more appropriate or easy to understand?

3) How would you describe the ease or difficulty of heating up the infant warmer?

- Was it easy or difficult to obtain hot water in order to heat up the warmer?
- Once put in hot water, did it warm up quickly enough?

4) What other methods have you used, or seen used to provide heat to a newborn who is cold, other than kangaroo mother care?

- How does heating the infant warmer compare to these other methods?
- Have you ever seen new babies kept warm on an electric warming table?

- If so, do you think the infant warmer is more helpful/safe or less helpful/safe than an electric warming table?
- 5) How do you decide when it is safe to begin using the infant warmer?
- Is it easy or difficult to see changes in the color indicator?
 - Was there ever a time when you weren't sure the infant warmer was ready for use?
 - *If yes:* please describe what happened
- 6) How would you describe the ease or difficulty of putting the infant onto the warmer as instructed?
- Were there any challenges measuring the infant's temperature while the infant was on the warmer? If so, please describe.
- 7) How would you describe the ease or difficulty of cleaning the warmer?
- How much time does it take to clean the warmer?
 - Where do you find clean water and soap in order to clean the warmer?
- 8) The infant warmer was designed to be used in routine post-partum care, reanimation, and during transport. In which of these ways have you used the warmer?
- For each of the ways you have used the warmer:
 - How did it work in this circumstance?
 - Is there one setting in which it worked better than in others? How so?
- 9) If the infant warmer were to be used routinely at this health facility, how many warmers would you need in order to be prepared in time for all circumstances?
- Would you need one especially for emergencies? Non-emergencies?
 - Would you need one especially for infants who must be transported to the hospital?
 - What is the greatest number of women you have ever had delivering at the same time at this facility?
- 10) Did you notice any material breakdown or other change in the way the warmer looks or works?
- Were there any scratches, burns, or other changes to the material of the warmer?
 - Were there any changes in how the color indicator changes when it changes temperature?
- 11) How would you describe the way the warmer looks and feels?
- Is it comfortable for the infants?
 - Does it look like a safe thing to put an infant onto?
 - How do mothers and family members react to the way the warmer looks and feels?
- 12) In your experience, does it seem comfortable for mothers to use in addition to KMC?
- *If no:* what are the aspects of using the infant warmer that the mothers do not find comfortable?
- 13) Does having the infant warmer change how often you recommend mothers to do KMC?
- Are there still circumstances when you recommend using only KMC and not the infant warmer?
- 14) Are there any other ways you could think to improve the infant warmer?
- 15) Is there anything else you can tell me about your experience with the infant warmer before we finish our conversation?

Thanks so much for participating in this interview!

INSHUTI MU BUZIMA
PARTNERS IN HEALTH RWANDA

Icyiciro cya kabiri cy'ubushakashatsi
Ibibazo bigamije gucukumbura ireme bigenewe abaforomo (kazi) bo ku Bigo Nderabuzima

Amazina y'umushakashatsi: _____

Itariki ikiganiro cyabereyeho: _____

Nimero yagenewe umuforomo muri ubu bushakashatsi: _____

Izina ry'ikigo nderabuzima: _____

Iriburiro:

Nkuko mubizi, turimo turakora igeragezwa ku buryo bushya bugenewe kongerera ubushyuhe abana bakivuka; mu rwego rwo kumva no gusobanukirwa neza uko bikorwa ndetse nukumenya uko abakoresha ubwo buryo babwumva kandi banabwemera. Nk'umuforomo (kazi) wagize uruhare muri ubu bushakashatsi, uyu muni twaje kuganira nawe ku birebana nuko wabonye ubwo buryo bwo kongerera ubushyuhe abana bakivuka. Muri ubu bushakashatsi amakuru utanga agirwa ibanga, amazina yawe nta wundi uzayamenya. Ibitekerezo byawe ni ingenzi kuri twebwe, muvuge icyo mubitekerezaho. Nta bisubizo bitari byo, ndetse dushishikajwe cyane no kumva imbogamizi cyangwa ibibazo bikomoka kuri ubu buryo bwo kongerera ubushyuhe abana bakivuka mwaba mwarahuye nabyo. Iki kiganiro tugirana ndagifata mu byuma bifata amajwi kugira ngo nzabashe kwibuka ibyo twaganiriye byose. Hari ikibazo cyangwa icyo mushaka gusobanuzwa mbere yuko dutangira iki kiganiro?

