

# PROJECT TIGER BREATH

A program and evaluation plan for an innovative approach to reducing neonatal mortality  
in low-resource areas.

by

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## INTRODUCTION

The advent of mechanical ventilation in the 1960's and 70's revolutionized the approach to newborn illness and improved infant mortality significantly.<sup>1</sup> Neonatal intensive care has developed into an entire medical specialty using tools such as surfactant replacement and extracorporeal membrane oxygenation to bring sick infants through the perilous first few days of life.

For much of the world through, access to these advances is still many years away. If we consider India, where the project was conceived, mechanical ventilation arrived in there in the early 1990's<sup>2</sup>, but its advantages have not been shared throughout the country. Describing the situation from a critical care center in New Delhi, Nangia *et al* comment that mechanical ventilation "is an expensive and complex technique and a large investment in terms of money, time, skill, and labor..."<sup>2</sup> Rough estimates postulate that 80% of India's population lives in areas lacking adequate intensive care services.<sup>3</sup> India's population in 2009 was estimated to be 1.15 billion people<sup>4</sup> leaving roughly 920 million people without access to intensive care.

Using India's crude birth rate of 32 per 1000 people (as of 2010)<sup>5</sup> that would mean that 29.4 million children are born every year without access to state-of-the-art ventilation. If you consider respiratory distress syndrome (RDS) alone, 2-3% of all neonates will require mechanical ventilation.<sup>6,7</sup> Combining RDS with sepsis and meconium aspiration syndrome, that number could easily be 5-10%. If 5% of all infants born to resource-poor areas of India that lack access to mechanical ventilators require ventilation that represents a burden of disease of 1 million people a year, for India alone.

From personal experience, in rural areas where ventilation is not available the solution is use manual intermittent positive pressure ventilation (IPPV). In lay terms, parents are required to “hand bag” newborns using an ambu bag for days on end as their only means of respiration. Ambu bags<sup>8</sup> are self-inflating air reservoirs that are typically used for temporary ventilation during cardio-pulmonary resuscitation (CPR) or neonatal resuscitation. When they are the only means available for ventilation, parents are typically taught to squeeze the bag with some sort of rhythm. One could imagine that fatigue, hunger, conversations, anxiety, and boredom make this responsibility quite daunting.



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**Figure 1. Infant ambu bag used for manual ventilation**{316 Surgical Shop; }

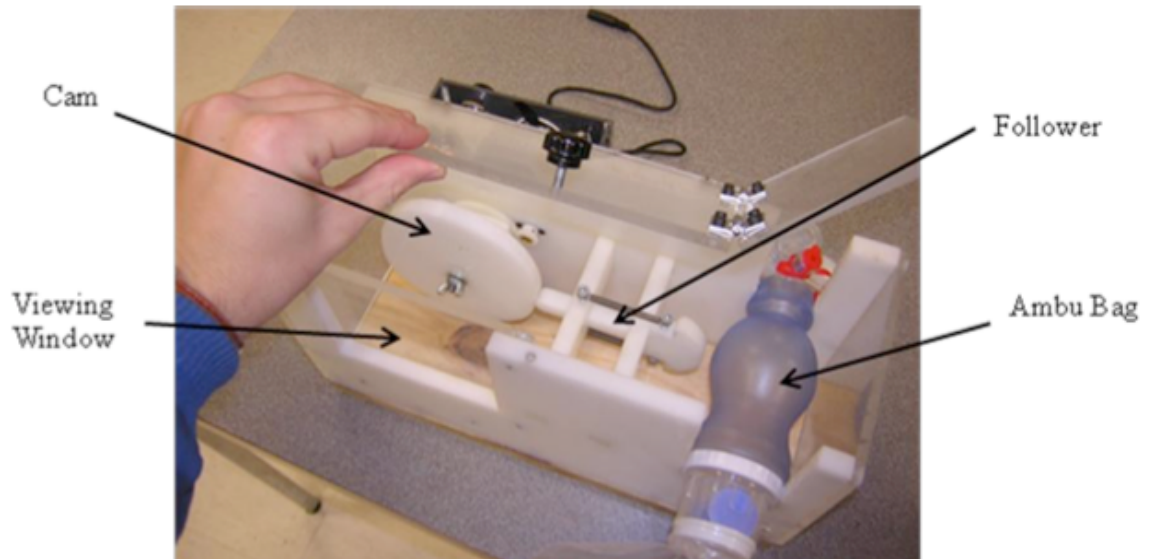
Project Tiger Breath is a program designed to create and deliver a low-cost form of mechanized ventilation to hospitals in the developing world. I say mechanized ventilation rather than mechanical ventilation because I do not want to suppose that the device should create the illusion that it offers all of the same features common to mechanical ventilation like air filtering, fraction of inspired oxygen (FIO<sub>2</sub>) control, precise pressure and volume settings, and many more.

By discussing the need for new technology, one crosses over from the world of non-governmental organizations (NGOs) and public health into a world of design, manufacturing, and distribution. Often these two worlds find it difficult to communicate, but there is hope that collaboration can reverse this.<sup>9, 10</sup>

The creation and distribution of medical devices is driven by supply and demand. However, many common medical devices have not been able to penetrate global markets because “without money, need does not translate into demand.”<sup>10</sup> Without a sizeable demand in a well-defined market, companies are reluctant to invest in new medical devices. Because of this Project Tiger Breath is a university-based program that will rely on public-private partnerships in order to translate the ingenuity and resources of university students and faculty into health outcomes for low resource areas.

Project Tiger Breath is program that is intended to organize and oversee the design, manufacturing, distribution, and use of the Tiger Breath Ventilation Assist Device (VAD). The program will coordinate the efforts of several “partners” including university-based design teams, clinical advisors, international practitioners, and funders, as well as manufacturing, distribution, and advertising companies. The program will be lead by a project manager that acts as the intermediary between all of the program partners.

Project Tiger Breath began through a partnership with the Mechanical Engineering Department at Clemson University during the fall of 2010. The project manager presented the mission and vision to the students at the beginning of the semester and charged them with creating a device that was low-cost, small, lightweight, safe, and durable that could take the place of a parent’s need to provide manual support. What they created was an electrical motor driven cam-follower system that uses interchangeable cams to control the ventilation parameters for the device.



**Figure 2. Tiger Breath VAD Clemson Prototype**

The following is a discussion of the program plan and evaluation for Project Tiger Breath. It is will be presented in three parts. The first part is a systematic review of the literature that discusses similar programs that have developed devices for low-resource settings. The next part is a detailed description of the program plan that includes the program theory, goals and objectives, logic model, and implementation plan. The third part outlines a plan for evaluation that will be used to monitor the success of Project Tiger Breath over time. Finally, the conclusion of the paper will discuss Project Tiger Breath within the context of global device design and manufacturing and the implications for future directions.

A consistent theme through out this discussion of Project Tiger Breath will be to highlight the importance of collaboration and partnership as key to developing successful, innovative programs in the twenty-first century. Too often, the worlds of engineering and public health fail to interact in an optimal way that combines the talents of both groups and mediates their individual inadequacies. Project Tiger Breath also takes into account

the fact that design and program planning are not all that are necessary to deliver a new medical device. The collaborative mindset seen in the early stages of design and testing will carry over in the later stages of the program as Project Tiger Breath networks with partners in advertising, distribution, graphic design, management and many others.

This discussion is important because it provides the framework for insuring that a new device will be accepted in the market. It will build off of the examples found in the systematic review and use the tools of program planning and evaluation to in a sense “rethink” how university-based global partnerships that cross the boundaries of culture and commerce can cooperate to build a new medical devices to supply the places of greatest need.

# SYSTEMATIC REVIEW

## INTRODUCTION

The following systematic review focuses on gaining a knowledge base to guide the development, implementation, and evaluation of the Tiger Breath Ventilation Assist Device. Project Tiger Breath will need to meet several guiding tenants if the project is to be deemed successful. It is essential that the following elements be addressed from the outset of the program plan.

