Helping Babies Breath

Project Abstract

Birth asphyxia is responsible for the death of 904,000 babies every year, with many more suffering severe brain damage and disabilities. In low-resource settings, this can be a result of insufficient human resources at the time of birth and inadequate resuscitation equipment that can be dangerous and ineffective. The device described here is designed to be used easily by midwives and nurses, provides effective and safe resuscitation, and is appropriate for low resource settings that face material, emergency transport, and human resource limitations.

The product envisioned will contain a pump-based resuscitator with a mask, as well as a positioning pillow that also functions as a heart rate monitor. The resuscitator will provide an intuitive way to control both a peak inspiratory pressure (PIP) and positive end expiratory pressure (PEEP), as well as control over the length of breaths, with a beeping sound in the proper rhythm to guide the attendant. The pumping mechanism will also have an oxygen inlet to enable mixing with air. The positioning pillow device will ensure proper placement of the infant, an accurate chin tilt, and reduce the risk of damage to the head. A heart rate monitor contained within the positioning pillow will provide an audible heartbeat, and an alarm to notify the healthcare worker when the heart rate is adequate. Both components will be powered with rechargeable batteries, enabling complete portability.

Context

Background

In spite of advances in prenatal medicine, asphyxia is still one of the most significant causes of infant mortality. WHO has defined prenatal asphyxia as a "failure to initiate and sustain breathing at birth". Severe asphyxia is defined as no breathing or an Apgar score of 0-3 at 1 minute of age.

There are 26 million births annually in India. This represents 20% of all global live births. There are also over one million neonatal deaths per year in India. This is 25% of the total global burden of neonatal deaths. Data from National Neonatal Prenatal database suggests that prenatal asphyxia contributes to almost 20% of the total neonatal deaths in India, or nearly 200,000 infants.

