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ORIGINAL RESEARCH ARTICLE

FABRICATION AND EVALUATION OF AN AFFORDABLE INFANT RADIANT WARMER FOR USE IN LIMITED RESOURCE SETTINGS

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ABSTRACT

The challenges of thermoregulation due to hypothermia, which is believed to underlie high infant morbidity and mortality rate, is common with underweight or preterm infants especially those from limited resource settings. Available devices in the market to check hypothermia are expensive, especially for most countries with between 2% to 10% of GDP on the healthcare budget. Affordable thermoregulation realization for infants is therefore of significant clinical importance in these settings. The aim of this study was to design and fabricate an affordable ($110) and clinically useful radiant warmer to facilitate hypothermia treatment. The radiant warmer was fabricated with an overhead radiant heater for heat radiation targeted at infants laid in a clinically comfortable foam mattress in a bassinet. A portable fan was placed above the heating element to facilitate downward heat flow. A biocompatible temperature sensor was also placed on the bassinet to monitor the infant's body temperature. The warmer incorporated an Arduino-based PID temperature microcontroller to regulate the temperature of the heating element. The warmer, with castor wheels to aid the device's mobility, has a strong and durable galvanized pipe stand capable of supporting the device. The device performance indicated an acceptable physiological heating temperature range of 36 °C - 36.5 °C within 20 min of warm-up and up to 36.7 °C in 30 min of use. Therefore, the device can be adjudged potentially useful in facilitating thermoregulation in infants by providing suitable thermal support. With these results and the potential of the device to reduce infant mortality rates and promote their growth, it is hereby recommended that the device may be fully deployed for clinical application.

1.0 Introduction

Neonatal hypothermia is believed to be a global health challenge (Beletew et al., 2020) as approximately 40% of the global incidences of neonatal mortality are due to hypothermia (Lawn et al., 2014). Hypothermia is an abnormal and unsafe drop in body temperature (≤ 36.5°C) (WHO, 1997; Mohamed et al., 2021). Literature evidence (Lawn et al., 2005) suggests that up to 99% of infant mortality incidences are in limited resource settings. One reason for this may be due to the fact that up to 85% of infants in these environments are often exposed to cold stress (Lunze et al., 2013) without efficient means of prevention. In addition, underweight infants (weight less than 2.5 kg), which account for 20 million annual infant deliveries (World Health Organization, 2016), are most vulnerable to morbidity due to less body fat that often leads to thermoregulation challenges (Nahimana et al., 2018). As the economic growth in terms of gross domestic product (GDP) per capita reduces infant mortality (Nishiyama, 2011), most developing countries are unable to meet the minimum threshold for healthcare financing, and "basic neonatal care technologies are inadequate" (Maynard et al., 2015). Therefore, with between 2% to 10% of GDP budgeted for healthcare in most developing countries as against the minimum of 15% recommended by the African Union for developing economies (Organisation of Africa Unity, 2001), mothers are left with the only option of the affordable or traditional methods of keeping their babies warm. Unfortunately, the available inexpensive and or traditional methods to promote thermoregulation such as kangaroo mother care may be inefficient especially when the infant is ill and need constant clinical monitoring (Ahmed et al., 2011; Nahimana et al., 2018). Furthermore, the mother may be ill or too busy to provide adequate thermoregulation supports through this method (Gupta et al., 2015; Nahimana et al., 2018). For this reason and better infants' thermal stability, the challenges of thermoregulation are believed to be significantly addressed by a radiant warmer (Boundy et al., 2016). This is also due to the fact that incubators are too expensive for limited resource settings (Maynard et al., 2015) and may readily impair infants' thermal environment (Chaseling et al., 2016). Specifically, a radiant warmer uses a controlled heating element to keep infants healthily warm, promote thermoregulation and facilitate easy access to the infants, especially while under observation (Bell, 1983), stability after birth, and during surgical procedures (Knobel-Dail, 2014). Another important strength of this "open care system" is the ability to facilitate the regulation of heat loss and metabolic rate (Bell, 1983) while promoting the infants' neurodevelopment (Nahimana et al., 2018) and keeping them in good clinical condition. Radiant warmers also provide the required source of heat energy and reduce conductive heat losses by providing a warm environment surrounding the infants.