1. The intervention must not harm infants, and should produce better outcomes than current interventions for neonates in low-resource settings.
2. The intervention must be low-cost so that it is readily obtainable in the target area either through hospital funding, NGO purchase orders, or private payers.
3. The intervention must be culturally and professionally relevant so that it honors the efforts of health care providers by respecting their desire for professional equipment.
4. The intervention must be sustainable so that the Tiger Breath VAD does not become irrelevant a short time after purchase.

To accomplish these objectives, several questions needed to be addressed.



## METHODS

RESEARCH QUESTIONS. The systematic review of the literature sought to answer three distinct questions that would lay the foundation for implementing Project Tiger Breath.

- What is the burden of neonatal illness requiring mechanical ventilation in low-resources areas of the world, particularly Asia?
- Have similar devices been invented that are intended to increase access to mechanical ventilation?
- How have other devices and their programs that address other health problems been designed, implemented and evaluated for use in low-resource settings?

SEARCH STRATEGY. PubMed served as the online database used to identify relevant studies that address the three research questions above. To ensure thoroughness, I used MeSH terms in the search strategy wherever possible in order to capture the appropriate categories within PubMed. Applicable MeSH terms included respiration, artificial; developing countries; infant, newborn; intensive care, neonatal; and equipment design.

The following search strategies were used to identify potentially relevant articles:

- "developing countries"[MeSH] AND "equipment design"[MeSH] AND "infant, newborn"[MeSH]
  - 8 articles
- "low-cost" AND "developing countries"[MeSH] AND "infant, newborn"[MeSH]
  - 46 articles
- "respiration, artificial"[MeSH] AND "developing countries"[MeSH] AND "infant, newborn"[MeSH]
  - 24 articles

- "low-cost" AND (ventilation OR ventilator) AND "developing countries"[MeSH]
  - 6 articles
- "low-cost" AND (ventilation OR ventilator) AND "developing countries"[MeSH] AND "infant, newborn"[MeSH]
  - 2 articles
- "low-cost" AND "equipment design"[MeSH] AND "developing countries"[MeSH] AND "infant, newborn"[MeSH]
  - 1 article
- "low-cost" AND "equipment design"[MeSH] AND "developing countries"[MeSH]
  - 18 articles

I reviewed the title of each of these 105 articles, recognizing many of them to be repeated in the similar searches. If the title of the article seemed appropriately relevant to one of the three research questions, I reviewed the abstract as well. Inclusion criteria for a study were as follows:

- The article must represent information that is relevant to one of the three research questions.
- The data must come from developing countries.
- It must be written in English.
- The article should be available within the University of North Carolina at Chapel Hill's online library. *(Two articles were purchased using intralibrary loan, but the return on each \$5 investment limited the ability to purchase more.)*

I conducted a hand search of the reference list for relevant articles as well as the “similar articles” feature in the PubMed database. In all, I thoroughly reviewed 35 articles. Much of the information from the articles related to burden of suffering related to neonatal ventilation was reported in the INTRODUCTION section of this paper. I found no similar device that could provide supplemental ventilation to a newborn in the published literature. Four studies describing low-cost devices were found that also had intervention plans discussed. A summary of each of these studies can be found below.

#### SUMMARY OF LOW-COST DEVICE INTERVENTIONS

##### BEYOND THE WHEELCHAIR-*THE SKEETER*

The Biomedical program at the University of Alaska<sup>11</sup> recognized that in many developing countries individuals that are disabled are restrained from living otherwise productive lives because they lack access to wheelchairs that are capable of functioning in settings where there are poor roads.<sup>11</sup> The solution they designed was a wheelchair carriage that was motorized, but was made of bicycle parts and a low-cost custom frame that could be feasibly maintained in a low-resource area. They focused on Cambodia, a country that has experienced years of conflict and civil war leaving many of its citizens disabled from devastating injuries.

Disability is a problem that is experienced far too often in the developing world. The WHO “estimates that up to 10% of the world’s population has a disability, and 80% of those people live in developing countries.”<sup>11</sup> Lack of transportation for these people is an almost independent predictor of poverty. Without transportation, individuals are restricted to a lifetime of begging “because it is generally difficult to impossible to gain access to vocational training, rehabilitation, or even the most meager employment.”<sup>11</sup>

Their study focused primarily on the design of the device, giving a fair amount of attention to making it sustainable in the developing world. Their guiding principles included the following:

- Inexpensive (less than \$250)
- Manufacturable in target countries
- Repairable
- Applicable to a variety of impairments
- Useful
- Safe

To accomplish this, they changed their focus from using motorcycle parts to using components that were also used with bicycles, which are ubiquitous in developing countries.



**Figure 3. The Skeeter device**

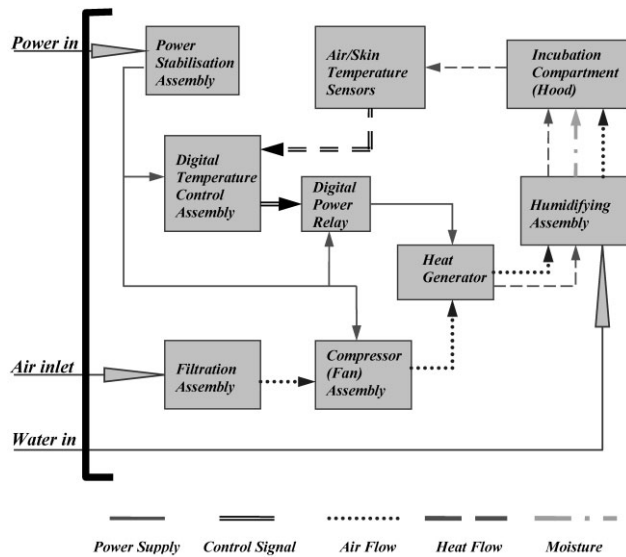
They also implemented cost-saving measures like using local manufactures and local techniques to build the device, along with purchasing parts from nearby countries like China or India. One of the biggest cost-saving opportunities was to use local labor for production. They ensured the safety of the device by limiting the maximum speed, adding a secure rear gate, and widening the wheelbase to avoid rollovers.

For the distribution of the device, the authors proposed three avenues of funding: private donations from interest groups in wealth nations, NGOs that are currently purchasing less useful devices, and micro-loans that are given to the individual and are repaid after the person has obtained stable income.

This device would not require any sort of implementation trial because it is not technically a “medical device.” The authors had collaborators in Cambodia that were ready to proceed with manufacturing and distribution. The authors do not provide any information regarding an evaluation plan.

RECYCLED INCUBATORS AS ALTERNATIVES FOR MODERN SYSTEMS

This study took place in Nigeria, in conjunction with the bioengineering department at Imperial College in London, England. They sought to address the need for neonatal incubators in Nigerian hospitals by recycling older incubators that were no longer used in the Nigerian hospitals. They identified the need for incubators by interviewing clinicians and administrators in the local hospitals, rather than coming up with their own idea.



The researchers identified that “it is difficult if not impossible for neonatal centres in developing countries to purchase modern systems.”<sup>12</sup> The developed a technique to use parts from obsolete incubators and make digitally

**Figure 4. Recycled assembly block diagram**

controlled systems that would be similar to modern systems. Using nineteen dysfunctional and obsolete incubators from Nigerian hospitals, they were able to reconstruct them with the new design onto sixteen units divided across four NICUs in Nigeria. Before the manufacturing ever started they searched the global market (via the

Internet) for the lowest price of components that could not be salvaged, organized an engineering team, and established their design criteria.

The recycled devices were tested for 6 months and subject to “rigorous performance characterization.”<sup>12</sup> Their performance was compared to a cohort of modern incubators that the researchers also supplied to the hospitals using a 10-point scale that measured ten performance characteristics.