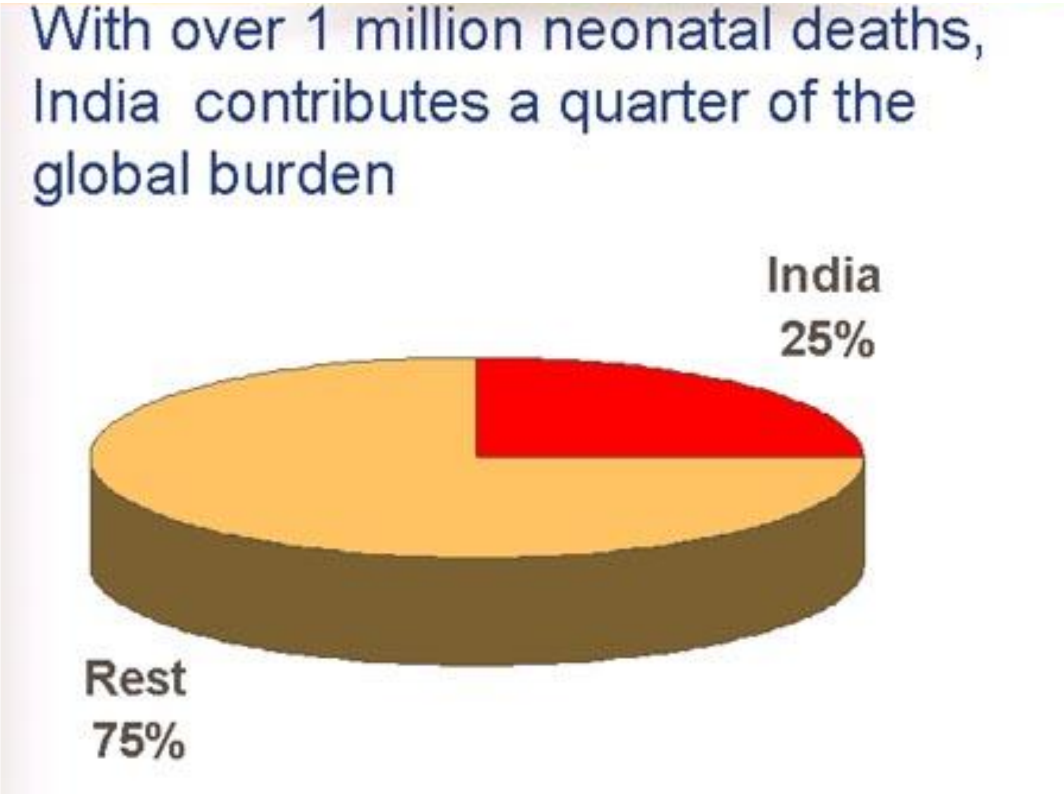

Figure 1: Neonatal deaths worldwide

Infants experiencing asphyxia who are not resuscitated effectively within 3 minutes of birth can experience varying degrees of damage to essential organs including kidneys, lungs and liver but the most serious effects are seen on the central nervous system. Good supportive care is essential in the first 48 hours after asphyxia to prevent ongoing brain injury, which can be expensive and a burden to the family and community.

Challenges:

Despite being relatively simple and inexpensive, effective neonatal resuscitation is not universal. Although resuscitation principles might be straightforward in healthcare environments with highly-skilled teams, it is difficult in low resource settings where practitioners lack training in newborn care and where access to essential resuscitation equipment is limited. Globally each year an estimated 10 million babies require assistance to initiate breathing. Between 5%–10% of all babies born in facilities need some degree of resuscitation, such as tactile stimulation or airway clearing. Approximately 3%–6% require basic neonatal resuscitation with assisted ventilation (most often with a self inflating bag device).

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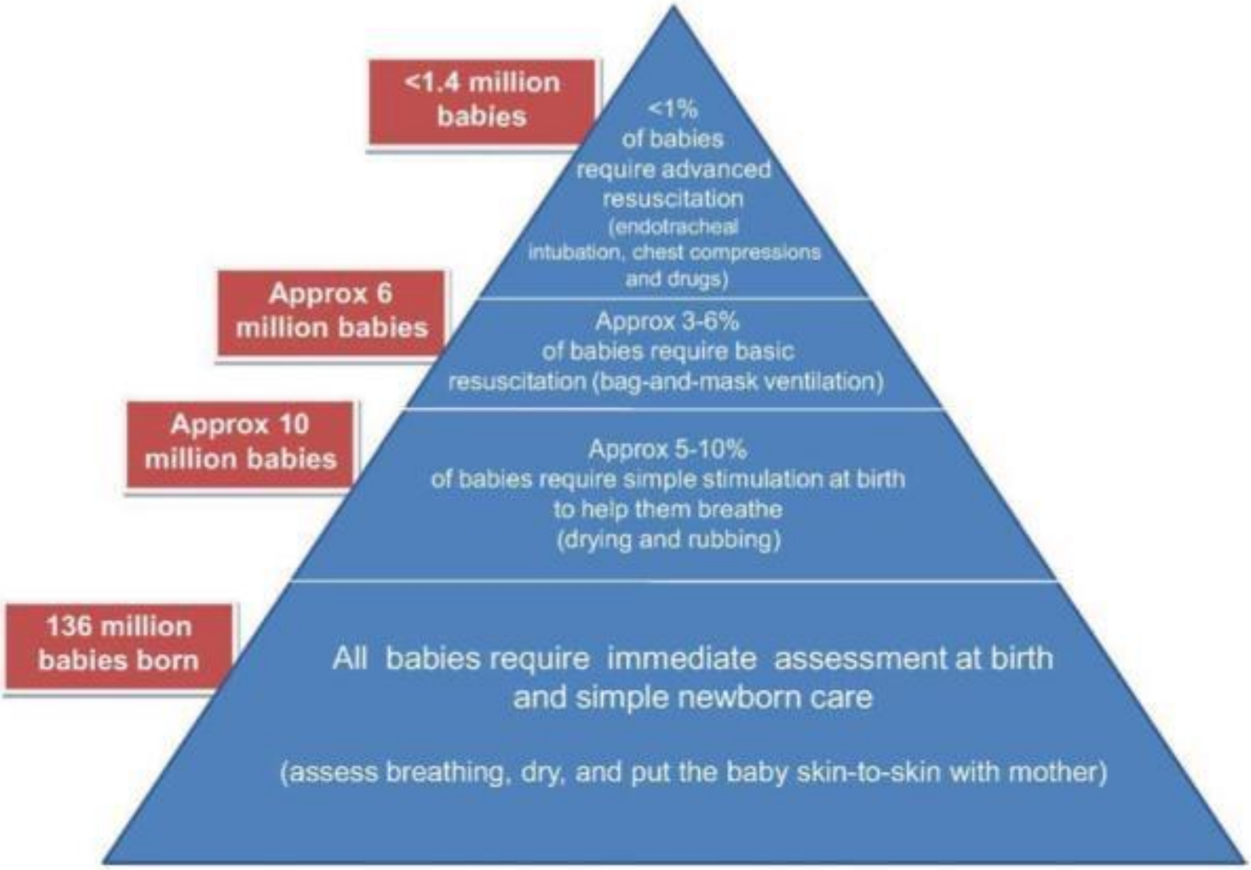

