Public Health Action

International Union Against Tuberculosis and Lung Disease
Health solutions for the poor

VOL 8 NO 4 PUBLISHED 21 DECEMBER 2018

A low cost, re-usable electricity-free infant warmer: evaluation of safety, effectiveness and feasibiliy

E. Nahimana,[1] L. May,[2,3] A. Gadgil,[4,5] V. Rapp,[4] H. Magge,[1,2,6] M. Kubwimana,[1] A. Nshimyiryo,[1] F. Kateera,[1] H. A. Feldman,[2,7,8] F. Nkikabahizi,[9] F. Sayinzoga,[10] A. Hansen[2,8]

http://dx.doi.org/10.5588/pha.18.0031

Setting: Rural Rwandan hospitals, where thermoregulation is critical yet a challenge for pre-term, low-birthweight (LBW) or sick newborns.
Objective: To assess the safety, effectiveness, and feasibility of an inexpensive, reusable, non-electric warmer to complement kangaroo mother care (KMC).
Methods: Prospective single-arm, non-randomized intervention study. Enrolled infants were hypothermic or at risk of hypothermia due to prematurity/LBW. Infants used the warmer in conjunction with KMC or as the sole source of external heat. Temperatures of the infant, warmer and air were measured for up to 6 h.
Results: Overall, 33 patients used the warmer for 102 encounters: 43 hypothermic and 59 at risk of hypothermia. In 7/102 encounters (7%), the infant developed a temperature of >37.5°C (37.6°–38.2°C). For 43 hypothermic encounters and 59 at-risk encounters, hypothermia was corrected/prevented in respectively 41 (95%) and 59 (100%) instances. The warmer maintained goal temperature for the study duration in ⩾85% of uses. Two/12 warmers broke down after <10 uses. In no instances was the warmer used incorrectly.
Conclusion: Our results are promising for this prototype design, and warrant testing on a wider scale.

Thermoregulation is critical for all newborns, and is particularly challenging for those born preterm, with low birth weight (LBW), or ill.[1–5] Hypothermia is estimated to contribute to 40% of the 2.9 million neonate deaths worldwide each year.[1,6] Neonatal hypothermia increases mortality risk by 2–30 fold.[7] The reported prevalence of neonatal hypothermia in resource-limited settings ranges widely, from 32% to 92%.[8,9] Beyond survival, providing adequate warmth reduces metabolic demand, with a 22% reduction in oxygen consumption in warmed term infants compared to controls.[10] Supporting thermoregulation promotes nutrition and weight gain, both critical to optimize neurodevelopment.

The current recommended method of providing thermoregulation for infants at ⩾28 weeks gestation in resource-limited settings is kangaroo mother care (KMC) and electric warmers for unstable infants.[7,11–14] Electric warmers are expensive, depend on electricity, and require considerable training to be used safely. Servo mode, which is used to monitor the infant's skin temperature, requires a temperature probe that is often unavailable. KMC also has important limitations: when an infant is ill, the position on the mother's chest may not be conducive to providing medical assessments and interventions.[15,16] If the mother dies during childbirth or is too ill post-partum, she is unable to provide KMC. Finally, many mothers have other responsibilities that prevent them from being able to provide continuous KMC, and local customs and cultures may create barriers to effective promotion of KMC. There is therefore a need for a safe and affordable complement to KMC.[17–19]

Current low-cost alternatives to KMC and electric warmers include polyethylene wraps, bags and caps, light bulbs, hot water bottles, and hot mattresses made of water, sodium acetate gel packs or phase-change material (PCM). In the rural medical and home setting, hot coals, thermal boxes and room warmers are reportedly also employed.[18,20–22] Each of these options has major limitations related to cost, effectiveness, safety, sanitation, portability, effect on the mother-child interaction, and need for electricity.[18,20–22]

In response to these limitations, Lawrence Berkeley National Laboratory (LBNL), Berkeley, CA, USA, worked with field-based input from clinical partners at Boston Children's Hospital (BCH; Boston, PA, USA), Partners In Health in Rwanda-Inshuti Mu Buzima (PIH-IMB; Kigali, Rwanda), and the Rwandan Ministry of Health (MOH; Kigali, Rwanda) to develop an easy-to-use, inexpensive, reusable, easily washable, non-electric infant warmer that supports KMC. This simple infant warming device has the potential to overcome many of the limitations encountered by current alternatives.[17,18] The infant warmer is modeled on a heating pad made of a PCM that changes from solid to liquid at skin temperature (See Appendix for design details). The mattress is rolled up and placed in an accompanying sturdy, wide-based thermos filled with boiling water, and the PCM is allowed to melt, which happens in approximately 30 min. In settings without electricity, the water can be boiled with coal or other heat sources. In settings with electricity, it can be boiled using a kettle (or the mattress can be placed in a small, low temperature oven that can be purchased for approximately US$100). The mattresses can be heated in advance of use in the thermos (or oven). When needed, the mattress is removed from the water and dried. The temperature of the mattresses is then assessed using a color indicator (liquid crystal thermometer) that clarifies the safe/effective use zone (from 38°C to 35°C). If the mattress remains at >38°C, it is allowed to cool until it falls into the safe zone of the color indicator, which can take up to 15 min. The mattress is then slipped into an accompanying insu-