Research interventions toward facilitating easy access to this device, therefore, hold huge benefits for urgent neonatal care technologies through the reduction of infant morbidity and mortality rates. Previously, researchers have developed some viable alternatives for this purpose. However, cost (especially due to running and spare part costs) and the issue of maintainability have prevented the success of these efforts in low resources settings. To overcome the highlighted challenges with available options, we sought to design and construct an affordable radiant warmer that could be easily maintained and used in limited resource settings to improve neonatal care through the facilitation of thermoregulation. This device was designed to address the shortage of clinical-grade radiant warmers in limited resource settings while keeping its cost affordable and its use simple even for inexperienced caregivers.

2. Materials and Methods

2.1 System design and block diagram

The design is modularized into different segments that interconnect and work together as a whole to provide regulated warmth for neonates. The block diagram of this arrangement is shown in Figure 1. The heater control unit consists mainly of the rotary encoder and the Arduino board. There is also a ceramic insulated heater placed above the infant bassinet (where the infant is placed). The power supply unit powers the heater control circuit, the heater, the display unit, and the temperature sensor.

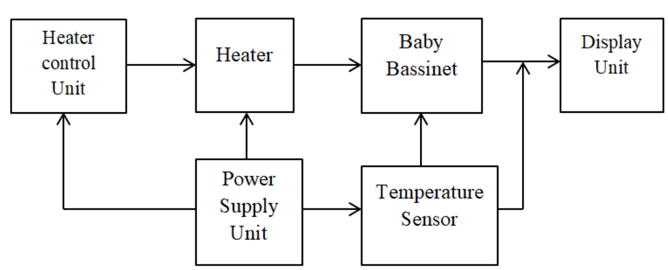

Figure 1: System block diagram

Design considerations and assumptions were based on the fact that infants, especially those that are underweight need thermal supports for survival. The device's is well above 1 metres from the ground to the infant bassinet to present dusty air from reaching the infant. It is assumed that the ambient temperature will not impair the temperature to be gained by the infant during device's operation. The interface between the infant and the device (foam mattress inside the bassinet) is biocompatible. The device is designed in such a way that the infant will be accessible and clearly visible by the care givers. Other considerations and assumption for safe operation of the device has been discussed further under system description.

2.2 Materials

Compliance with the safety standard based on the target infant population and consideration for the cost-effectiveness is the major design and material selection considerations in this study. These factors influenced the technology deployed and the material used in this study. Material availability within our environment, or those that can be seamlessly ordered within the country or from abroad, at an affordable cost was also prioritised once they are durable and able to support the required technical specifications. In Table 1, we have presented the materials selected and the justification for their selection. The materials listed in Table 1 are locally available within the country or can be ordered from abroad seamlessly.

Table 1: Material selections and their justification:

S/N	Materials	Warmer modules	Justification
1.	Galvanized pipes, Nuts and bolts	Hardware	Locally sourced, durable, and resistant to corrosion and cracking especially for the environment for the purpose to serve.
2.	Microcontroller board (Arduino MEGA 2560)	Hardware and Software	Capable of creating interactive objects, interfacing multiple sensors, sensing, and effective temperature regulation.
3.	AC 220V 750W Ceramic Insulated Heater	Hardware	Portable, compatible for the purpose, and very high melting point.
4.	Transparent plastic sheet acrylic board	Hardware	Low weight, good impact strength, transparent, and safe for infants.
5.	Portable infant bassinet	Hardware	Portable, cheap, durable, easy access to the infant, and safe for use.
6.	Thin Film Transistor and Liquid Crystal Display Module for Arduino board	Hardware	Cheap, portable, good response time, and visible from far a distance
7.	TRIAC	Hardware	Requires a single fuse for protection, power control
8.	Humidity and Temperature sensor (DHT22)	Hardware	Small size, cheap, fast in operation, high accuracy and reliability.
9.	Buzzer & Light Emitting Diode (LED)	Hardware	Affordable, light and sound indicator in one sensor—portable.
10.	120W 30V transformer for power unit	Hardware	Good capacity and high efficiency
11.	Portable AC Fan	Hardware	Affordable and efficient
12.	Silicone sealant	Hardware	Minimal waste, rapid drying, water resistance, transparent
13.	K type thermocouple + MAX6675 board	Hardware	Efficient, wide temperature range (0–1024 °C), ability to digitize temperature, and no self-heating issue.
14.	Bridge rectifier	Hardware	Provides DC voltage (0-15 V) and efficiently
15.	Opto-Isolator	Hardware	Complete electrical isolation between input and output and promote safety inexpensively.
16.	Buck converter power supply	Hardware	Step down capability and filtering with few external components.