- Set-point accuracy
- Maintainability
- Ease of hood accessibility
- Heating transient response
- Sensitivity and response to erratic power supply
- Humidification
- System aesthetic appreciation
- Inherent noise during operation
- Response to high ambient temperature
- Cost of system procurement

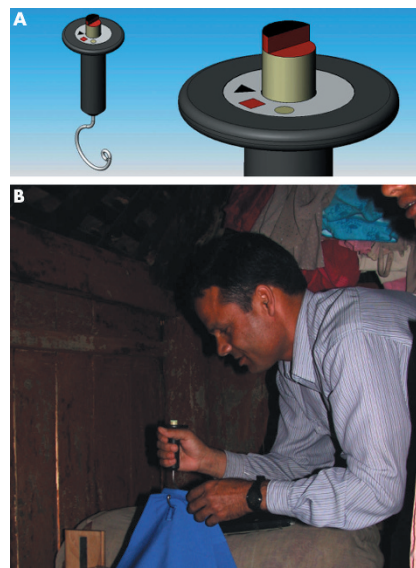
The overall performance scores for the recycled and the modern incubators were the same (65.9% vs. 65.8%). The areas where the recycled incubators were the most different were aesthetic appreciation and cost of procurement. These two obviously go hand-in-hand, but the very good cost scores could easily outweigh (but not negate) the poor aesthetics. Overall, the recycled incubators were much more affordable, maintainable, and responsive making them a more cost-effective solution for the Nigerian hospitals.

The authors concluded that the use of outdated incubators in developing countries presented a significant risk to newborn children; however their study showed that with a few modifications those old incubators could be recycled and be as effective and safe as other more expensive incubators that are not practical even for tertiary care centers to purchase. The authors do not report any attempt to evaluate their program or their plan choosing to focus only on the device.

#### COLOR-CODED SCALE FOR LOW-BIRTH WEIGHT INFANTS

This medical device originated from the Bloomberg School of Public Health at Johns Hopkins University.<sup>13</sup> The intention was to make a device that could easily and accurately delineate newborns that were  $\geq 2500$  g, 2000-2499 g, and  $\leq 2000$  g in developing countries where access to scales may be limited. The information gained from the delineation helps to classify newborns into the appropriate risk category so that they can receive proper treatment.

This particular study reports the design and implementation of the BirthWeigh III that was developed in conjunction with the Program for Appropriate Technology in Health (PATH). The first and second models had failed to be sensitive and specific enough to be implemented.



**Figure 5. Birthweight scale in use**

In this region of Nepal, 95% of the children are born at home. The BirthWeigh device is designed to be used in homes by birth attendants and was analyzed within a larger study that was taking place in Nepal. Infants were weighed at home by the project

workers and then with a digital scale. The device itself is lightweight, composed of only four main parts, and made of inexpensive materials. Its estimated costs is only \$5.00 USD. Other costs included training 11 project workers and providing a written and pictorial manual.

The trial was nested in a larger parent trial containing 1070 newborns. As a result, none of the  $\geq 2500$  g babies (28%) were classified wrongly into the lowest category, and only 1  $\leq 2000$  g infant was inappropriately labeled as  $\geq 2500$  g. In all, only “seven infants weighing  $\geq 2000$  g were misclassified...as  $< 2000$  g, and...six were within 60 g of the cutoff.”<sup>13</sup> Eleven infants that were  $< 2000$  g failed to be detected that should have been detected. The specificity of the BirthWeigh III (the ability to identify a truly  $< 2000$  g infant) was 99.6 with positive and negative predictive values of 91.9 and 99.4, respectively.<sup>13</sup> The researchers concluded that this study proved that the BirthWeigh III was a suitable device that could safely identify children that are low-birth weight at a low cost that could be obtainable in a developing country.

#### PHOTOTHERAPY USING LEDs

The Duke-Engineering World Health (EWH)<sup>14</sup> program sends 50 or more engineers around the world every year. One device reported in April 2010 was a new solution to an old problem—neonatal jaundice. Phototherapy has been the mainstay for treatment for neonatal jaundice/hyperbilirubinemia for many years in the developed world, but this technology costs between \$3000 and \$5000 USD and has remained out of reach for most of the developing world. Many of these machines are available to be donated around the world, but the bulbs alone (which last for two to three months) can



put them out of reach for most hospitals. The solution was to invent an LED-based device that was powered by a car or motorcycle battery.

The design process began with a series of interviews conducted with medical doctors working in villages, asking them what relevant technology would be most helpful to them. After selecting phototherapy as the focus project for 2005, they identified that the lack of replacement bulbs and power supply were the most common causes of device failure. The project incorporates students that take a class at Duke that provide initial designs that are later provided to the public for improvement. For this project, a public design firm, Tackle Design, took on the project and refined it.

The team consulted US physicians and incorporated the thoughts of many different professionals into the final design of the device. After taking into consideration all the design input, the team conducted bench tests to evaluate the device's performance in critical aspects of the design like battery life, light source characteristics, and longevity.



**Figure 6. A baby under the phototherapy device**

was \$65.62 USD, which is dramatically less than the multi-thousand dollar units that are commercially available. From the first trial, the field teams noted one important concern. First, the staff in the hospitals complained that parts of the device looked “homemade”<sup>14</sup>

Next, the team proceeded to field trials, implementing 114 units divided amongst four countries in hospitals ranging from very small to very large. Two engineers went with every device to help install the device, train the staff, and conduct follow-up interviews. The final cost of the device

which made them reluctant to use the device even when the alternative was no therapy at all. One person asked about FDA or CE approval, and no one asked about clinical efficacy data.

A second round of testing incorporated a new custom power supply, improved aesthetics, and a reduced cost to \$45 USD. Thirty-five units were tested in the same hospitals in Tanzania, Nicaragua, and Honduras. All the units worked well for the first month of use and there were no complaints from the staff about the device.

The third and final round was conducted entirely in Kenya. This time, previous shipping problems were corrected and all of the 28 units worked upon arrival. All the staff members eagerly accepted the device and were glad to use it because they had no other option for treating infantile jaundice.

This device is an excellent example for the potential of a university-designed project to be implemented internationally. The authors comment on the obstacles that exist for bring a device to market. For many products, the cost of design and implementation can be \$10-20 million USD <sup>14</sup>, a price that exceeds the market for many design ideas. Major companies are reluctant to create products that could not make a profit in the developing world. That leaves the non-traditional, university-based program to serve as crucibles of innovation that can partner with the power of the private sector to accomplish the task of medical device generation.

## ANALYSIS

Each of these programs provides valuable insight into the planning and evaluation of a program to deploy a low-cost medical device in a low-resource setting. Table 1 in the Appendix shows the important elements that are utilized in the studies. One theme that was consistent throughout all four projects is that development does not exist in a vacuum, nor is it accomplished by the isolated efforts of passionate individuals. The above examples demonstrate that the most effective way to implement a new device in a low-resource setting is to collaborate with multispecialty teams.

### PROGRAM ORGANIZATION

The cited studies had several similarities in design-team structure that helped to ensure success at every level of the program plan and evaluation. All of them were university-based, which allowed the teams to utilize student and volunteer labor that would significantly reduce the design and prototyping costs. Universities have more opportunity to work outside of the bounds of the commercial marketplace and to pursue projects that find their value in benefiting humanity rather than generating a profit. Having said this, three of the groups consulted with and found support from private non-university organizations in later stages of product development. They make no comment about obtaining outside funding sources such as the National Institutes of Health (NIH) or the Bill and Melinda Gates Foundation (Gates Foundation). Only Owens and Simmons<sup>11</sup> mention the use of microfinance as a proposed funding source in their discussion. It fit their project particularly well, but it is an option that deserves further exploration as I go forward with the program plan.

It is also essential to see the patience displayed in these organizations as they remain faithful to their intentions in the face of design failure. Three of them reported device failures that required redesign and new implementation plans. This perspective would need to be built into the group purpose early on in the process so that hindrances do not oppose the mission, but instead help to refine it and make it more successful in the long run.

#### DESIGN OBJECTIVES

The design teams for these projects presented important design principles that will be beneficial for Project Tiger Breath. Owens and Simmons<sup>11</sup> made local manufacturing a priority for cutting-costs. Other groups suggested purchasing components from India and China as a means of cutting costs, but direct manufacturing is an important concept that not only will reduce costs, but would also provide local jobs in a resource-poor area. Specific cautions would need to be taken by the group to ensure that manufactures were able to provide quality products without resorting to oppressive labor practices such as child labor and/or non-sustainable wages, but that is beyond the scope of this discussion.

