Point of View

Challenges posed by infant incubators and their potential mitigation

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Introduction

Babies born before 37 gestational weeks are labelled preterm births[1]. As per World Health Organisation (WHO) 2019 data, around 1 million preterm babies die annually due to unavailability of mother's womb like environment in extra-uterine life[2,3]. Categories of gestational age are shown in Table 1.

Table 1: ***Categories of gestational age***

Gestational age (weeks)	Category
32-37	Late preterm
28-32	Very preterm
Less than 28	Extremely preterm

Reasons for infant mortality are very low birth weight (<1000g), insufficient gestational age for infant to develop the mechanisms required to cope with the environment outside the mother's womb and heat loss though radiation, conduction, convection and evaporation[4,5]. Prematurely born babies (Preemies) are unable to conserve heat or change their posture to avoid thermal stress and cannot be kept in an open crib but should be provided an appropriate microenvironment which should be like an artificial mother's womb[4].

An infant incubator is a device where the infant will be kept and is a device with facilities to control various parameters of its microenvironment for the infant's comfort and benefit[5]. It can take special care of the incumbent infant by controlling temperature, relative humidity, weight gain, baby movements and oxygen concentration inside it. Some advanced neonatal incubators can also control the intensity of incident light, sound, stop unwanted smells and reduce the chances of the preemie getting infections[4]. The latest infant incubators can communicate the status of the incumbent preemie with the concerned doctor and family members[5]. Broadly there are 3 types of infant incubators available in the market. First type is a fixed incubator which can perform all required functions but is immovable and unaffordable. Second type is a mobile incubator which can perform all required functions and can also be shifted to any desired location but which is also expensive. Third type is a transport incubator, which can transport the preemies from one place to another but which can have major problems like thermoregulation failure and electrical shock hazards[6]. Usage of infant incubators can increase the survival rate of premature babies and hence reduce the infant mortality rate[3].

This paper focuses on the challenges faced by existing incubators and suggests potential remedies.

Infant Incubator

It has the following features:

- *Temperature control mode:* This maintains the baby's body temperature and the incubator air temperature within the WHO recommended range and enables us to control the temperature both manually and automatically. Failure to do this could cause hypothermia leading to insensible water loss from the skin of the preemie[6].
- *Relative humidity (RH) control mode:* This keeps the RH inside the incubator with an adjusting facility from lowest to highest percentage limit. It maintains the desired percentage of humidity converting the water into vapour. Incubator needs a water storage tank for this purpose[7].
- *Oxygen control mode:* This maintains the oxygen concentration inside the incubator at a specified level essential for the baby's wellbeing. Above three features of the incubator are servo controlled and are continuously measured and checked with the specified values to find if there is any error and regulates them immediately to obtain zero error[6].
- *Weighing mode:* Only sophisticated incubators have this feature. It measures the weight of the baby all the time ranging from 0 to 6 kg. Resolution of this feature is

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important for preemies with low birth weight[7].
- *Optional integrated monitoring of vital functions:* This is the difference between an infant incubator and the neonatal intensive care unit (NICU). Infant incubator provides the required environment for the baby but NICU can also measure the baby's vital functions like oxygen saturation, pulse rate, perfusion index, pleth variability index and non-invasive continuous haemoglobin.
- *Connectivity:* This enables the infant incubator to communicate the status of vitals of the baby with the concerned doctor and parents. Some infant incubators can also send a live feed inside an infant incubator direct to the mobile phone of the concerned parties with the help of a webcam.

Some international and Indian infant incubator manufacturing companies and their popular products are shown in Table 2.

Table 2: *Popular products of international and Indian companies and their feature comparison*

Name of company	Temperature	Relative humidity	Oxygen	Weighing scale	Vitals	Connectivity	International /Indian	Popular product
G E Healthcare	Yes	Yes	Yes	Yes	No	Yes	International	Giraffe incubator
Atom Medical Corp	Yes	Yes	Yes	Yes	Yes	No	International	Atom-Model-101
Bistos Co. Ltd.	Yes	Yes	Yes	Yes	Yes	Yes	International	BT-500 infant incubator
Fanem Ltd.	Yes	Yes	Yes	Yes	Yes	No	International	Vision advanced 2286 incubator
Universe surgical	Yes	Yes	Yes	No	No	No	Indian	Infant incubator
Desco Medical India	Yes	Yes	Yes	No	No	No	Indian	BCBI 105&106
Draeger India Pvt. Ltd.	Yes	Yes	Yes	No	No	No	Indian	Isolette® C2000
Medi Waves Inc India	Yes	Yes	Yes	Yes	No	No	Indian	Baby incubator

It is observed that Indian manufacturers, unlike international manufacturers, aim to provide only features like thermoregulation, RH level control and oxygen level control but not features like vital monitoring and connectivity. This approach must change in order to reduce importation of incubators from high income countries.