17.	PVC Pipe	Hardware	Easy installation and proper cable enclosure.
18.	Rotary Encoder	Hardware	Reliable, accurate, high resolution, and compact size
19.	Power Cable	Hardware	High reliability
20.	Castor Wheels	Hardware	Ease of movement of the whole device and durability
21.	Plastic Case Box and lid	Hardware	Portable, lightweight, resistive
22.	Blue and White Spray Paint + Gloss varnish	Hardware	Protects and resists dirt retention, non-tacky, improves surface durability

2.3 System description

The device was made with safety considerations specifically to accommodate tender neonates and infants. The radiant warmer was kept within the "physiologically accepted range" of 36 $^{\circ}$C - 36.5 $^{\circ}$C, based on international standards (World Health Organization, 1997). This temperature range was attained in 20 min after the heater was switched on and was maintained for up to 2 hours (Table 3). The heat generated by the heater was controlled by a control knob (rotary encoder) with the use of Proportional Integral Derivative (PID) controller in the Arduino board. The warmer was built in such a way that cleaning and disinfection could be done easily especially, the infant's mattress. This was made possible by the materials used for these components of the warmer. Appropriate safety arrangements for this device included the alarm and visual indication of the infant's skin temperature. Due to the nature of the heater used, the warm-up time was ≤ 20 min and this could be considered appropriate and acceptable as available for most proprietary warmers (Bell, 1983) and as recommended by United Nations Children's Fund (UNICEF) (UNICEF, 2018) that similar warm-up time is appropriate for infants suffering from hypothermia.

The radiant warmer consists of three different modules that were constructed in three stages: (i) hardware module (ii) software module, and (iii) integration of the hardware and software modules to form a complete system. The structure/ frame of the device consists of galvanized pipes and other metallic materials joined together by welding. This network was thereafter painted and varnished to produce a quality gloss finish. The total height of the device stands at over 2 meters with the distance between the heater and the bassinet being at approximately 1 meter. Following the device's design, its isometric and orthographic views were developed and are shown in Figure 2, with Figure 3 representing the various parts of the radiant warmer.

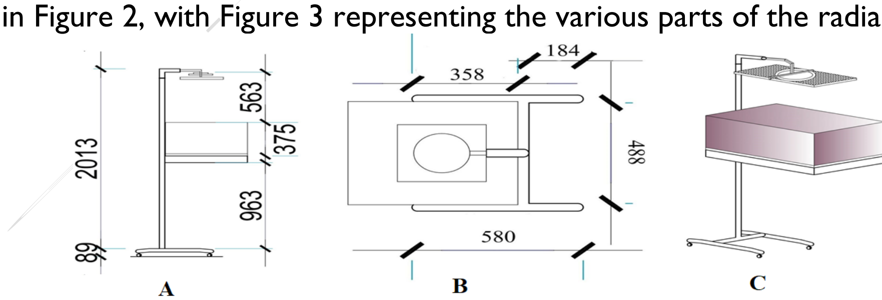

Figure 2: Isometric and orthographic views of the radiant warmer with measurements made in mm. A: Side view; B: Plan view and C: Isometric view.

The detail information about the component of the designed radiant warmer could be found in Figure 3 and complemented by the information in Figure 4.

Figure 3: Various parts of the radiant warmer

Figure 4 presents the complete radiant warmer which consists of the mounted heater, acrylic panel and bassinet while the control panel, and the device's frame are mounted to stand on castor wheels to facilitate mobility. The design, development, and testing of the device were carried out in a laboratory setting. The PID control system was used to regulate the heating element.

Figure 4: The complete radiant warmer

2.4 Mode of operation and performance evaluation

To demonstrate the device's performance for objective evaluation the following procedures were taken. The time taken to warm up the infant's compartment as pre-set was identified and reported. The following steps were thereafter taken to put the radiant warmer into use: (i) the external surfaces of the warmer were disinfected to prevent infection transmission using antiseptic solution; (ii) the room temperature was checked to ensure that the initial set temperature was normal and to ensure that no other source of heat could move towards the warmer; (iii) the infant mattress was pre-warm for easy habituation for the infant and in order not to expose the infant to a sudden cold environment; (iv) infant placement into the bassinet prior to the attachment of the humidity and temperature sensors with a biocompatible self-adhesive tape; (v) thereafter, the temperature as indicated on the LCD display was modulated by the rotary encoder to set, adjust and keep the temperature within physiologically acceptable range; (vi) the infant position was manually and frequently changed (as necessary) to ensure an even temperature distribution; (v) after use, the infant was carefully removed with the infant wrapper and the device was disinfected before subsequent use. As mentioned earlier, the ambient temperature in the infant's compartment was kept within the "physiologically accepted range" (36 ˚C – 36.5 ˚C), based on international standards (World Health Organization, 1997).

