Informed Consent Statement

Study Title: Pilot clinical assessment of the IncuBaby device in monitoring temperature and treating hypothermia in infants

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Background and purpose of this study

The purpose of the study is to design a low-cost incubator to provide thermal care to babies in low-resource hospitals. An estimated 13 million babies are born preterm every year, and prematurity at birth is responsible for more than 1 million neonatal deaths. Hypothermia is especially common among premature babies; thermal care with close monitoring is essential for mitigating the effects of neonatal illnesses and complications. We wish to evaluate a low-cost infant incubator that was specifically designed for use in low-resource hospitals. This study will test whether this incubator can effectively warm babies to an appropriate temperature and then regulate their temperature in the normal range. The results of this study will help us know if the incubator is easy to use and how well it works in clinics here in Malawi. This study will also help us decide if any design changes are needed. **Phase I** of the study will *validate the temperature sensor in a three hour monitoring period***,** and **Phase II** of the study will *evaluate the efficacy of the incubator*.

Why are we doing this study?

We hope to demonstrate that this incubator is effective at keeping babies warm. We also want to see if this device is easy for the nurse to use.

Procedures

If you agree for your child to take part in this study:

1. You will review and sign this form.
2. The nurse will attach the IncuBaby temperature sensor to your baby. The sensor is a stretchy band placed around a baby's abdomen to detect the temperature. The nurse will also attach a commercially available temperature monitor to your baby.
3. A trained researcher will be present and will help the nurse with attaching the device if needed. The researcher will routinely monitor the devices and collect electrical signals from both devices using a laptop.
4. The researcher will record the following information about your baby's monitoring:
    a. Date of Study
    b. Date of Birth
    c. Gestational age at birth

d. Corrected gestational age
e. Sex
f. Birth weight
g. Type of delivery
h. Current weight
i. Admission temperature
j. Temperature measurements taken as standard of care
k. Other comorbidities
l. Medications/treatments given
m. Abdominal circumference

*Phase II only***:**

5. Your baby will be placed in the IncuBaby device for warming. The commercial temperature monitor and IncuBaby monitor will both be used continuously to ensure your baby stays at a safe temperature.
6. Care will be continued at the discretion of the clinician until the infant can be weaned from the IncuBaby device. The infant may be weaned to the standard of care or end thermal treatment.

Temperature values will be recorded automatically by the study equipment. *For Phase II, alarms and co2 levels will also be automatically recorded. Clinician and researcher observations will also be recorded. The nurse may intervene with standard of care at any time.*

Duration:
Phase I: The monitoring period will last for up to three hours.

Phase II: The IncuBaby device can be used for treatment as long as the clinician deems necessary. Additionally, the study will cease if you elect for your child to discontinue treatment for any reason.

Location: Neonatal ward at Queen Elizabeth Central Hospital

Participant Requirements:
1. Parental consent
2. The patient is currently being treated at QECH in the neonatal ward.
3. The IncuBaby device and vitals monitor are available for use at the time.

Phase II only:

4. The patient is deemed to be in need of thermal care.

How many people will this study enroll?
Phase I: We plan to enroll up to 30 babies in this phase.
Phase II: We plan to enroll up to 30 babies in this phase.

Can I change my mind if I decide that I prefer not to continue in this study?
Yes, if at any time you decide you do not want your baby to continue with the study, the treatment and/or monitoring by IncuBaby and the commercial device will be stopped and your baby will receive the standard of care.

What if I do not wish to enroll in the study?
Your baby's entry into the study is entirely voluntary. Your baby's monitoring will be conducted in the standard way and your decision will not influence the care you receive.

Risks of Side Effects and Discomforts to Participants
Phase I: The risks and discomfort if your baby participates in this study are the same as during routine pediatric checkup. The trained study nurse will assess the subject for clinical complications before using the IncuBaby device. If you, the researcher, or the nurse, indicate concerns during the tests, the use of the device will be discontinued and your baby will undergo the hospital's standard monitoring by nurses.

Phase II: While undergoing treatment with the IncuBaby device, there is the potential that your baby's temperature will rise outside of the normal range. To prevent this from happening, your baby will also be monitored using a commercially available temperature monitor and using the axillary temperature measurements given as the standard of care. This monitoring will allow us to ensure that your baby stays at a safe temperature, and treatment can be discontinued at any time if you, the researcher, or the clinician indicates concern.

Compensation
You will not receive financial compensation for participation in this study. However, your baby may benefit from additional monitoring and care provided during the study.

Confidentiality
There is a small risk of loss of confidentiality in this study. Researchers will take all precautions to ensure your personal information remains protected and confidential. All data sheets related to this study will be given a unique code and not labeled with any identifying information. This informed consent document will be kept in a locked cabinet in the office of the lead researcher of this study.

Have you understood the study?	Yes	No
Are you willing to be enrolled in the study?	Yes	No
Have you any questions to ask that we have not answered?	Yes	No

_____	_____	_____
Name	Signature	Date
_____	_____	_____
Person Obtaining Consent	Signature	Date

Complete for Phase II only:

Are you willing for your baby to be treated with the IncuBaby device? Yes No

_____	_____	_____
Name	Signature	Date
_____	_____	_____
Person Obtaining Consent	Signature	Date