AFFILIATIONS
1 Partners In Health, Inshuti Mu Buzima, Kigali, Rwanda
2 Boston Children's Hospital, Boston, Massachusetts, USA
3 Children's Hospital of Colorado, Aurora, Colorado, USA
4 Lawrence Berkeley National Laboratory, Berkeley, California, USA
5 University of California, Berkeley, California, USA
6 Brigham and Women's Hospital, Boston, Massachusetts, USA
7 Institutional Centers for Clinical and Translational Research, Boston Children's Hospital, Boston, Massachusetts, USA
8 Harvard Medical School, Boston, Massachusetts, USA
9 Rwinkwavu District Hospital, Rwanda Ministry of Health, Kayonza, Rwanda
10 Rwanda Biomedical Center, Kigali, Rwanda

CORRESPONDENCE
Anne Hansen
Division of Newborn Medicine
Boston Children's Hospital
Hunnewell 4
300 Longwood Ave
Boston, MA O2115, USA
e-mail: Anne.Hansen@childrens.harvard.edu

KEY WORDS
non-electric warmer; kangaroo mother care; low-resource setting

EN and LM are co-first authors.

Received 16 May 2018
Accepted 19 October 2018

PHA 2018; 8(4): 211–217
© 2018 The Union

lating pad at which time it is ready to use (Figure 1). The warmer maintains the phase change temperature of 37°C for about 6 h. The mattress and insulating pad are purposefully designed of sturdy, smooth materials with no attached fabric, Velcro or other materials that would inhibit cleaning.[23] It can be re-used after thorough washing by wiping down with local hospital cleanser or soap and water.

The cost of each infant warmer, when mass produced, is anticipated to be approximately US$40, making it significantly less expensive than other options currently available.[17] Illustrations of basic newborn care and instructions for use are printed on the device. Its overall intuitive simplicity allows for minimal training. The infant can either be placed on the warmer as it lies flat, or the warmer can be positioned over the infant's back while the mother provides KMC (Figure 1). These two options allow the degree of heat provision to be modified based on need. If the infant needs closer monitoring than is possible during KMC (e.g., in settings of respiratory distress), the infant can be placed on the warmer and only covered in areas that are non-critical for observation.

Our study objective was to investigate the safety, effectiveness, and feasibility of this infant warmer in a low-income setting, in both a cooler and warmer climate in Rwanda.

METHODS

Infant warmer design

The warmer was designed by a team of engineers at LBNL. It underwent extensive laboratory testing for safety, performance and durability before use with humans. US Food and Drug Administration (FDA) International Standard (ISO) guidelines were used as gold standard. When no standard existed, a protocol was created by technical experts in medical product design. The warmer's biological safety has been ensured by selecting materials that are either FDA-approved or have previously been tested and certified safe. Further details of the infant warmer design and testing are provided in the Appendix.

Study design

We conducted a single-arm, non-randomized, prospective intervention study of a warmer for hypothermic newborns, or those at risk for hypothermia based on their weight or estimated gestational age, when KMC was not possible or inadequate. The sample size of 102 encounters was sufficient to determine the percentage of encounters in which target temperature was achieved, with a precision of 4% (standard error) or, better, assuming conservatively that the rate of success would be roughly 80%. The implicit assumption of independent encounters was shown in the final analysis to have negligible impact. We assessed the warmer's safety and effectiveness based on clinical observation and its feasibility based on direct observation by the study nurse.

We defined hypothermia as <36°C and euthermia as 36.5°–37.5°C based on the Rwandan National Neonatal Protocols.[24] The study was conducted in the neonatal wards at two PIH-IMB-supported district hospitals in Rwanda, in one relatively cool (Butaro, median temperature based on study data: 23.3°C) and one warm (Rwinkwavu, median temperature based on study data: 28.8°C) region. Both of these sites have electricity. The study nurse spent 2 h orienting the clinical nursing staff to the study and training them on the proper use of the warmer.

The study nurse identified potential participants on the neonatal unit based on inclusion and exclusion criteria (Table 1) and obtained informed consent. Infants were eligible to use the warmer every time they met the inclusion criteria; some infants participating in the study thus used it multiple times, each referred to as an 'encounter'. If the infant's starting temperature was <35°C, our intent was to offer an electric warmer if available until the temperature rose to 36°C, and then initiate the non-electric warmer. A total of 12 non-electric warmers were used in the study, six at

ACKNOWLEDGEMENTS
The authors thank Lawrence Berkeley National Laboratory, Berkeley, and their Institute for Globally Transformative Technologies, Berkeley, CA, USA, for support of the technical design of the infant warmer, with special thanks to J Slack and M Elam; Institute for Transformative Technologies for assistance with transporting the infant warmer units from the United States to Rwanda; the Rwanda Ministry of Health, Partners In Health/Inshuti Mu Buzima and the neonatology teams from Rwinkwavu and Butaro Hospitals for their critical support in facilitating the study; patients and families who are the true inspiration for this innovation; B Hedt-Gauthier for her assistance in study design and statistical analysis; and A Manirakiza, E Dushimimana, and P Drobac for their technical support. The study was funded by the Arthur Rosenfeld Fund at the Harvard Medical School, Boston, MA, USA.
Conflicts of interest: none declared.