With the use of an Arduino mega 2560 (Arduino, Scarmagno, Italy), that serves to perform all the instructions and commands of the device, the infant's temperature could be modulated from the initial temperature to 36.5°C for hypothermic neonates. This temperature could be maintained with the use of an embedded PID controller which uses a control loop feedback or process variable that senses the output of the heater and feed it back so that the system can make adjustments accordingly to monitor where the output should be. The constant set temperature used was 36.4°C which is within the range recommended by the World Health Organization (World Health Organization, 1997).

Apart from the versatility of the PID controller as an excellent component for the protection of the infant by controlling the heat that flows towards the bassinet where the infant is located, an alarm system was also incorporated to indicate when there is a problem with either the heater output, power or the temperature sensor. This arrangement is meant to prevent any kind of compromise on the infant as an additional safety feature. Specifically, the alarm buzzer was designed to be activated once there is an abnormal situation, and continuous noise indicates that the device is due for maintenance. An emergency power switch was also put in place in case of an emergency stop which is designed to completely deactivates the functionality of the warmer. Instructions to the users will include procedures to perform basic and regular electrical safety checks to reduce the risks of damage to the device and avoid overloading and electrical surges, and other abnormal situations may also affect the users and the infants.

As an additional instruction to ensure the safety and uninterrupted operation of the device, there is a need to avoid human error by not placing any accessories directly over the infant's compartment and not placing items on top of the heater except for the mounted fan. The special user instructions will include the need to properly sterilize the device before and after every each use so far the infant is placed inside the infant's compartment. This will include the need to ensure that the warmer is not positioned or used near flammable anaesthetics or other clinical items that are flammable. All the infants connecting tubes or cables must be inspected before and after moving the device and before use.

3. Results and Discussion

3.1 Results

Infant compartment temperatures were taken at intervals as shown in Table 2 to observe the heater's response with time under the control of a rotatory encoder. The results' readings were obtained considering the time spent to heat up the infant's compartment and to observe the duration for which the infant's compartment can be kept within the allowable temperature range (and in order to be in thermal equilibrium). Within two hours of testing, Table 2 presents the results obtained.

Table 2: Infant's compartment temperature at different times

S/N	Time spent/ (minutes)	Heater temperature/ (°C)	Measured infant compartment temperature/ (°C)	Expected infant compartment temperature (°C)
1.	10	133	34.3	36.4
2.	20	146	36.3	36.4
3.	30	150	36.7	36.4
4.	60	147	36.4	36.4
5.	120	145	36.3	36.4

A t-test to compare the measured infant compartment temperature and expected infant compartment temperature using Stata 14.2 software (StataCorp LLC Texas, USA) gave a p-value of 0.7969. The p-value indicated no observed difference in the measured and expected results. Hence, the device worked efficiently. A correlation table of relationship between parameters is shown in Table 3.

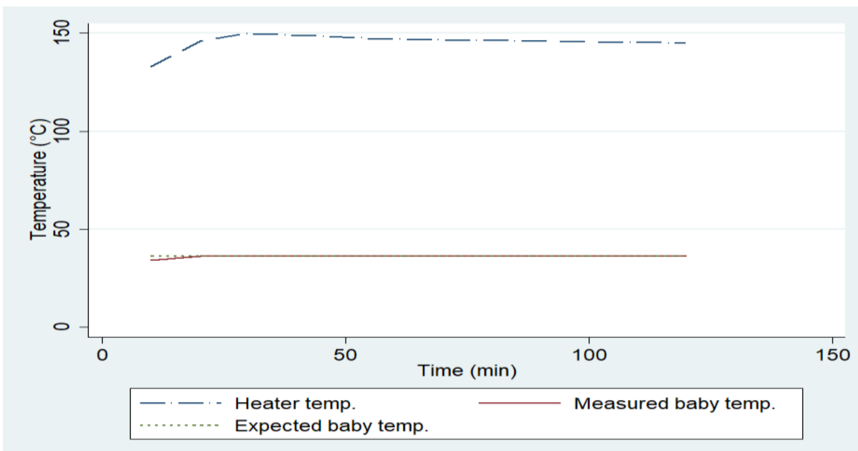

Figure 5: Variation of heater and infant compartment temperature with time

Figure 5 presents the variation of heater and infant compartment temperature with time. It shows that the measure and the expected temperature has a strong correlation.