Challenges posed by infant incubators

Direct challenges affecting preemies and their mitigation

- *Inaccurate thermoregulation*: Most infant incubators are not performing thermoregulation effectively as they do not take into account all radioactive, conductive, convective and evaporative exchanges with the surrounding environment[7]. This can be resolved using generalised predictive control (GPC) that takes into account all parameters involved in maintaining the temperature inside an infant incubator[5].
- *Lack of standardization of relative humidity (RH) levels:* Preemies face conditions like trans-epidermal water loss (TEWL), hypothermia, electrolyte imbalance, oxygen consumption, infection, skin integrity and will be affected by the amount of RH inside the infant incubator. There is also a practice gap in the nurses handling these incubators due to lack of standardization of RH. The inconsistent use of these levels and gaps in nursing practice have an adverse effect on the preemie[8]. It is also found that non-standard use of high RH even after the first week of life of the preemie will cause broad disparities in RH management in clinical practice. This challenge can be mitigated by the standardization of RH levels and giving practice guidelines to adhere to the incubator handling nurses[9].
- *Slow and non-homogeneous temperature distribution:* To avoid health risks to the preemie, infant incubator must be able to keep the temperature inside the hood at a homogeneous level and should also be able to maintain the desired temperature as quickly as possible as there will be unavoidable disturbances to the microenvironment inside the infant incubator by parents and health professionals. Unfortunately, existing incubators are unable to do these things and this problem can be mitigated with an infant incubator having a modular thermoelectric heat pump system (MTEHPS)[10].
- *Inefficient thermoregulation:* About 85% of the total electrical power used by existing incubators is consumed by the resistive heating element and they also have temperature fluctuations (± 0.8°C) in the hood; these systems are generally designed to work at room temperature and have only a temperature increasing mechanism; in case it is being transported or shifted to some other place and the temperature is high during transition, they are not equipped to lower the temperature so that the preemie would not get hyperthermia. This problem can be solved with the help of an infant incubator with an improved modular thermoelectric heat pump system[10].
- *Inability of current infant incubators when*

ambient temperature (T_{amb}) is more than desired temperature (T_{des}): Infant incubators manufactured at present are Commercial Resistance Incubators (CRI) which use a resistive heating element and they can only provide features like temperature and RH level control when the ambient temperature (T_{amb}) is below the desired temperature range (T_{des}) and they will fail to provide the necessary microenvironment that is comfortable to the preemie when $T_{amb}>T_{des}$ which is quite possible in various geographical locations globally. It is also possible to get $T_{amb}>T_{des}$ during transportation of infant incubators from one place to another during daytime on sunny days in any geographical location. This challenge can be mitigated by using a modular thermoelectric heat pump system driven infant incubator[10].

- *Negative impact of electrometric field (EMF)*: EMF in the infant incubators is described as potentially hazardous for the babies inside them as well as the caregivers who work near them as EMF levels higher than 200mG interfere with melatonin production or with vagal tone. It is possible to reduce the EMF emissions by re-designing the incubator components using plastic instead of a metallic skeleton, increasing the distance between mattress and source of emission and using Ferro absorbing panels to shield the baby and caregiver[11]. The negative impact of EMF on the preemies and their caregivers is not measured completely as yet and might have unknown implications. It is advised to make the infant incubators with minimum possible EMF exposure to the baby as a precaution[12].

Table 3 summarises the merits and demerits of the mitigation methods.

Table 3: ***Summary of direct challenges posed by infant incubators and their mitigation methods***

Direct challenge	Mitigation method (MM)	Merits of MM	Demerits of MM
Inaccurate thermoregulation	Generalised predictive control (GPC)	Fast transient response, high efficiency of fluctuation rejection and greater stability	Undesirable overshoot in the step response
Lack of standardisation of relative humidity (RH) levels and duration	Standardisation of RH levels and duration	Reduced risks of trans-epidermal water loss, over body cooling and possibility of infection	None
Slow and non-homogeneous temperature *Inefficient thermoregulation* *Inability of current incubators when ambient temperature (Tamb) is below desired temperature (Tdes) range*	Modular thermoelectric heat pump system (MTEHPS)	Very quick, high precision, no need of working fluid, no moving parts and benefits of closed loop control	Larger volume requirement and TEC systems + PWM is less effective compared to TEC systems + TEC controller
Negative impact of electrometric field (EMF)	Minimum exposure, increasing distance between EMF source & Preemie & re-designing incubator components	Diminished interference with melatonin production or with vagal tone and radical drop in EMF values	Extra cost burden, increased complexity, size and weight of infant incubator

Indirect challenges of infant incubator affecting the preemies and their mitigation