FIGURE 1 Infant warmer.

TABLE 1 Inclusion, exclusion and stop criteria

Inclusion criteria	Exclusion criteria
• Hypothermic infants: axillary temperature ⩽36°C with care giver not available for KMC, or KMC not adequate (<0.5°C/h temperature rise) • Infants at risk for hypothermia: estimated post-menstrual age <35 weeks or current body weight <2.5 kg	• Mother deemed not medically stable by nursing staff to be approached for consent • Infant medically unstable and electrical heating source available • Infant with skin condition that could be interpreted as an adverse reaction to warmer

Stop criteria: If an electric heating source was available, the infant was taken off the study and warmed with an appropriate source of electric heat if the infant:

- Was hypothermic and temperature decreased on any measurement
- Was hypothermic and temperature did not begin to rise within 30 min
- Was hypothermic and not heating at a rate of >0.5°C/h until temperature was >36.5°C
- Had a temperature that fell below 36°C despite maximum exposure to the heat source
- Was ever considered to be too severely ill by the medical team to be safely cared for in the non-electric infant warmer

KMC = kangaroo mother care.

each site. Use of the blanket and the hat with the warmer was encouraged. Infants only wore clothing with the warmer by parental preference, as it diminishes heat transfer. No infants wore diapers during the study.

The temperature of the infant, warmer, and ambient air were measured every 15 min for the first hour, and then hourly and as needed for the remainder of use. Again, to provide standard of care, it was our intention to offer an electric heat source if available to any infant who met one of the 'stop criteria' (Table 1) during the study. Otherwise, the study was complete when the temperature of the warmer fell below the effective temperature, as evidenced by the color indicator (<35°C), or when the mother requested to discontinue the warmer for any reason (typically to resume KMC). The study nurse observed the preparation, use and cleaning for each encounter, and recorded whether or not these steps were undertaken correctly. The nurse was instructed to intervene if she observed any deviation from the recommended warmer use that raised a safety concern, and to collect data regarding the potential mistake.

Outcome measures

Safety was assessed by incidence of hyperthermia (temperature > 37.5°C), skin rash or other observed adverse events. Effectiveness was assessed by attainment of temperature ⩾36.5°C in initially hypothermic infants (hypothermia was defined as temperature of <36°C); maintenance of temperature ⩾36°C in infants initially at risk for hypothermia; and rate of temperature rise for hypothermic infants by ⩾0.5°C/h.

Feasibility was assessed as both functionality and usability. Functionality was assessed by measuring the duration of the warmer at goal temperature, and external signs of wear and tear of the warmer with repeated uses. Usability was assessed by observation of correct preparation, use and cleaning of the warmer.

Analysis

Data were analyzed using Stata v 13.1 (Stata Corp, College Station, TX, USA) and SAS v 9.4 (Statistical Analysis System, Cary, NC, USA). Numbers and percentages were reported for categorical variables, and medians, interquartile ranges, minimums and maximums for continuous variables. The rate of temperature increase for each hypothermic encounter was calculated by linear regression over the period leading up to attainment of 36.5°C, or the entire time course if the target was not reached. The calculated rates were correlated with mean ambient air temperature using Pearson's correlation coefficient r and dichotomized at 0.5°C/h for purposes of comparison between the cooler and warmer study sites by Fisher's exact test.

Three indicators of successful warming were assessed in hypothermic infants: 1) attainment of 36.5°C, 2) attainment of 36.5°C within 2 h, and 3) rate of rise ⩾0.5°C/h. The percentage success for each indicator was estimated using logistic regression analysis, with success as the binary dependent variable. Regression was adjusted for correlation among multiple encounters for a single infant using the Generalized Estimating Equation technique.[25] Gestational age, birth weight, and mean ambient temperature were added to the regression model as covariates to test their influence.

Ethics and consent

The study was approved for human research review by the Boston Children's Hospital Institutional Review Board, Boston, MA, USA; the Rwanda National Ethics Committee, Kigali (reference # 849/RNEC/2016); the Rwanda National Health Research Committee, Kigali (reference # 514); and the Rwanda MOH, Kigali, Rwanda. The study was also registered at ClinicalTrials.gov (registration #: NCT03031431).

Anyone who is represented in a photograph in this article has provided written consent.