Figure 2: Treatment of newborns in case of asphyxia

Self inflating bags (SIBs) are the most widely available resuscitation device and are recommended in resource-limited settings. They are relatively inexpensive but their ability to provide a sustained inflation has been questioned. Studies suggest that it is difficult to consistently provide sustained inflations longer than 3 s when using a self-inflating bag. Additionally, evidence shows that inconsistent pressures can cause bruising in the neonatal airway and can result in further complications. Incorrect positioning of the mask can cause air leaks and an improper head tilt can fail to open the airway. Training for artificial resuscitation with a SIB must be reinforced monthly and practiced regularly to ensure it remains second nature for anyone called upon to perform this critical intervention. Competency based refresher courses are necessary but often not implemented and healthcare workers can effectively lose their training within 6 months.

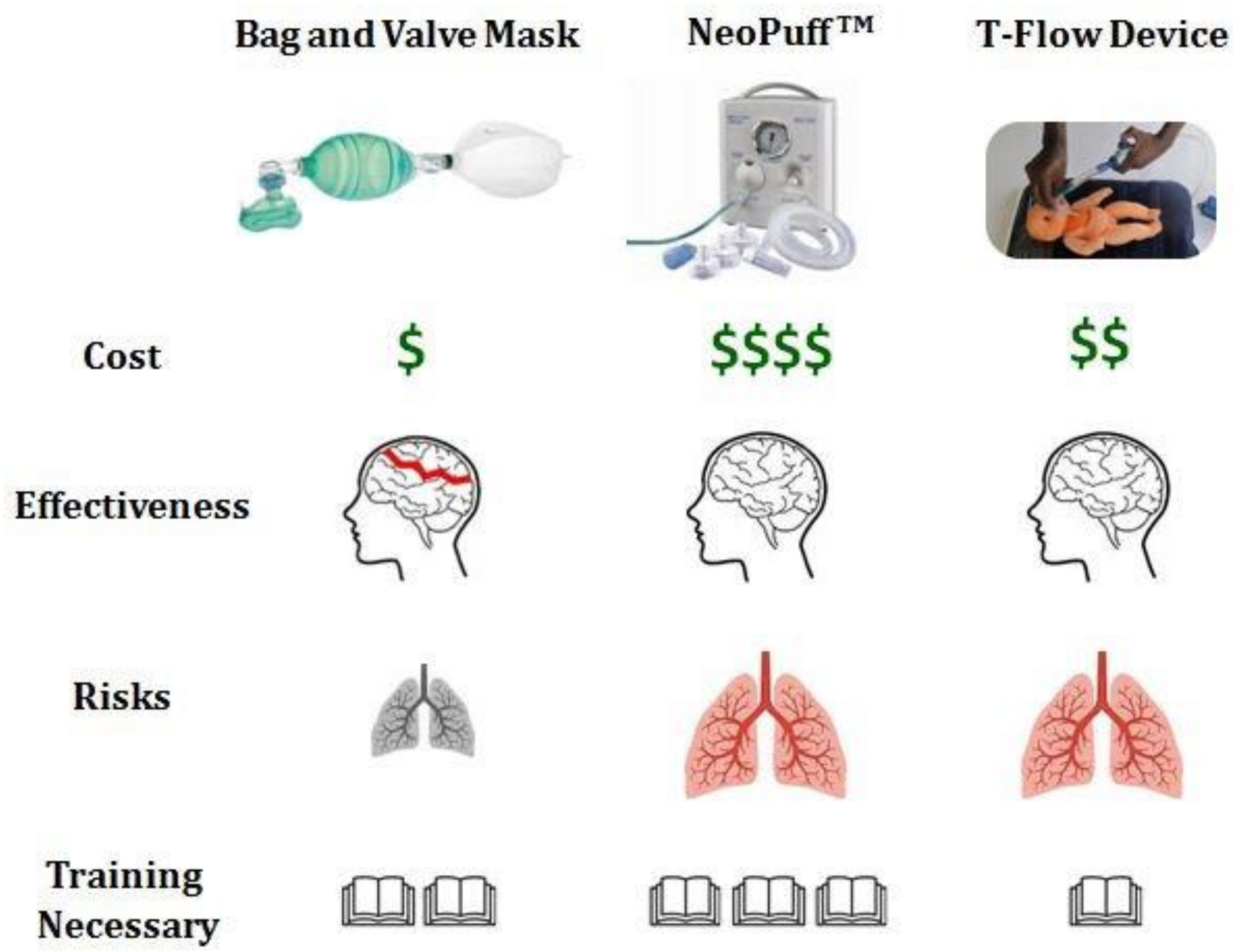

Figure 3: Overview of the different resuscitation devices and their features

Many clinics across the world don’t have access to resuscitation equipment and rely on mouth to mouth resuscitation. Where resources exist, the most commonly used device is the bag and valve mask. It is relatively inexpensive, but there are many challenges to using it. There is no way to know how much pressure to give. Each breath is different because it depends on the hand pressure of the user. Too little pressure can result in ineffective resuscitation and cause death or brain damage. Too much pressure can result in lung damage. This technique relies on the proper use by the nurse.

Another device is the NeoPuff. It addresses the problem of effectiveness because it gives both a high pressure and a low pressure, which keeps the lungs from collapsing. It also allows for a sustained inspiratory breath of 1-2 seconds, which is impossible with the bag and valve mask. The device fixes the pressures so that consistent breaths which limits the risk of excessive pressures. However this device is $1000 and also depends on the clinic having an oxygen source. It requires a lot of training because of the complexity and number of adjustments possible.