- *Health risk produced by high-level noise in NICU*: NICUs have increased the survival of very low birthweight babies and preemies significantly. However, noise level in the NICU is very high due to obvious reasons of the surroundings of any healthcare facility like alarms, loudspeaker announcements, nurse talk, radiator warmer and other activities[6]. The high levels of noises in the NICU have been shown to cause many negative health problems including sleep disturbance and other forms of stress, as well as changes in physiological responses such as heart and respiratory rate, blood pressure and oxygen saturation[13]. These health risks can be avoided by using wireless-communication integrated hybrid active noise control system (HANCS) in infant incubators to improve the health outcomes and to improve bonding opportunities for infants and parents[14].
- *Unavailability of low-cost, foldable and portable neonatal incubators:* Conventional neonatal incubators are very expensive and many healthcare institutions in poor countries cannot afford them. This challenge can be met by using low-cost incubators with better performance like Kangaroo Mother Care (KMC), Embrace Warmer (EW) and Handy Incubator (HI)[3]. These use Internet of Things Technology, cloud computing and wireless medical sensor networks in designing and developing neonatal incubators, which reduce the total cost of manufacturing infant incubators and has significantly improved remote healthcare monitoring[15]. Very few infant incubators, like neonatal portable foldable emergency incubator and MOM incubators are foldable or inflatable, hence occupying very small space and making them portable and ideal for emergency applications[16]. If these incubators are manufactured locally in low-income countries instead of importing them

from high-income countries where the labour cost is more, they will become more affordable, user friendly and easy to maintain[17].

- *Balance between cost benefit and safety:* Annual medical device maintenance and calibration cost in healthcare institutions is approximately 1% of the total budget. Due to this huge money requirement healthcare institutions tend to use cost-cutting measures which affect the safety and quality of healthcare provided to patients. Only 30% of the ISO 17025 accredited laboratory tested medical devices like mechanical ventilators and infant incubators are working properly and complying with international standards for all measured parameters[18]. This problem could be solved by introducing machine learning algorithms like Decision Tree Algorithm instead of the traditional Medical Device Management Strategies (MDMS), which will increase the safety and quality of healthcare provided by healthcare institutions while getting cost optimization and better resource management[1].
- *Unwanted disturbances to the microenvironment of the preemie*: Preemies need a microenvironment that is similar to the mother's womb and it should not be disturbed unnecessarily or should be disturbed the least number of times possible. It is possible to reduce these disturbances with the help of technologies like Near Field Communication (NFC) interface that allows the identification of doctors, the view of the patient evolution with tablets and the introduction of new data by the doctor[2]. It is also suggested to use contactless methods to measure and monitor the vitals of the infant without disturbing the microenvironment of the incubator with the help of techniques like infrared imaging[19].
- *Problems faced by end users:* Nurses and technicians are the predominant users of infant incubators. They use incubators to perform various tasks but predominant usage is for admission of preterm newborns and troubleshooting of the equipment. Even though they face many problems while using incubators, the most significant problems refer to alarms and configuration of the air and skin modes as the interface is not intuitive to users. These challenges can be overcome by making conscious efforts to mitigate errors from the beginning of the product development process to the training of the main users and by using Human Factors Engineering (HFE) instead of Conventional Product Design (CPD)[20].
- *Internet dependency for networking of incubators:* Infant incubators that are existing in different locations can be connected to a centralized network using wireless technologies like Wi-Fi (802.11n) or Low Power Wide Area Network (LPWAN) protocols in the range of 30 – 100m but with the help of latest technology like Long Range Networks (LoRa) it is possible to send data through a very long distances at very low power. Using LoRa it is possible to connect all infant incubators existing within a radius of a hundred kilometres to a single central network without using internet and transport them from once place to another without losing connection to the central database. Different branches of a healthcare institution can form a centralized network which can register the medical data in a common database without any threat from cyber-attacks of the internet and it would be easy to use the pooled resources and it also gives cost benefit to the healthcare institution[2].

Table 4 summarises the merits and demerits of the mitigation methods.

Table 4: ***Summary of indirect challenges posed by infant incubators and their mitigation methods***

Indirect challenge	Mitigation method (MM)	Merits of MM	Demerits of MM
Health risk produced by high-level noise in neonatal intensive care unit (NICU)	Wireless-communication integrated hybrid active noise control system (HANCS)	Reduced health risk, less stress & improved relationship between infant & parents/ health professionals	Possible auditory deprivation
Unavailability of low-cost, foldable and portable neonatal incubators	Kangaroo Mother Care (KMC), Embrace Warmer (EW), Handy Incubator (HI), MOM incubator (MOMI)	Low cost, foldable, portable and maternal-preemie bond (MPB)	KMC & EW cannot monitor vitals of preemie, HI costliest, HI and MOMI have no MPB
Balance between cost benefit and safety	Machine learning algorithms like Decision Tree	Highest accuracy, enhanced safety, improved quality of healthcare, cost optimization & better resource management	Requirement of huge device database and skilled technicians
Unwanted disturbances to the microenvironment of the preemie	Near field communication (NFC) and infrared thermal imaging	Identification of doctors and relatives of the preemie and easy progress checking	Contributing to electrometric field (EMF)
Problems faced by end users	Human factors engineering (HFE)	Optimisation of safety and minimization of the risk of error	Limited expertise
Internet dependency for networking of incubators	Long range networks (LoRa)	Long communication range, very low power consumption, transportation without loss of link	LoRa is proprietary and data rates are very low

Conclusion

The healthcare community must come together to standardize the RH levels used in incubators for the benefit of the babies. More studies and analyses are needed to know the exact impact of the electromagnetic fields. Efforts must be continued to reduce the overall cost of infant incubators so that it could become a homecare product and its interface should be made as end-user-friendly as possible. The benefits of foldable and portable neonatal incubators should not come at the expense of important features like RH level control and vital monitoring

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