RESULTS

Thirty-three participants were enrolled, providing 102 encounters between August and November 2016 (Table 2). The majority of the patients were LBW and premature (gestational age was often unknown due to limited prenatal testing). There was a significantly greater percentage of enrollment secondary to hypothermia in the cooler than in the warmer region (56.9% vs. 27.4%, P = 0.01).

For hypothermic infants, the starting temperature ranged from 34.4°C to 35.9°C (median 35.6°C). For infants at risk of hypothermia, the starting temperature ranged from 36.0°C to 36.9°C (median 36.4°C). No patients were able to be transferred from the non-electric to the electric warmer when their starting temperature was <35°C or their rate of temperature rise was <0.5°C/h due to the lack of availability of electric warmers in these limited-resource neonatal wards. These were real-world conditions in these neonatal wards before, during and after the study. All infants used a blanket in addition to the warmer. Hat use was not constant over the 6-h study window, ranging from 84% of encounters at study initiation to 98% at 6 h. Only one infant (1%) wore clothes while on the warmer.

KMC was combined with the warmer in 17 (16.7%) encounters, including 12 (12%) encounters when KMC was applied at the start. Of these encounters in which KMC and the warmer

TABLE 2 Characteristics of study participants

Variables	Hospital/study site: Butaro (*n* = 17) *n* (%)	Rwinkwavu (*n* = 16) *n* (%)	Total (*n* = 33)* *n* (%)	*P* value
Estimated gestational age, weeks†	*n* = 11	*n* = 10	*n* = 21	
<37	7 (63.6)	10 (100.0)	17 (81.0)	
>37	4 (36.4)	0	4 (19.0)	0.09
Birth weight, g‡	*n* = 16	*n* = 16	*n* = 32	
Normal (⩾2500 g)	7 (43.8)	2 (12.5)	9 (28.1)	
Low (<2500 g)	3 (18.8)	5 (31.2)	8 (25.0)	
Very low (<1500 g)	5 (31.2)	9 (56.3)	14 (43.8)	
Extremely low (<1000 g)	1 (6.2)	0	1 (3.2)	0.13
Weight at first encounter, g	*n* = 17	*n* = 16	*n* = 33	
⩾2500	8 (47.0)	2 (12.5)	10 (30.3)	
<2500	7 (41.2)	9 (56.3)	16 (48.5)	
<1500	2 (11.8)	5 (31.2)	7 (21.2)	0.09
Age at first encounter, days	*n* = 17	*n* = 16	*n* = 33	
1–7	7 (41.2)	2 (12.5)	9 (27.3)	
8–31	8 (47.0)	10 (62.5)	18 (54.5)	
⩾32	2 (11.8)	4 (25.0)	6 (18.2)	0.19
Study inclusion criteria (*n* = 102)§	*n* = 51	*n* = 51	*n* = 102	
Hypothermic (<36°C)	29 (56.9)	14 (27.4)	43 (42.2)	
At risk for hypothermia	22 (43.1)	37 (72.6)	59 (57.8)	0.01
Starting infant temperature, °C, median [IQR] (*n* = 102)§	35.8 [34.4–36.9]	36.4 [34.8–36.9]	36.1 [34.4–36.9]	<0.01

*A total of 33 infants participated in the study at both sites.
†No estimated gestational age was recorded for 12 infants.
‡No birth weight was recorded for one infant.
§102 encounters for the 33 individual infants who participated in the study.
IQR = interquartile range.

were used simultaneously, 11 were hypothermic, while the other six were at risk of hypothermia. In all of these encounters, the mother stopped providing KMC in <1 h because she was either tired or called to other responsibilities. The mean ambient air temperature during hypothermic encounters ranged from 21.5°C to 24.5°C for 29 encounters in the cooler region and from 26.3°C to 29.7°C for 14 encounters in the warmer region.

Safety

In 7/102 (7%) encounters involving five different patients, the infants' temperature exceeded 37.5°C. Instances of hyperthermia occurred between 2 h and 6 h after being placed on the warmer, at which time the infants were taken off the warmer according to study protocol. In five of these cases, the maximum temperature was 37.6°C, in one case 37.9°C, and in one case 38.2°C. In only one instance was the warmer recorded to be hotter (37.7°C) than the infant (37.6°C). At the time that the infant's temperature was 38.2°C, the temperature of the warmer was 37.1°C. There were no instances of skin irritation or other adverse events in association with warmer use.

Effectiveness

Effectiveness data are summarized in Table 3. Of the 43 encounters in hypothermic infants, a temperature of ⩾36.5°C was reached in all but two. One of these infants had an estimated gestational age of 34 weeks, a birth weight of 2320 g, the ambient temperature was 23.2°C, the infant's starting temperature was 34.4°C and ending temperature was 36.0°C after spending 4 h on the warmer. The second of these infants had an estimated gestational age of 35 weeks, a birth weight of 1650 g, the ambient temperature was 27.9°C, the infant's starting temperature was 35.6°C and ending temperature was 36.2°C after spending 4 h on the warmer. Both of these infants participated in the study on six additional occasions, and achieved a temperature of ⩾36.5°C during all the other encounters.