Malkin and Anand<sup>14</sup> addressed the importance of device aesthetics and how they effect the end-user receptivity. Hospital staff members in the implementation centers for the phototherapy program were reluctant to use a fully functional device because in their opinion it looked “homemade.” Being American, the design team had more of a “function-centered” approach and admittedly assumed that the hospital staff would be eager to embrace their device because they had no other option. <sup>14</sup> They failed to take into account the pride and respect that their target cultures had for their own work. The local

workers were offended, and in some manner insulted, by the assumption that they didn't deserve professional appearing products.

#### PROGRAM ELEMENTS

Two programs<sup>13, 14</sup> were able to collect pre-design data from their target regions about what health concerns they wanted to see addressed by new technology design. Another used their personal experience in the target area and generated their own solution to the common problem of disability transportation.<sup>11</sup> For future projects, based on this review I would recommend that significant effort be given to collect pre-design data that identifies specific needs and supports the selection of the proposed project. Otherwise, you may run the risk of creating a product that is neither needed nor implementable.

The researchers were able to incorporate laboratory trials into their implementation plan as the first step to ensure safety and functionality. This step requires an addition phase to be planned as part of the program plan, but it would likely pay dividends by making the real implementation phase more successful. Consistent with the theme of running trials, the teams also planned multi-phased implementation plans. This is important to assume from the outset because it allows a program to accept as "steps" what otherwise would be perceived as failures.

Another important implementation element that this review identified was the use of multi-site implementation as opposed to collecting data from only one site. This approach adds diversity and provides access to greater numbers of patients that can be a part of the evaluation. This facet of the plan could be completed regionally (e.g. multiple hospitals in northern India) or globally (e.g. India, Ghana, Honduras) with different evaluation plans in place for both schemes.

## EVALUATION

None of the studies focused a lot of attention on the evaluation steps of their design programs. This is likely because they were written for a predominantly engineering-based audience. Two programs did collect both qualitative and quantitative data that could be used to define success for the program implementation and guide the next round of design and implementation.<sup>12, 14</sup> Interestingly, none of the programs reported pursuing federal approval for their medical devices. Likely only two programs would have had possible concerns for their devices. Malkin and Anand state, “We believe that very few, if any, medical-device manufacturers in the developed world would build a device for distribution in the developing world without FDA approval or a CE mark. Indeed, under section 802 of the FDA rules, manufactures of a medical device exclusively for export from the United States must still be able to obtain approval, although actually obtaining such approval is not required.”<sup>14</sup> In their view, ignoring these regulatory bodies is an efficient way to reduce costs.

## CONCLUSION

Team-based device design and implementation is a vibrant way for (deleted Western) engineers to be involved in contributing to global health care disparities and fostering international collaboration. These four programs represent the extent of the published literature on low-cost device design for low-resource areas. It is likely that many more devices have been created and have never been published. The programs that were discussed provide general guidelines and a valuable framework for Project Tiger

Breath including being university-based, focusing on longevity, ensuring local relevance, and investigating the project results.

Based on the systematic review, it is evident that good program planning and evaluation are ingredients for a successful medical device program. The following sections will outline the program plan for Project Tiger Breath and discuss how each aspect of program planning and evaluation can be achieved collaboratively.

# PROGRAM PLAN

## OVERVIEW

Project Tiger Breath is intended to develop a method for providing sustained, mechanized ventilation for newborn children in low-resource areas around the world. It is slightly different from most public health interventions because it begins with the development of a physical device that will then be used as part of a program to test and evaluate the device and effectively provide the device to areas where it is of greatest need. The success of Project Tiger Breath depends on the coordinated efforts of engineers, physicians, nurses, patient families, and researchers. The ultimate aim of Project Tiger Breath is to reduce infant mortality in low-resource areas by providing a therapeutic bridge for newborns that are experiencing respiratory distress.

The project was conceptualized while I was working in Duncan Hospital in Bihar, India. Because of this, it is likely that the initial focus of the project and the first round of clinical trials will be in India. Once the device is created and shown to be effective it will not be limited to only the Indian subcontinent.

Duncan Hospital is a 200-bed hospital located in Raxaul, India on the border of Nepal. It is the only secondary referral center run by the voluntary sector for 3 districts in North Bihar (6 million people) and Southern Nepal (5 million people). The service priorities of the hospital are Obstetrics and Gynecology, Medicine, Surgery, Pediatrics, Ophthalmology, Dentistry, and Radiology. They average ~5000 deliveries a year and are staffed by 1 obstetrician and 2-3 junior medical officers. Newborns requiring intensive care are transferred to an intensive care unit (ICU) staffed by an anesthesiologist,



pediatrician, and internist, each of which trained a state-of-the-art medical institutions in the south of India.

Project Tiger Breath will be university-based, capitalizing on the potential of universities as centers for humanistic entrepreneurship with the freedom to innovate for the betterment of society. Their role will be to develop the ventilation device, the Tiger Breath Ventilation Assist Device (VAD). The program plan involves three phases: Development, Implementation, and Evaluation. Each of these phases will be discussed further in the following program plan.

## PROGRAM CONTEXT

### POLITICAL ENVIRONMENT

India is striving to make large leaps in public health in the current political environment. As globalization continues to advance, India is looking to solidify its position as a reputable country well on its way to successful development. The National Rural Health Mission, the government agency in charge of improving health for India, has been working aggressively since 2005 to address maternal and child health in particular along with communicable diseases, hospital quality, overall infrastructure, and the list goes on.<sup>15</sup> Working to effectively provide improved care to children at low cost using resources that already exist in the health care system is likely to not face much political opposition.

### LOCAL, STATE, AND NATIONAL PRIORITIES

I believe that the hardest level to penetrate would be the local priorities. On a state level, Bihar is similar to the old Wild West. The rule of law and policy is often only a formality and bribery actually gets things done. Duncan Hospital operates within this

culture, striving to be above reproach and ethical, not being a part of the lawlessness in their state. State politics and barriers could be overcome, but there may be some opposition such as tariffs or fees.

#### PROVIDERS AND RECIPIENTS

Locally, the staff at Duncan Hospital is composed of well-trained doctors working in a low-resource hospital. I would fear that there might be opposition to using a ventilator that did not look professionally made even if no ventilator is the other option. The device would have to be studied such that it can be proven beneficial and cost-effective as well as manufactured using a professional casing and branding that add to the authenticity of the device. It may be that simply introducing a new device that requires training, adaptation, and maintenance will be overwhelming to the ICU staff. As a primary testing center, Duncan Hospital would receive the devices free of charge, and Project Tiger Breath would be willing to provide the finances needed to conduct the project in Bihar.

#### POSSIBLE FINANCIAL RESOURCES

US-based funding from the NIH and the Bill and Melinda Gates Foundation are possible sources for funding the development and prototype phases of implementation as well as the first year of testing and evaluation. Future expansion of the device is intended to be accomplished using sales and donations. The device is priced such that low-resource hospitals or donors that are interested in serving a specific area could easily purchase it.

#### TECHNICAL FEASIBILITY

The device is designed to be easy to implement into current respiratory protocols. It accommodates ambu bags that are ubiquitous in most hospitals and has few moving parts. The device has well-labeled, easy to use knobs that control the breaths per minute. There are 9 labeled cams that can be used for 9 different combinations of volumes of air delivered at different speeds. The device comes with complete instruction manuals for its few moving parts.

#### STAKEHOLDERS

Because Project Tiger Breath is being completed through collaboration there will be some need to balance the stakeholders in the project. The first design iteration for the Tiger Breath VAD has already been completed at Clemson University. At any given point the project remains my intellectual property as the primary program planner. Clemson University is not interested at this point in continuing the project. As an effort to thank them for their involvement, the device was named after Clemson's mascot, and their involvement will be plainly noted on all materials. In the future, other universities such as UNC-Chapel Hill, Duke, or Wake Forest may collaborate as well. Prior to beginning any future relationships, proprietorship will be discussed.

Hospitals where the device is used will have a large stake in the success of Project Tiger Breath because it is their patients that will be directly affected. The management team for Project Tiger Breath will have to negotiate the impact the program implementation makes on local hospitals, state health departments, and governmental ministries of health.