1) Mu gutangira, nshishikajwe cyane no kumva uko wakiriye gukoresha ubu buryo bushya bwongerera abana bakivuka ubushyuhe?

- Waba wibuka igihe ugomba gushyira umwana ukivuka mu kiringiti cyimwongerera ubushyuhe cyangwa se kukimukuramo?
- Haba hari ikintu cyaba cyarakubereye imbogamizi mu buryo bwo kwiga uko bakoresha neza iki kiringiti cyongerera ubushyuhe abana bakivuka?

2) Niki utekereza ku birebana n'amabwiriza yo gukoresha ubu buryo bw'ikiringiti kongerera ubushyuhe abana bakivuka? (Ereka uwitabiriye iki kiganiro amabwiriza agenga imikoreshereze y'ubu buryo bwo kongererera ubushyuhe abana bakivuka?)

- Hari ubwo wifashishije kenshi aya mabwiriza mu gihe wakoreshaga ubu buryo bushya bwo kongererera ubushyuhe abana bakivuka? Kubera iki/ kubera iki utayifashishaga?
- Aya mabwiriza yaba yanditse mu buryo bworoshye ku yumva no kuyasobanukirwa?
- Hari ubundi buryo ayo mabwiriza yahindurwa kugira ngo yumvikane neza ku buryo bworoshye?

3) Ni gute watubwira uburyo bworoshye cyangwa se bukomeye bwo gushyushya ikiringiti cyongerera ubushyuhe umwana ukivuka?

- Byari byoroshye cyangwa byari bigoranye kubona amazi ashushye yo gukoresha mu gushyushya ikiringiti
- Umaze gushyira uburingiti mu mazi ashushye, cyahise gishyuha vuba?

4) Ni ubuhe buryo wigeze ukoresha cyangwa wabonye abandi bakoresha mu kongerera ubushyuhwe abana bakivuka bibasiwe n'ubukonje, uretse uburyo bwo gushyira umwana mu gituzo cya nyina?

- Ni gute wagereranya ubu buryo bw'ikiringiti cyongerera umwana ubushyuhwe n'ubundi buryo busanzwe bwo kongererera ubushyuhwe umwana ukivuka?
- Waba warigeze ubona abana bato bakivuka bongererwa ubushyuhwe hifashishijwe itara ryongera ubushyuhwe?
- Niba wari wigeze ubona aho abana bongererwa ubushyuhwe hakoreshejwe iryo tara, ucyeka ko ubu buryo bw'ikiringiti cyongerera abana ubushyuhwe bufite akamaro/ bwizewe cyangwa nta kamaro/ntabwo bwizewe ugereranyije n'uburyo bwo kongererera ubushyuhwe umwana hakoreshejwe itara?

5) Ufata icyemezo gute cyo kugena igihe cyo gukoresha uburyo bw'ikiringiti cyongerera ubushyuhwe abana bakivuka?

- Ese biroroshye cyangwa biragoye kubona impinduka ugendeye ku kimenyetso fatizo cy'ibara?
- Byaba byarakubayeho ko hari igihe utari wizewe gukoresha ikiringiti cyongerera ubushyuhwe kubera ko icyo kiringiti cyongerera ubushyuhwe kitari cyateguwe?
➤ Niba byarakubayeho: tubwire uko byagenze?

6) Ni gute watubwira uburyo bworoshye cyangwa bugoye bwo gushyira umwana mu kiringiti cyongerera ubushyuhwe umwana ukivuka nkuko wabyigishishijwe?