Of 43 infants, 31 (72%) warmed at ⩾0.5°C/h, including 22/29 (76%) in the cooler and 9/14 (64%) in the warmer environments ($P = 0.48$ by Fisher's exact test). Cluster-adjusted logistic regression indicated that the likelihood of warming at ⩾0.5°C/h was not related to gestational age ($P = 0.55$), birth weight ($P = 0.12$), or ambient air temperature ($P = 0.57$). The median time to a temperature of ⩾36.5°C was 60 min (range 15–240, standard deviation 52 min). More than 60% of infants achieved a temperature of ⩾36.5°C within 1 h of study initiation (Figure 2). All 59 of the encounters of infants 'at risk of hypothermia' maintained the initial temperature of ⩾36°C. Of 102 encounters, 100 (98%) corrected or prevented hypothermia.

Feasibility

Functionality

The warmer was within the goal range for 87 of 102 encounters (85%). The median temperature was 37°C for the 6-h study period (Figure 3). When out of range, the warmer measured between 38.1°C and 38.5°C. In 70/82 encounters that lasted at least 4 h, and 35/40 (88%) encounters that lasted at least 6 h, the warmer remained in the desired temperature range.

Of the 12 warmers, the internal plastic divider between the wax rows broke down in two after six and nine uses. Because of the warmer's double liner design, no wax leaked outside of the

TABLE 3 Attainment of effectiveness targets

Initial condition	Outcome	Unit	Total	Successes	Failures	Probability of success % (95%CI)*
Hypothermic (<36°C)	Reach 36.5°C	Encounters	43	41	2	95.4 (85.0–98.7)
		Infants†	26	26	2	
	Reach 36.5°C by 2 h	Encounters	43	36	7	83.7 (71.7–91.3)
		Infants	26	25	6	
	Rise ⩾0.5°C/h	Encounters	43	31	12	72.1 (58.2–82.7)
		Infants	26	22	9	
At risk (≥36°C)	Maintain 36°C	Encounters	59	59	0	100
		Infants	22	22	0	

*From logistic regression analysis adjusted for within-infant clustering. Covariates (gestational age, birth weight, mean ambient air temperature) showed no significant influence and were dropped from the regression model. The cluster-adjusted estimates differ negligibly from simple percentages.
†Of 33 infants enrolled, 26 had at least one encounter with initial hypothermia; 22 had at least one at-risk encounter. For a particular outcome, successes + failures may exceed total infants because some infants had both successful and unsuccessful encounters.
CI = confidence interval.

warmer. These warmers were returned to the laboratory for evaluation to re-design for improved robustness.

Usability

Based on direct observation by the study nurse, there were no attempted deviations from recommended warmer preparation, use or cleaning, including no instances when the infant was placed on the warmer before it had cooled adequately, or was positioned on the warmer incorrectly.

DISCUSSION

Here, we report on the first field testing of a low-cost, non-electric infant warmer designed to be intuitively simple to use, to complement or supplement KMC, and to allow access to the infant for assessment, stabilization and resuscitation. We found the warmer to show promise regarding safety, effectiveness, and feasibility. In seven encounters, the infant developed hyperthermia, although in five of these cases the maximum temperature was only 37.6°C. With the use of incubators and radiant warmers, there is an inherent risk of causing hyperthermia, and their use requires high-level training and close monitoring, which can be challenging in many frontline facilities.[26] To ensure optimal thermoregulation, hypothermic patients must be monitored closely, whether during KMC, while receiving an electric heat source or while on a warming pad. There were no concerns regarding skin irritation or other safety issues. We attribute this to safety features of the warmer, including the temperature indicator, double-liner mattress design and use of non-toxic materials. Of the 102 encounters, in all but two, the infant warmer corrected or prevented hypothermia. In the vast majority of encounters, the rate of temperature increase exceeded our goal of ⩾0.5°C/h and hypothermia was corrected within 1 h. The rate of temperature rise during hypothermic encounters was not correlated with gestational age, birth weight or ambient air temperature. The warmers stayed at goal temperature for the duration of the study in 85% of 4 h encounters and 88% of 6 h encounters. The instances when it measured too hot may have been due to the margin of error of the thermistor probe, given that these measurements existed at the 2 h and 3 h mark when, by the chemical properties of the PCM, the warmer had to have been at the phase change temperature of 37°C. To ensure that the warmer remained at goal temperature for longer, either more PCM or more insulation could be added. This would have implications regarding both weight and cost. Of note, the heating pads were used routinely to provide bridge heating to preterm infants for stabilization and transfer from a delivery room to a neonatal intensive care unit are set at 40°C.[27] When mothers are febrile (e.g., are exposing babies to their skin temperature of >37°C), this is not considered a safety concern for KMC.