## GOALS AND OBJECTIVES

### GOAL

To provide low cost effective mechanical ventilation to neonates in under-resourced areas around the world.

### OBJECTIVES

#### SHORT TERM

1. By the end of 2011 the project manager will have identified all components of the design team including university affiliates, medical advisors, international partners, collaborative companies, and private investors.
2. By June 2012 the project manager and associated team members will have applied for and received sufficient funding for furtherance of the project.
3. By the end of 2012 the design team will have a fully functional prototype that has passed laboratory testing and is ready to be implemented in target hospital(s).
4. By the end of 2013 the initial trials will show that the TBVAD is safe and effective as a ventilation device.
5. By the end of 2013, the evaluation team will show that PTB has been implemented in a culturally relevant and beneficial way for the hospitals in which it operates.
6. By the end of 2013, PTB will continue to function in an organized, cost-effective way that is making progress towards the appropriate goals.

#### LONG TERM

7. By the end of 2014 the development team will have distributed the Tiger Breath VAD to at least 50 hospitals
8. By the end of 2015 the development team will have distributed Tiger Breath VAD to at least 150 total hospitals
9. By the end of 2015 completed trials that show a 20% reduction in respiratory-related neonatal mortality
10. By the end of 2016 the development team will reconsider whether the prototype design needs to be readdressed and updated with better technology.

## PROGRAM THEORY

### PROGRAM THEORY

The goal of a program theory is to explain how a specified program will address an identified health problem.<sup>16</sup> The “diffusion of innovation”<sup>17</sup> theoretical model is designed to allow public health practitioners to use their resources most efficiently for “the reach, adoption, implementation, and maintenance of programs.”<sup>17</sup> At the base of this theory is the belief that innovation spreads through a society, rather than being planted as a typical program might. It takes into account the reality that for an innovation to be successful it must be accepted within a social system in a timely manner; first by innovators and early adopters and ultimately reaching the late adopters and laggards in the group.

The main attributes of the theory are as follows: relative advantage, compatibility, complexity, trialability, and observability.<sup>17</sup> I will discuss each of these below.

### DIFFUSION OF INNOVATION THEORETICAL MODEL

Implementing the Tiger Breath VAD will involve developing the device, conducting laboratory testing, designing proof-of-concept studies, implementing the device in hospital protocols, and evaluating the performance. For much of the developing world, there is a disconnect between the technology that is available in modern hospitals and the reality that exists in local wards. It is hoped that this device, being low-cost, simple in design, and similar to current methods will help to bridge the gap as hospitals work on modernizing their intensive care systems.

The plan to implement Tiger Breath will be rooted in the “diffusion of innovation” theory.<sup>17</sup> This theory examines how new ideas overcome their novelty in

order to be spread to become a part of what a society perceives as normal. It accomplishes this based on the following concepts:

#### INNOVATION

The Tiger Breath VAD is a simple device that is meant to make a small and incremental change that improves the outcomes for children and families that require mechanical ventilation in areas where no ventilators exist. This product will be perceived as unique by some institutions simply because it will be an obvious intervention where there had not previously been one. It will create a new barrier of mechanization that will need to be understood by staffs and families at a pivotal point in a new child's life.

#### COMMUNICATION CHANNELS

Information about Project Tiger Breath will be transmitted through a variety of channels. Initially, testing and primary implementation will take place through connections that are established with the design team. Following testing and proof-of-concept evaluation phases, the performance of the Tiger Breath VAD would need to provide specific communications that will demonstrate the value of the product. These communications will need to reach doctors working in the far reaches of low-resource areas, so creativity will be required.

#### SOCIAL SYSTEM

The innovation would need to be adopted by physicians and nurses in rural hospitals. Several barriers are likely to impede full adoption. A similar device, discussed in the Systematic Review<sup>14</sup> was slowly received by staff at the testing hospital because they feared it looked "homemade." Despite having proven efficacy and being well-adapted for their conditions, the device still had to be accepted as legitimate for use on

humans. Many providers that work in rural hospitals around the world trained in university medical centers and would be reluctant to accept a device that deviated from the quality they would expect from a medical device. This will be an objective for the design partners and a final design plan will not be accepted without addressing it.

#### TIME

Adopting the Tiger Breath VAD could happen quickly. The device is budgeted to be produced in an initial order of 1,000 so availability would not be an issue.

Incorporating the device into hospital protocols would be smooth, especially since the protocol would have previously included “teach the parents to control bag compression.”

Ultimately, the time required to diffuse an innovation will be dictated by the effectiveness of the design. The Diffusion of Innovation theory provides a framework for estimating this by defining the key attributes that will determine the rate of diffusion.

#### RELATIVE ADVANTAGE

A new design is only an innovation if it improves the process it is intended for. Tiger Breath is designed to be implemented only in places where mechanical ventilation is not available. If it is proven to operate safely without introducing any hazard to children, it will be likely to be better than having no intervention at all. The studies accomplished in the evaluation will confirm this improvement for hospitals that adopt it.

#### COMPATIBILITY

The Tiger Breath VAD is designed to work easily in a low-resource environment. It is capable of functioning at a range of voltages (up to 220 V found internationally). The Tiger Breath VAD will utilize a battery back-up power system that has a battery that is charged using electricity coming from the grid that is wired in parallel and able to

provide power seamless in the event of rolling power outages. The material is easy to sterilize and has interchangeable parts that can be used while others are being cleaned. The Tiger Breath VAD was designed with compatibility in mind. It can be adjusted to accommodate any style of ambu bag and keeps the moving parts microbiologically isolated from the airway.

#### COMPLEXITY

Incorporating a set of only nine different cams, the Tiger Breath VAD can easily be adjusted and used for a variety of neonate sizes and breath rates. With the turn of a dial and switching of a plastic piece the device can easily work on any given neonate.

#### TRIALABILITY

The innovation will not be easy to try without adopting, simply because of shipping costs. The device can be tried for a short period of time without much of an investment and could be returned if facilities are not satisfied with the device. The advertising of Tiger Breath would include online demonstrations and a full description so that hospitals could be fully informed of their investment prior to purchasing.

#### OBSERVABILITY

The impact of Project Tiger Breath will be simultaneously subtle and apparent. Children that use the machine will likely recover at better rates than they do using only manual ventilation, and that would be encouraging and obvious. In addition to the clinical outcomes seen in the newborns, the Tiger Breath VAD is likely to alleviate much of the psychological and physical stress that parents experience when they bear the responsibility of providing ventilation to their newborn. These effects will likely be large



and valuable and will therefore be studied in the pre- and post-implementation phases so that an improvement can be tracked.

## IMPLEMENTATION PLAN

Project Tiger Breath is a multidisciplinary effort to provide a mechanical device that supplies ventilation for newborns in low-resource areas. In order to do this, it is necessary to ensure that a few essential elements are covered. The program's goal is to ultimately reduce neonatal mortality due to respiratory distress by 20% in the serviced regions within 3 years of the beginning of clinical trials. Along the way, other intermediate goals and requirements will be addressed by the program's activities. The important program activities include device design, clinical trial organization, and product diffusion. Each of these activities will be judged based on core requirements of effectiveness, relevance, and sustainability.

### DEVICE DESIGN

Universities will serve as the incubators for Project Tiger Breath. As seen in the systematic review, the resources and missions of universities enable them to provide multidisciplinary design teams often at little to no cost. By partnering with universities, Project Tiger Breath will accomplish two different purposes. At first glance it seems like the only purpose for partnering with training institutions is to have access to cheap labor, but that focus is too limited in scope. Partnering with students invites them to reconsider their plans for the future and teaches them that their skills are applicable and needed for helping to improve the conditions of people all over the world. This adds to the sustainability not only of Project Tiger Breath, but also of new projects that have yet to be created. Providing globally focused design projects whether as class credit or volunteer activities helps students to develop a more thorough and diverse view of their potential in their chosen career path. Achieving this objective ought to be desirable for

universities leading them to be interested in a partnership.

University teams will be composed primarily of engineering students from either biomedical, electrical, or mechanical engineering as well as other students from disciplines like business, advertising, graphic design, packaging science, etc. They will be led by the project manager and appropriate faculty members. Their responsibility will be to design and optimize the device using the tools and resources at their disposal.