- Hari ubwo waba warahuye n'imbogamizi zo gupima ibipimo by'ubushyuhwe by'umubiri w'umwana mu gihe umwana yari mu kiringiti cyongerera ubushyuhwe umwana ukivuka? Niba warahuye nizo mbogamizi, tubwire uko byagenze

7) Ni gute watubwira uburyo bworoshye cyangwa bugoye bwo gusukura iki kiringiti cyongerera ubushyuhwe abana bakivuka?

- Bifata igihe kingana iki gusukura iki kiringiti cyongerera ubushyuhwe bw'abana bakivuka?
- Mukura he amazi meza ndetse n'isabune mukoresha musukuru iki kiringiti cyongerera ubushyuhwe abana bakivuka?

8) Ubu buryo bw'ikiringiti cyongerera ubushyuhwe abana bakivuka bwashyizweho kugira ngo bujye bukoreshwa mu bikorwa by'ubuvuzi bitanga nyuma yo kubyara, mu gihe cyo kuzanzamura umurwayi ndetse no mu gihe bamutwaye ku bitaro? Ni mu buhe buryo mwakoresheje iki kiringiti cyongerera ubushyuhwe abana bakivuka?

- Mu buryo bwose wakoreshejemo ubu buryo bw'ikiringiti cyongerera ubushyuhwe abana bakivuka:
➤ Byagenze gute icyo gihe?
➤ Haba hari uburyo wagikoresheje bikagenda neza ugereranyije n'ubundi buryo? Byagenze gute?

9) Mu gihe bibaye ngombwa ko ubu buryo bw'ikiringiti bwongerera ubushyuhwe bukoreshwa buri gihe kwa muganga, ubona hakenerwa ibiringiti byongerera ubushyuhwe abana bakivuka bingaha kugira ngo buri gihe muhore mwiteguye mu bihe ibyo aribyo byose?

- Kubw'umwihariko kimwe cyakenerwa mu butabazi bw'ibanze bw'indembe? Kimwe kizifashishwa mu bihe bitari by'ubutabazi bw'ibanze bw'indembe?
- Uzakenera byumwihariko kimwe kizafashishwa mu gutwara umwana ukivuka ku bitaro?
- Ni uwuhe mubare munini mwagize ku birebana n'ababyeyi babyariye rimwe muri kigo nderabuzima?

10) Hari ubwo wigeze ubona kwangirika cyangwa se impunduka ku birebana n'imiterere cyangwa se imikorere y'iki kiringiti cyongerera ubushyuhe abana bakivuka?

- Hari aho cyaba cyaracitse, cyarahiye cyangwa se indi mpinduka ku bigize iki kiringiti cyongerera ubushyuhe abana bakivuka?
- Haba hari impinduka ku birebana nuko ikimenyetso fatizo cy'ibara gihunduka mu gihe igipimo cy'ubushyuhe gihindutse?

11) Watubwira uko iki kiringiti cyongerera ubushyuhe abana bakivuka kigaragara cyangwa se uko kimeze iyo umuntu agikozeho?

- Nta kibazo cyatera abana bakivuka?
- Ubona ari igikoresho kizewe bashobora gufurebamo umwana ukivuka?
- Ubona ababyeyi ndetse n'abandi bagize umuryango w'umwana bakira bate uburyo iki kiringiti cyongerera umwana ubushyuhe kigaragara cyangwa se kimeze iyo bagikoze?

12) Ushingiye kubyo uzi, ubu buryo ubona bunogeye ababyeyi ku buryo babukoresha bwiyongera ku buryo busanzwe bwo gushyira umwana mu gituzo kugira ngo ashyuhe?

- Niba atariko bimeze, ni ibiki bigize kiringiti cyongerera ubushyuhe abana bakivuka ababyeyi babona bitabanogeye?

13) Hari ubwo ubu buryo bw'ikiringiti cyongerera ubushyuhe abana bakivuka buhindura inshuro wajyaga ubwira ababyeyi gukoresha uburyo bwo gushyira abana mu gituzo kugira ngo bashyuhe?

- Haba hakiri aho ugira inama gukoresha uburyo bwo gushyira umwana ukivuka mu gituzo aho kubagira inama yo gukoresha uburyo bw'ikiringiti cyongerera ubushyuhe abana bakivuka?