By direct observation conducted by the study nurse, the warmer was prepared, used and cleaned per study standards in all instances, confirming the warmer's simplicity of design. Leakage occurred between the internal seals that separate the PCM rows. This did not affect the warmers' function or heating capacity, as there was no loss of PCM to the exterior environment. These warmers

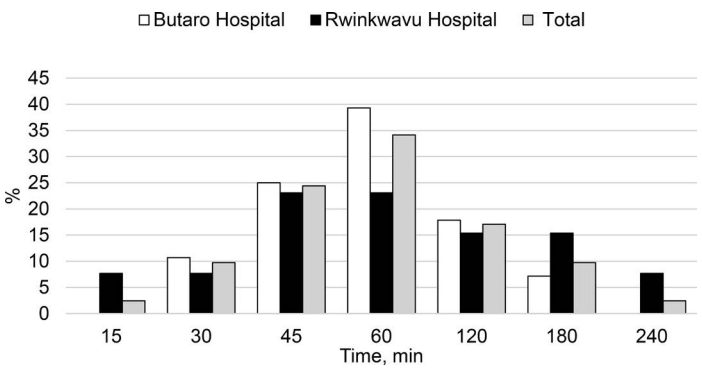

FIGURE 2 Time to correction of hypothermia in hypothermic infants.

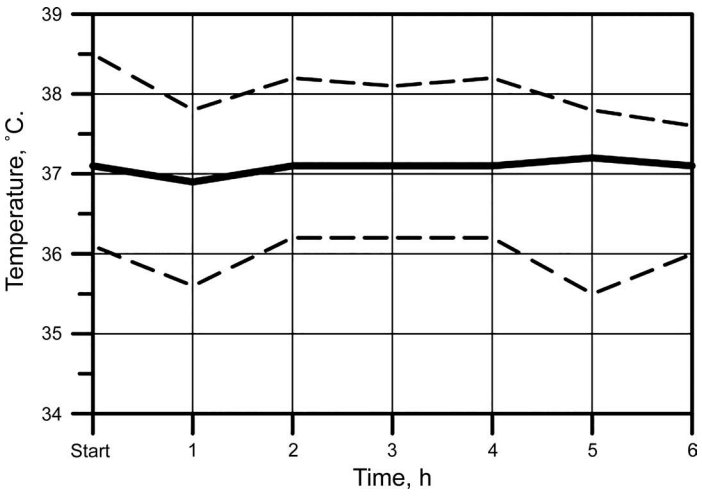

FIGURE 3 Warmer temperature over time.

were prototypes made individually by hand. We expect improvement in robustness once manufactured by machine. We have since identified a stronger plastic that is currently being tested with the goal of lasting 1000 cycles. The observation of wear and tear provides information necessary for improving the materials and the manufacturing process, which will increase reliability and adoption.

The study had several limitations. Because of the ethical concerns of allowing infants to experience hypothermia, our trial design was not a randomized-controlled trial to compare the effectiveness of the warmer to standard of care. We have historical control data from 2013 to 2014 at two PIH-IMB-associated Rwandan hospitals; 36.4% of LBW infants had an admission temperature of <36°C, 57.7% of whom persisted with a temperature <36°C 2 h after admission.[28] These data came from 1518 patients from Rwinkwavu (our warmer site) and Kirehe (similar hospital, also in a warmer location) hospitals; we therefore expect that Butaro (our cooler site) would have similar to higher rates of hypothermia. The goal of this observational, single-arm study was to assess the safety and effectiveness of the infant warmer in a convenience sample under real-world conditions. In addition, we conducted the study in a setting with electricity, and the hot water was prepared using an electric kettle. Most communities have local systems for boiling water for drinking, but this is an area we investigated in a recently completed study conducted in health centers and on transport, where there are fewer nurses and electricity is limited. In that study, we also conducted qualitative interviews of mothers and nurses to further explore the relationship between the warmer and KMC.

CONCLUSION

Our results are promising for this prototype design. This simple, low-cost, non-electric warmer could be an important option for governments and health systems in reducing the estimated 1 million annual neonatal deaths in which hypothermia is a contributing cause; the warmer therefore warrants further study.