We have designed the T-Flow device that gives both high and low pressures to increase the effectiveness of resuscitation. The pressures are fixed so that excessive pressures cannot be applied. By simplifying the adjustment process, we decrease the reliance on skilled professionals to operate the device effectively. We also include real-time guidance – a positioning device, sound guidance, to help the user know the length and rhythm of breaths to give, and a heart rate monitor contained in a positioning device. The device is low cost and does not require expensive oxygen cylinders or a concentrator.

Community description

A team of six members visited four healthcare Centres in the Chengalpet region of Tamil Nadu, India. Centres included Salavakkam Primary Health Centre, Manamathi Primary Health Centre, Uthiramerur Primary Health Centre and Chengalpet Government Hospital. Six nurses were interviewed and the the most prominent concern identified was lack of human resources in the delivery room.   In all four centres it was common practice to have only one nurse in attendance in the maternity during delivery, yet the ratio of health workers to population has a direct relationship with survival of women during childbirth and children in early infancy: as the number of health workers declines, survival declines proportionately. The second concern was delay in emergency transport. One nurse reported that an ambulance could take up to two hours to respond, leading to delays in cesarian sections. When a necessary cesarian section is delayed, the consequences can be life altering. A child may suffer from birth injuries such as cerebral palsy or brain damage, and in severe cases, the mother or child may die.

Design Process

Problem Framing Statement

Maternity and newborn care attendants struggle with effective resuscitation support for neonates because of a lack of human resources at delivery, limitations with resuscitation equipment and lengthy delays in emergency transport that we address by designing a device that is easy to use, safe, effective, and appropriate for low-resource settings.

Problem Framing Tree

The problem framing tree is an abstract method to detect problems. Each main problem topic is a big stem and this stem has a few branches which are problems related to the main one. It is an easy method to define varieties of problems and to see them at a glance. It helps the group prepare for the decision finding process. The problems we defined are related to the answers we got from interviews conducted in various communities. We structured the different answers by topics in order to fill the placeholders in the problem framing tree. Additionally we noted basic ideas for possible solutions. The four levels of our problem framing tree are:

1. Monitoring: Problems in the prenatal and delivery stage can be detected easily to avoid complications. Interview parteners in the rural health centres informed us that if there are any risks with a pregnancy or during delivery expectant mothers are brought to the general hospital for advanced care and monitoring. It is necessary to detect problems during the early stage in order to transport and treat quickly for positive outcomes.
2. Education: From information gathered we learned that many nurses and midwives in rural areas do not receive regular refresher traning to properly utilize the ambu bag (the device currently being used to resuscitate). To ensure safe, effective operation of the device, midwives and nurses must practice at least once per month. Some of the nurses interviewed had not used an ambubag , or received refresher training in more than three years. The other problem identified was lack of knowledge by expectant mothers regarding early risk signs surrounding asphyxia.
3. Emergency Transport: Although Chengalpet has a neonatal ambulance, it serves an extremely large poulation and multiple rural clinics. Response time from the emergencey medical team can take up to 2 hours. Rural clinics are equiped only with ambubags, which are inadequate to provide sustained breathing. Lack of timely intervention can lead to complications, brain damage and death. The high cost of more advanced equipment prevents rural clinics from purchasing.
4. Treatment and Care: The treatment of infants is difficult; nurses and midwives often struggle in emergency situations. There are many factors which play a part in the successful treatment of infants and often the medical devices that are the most effective at resusitating, are to complicated for a nurse to handle.