14) Haba hari ubundi buryo utekereza bwo kunoza birenzeho ubu buryo bw'ikiringiti cyongerera ubushyuhe?

15) Haba hari ikindi kintu ushobora kutubwira ku birebana n'ubunararibonye ku mikoreshereze y'ubu buryo bw'ikiringiti cyongerera ubushyuhe abana bakivuka mbere yuko dusoza iki kiganiro?

Turagushimira kuba witabiriye iki kiganiro!

Appendix K: Infant Warmer Qualitative Interviews: Purposive Sampling Matrix

Instructions: for each participant who agrees to an interview, check the box next to the option that fits best (check one option in each column).

Health Center Name: _____

Participant Code #	Mode of thermoregulation (check all that apply)	Setting of use	Observer audit results
	<input type="checkbox"/> IW alone <input type="checkbox"/> IW+KMC + bundling <input type="checkbox"/> IW+KMC <input type="checkbox"/> IW+bundling <input type="checkbox"/> Other _____	<input type="checkbox"/> Routine post-partum <input type="checkbox"/> Reanimation <input type="checkbox"/> Transport	<input type="checkbox"/> Optimal use of the warmer <input type="checkbox"/> 1 + usage mistake made
	<input type="checkbox"/> IW alone <input type="checkbox"/> IW+KMC + bundling <input type="checkbox"/> IW+KMC <input type="checkbox"/> IW+bundling <input type="checkbox"/> Other _____	<input type="checkbox"/> Routine post-partum <input type="checkbox"/> Reanimation <input type="checkbox"/> Transport	<input type="checkbox"/> Optimal use of the warmer <input type="checkbox"/> 1 + usage mistake made
	<input type="checkbox"/> IW alone <input type="checkbox"/> IW+KMC + bundling <input type="checkbox"/> IW+KMC <input type="checkbox"/> IW+bundling <input type="checkbox"/> Other _____	<input type="checkbox"/> Routine post-partum <input type="checkbox"/> Reanimation <input type="checkbox"/> Transport	<input type="checkbox"/> Optimal use of the warmer <input type="checkbox"/> 1 + usage mistake made
	<input type="checkbox"/> IW alone <input type="checkbox"/> IW+KMC + bundling <input type="checkbox"/> IW+KMC <input type="checkbox"/> IW+bundling <input type="checkbox"/> Other _____	<input type="checkbox"/> Routine post-partum <input type="checkbox"/> Reanimation <input type="checkbox"/> Transport	<input type="checkbox"/> Optimal use of the warmer <input type="checkbox"/> 1 + usage mistake made
	<input type="checkbox"/> IW alone <input type="checkbox"/> IW+KMC + bundling <input type="checkbox"/> IW+KMC <input type="checkbox"/> IW+bundling <input type="checkbox"/> Other _____	<input type="checkbox"/> Routine post-partum <input type="checkbox"/> Reanimation <input type="checkbox"/> Transport	<input type="checkbox"/> Optimal use of the warmer <input type="checkbox"/> 1 + usage mistake made
	<input type="checkbox"/> IW alone <input type="checkbox"/> IW+KMC + bundling <input type="checkbox"/> IW+KMC <input type="checkbox"/> IW+bundling <input type="checkbox"/> Other _____	<input type="checkbox"/> Routine post-partum <input type="checkbox"/> Reanimation <input type="checkbox"/> Transport	<input type="checkbox"/> Optimal use of the warmer <input type="checkbox"/> 1 + usage mistake made
	<input type="checkbox"/> IW alone <input type="checkbox"/> IW+KMC + bundling <input type="checkbox"/> IW+KMC <input type="checkbox"/> IW+bundling	<input type="checkbox"/> Routine post-partum	<input type="checkbox"/> Optimal use of the warmer

	<input type="checkbox"/> Other _____	<input type="checkbox"/> Reanimation <input type="checkbox"/> Transport	<input type="checkbox"/> 1 + usage mistake made
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