The first design iteration for Project Tiger Breath has already taken place at Clemson University where in the fall of 2010 approximately 25 senior engineering students collaborated as 5 teams to design the first prototype. The students completed this project as part of one of their required design courses. The process required the project manager to prepare a lecture providing the vision for the project, the background information, basic physiology, and design parameters. After that initial meeting, the project manager corresponded with the teams on a weekly basis as they had questions and developed their design. For Clemson, this project did not require additional resources because the students were required to complete some type of design project already. This process will be repeated in future iterations of the product design.

The first objective, scheduled for the end of 2011, is to identify all of the components of the design team, including the university affiliates. The possibilities for partnership include three programs: Clemson University, either with the mechanical engineering department or an Engineers Without Borders chapter; UNC Chapel Hill, in collaboration with the Gillings School of Global Public Health's Innovation Lab; or Wake Forest University where the project manager will be continuing his training. Once the partnership is formed, the university affiliate will be responsible for completing the

final, fully functional prototype by the end of 2012.

### CLINICAL TRIALS

Beginning in 2012, Project Tiger Breath will move into the clinical trial phase. According to Objective 1, the project manager will identify international hospitals that are ready and willing to conduct clinical trials of the device in 2011. The first trials will take place at only one hospital and will be effectiveness trials not superiority trials, with the aim of supporting that the device can be safely implemented. They will be conducted by medical students that have been recruited from either UNC Chapel Hill or Wake Forest Bowman Gray and by local physicians that are personally invested in the project. One or two engineering students will accompany the device to its destination to help with the first few weeks of training the local staff to use the device. The outcomes of these trials will be short-term neonatal outcomes including pulse oximetry readings, blood pH, and discharge from the hospital. Based off of the information collected in the trails, appropriate changes will be made to the device.

The first clinical trial will also test the program's relevance in the low-resource hospital setting. Although extensive predesign data collection will have been done to guide the team, the first clinical trial will confirm their findings. This phase will teach the program planning team about the obstacles that will be prevalent as hospitals begin to incorporate the Tiger Breath VAD into their hospital protocols. It may be that despite the best intentions of the engineers and planning teams there is a risk that the project will not be relevant. Incorporating international partners early in the process as a part of objective 1 in 2011, prior to the trials in 2012 is the best way to minimize this risk and insure project sustainability.

## PRODUCT DIFFUSION

Once the efficacy trial is complete, the design team will incorporate any changes that were deemed necessary following the trial.. At this point, Project Tiger Breath will move into its third phase—product diffusion. Distributing the project will require more input from volunteer and like-minded organizations. The first long-term objective is to have the Tiger Breath VAD distributed to 50 hospitals by 2014. In order for this to happen hospitals, donors, travelling volunteers, and hospital suppliers need to know that it is available.

By the end of 2013, we anticipate having published the findings from the efficacy trial in a global health journal. This will provide a form of advertising to potential physicians that may be interested in purchasing a few products. These physicians may also be willing to help be a part of a long-term trial that can be used to evaluate the success of Project Tiger Breath. Unfortunately, the vast majority of the physicians that could use the Tiger Breath VAD would not have access to journal articles, nor have the time to read them every month.

Project Tiger Breath will have to be more creative and use other avenues for distribution. The most likely source will be to tie into other existing channels for distributing medical devices that other companies use in India, for instance. There is no reason to recreate an infrastructure that already exists. The Tiger Breath VAD should be sold to medical device companies as a product they can then represent and disperse as they would any other device.

American volunteers would likely also serve as an avenue for distribution. The device was designed originally to fit into a suitcase that could be carried to a low-

resource hospital by a visiting volunteer and left as a donation to the hospital. Potential volunteers would find out about Project Tiger Breath through electronic resources such as a website, Twitter feed, and online advertisements. The largest barriers to distribution are ultimately the sustainability of the product and its short-term effectiveness. The ventilation device is budgeted to cost less than \$100 USD, but even that seemingly small of an investment, without significant results the program will never be successful.

### RESOURCES

During the first phase of product design, the program will require minimal resources thanks to the partnership with universities. If funding is secured in time, it would be ideal to be able to provide ~\$1000 to help support the design teams to make multiple prototypes and conduct safety testing. The second phase, which involves travel for at least 4 people, will be the first major expense. Travel expenses will depend on the funding source, but ideally there will be \$10,000 set aside to at least assist the 4 students with the 1-2 months abroad. Once it is time to begin advertising and distributing the Tiger Breath VAD the costs will increase substantially. Depending on the source used, 1 year of advertising would cost ~\$2000/month, or ~\$24,000. This is yet another reason why Project Tiger Breath should focus on using existing medical device sales companies to disperse the Tiger Breath VAD.

### FUNDING

Project Tiger Breath is designed to be sustainable once it has reached a critical distribution, but until that point outside funding will be necessary to sustain the program. Because infant mortality is such an important metric for improving health around the world, several funding organizations are likely to support efforts like Project Tiger Breath.

Objective 2 indicates that by June 2012 the program team will have applied for and received funding that will carry the program through 2016. Currently, the NIH and Bill and Melinda Gates Foundation as well as other smaller foundations prioritize sustainable innovation for addressing the Millennium Development Goals. Other organizations such as the Program for Appropriate Technology in Health (PATH) are potential partners that would be able to provide capital for making the project sustainable early on.

#### SUSTAINABILITY

The best way to ensure sustainability is to design the best product possible that works well, is reliable in variable conditions, and has parts readily available. A recent study of broken medical devices in the developing world showed that the most common causes of machines not working were power supply, user error, and lack of spare parts.<sup>18</sup> The Tiger Breath VAD is designed to work on a variety of power supplies and can be battery operated at any time that power is not available. It is purposely simple to use and is designed using common parts that are more likely to be available overseas.

Overall program sustainability will depend on funding of the program, communication between the partnering organizations, and a commitment to excellence. These elements will be covered more thoroughly in the Evaluation section of this discussion. Ultimately, the program will transition into mostly a manufacturing and distribution program that will be sustained through individuals purchasing the product and using it in their hospitals.

# EVALUATION PLAN

## RATIONALE FOR EVALUATION

In her book *Applying Quality Management in Healthcare*, Diane Kelly states, “Conducting an activity is not the same as achieving the results intended by that activity.”<sup>19</sup> Because this reality is possible, evaluation is a necessary part of the life of a program. In this discussion I will address why an evaluation is necessary for Project Tiger Breath as well as begin to answer a few questions about the evaluation process that are important to discuss at the outset.

Each program will have its own purposes for performing an evaluation. Some parts of an evaluation will be quantitative and goal-oriented. These focus on whether or not the program is producing the desired outcomes and is on track to meet its goals. Other parts will be more qualitative and process-oriented. These parts are concerned with how the outcomes are being obtained and provide information that goes deeper than numerical outcomes. Additionally, because of increasing attention to fiscal accountability in the current funding culture, a program needs to be judged based on its efficiency and cost-effectiveness. These aspects of an evaluation focus on how resources are utilized so that supporters can be confident that their money is being properly appropriated. Ultimately, the purpose of an evaluation is to give structure to the process of continuous quality improvement so that a program can reach its goals as effectively as possible.

For an evaluator of Project Tiger Breath, the role would be three-fold: The project must prove to be safe and medically effective; it must be implemented in a culturally relevant and sustainable way; and it must be progressing towards its goals in a timely fashion. The evaluator will be an important bridge between the high-resource, university



teams and the low-resource, clinical teams that will provide opportunities for objective communication. For Project Tiger Breath, I would recommend that we begin with an internal evaluation, possibly from an experienced board member, during the first 2 years while the project is still in the trial phase. Once the project is in the distribution phase and becomes more sustainable, Project Tiger Breath should budget for and hire an external evaluator that helps to monitor the process from manufacturing to use in a hospital setting.