References

1 Lawn J E, Blencowe H, Oza S, et al. Every newborn: progress, priorities, and potential beyond survival. Lancet 2014; 384: 189–205.
2 McCall E M, Alderdice F A, Halliday H L, et al. Interventions to prevent hypothermia at birth in preterm and/or low birthweight infants. Cochrane Database Syst Rev 2010; (3): CD004210.
3 Jefferies A L; Fetus and Newborn Committee. Kangaroo care for the preterm infant and family. Paediatr Child Health 2012; 17: 141.
4 Seidman G, Unnikrishnan S, Kenny E, et al. Barriers and enablers of kangaroo mother care practice: a systematic review. PLOS ONE 2015; 10: e0125643.
5 Lunze K, Bloom D E, Jamison D T, et al. The global burden of neonatal hypothermia: systematic review of a major challenge for newborn survival. BMC Med 2013; 11: 24.
6 Darmstadt G L, Walker N, Lawn J E, et al. Saving newborn lives in Asia and Africa: cost and impact of phased scale-up of interventions within the continuum of care. Health Policy Plan 2008; 23: 101–117.
7 Mullany L C. Neonatal hypothermia in low-resource settings. Semin Perinatol 2010; 34: 426–433.
8 Black R E, Cousens S, Johnson H L, et al. Global, regional, and national causes of child mortality in 2008: a systematic analysis. Lancet 2010; 375: 1969–1987.
9 Lawn J E, Cousens S, Zupan J. 4 million neonatal deaths: when? where? why? Lancet 2005; 365: 891–900.
10 Hey E N, O'Connell B. Oxygen consumption and heat balance in the cot-nursed baby. Arch Dis Child 1970; 45: 335–343.
11 Boundy E O, Dastjerdi R, Spiegelman D, et al. Kangaroo mother care and neonatal outcomes: a meta-analysis. Pediatr 2016; 137: 1–16.
12 World Health Organization. Pregnancy, childbirth, postpartum, and neonatal care: a guide for essential practice. Geneva, Switzerland: WHO, 2015.
13 Ibe O E, Austin T, Sullivan K, et al. A comparison of kangaroo mother care and conventional incubator care for thermal regulation of infants <2000 g in Nigeria using continuous ambulatory temperature monitoring. Ann Trop Paediatr 2004; 24: 245–251.
14 World Health Organization. Kangaroo mother care: a practical guide. Geneva, Switzerland: WHO, 2003.
15 Ahmed S, Mitra S N, Chowdhury A M R, et al. Community kangaroo mother care: implementation potential for neonatal survival and health in very low income settings. J Perinatol 2011; 31: 361–367.
16 Lee H C, Martin-Anderson S, Dudley R A. Clinician perspectives on barriers to and opportunities for skin-to-skin contact for premature infants in neonatal intensive care units. Breastfeed Med 2011; 7: 79–86.
17 Gupta R, Patel R, Murty N, et al. Developing sustainable global health technologies: insight from an initiative to address neonatal hypothermia. J Public Health Policy 2015; 36: 24–40.
18 Program for Appropriate Technology in Health. PATH report. Newborn thermal care devices: establishing a value proposition for low-resource settings. Seattle, WA, USA: PATH, 2009. https://www.path.org/publications/files/TS_newborn_thermal_rpt.pdf Accessed November 2017.
19 Thairu L, Wirth M, Lunze K. Innovative newborn health technology for resource-limited environments. Trop Med Int Health 2013; 118: 117–128.
20 Bhat S R, Meng N F, Kumar K, et al. Keeping babies warm: a non-inferiority trial of a conductive thermal mattress. Arch Dis Child Fetal Neonatal Ed 2015; 100: 309–312.
21 McCall E M, Alderdice F, Halliday H L, et al. Interventions to prevent hypothermia at birth in preterm and/or low birthweight infants. Cochrane Database Syst Rev 2010; (3): CD004210.
22 Carmichael A, McCullough S, Kempley S T. Critical dependence of acetate thermal mattress on gel activation temperature. Arch Dis Child Fetal Neonatal Ed 2007; 92: F44–F45.
23 Elam J M, Slack J L. US Patent No USD773681S1. Washington DC, USA: Patent and Trademark Office, 2016.
24 Republic of Rwanda Ministry of Health. National neonatal care protocol. 2nd ed. Kigali, Rwanda: MOH, 2014.
25 Lipsitz S H, Fitzmaurice G M, Orav E J, Laird N M. Performance of generalized estimating equations in practical situations. Biometrics 1994; 50: 270–278.
26 Baumgart S. Iatrogenic hyperthermia and hypothermia in the neonate. Clin Perinatol 2008; 35: 183–197.
27 Cooper Surgical. Transwarmer infant transport mattress. Trumbull, CT, USA: Cooper Surgical, 2013. https://www.coopersurgical.com/Medical-Devices/Detail/slug/transwarmer-infant-transport-mattress Accessed November 2017.
28 Nyishime M, Borg R, Ingabire W, et al. A retrospective study of neonatal case management and outcomes in rural Rwanda post implementation of a national neonatal care package for sick and small infants. BMC Pediatr 2018: 18: 353.

APPENDIX Summary of infant warmer design and laboratory testing

Design

The heating component of the infant warmer is a mattress that measures 45.7 cm x 25.4 cm wide x 1.91 cm thick. It is comprised of 12 individual phase-change material (PCM) candles made of PureTemp 37 wax (Entropy Solutions, Minneapolis, MN, USA; http://www.puretemp.com/). Each individual candle holds about 100 g of PCM. The construction is double-sleeved to ensure no leakage of PCM over many repeated cycles of heating and cooling. Additional details for the mattress design can be found in US Patent No USD773681S1 by Elam & Slack, granted in 2016, and assigned to the University of California, Berkeley, CA, USA. The casing for the PCM is a co-extruded film made with polyethylene and nylon.