Table 3: Relationship between variables using correlation

	Time	Heater	Measured	Expected
Time	1.0000			
Heater	0.3120	1.0000		
measured	0.4088	0.9918	1.0000	
Expected	-	-	-	-

It can be seen from the Table 3 that measured infant compartment temperature strongly correlates with the heater temperature. This shows that the measured temperature is being controlled by the heater temperature.

Electrical safety testing of the device's components was carried out based on the global standard ("IEC60601-1") to prevent both internal and external electrical damage and safety of the users (Grodt, 2018). Specifically, the following test and results were carried out to ensure the electrical safety of the device which is arguably the most important test. An insulation resistance test was conducted to measure the total resistance of the device's insulation by applying a high voltage of 700 V (Grodt, 2018). The value of resistance for the radiant warmer (i.e., with heating element)

(Weithöner) after the insulation resistance test was 1.1 MΩ, which fell within the safety range of the IEC standard (Grodt, 2018). Earth continuity test was also carried out by measuring the resistance between the device's metal body and the ground pin (i.e., the terminal in the control circuit board that connects the body of the device to the circuit earth/ ground terminal). Following this test, the value obtained was 0.5 Ω. The test was carried out at a higher current (35 A) (EMBE, 2019) so that the ground bond test of the circuit maintains safe voltages before the circuit breaker trips in emergency situations. This step was essential to serve as an additional protection to prevent injury which may be due to electric shock in the developed radiant warmer. Another important test performed was the leakage current test (Weithöner). This test was conducted to measure the undesirable leakage current that may flow across the device. The limit leakage current recorded was 95 μA, which was less than 100 μA according to the IEC standard (Jonsson and Stegmayr, 2000; Zion, 2022).

Thereafter, physical condition checks were also performed on the device. This included the functional test to ensure the infant's compartment would not collapse during movement or due to the infant weight or external load placed on it. Specifically, this test was performed through the placement of a load of up to 20 kg (in gradual increments from 2 - 20kg) on the device's bassinet. The device was rigorously dragged and moved across the laboratory to test the durability of its stand and welded joints. An abrasion test was also conducted on the device to ensure that its wheels would not tear if dragged along rough surfaces. The wheels were tested against bumps, abrasive surfaces, and floors which it may typically encounter when in use in low resource settings. These surfaces were made up of cement concrete, sheet vinyl, or tile floors. The direction of wheel rolling was reversed and tested to ensure that it could withstand deformation, wear, or physical failure. Before switching on the radiant warmer to a set point, the ambient airflow velocity was measured which was ≤ 0.3m/sec using a portable anemometer and this was adjudged a good level since we intended to minimize the heat loss.

The alarm levels and functions were also tested to ensure that they were loud enough for the clinical staff or operator but were quiet enough in order not to impair the infant's hearing. With the alarms turned on, after measuring the audio level from inside the infant's compartment, the sound pressure, using the decibel X app (SkyPaw Co., Ltd, Hanoi, Vietnam) (Capriolo et al., 2022), was recorded at 72 dB while the sound pressure recorded 3 meters away from the radiant warmer was 58 dB. According to the WHO (Etienne Krug et al., 2015) and the Centers for Disease Control and Prevention of the USA (CDC, 2022), these values are below the harmful range for the general population but slightly beyond the recommended level only for the "preterm or very low birth weight infants" (Almadhoob and Ohlsson, 2020). However, the values can be considered safe especially since the exposure time is very short and only necessary when the temperature is out of the threshold.

Table 4 also presents the analysis of the cost for the selected materials in this study. Based on the market survey, the cost of production of this device at USD 110 is under 10% of some commercialized and standard radiant warmers.