The stakeholders for Project Tiger Breath include the engineering design team, physician consultants, in-country medical practitioners, and project funders, as well as the patients and their families and the population of the communities in which Project Tiger Breath is implemented. The engineering design team will need to have questions about the safety of the device answered and will want to know areas where it can be improved. Physician consultants will be interested in the outcomes for the children that are using the Tiger Breath Ventilation Assist Device (VAD). In-country practitioners, patients, and communities will want to know that the devices is being used in a way that is beneficial for them, and in a way that is sustainable and profitable for their hospital and community. Finally, the financial stakeholders will want to see that the project is meeting its goals with respect to outcomes and distribution on schedule.

The evaluation will surely face difficulty. The most obvious one is that it will definitely cross countries, and probably function on 4-5 continents. This is why I feel that having an internal auditor that is already comfortable with the idea of crossing cultures and travelling abroad will be helpful for the project. The evaluation will also wrestle with the tension of having to deal with the reality for hospitals that operate in low-resource settings. The evaluation and recommendations will have to be made with a strict

adherence to cost-effectiveness and may need to concede some elements of quality for the sake of sustainability. These challenges will not be easy, but processing through them will ultimately make Project Tiger Breath a better and more successful program.

## EVALUATION STUDY DESIGN

The evaluation for Project Tiger Breath will focus on three basic questions that will be used to judge the success or failure of the project in the short-term:

1. Is the Tiger Breath VAD safe and effective?
2. Is project being implemented in a sustainable way that is culturally relevant and beneficial for the hospitals in which it operates?
3. Do all the stakeholders feel that the project working in an organized, cost-effective way towards the appropriate goals?

The first evaluation question is outcome-oriented and will be addressed in a quasi-experimental. The last two questions are process-oriented and will be addressed using qualitative methods that are more observational in nature.

### OUTCOMES EVALUATION

The primary goal of Project Tiger Breath is to reduce infant mortality in the communities that are supplied with the Tiger Breath VAD. This goal will have short-term, individual outcomes as well as long-term population outcomes. Evaluation question #1 is concerned with the individual outcomes that will serve as intermediate outcomes that will point toward the long-term goal of reducing neonatal mortality. Measuring outcomes in a controlled, hospital environment is easier than some other settings that public health programs function within, but it is not without difficulty. Serious attention will need to be given to ensure that data collection is done in a rigorous fashion.

Question 1 will be addressed using a two-group, prospective quasi-experimental cohort study. Project Tiger Breath plans to have a functional prototype ready for evaluation at the beginning of 2012, however it will have the three partner hospitals

identified by the end of 2011. During 2011, the children that experience respiratory distress syndrome will be used as the unexposed cohort. These children will receive the standard of care in their hospital at the time, either intermittent manual positive pressure ventilation or no ventilation, and their outcomes will be tracked. Throughout 2012, basic records will be collected about the births that take place in the hospital so that the outcomes for children can be reported with per 1000 live-births as a denominator. After 2012, once the Tiger Breath VAD has been delivered and the teams have been trained, the international partners will collect data on the outcomes for all the children born in the hospital that experience respiratory distress syndrome and require ventilation. For the moment, children that are not born inside the hospital will not be included in the study. While this obviously fails to include a large percentage of most rural populations, there is not a way to ensure that treatment could be equal between the two groups.

#### IMPLEMENTATION EVALUATION

The second and third evaluation questions address the implementation of Project Tiger Breath. They will be observational studies that use qualitative measurements. Question 2 is primarily concerned with how the project is being implemented in the low-resource hospitals. As a matter of definition, this question assumes that a program that is being implemented in a context-appropriate way that improves the workplace for international workers is sustainable. The evaluation will be an outcome documentation that is pre-experimental and will collect data from one group (i.e. hospital employees) after the intervention has taken place. These data will then be analyzed and used to improve the Project Tiger Breath implementation process. The motivation for this question come from the results found in the systematic review from Malkin *et al* that

indicate hospital staff not accepting a device as a valid medical device because of its ruggedness can be a cultural insult and a barrier to the success of the program.

The third question will be a similar design, but will focus more on the activities that are taking place in the United States for Project Tiger Breath. This process will be an observational study that documents the outcomes of the program after the first 1-2 year interval. The evaluation will gather information about the budget for Project Tiger Breath compare that to money actually spent. It will also focus on making sure that all of the stakeholders are on the same page with the mission and vision of the project as well as their role in it.

## EVALUATION METHODS

The evaluation for Project Tiger Breath will use several different methods to measure the success of the program. The use of the methods will be somewhat different for each of the three evaluation questions, so they will be dealt with individually.

The first question, which focuses on outcomes, will collect data quantitatively. The information will come from a data registry that is collected prospectively for each of the cohorts of patients. The variables of interest will include maternal demographics, maternal complications, delivery method, delivery complications, birth weight, gender, diagnosis, intrapartum complications, APGARs, time from delivery to recognition of symptoms, time from symptoms to ventilation, duration of ventilation and settings used, neurological function, as well as diagnosis and any laboratory findings. The primary outcome for the study will be discharge from the hospital. Secondary outcomes will include length of time on ventilator, recorded acidosis/alkalosis, and neurological function of the infant at discharge. Data will be collected with respect to each of these variables and will be used in a statistical analysis.

The second question will be addressed qualitatively, deriving most of its information from focus groups and key informant interviews. After the training and implementation the evaluator will conduct focus group discussions with the hospital staff to gather input about their experience of the training and the implementation. The training and implementation will be viewed as two separate events needing to be evaluated, not a time course pre/post-test data collection. The hospital physicians and nurse managers will be interviewed as key informants using a structured interview asking specific questions about the cultural appropriateness of the program. Using these data, the evaluation team

will be able to make suggestions to the Project Tiger Breath board about the implementation of the program.

The third question will use online digital surveys, documentation review, and structured interviews to collect its data. Each of the stakeholders will be sent an online survey that asks them to rate their experience and understanding of the program's mission and vision. These surveys will include free response sections that will allow them to state in their terms their role within the project as well as to explain the mission of the project as they see it. At this point in the evaluation, the evaluator will also review the budget of Project Tiger Breath as well as the actual expenditures and will examine where the money is being spent and make a judgment call (based on the specified goals) whether the program is meeting its goals in a cost-effective manner. If specific issues are raised in the online surveys or in the budget analysis, the stakeholders of interest will be personally interviewed in order to gain as much information about possible shortfalls in Project Tiger Breath.

EVALUATION TABLES

<b>Short-Term Objective 4</b>	By the end of 2013 the initial trials will show that the TBVAD is safe and effective as a ventilation device.	
Evaluation Question	Participant	Evaluation Method
Did Project Tiger Breath complete the initial trials by the end of 2013?	Project manager	Review of records Publication manuscript
Did the trials show that Tiger Breath VAD was a safe device?	Project manager International partners	Statistical analysis Publication manuscript
Did the trials show that Tiger Breath VAD is an effective device?	Project manager International partners	Statistical analysis Publication manuscript
Were the trials run as planned whereby they reduced biases to the fullest extent possible?	Project manager International partners	Review of records Structured interviews for clarification
Were there any issues with the data collection and/or analysis that would invalidate the study?	Project manager International partners	Review of records Structured interviews for clarification
Do the results of the study provide enough information to allow Project Tiger Breath to move forward?	Project manager International partners	Review of records Structured interviews for clarification
Were any weaknesses identified in the trial that could be used to improve the process in future iterations?	Project manager International partners	Publication manuscript Structured interviews

<b>Short-Term Objective 5</b>	By the end of 2013, the evaluation team will show that PTB has been implemented in a culturally relevant and beneficial way for the hospitals in which it operates.	
Evaluation Question	Participant	Evaluation Method
Was Project Tiger Breath implemented in the target hospitals?	International partners	Structured interviews
What was the reaction of the staff to the training program for Project Tiger Breath?	International Partners	Focus Group Discussions
Did conducting the training and the clinical trial increase the staff's knowledge about the management of acute newborns?	International partners	Focus Group Discussion
Did the training and involvement in the clinical trial ultimately change the behavior of the staff in a positive direction?	International partners	Focus Group Discussion
How did the staff feel about being a part of the trial?	International partners	Focus Group Discussion