Laboratory testing

Durability

Five tests were conducted to validate the durability of the mattress. Each test was conducted using individual candles of liquid- and solid-state PCM and are described below:

1 Bending test to ensure the candle would not fail (either by plastic failure or seal failure) if bent
2 Functional test to ensure the candle would not rupture from external weight
3 Abrasion test to ensure the plastic would not tear if dragged along rough surfaces

4 Drop tests to ensure candles would not leak or rupture when dropped
5 Rapid cooling test to ensure the seals and plastic did not fail when placed directly in ice immediately after being boiled.

Results: The mattress design passed all five durability tests.

Temperature

To ensure the mattress maintained the desired temperature for a set time, the mattress was boiled and the temperature of the surface of the mat that would be in contact with the infant was measured sequentially to determine how long it remained between 35°C and 40°C in a 20°C room. The test was conducted with the mat uninsulated and then insulated with layer of blankets approximately 2.5 cm thick. The test ended when the temperature reading dropped below 35°C. Each test was repeated at least three times and the average of the replicate tests is reported.

Results: Average time in goal range for uninsulated mat: 2 h and insulated mat: 7 h.

Contexte : Des hôpitaux ruraux du Rwanda où la thermorégulation est cruciale mais complexe pour les nouveaux-nés prématurés, de faible poids de naissance (LBW) ou malades.
Objectif : Evaluer la sécurité, l'efficacité et la faisabilité d'un réchauffeur peu coûteux, réutilisable et non électrique pour compléter la méthode kangourou (KMC).
Méthode : Etude rétrospective d'intervention à un seul bras, non randomisée. Les nouveaux-nés enrôlés étaient en hypothermie ou à risque d'hypothermie liée à la prématurité ou au LBW. Les nouveaux-nés ont bénéficié du réchauffeur en conjonction avec la méthode KMC ou comme source unique de chaleur externe. Les températures des bébés, du réchauffeur et de l'air ont été mesurées pendant 6 h.
Résultats : Ont bénéficié du réchauffeur 33 patients pour un total de 102 utilisations ; 43 étaient en hypothermie et 59 à risque d'hypothermie. Dans 7/102 utilisations (7%), le bébé a atteint une température de >37,5°C (37,6°–38,2°C). Dans 43 cas d'hypothermie et 59 cas à risque, l'hypothermie a été corrigée/prévenue dans 41 (95%) et 59 (100%) instances, respectivement. Le réchauffeur a maintenu la température souhaitée pendant la durée de l'étude dans ≥85% des utilisations. Deux réchauffeurs sur 12 ont été hors d'usage après moins de 10 utilisations. Il n'y a jamais eu d'utilisation incorrecte.
Conclusion : Nos résultats sont prometteurs en ce qui concerne la conception de ce prototype et ils justifient une évaluation à plus grande échelle.

Marco de Referencia: En varios hospitales rurales de Rwanda, la termorregulación que es fundamental para los recién nacidos con bajo peso al nacer o enfermos, plantea dificultades.
Objetivo: Evaluar la seguridad, la eficacia y la factibilidad de un dispositivo no eléctrico, de bajo costo y reutilizable que genera calor como complemento al método de la madre canguro (KMC).
Métodos: Fue este un estudio prospectivo de intervención con un solo grupo, no aleatorizado. Se incluyeron lactantes que ya sea, estaban hipotérmicos o expuestos a la hipotermia debido a su prematuridad o el bajo peso al nacer. Con estos lactantes, se utilizó el calentador como fuente externa exclusiva de calor o en asociación con el KMC. Se midieron las temperaturas del lactante, el calentador y la temperatura ambiente durante un máximo de 6 h.
Resultados: Se utilizó el dispositivo en 102 encuentros con 33 pacientes, de los cuales 43 estaban hipotérmicos y 59 estaban en riesgo de entrar en hipotermia. En siete de los 102 encuentros (7%), el lactante alcanzó una temperatura superior a 37,5°C (37,6°–38,2°C). La hipotermia se corrigió en 41 de los 43 encuentros con lactantes hipotérmicos (95%) y se evitó en 59 de las 59 ocasiones con bebés expuestos (100%). El calentador mantuvo la temperatura buscada durante todo el estudio en ≥85% de los encuentros en los cuales se utilizó. Dos de los 12 dispositivos exhibieron degradación después de menos de 10 utilizaciones. En ningún caso se utilizó el calentador de manera incorrecta.
Conclusión: Los resultados obtenidos con este método prototipo son promisorios y se justifica realizar un ensayo clínico de mayor escala.

Public Health Action (PHA) The voice for operational research.
Published by The Union (www.theunion.org), PHA provides a platform to fulfil its mission, 'Health solutions for the poor'. PHA publishes high-quality scientific research that provides new knowledge to improve the accessibility, equity, quality and efficiency of health systems and services.

e-ISSN 2220-8372
Editor-in-Chief: Dermot Maher, MD, Switzerland
Contact: pha@theunion.org
PHA website: http://www.theunion.org/what-we-do/journals/pha
Article submission: http://mc.manuscriptcentral.com/pha