Table 4: Cost analysis of the radiant warmer

S/N	Item	Quantity	Unit price (₦)	Total price (₦)
1.	Galvanized pipes and other metallic materials	2	5000	10000
3.	Arduino MEGA 2560	1	3500	3500
4.	Alternating Current Insulated Heater	1	3000	3000
5.	Transparent plastic sheet acrylic board	1	4000	4000
6.	Portable infant bassinet	1	1500	1500
7.	Thin Film Transistor Liquid Crystal Display Module	1	1700	1700
8.	TRIAC	1	500	500
9.	Humidity and Temperature sensor	1	400	400
10.	Buzzer	1	200	200
11.	120 W Transformer	1	5000	5000
12.	Portable Direct Current Fan	1	2500	2500
13.	Silicone Sealant	1	1400	1400
14.	K type thermocouple + Max6675 Board	1	700	700
15.	Bridge Rectifier	1	350	350
16.	Opto-Isolator	2	300	600
17.	Buck Converter	1	300	300
18.	Trucking PVC Pipe	1	500	500
19.	Rotary Encoder	1	700	700
20.	Power Cable	1	1000	1000
21.	Nuts and bolts	10	50	500
22.	Castor Wheels	4	500	2000
23.	Plastic Case Box and Lid	1	2000	2000
24.	Blue and White Spray Paint + Gloss varnish	1	3000	3000
25.	Heat sink	1	300	300
26.	Connecting wires	5	300	1500
27.	Jumper wires	5	200	1000
28	Switch	1	350	350
29.	Resistors(pack)	1	100	100
	Miscellaneous			5,000
	Grand total			**53,600 = ~ USD 110**

3.2 Discussion

It is well known (World Health Organization, 1997; Trevisanuto et al., 2018; Mohamed et al., 2021) that body heat regulation in infants is less efficient and this condition is worse in preterm, low birth weight, and/or sick infants (World Health Organization, 1997). This low-cost device is specifically designed to reduce infant mortality, especially in low-resource settings. With this device, infants requiring urgent thermoregulation assistance within a reasonable budget in these settings could be facilitated. One of the major advantages of this locally fabricated radiant warmer is the ease of use (no ambiguous instructions and steps for operation). Operators of the device can quickly understand and master the uncomplicated process involved due to the simple control system used in its design and implementation. The structure of the device was also made to promote portability due to the use of strong and lightweight materials which helps in the ease of its movement from one location to another. The fast warm-up time as well as uniform heating of the infant's compartment also prove to save time and minimize unwanted heat leakages. Table 2 presents an acceptable heater's temperature response with time. The apparent thermal stability pattern shown in Table 2 after 20 min of warm-up time is in agreement with the range of temperature for which a radiant warmer should be during usage (Whiteside, 1978; UNICEF, 2018). Therefore, the design has demonstrated an encouraging response for clinical deployment.

For example, no statistical significant observed difference was found between the measured infant's compartment temperature and expected infant's compartment temperature.

Unlike the design proposed by Thavaraj et al. (2017), this present device is simpler to use and costs a significantly lower amount of capital for production. Warneford (2018) developed a prototype of a "neonate warming blanket". While the Author's work represented a good attempt at thermoregulation facilitation, in its current state, the prototype lacks some vital elements of a radiant warmer, and information on some important components and the device's assembly were not presented.

Also, Chandrasekaran et al. (2021) developed a disposable cardboard incubator for thermoregulation promotion. The system maintained the set temperature reliably (Chandrasekaran et al., 2021), however, the device is fragile and its durability and maintainability including cleaning are questionable. Generally, proposals on the development of radiant warmers that incorporate and report control systems, especially for temperature distribution appear uncommon in the literature. Thus, the radiant warmer designed, fabricated, and presented in this study has proven to be a viable alternative when compared to both the available prototypes, in terms of functionality, and commercially available options, in terms of affordability. This is because the cost of the radiant warmer reported in this study was also considerably lower compared to those previously designed and commercialized as our proposed device is specifically targeted for use in low-resource settings. Our approach to making the device affordable was based on the use of local source of materials and fabrication compared to other devices which are majorly made up of imported materials. Furthermore, over simplicity of some alternatives without a power supply for operation make such options lack flexibility and control and, therefore, may not be useful to the population of infants targeted in the current study. This may pose a significant limitation for such devices' deployment in rural settings.

4. Conclusion

The device developed in this study can specifically be used in limited resource settings to promote thermoregulation for needy patients. The device has the potential to improve neonatal care and reduce mortality rate and prevent complications due to hypothermia, especially in limited resource settings where pediatricians and those specialising in neonatology are grossly inadequate. The device has demonstrated a good performance with a good response of the heater within the time range from 10 min to 2 hours of usage. Considering the estimated cost of device production of $ 110, the device could be adjudged suitable and affordable for use in limited resource settings. Other alternative sources of power may be considered in the future to enable the deployment of this device to villages where constant electricity supply is a challenge. Also, additional facilities and optional accessories in the proprietary alternative warmers such as the integration of an oxygen blender and suction module will be incorporated in the future. With this, a preventable cause of infant mortality such as hypothermia could be checked with the affordable technology presented in this study, especially for vulnerable populations.

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