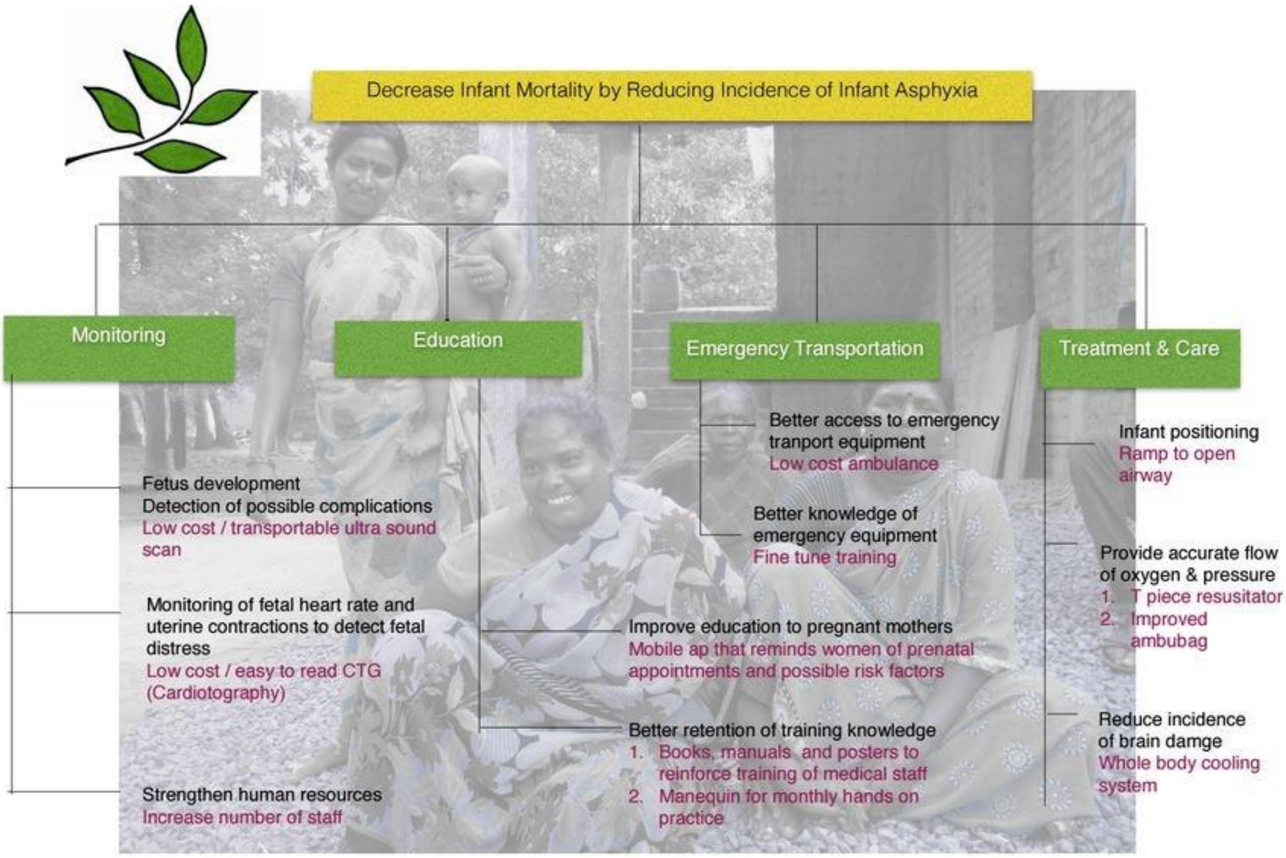

Figure 4: Problem framing tree

This problem framing tree gave us an overview in which areas we could start to work. We focused on three identified issues:

- Lack of practice with the ambu bag.
- A cheap monitoring device, which detects the heart rate of the fetus and the uterine contractions of the mother
- A resuscitator which is affordable, user friendly and could replace the ambu bag

Concept Evaluation

The main part of the concept evaluation was for our team to decide which problem, out of the detected three, we should focus on. First of all we had a discussion regarding which possible solution would have the most significant impact. In our opinion, solutions around the ambu bag were the weakest, due to the difficulties in usage. We predicted the ambu bag will be replaced within the next 10 -15 years, therefore the impact of solutions would be minimal. For the other two detected problems, the process was more difficult, as both potentially have a broader impact. From interviews with nurses and midwives we ascertained the value of a cheap heart rate monitoring device, due to the fact that resuscitation should be done at the general hospital in order to detect complication during the early stages.

Alternatively we still had the impression, that an easy to use and low-cost resuscitation device would be highly useful.

To find a decision regarding which project to focus on, we used a card sorting method. We wrote the advantages and disadvantages of the two devices on cards and grouped then between a matrix , then sorted by topics such as costs, needs, etc.
We then assigned each card a value and ranked them in order from most to least powerful. With the help of this method we decided to concentrate on a resuscitator.

Value proposition

- Decreases neonatal mortality and brain damage due to asphyxia
- Delivers inspiratory and expiratory pressure preventing lung collapse
- Reduces likelihood of lung damage due to excessive pressure application
- Guides nurse or midwife through audio to give sustained breaths
- Plays the newborn's heart rate signaling a successful resuscitation

Summary of design process

As we explained before, the resuscitator was for us the right choice. Our main reasons to decide against a heart rate monitoring device was that there are already devices on the market. They cost around 30$, which is in the price range of the hospitals and health care center we visited. One facility also showed us one of these devices.
Another reason to decide against the monitoring devices was that our interview partners said to us:

- "We don't treat them (babies with complications during delivery), because we don't have the right equipment, that's why we need a monitoring device to detect problems."

Out of this statement we started to ask deeper for the "right equipment" and we got the answers:

- "Resuscitators (which are available) are too expensive!"
- "A resuscitator is too complicated to use for nurses and midwives"

So now we had two of our main needs for the device we have to develop. It has to be cheap and it has to be easy-to-use.
After some research on existing resuscitation machines we had the insight it is no rocket science to develop the right device with the intended needs and we got an idea how our first prototype could look like.

Technology / Final Prototype

Design requirements

- Easy to use with minimal training
- Easy to set up with intuitive design
- Continuous flow of air
- Ability to provide both PIP and PEEP at correct pressures
- No reliance on oxygen cylinders or oxygen concentrators (but ability to use if available or and desired)
- Low cost
- As "Hands free" as possible (for places with low human resources, allows healthcare worker to leave the baby and attend to the mother in emergency situation)
- Battery operated
- Leak proof, reusable mask
- Compact and transportable
- Rugged, durable in the field
- Monitor for heartbeat and oxygen that notifies healthcare worker with an alarm
- Safety mechanism to avoid excessive pressure
- Proper release of CO_2

How Does it Work? / Performance

A small air pump continuously pumps air through the device and into the baby's lungs. Pressure is controlled using the T-piece (see Figure 5). At the top of the T-piece there is a hole. When the hole is closed with the thumb, a higher inspiration breath is given. This inspiration breath is termed the Peak Inspiratory Pressure (PIP). The WHO recommends a PIP of ____ for term babies and a PIP of ___ for preterm babies [REF]. When the hole is open, the carbon dioxide leaves the device and a small pressure remains in the lungs, termed the Positive End Expiratory Pressure (PEEP). The WHO recommends a PEEP of ___ for term babies and a PIP of ____ for preterm babies [REF]. Application of PEEP keeps the lungs from collapsing and is highly recommended to apply during resuscitation [REF].

The baby is placed on a positioning pillow which helps position the baby with its head tilted back just slightly. The positioning pillow is designed to raise the baby two centimeters above the surface according to the guidelines of the _____ [REF]. The neck of the baby is placed on a circular hump to allow for the head to be tilted back without applying dangerous pressure to the baby's skull, which is common when using the bag and valve masks [REF]. The pillow also contains a small speaker that plays a sound to guide the user in the correct length and rhythm of the inspiratory breaths. Lastly, there is a heart rate sensor contained on this pillow at the back of the neck. When resuscitation begins, the babies heart rate will be very slow, but will hopefully increase during the resuscitation increases. When the baby's heart rate gets above 90 bpm, it is a signal of a successful resuscitation and the user can stop giving breaths. Our device also enables the nurse to give a low pressure constantly to support the baby in breathing after resuscitation if needed.

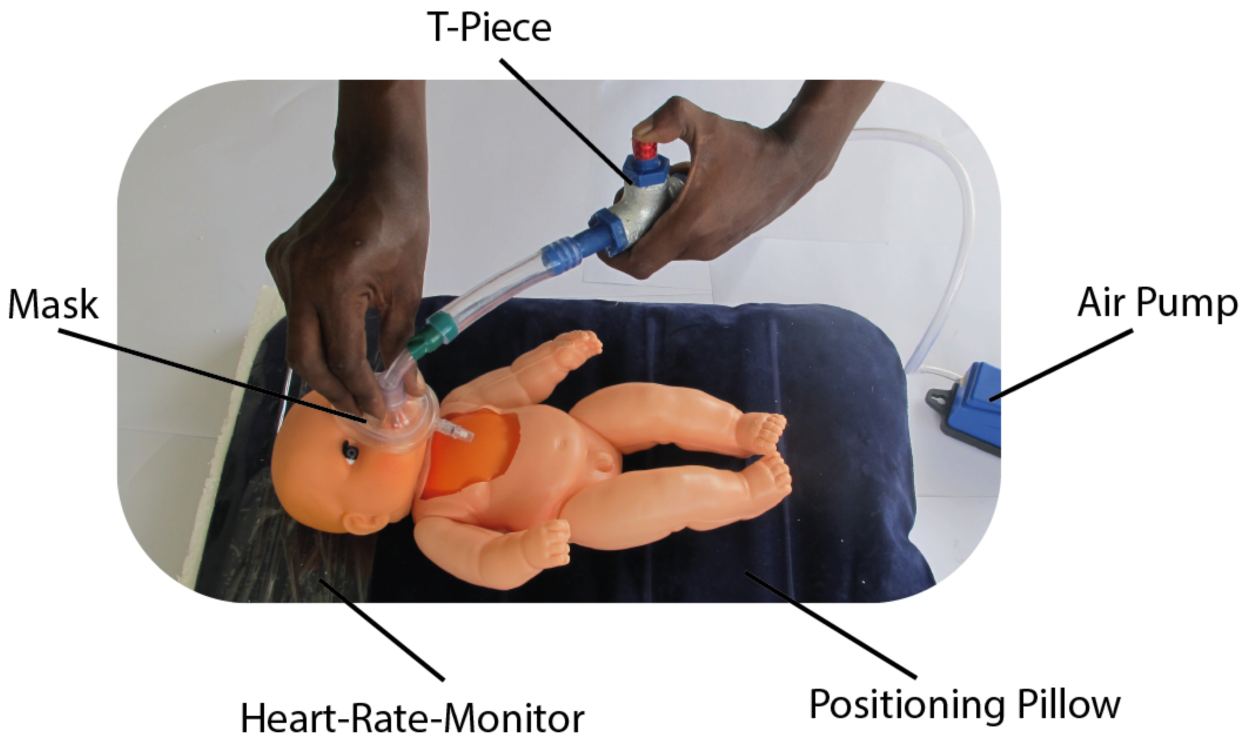

Figure 5: Components of the T-Flow

Bill of materials

- Mask
- T-piece
- Pump
- Control valves
- Pressure gauge
- Pressure pipes
- Doll
- Pipe
- Manometer

Components of a breathing system

Characteristics of ideal breathing system

1. Should be simple, safe, and inexpensive.
2. Able to deliver intended inspired gas mixture.
3. Permit spontaneous, controlled or assisted ventilation in all age groups.
4. Efficient and allow low fresh gas flow.
5. Able to protect patients from barotrauma.
6. Sturdy, compact, light weight.
7. Easily remove waste gases.
8. Warming and humidification of inspired gases.
9. Effectively eliminate CO_2.
10. Have low resistance: Should have minimal length, maximal internal diameter and be without sharp curves or sudden changes in diameter.
11. Dead space should be minimal.

Breathing tubes

- Large bore, usually corrugated tubes, made of rubber or plastic.
- Corrugations increase flexibility and resistance to kinking.
- Clear plastic tubes are lightweight and low resistance.
- Act as a reservoir in certain systems.
- Have some distensibility but not enough to prevent excessive pressures from developing in the circuit.[3]

Adjustable pressure limiting valve

- Also called as; pop-off valve, exhaust valve, scavenger valve, relief valve, expiratory valve, over-spill valve etc.
- This valve allows exhaled waste gases and fresh gas flows to leave the breathing system when the pressure within the breathing system exceeds the valve's opening pressure
- It is a one way, adjustable, spring-loaded valve.
- The spring adjusts the pressure required to open the valve.

Reservoir bag

- The reservoir bag is an important component of most breathing systems.
- Made of antistatic rubber or plastic. Black bags are antistatic whereas green bags are made of low charging material which will not create harmful charges but will the bag from electric fields.
- Accommodates fresh gas flow during expiration, acting as a reservoir available for use in next inspiration.
- Acts as a monitor of the patient's ventilatory pattern.
- Can be used to assist or control the ventilation

- Bag being the most distensible part of the breathing system, protects the patient from excessive pressure in the system.

Connectors and adaptors

- To connect various parts of breathing system.
- Extend the distance between patient and breathing system.
- Allow more flexibility for manoeuvring.
- They also increase dead space and resistance.
- Chances of disconnection increased.

Feedback notes after the presentation

- Timer (start with a button)
- Pillow inflated
- Warmer / cooling system included in the pillow
- Notebook / paper to monitor the temperature of the infant
- Constant pressures divided into steps (range 5 psi)
- Avoid air liking
- Thermometer with color scheme for fast understanding
- Arrangement of the different parts in a certain way to keep the chest visible
- T-piece far away from the babies face

Next steps / Project future

Reflection on project viability and other design opportunities

- Improving upon existing ambubag (easier to use, providing user feedback)
    - Augmented Infant Resuscitator (Kevin Cedrone Scale Up Fellow @ MIT D-Lab, testing in Uganda)
- Windmill Health ("NeoBreathe", Villgro)

6-month plan and team engagement (roles and responsibilities)

- Nicole is willing to stay engaged in the project in the US or in Uganda as needed...Grace Family Health Clinic and staff are available...accommodation in Uganda available....connections and networking in Uganda available
- Abdur Rahman is interested in developing its working prototype with help of team, sponsors and support from IDIN. Can also work on Pressure control valves and calclations related to it. This can be made as his final year project.
- Bastian developed interfaces for machines, he can start to think about the interaction between the device and the user. He can also get in contact with doctors to gather information around resuscitation. He also can do some calculations (physic) to define the sizes of tubes, values according to the pressure.

- Arielle is available to assist with research and applying for grants/funding.

Anticipated risks and challenges

- Finding people with the skill sets needed to assist with development
- Medical approval process
- Finding ways to communicate in between the team members

Stakeholders

- engineers
- doctors
- nurses / midwives

Contact information / List

Community partners

- FPA Sujatha +919840604599
- Chengalpat government hospital Dr. Satya +919443701730
- Salavakkam Primary Health Centre Dr. Thangameena +91948608059
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http://www.mncyn.ca/wp-content/uploads/2013/08/volume30.pdf

http://yourstory.com/2013/05/5-out-of-100-babies-wont-breathe-at-birth-startup-windmill-alleviates-the-situation-2/

Something interesting I found for our report check this link
http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3821268/a