How did the staff feel about the quality of the device?	International partners	Focus Group Discussion
Does the staff feel that the arrival of the Tiger Breath VAD and its implementation into their practice has been a positive experience for them, their hospital, and patients?	International partners	Focus Group Discussion
Were there any aspects of the implementation plan that could be changed in order to improve the international operation of Project Tiger Breath?	International partners	Focus Group Discussion Structured Interviews

<b>Short-Term Objective 6</b>	By the end of 2013, PTB will continue to function in an organized, cost-effective way that is making progress towards the appropriate goals.	
Evaluation Question	Participant	Evaluation Method
Is Project Tiger Breath functioning as an organized cooperation?	Project manager Advertising partner Manufacturing partner Shipping and processing partner International partner	Document review Online-survey with analyzed free responses Structured interviews
Is Project Tiger Breath function in a cost-effective way?	Project manager	Review of documentation
Do all of the partners feel that they are well informed about the about the vision and direction of the project?	Project manager Advertising partner Manufacturing partner Shipping and processing partner International partner	Document review Online-survey with analyzed free responses Structured interviews
Did Project Tiger Breath stick to its budget in the first two years of operation?	Project manager	Document review
What areas need to be readdressed so that resources can be used most effectively?	Project manager	Document review
Are there any areas where the	Project manager	Online-survey with

communication and involvement amongst partners needs to be changed?	Advertising partner Manufacturing partner Shipping and processing partner International partner	analyzed free responses Structured interviews
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<b>Long-Term Objective 1</b>	By the end of 2014 the development team will have distributed the Tiger Breath VAD to at least 50 hospitals in low-resource countries.	
Evaluation Question	Participant	Evaluation Method
Did Project Tiger Breath distribute VADs to at least 50 hospitals?	Project manager	Document review (orders)
What is the average number of units sold per hospital?	Project manager	Document review (orders)
Have there been any difficulties operating the device that were not anticipated in the design?	Project manager	Structured interview
How do the hospitals use the device, how often and for what conditions?	Partner hospitals	Document reviews (charts)
Do the hospitals feel like the Tiger Breath VAD was a good investment that has improved their outcomes?	Partner hospitals	Structured interview
Are there changes to the way the Tiger Breath VAD is designed, distributed, or implemented that need to be made?	Partner hospitals	Structured interview

<b>Long-Term Objective 2</b>	By the end of 2015 the development team will have distributed Tiger Breath VAD to at least 150 total hospitals in low-resource areas.	
Evaluation Question	Participant	Evaluation Method
Did Project Tiger Breath distribute VADs to at least 510 hospitals?	Project manager	Document review (orders)
What is the average number of units sold per hospital?	Project manager	Document review (orders)
Have there been any difficulties operating the	Project manager	Structured interviews

device that were not anticipated in the design?		
Has Project Tiger Breath adapted to be able to reach this large number of hospitals?	Project manager	Review of budget structure, database Open-ended discussion
Are there changes that need to be made to the leadership structure, information management, or other elements that will ensure Project Tiger Breath's success and future growth?	Project manager, all development partners	Video conference discussion

<b>Long-Term Objective 3</b>	By the end of 2015 completed trials that show a 20% reduction in respiratory-related neonatal mortality.	
Evaluation Question	Participant	Evaluation Method
Did the long-term trials in the 3-5 trial hospitals show a 20% reduction in mortality due to respiratory-related illnesses?	International partners Project manager Trial coordinator	Review report
What was the effect on mortality?	International partners Project manager Trial coordinator	Review report
Are there easily identifiable factors that make these results seem reasonable?	International partners Project manager Trial coordinator	Structured interview
Are there more elusive reasons that need to be considered that led to the results found?	International partners Project manager Trial coordinator	Structured interview
What intangible changes have resulted from the implementation of Project Tiger Breath in the families, staff, and communities affected by the project?	International partners Project manager Trial coordinator	Open-ended discussion
How can Project Tiger Breath use this long term data to improve the use of the Tiger Breath VAD and disseminated it more broadly around the world?	International partners Project manager Trial coordinator	Open-ended discussion

## DISSEMINATION PLAN

Project Tiger Breath will communicate the results of evaluations continuously throughout the course of the program. The first round of evaluation will be disseminated in 2014 summarizing the program performance through 2013 after the short-term objectives have been accomplished. The results will first be distributed to the project manager and the heads of each partnering organization that are a part of the project through a written report and a summary video that presents the results visually so that all of the stakeholders can get a better sense of what the other is doing.

After the heads of each facet have had the opportunity to review the results, individual aspects will be discussed further with the teams that make up each of the program's partnering organizations so that they can gain specific information about how their team can improve the overall program.

The program manager and evaluator will also seek to publish the results of the evaluation in a peer-reviewed scientific journal. The journal ideally will be an international journal with a wide distribution in developing countries that is also archived in PubMed so that interested researchers can easily locate the electronic version. The journal would need to appeal to an audience interested in pediatrics as well as medical technology. This method of dissemination should give potential purchasers awareness of the Tiger Breath VAD and provide them with some indication that it would work in their practice.

Future evaluations that address the long-term goals and objectives will follow a similar distribution plan. At each point in the life of the program greater emphasis will need to be given to different program partners. In the short-term phase, the program will

rely heavily on the design, clinical, and international partners while in the long-term phase there will be more focus on manufacturing and distribution. It is important to notice this transition in the life of the program, but it does not mean that there will be a time where one group's skills are not required e.g. early prototype production will require communication with manufacturing partners, etc.

## DISCUSSION

Developing medical devices that are low cost, easily maintainable, and medically effective is an important part of improving the health of people in low-resource areas.<sup>18</sup>

Project Tiger Breath shows how the idea of one individual, combined with diverse partnerships, can lead to improvements in health for a number of people. It comes on the heels of a movement at the University of North Carolina at Chapel Hill that sees universities as a source for innovation that can make a real impact on the world.<sup>20</sup>

Project Tiger Breath is rooted in a solid program planning methodology that should help to sustain it through the years of actual implementation. The skills learned as part of designing the program can also be rapidly applied to future programs as well.

Developing the program plan gave me the opportunity to clearly outline the background, reasoning, goals, activities, and evaluation of the project so that the necessary partners can be properly informed about the program from the outset. While the literature review was helpful, I believe that I learned as much from meeting with experts in the field of design and business and learning more about the resources available within the university.

I became more convinced that projects of this nature are best accomplished using a university-private partnership. Holden Thorp, the Chancellor of the University of North Carolina at Chapel Hill, along with Buck Goldstein endorsed this concept in their book *Engines of Innovation: The Entrepreneurial University in the Twentieth Century*<sup>20</sup> In their minds, universities need to carry their innovative thoughts through into real tangible translation, not just theoretical forms of translation. At the same time, business can open up new and creative market places in conjunction with the innovation streaming from universities. Relevant to Project Tiger Breath, the popular medical device company

General Electric (GE) has begun to enter the market of low-resource medical devices and shamefully acknowledge they intend to make a profit. Forays like this are only possible with the partnership of years of university-based research in epidemiology, public health, and medicine. Companies like GE are in the perfect position to partner with large university initiatives, multilateral funders, and international partners to lead new advances in medical technology.

My research into this topic has also shown me that Project Tiger Breath would be a small partner in a larger network of globally-minded design engineers. Engineering World Health (EWH)<sup>21</sup> is one such organization that comprises over 2000 engineers from six countries that is focused on developing creative solutions to some of the world's most prevalent problems.<sup>9</sup> In the future, Project Tiger Breath could learn from their methodology if new ideas are pursued as separate programs.

Unlike Project Tiger Breath's inception as an idea that immediately sought a prototype, EWH encourages engineers to create prototype only for what they call "Projects that Matter" ranging from new blood pressure measuring devices to neonatal incubators.<sup>21</sup> They also discourage prototype development until a manufacturer has been identified that can guarantee a feasible manufacturing plan.<sup>21</sup> Without this, too many well-intentioned products get lost in the pipeline of development and never make it to the market.<sup>10</sup> More than 95% of medical devices that are used in public hospitals in low-resource settings are imported, predominantly from China.<sup>18</sup> Learning this fact helped to shape Project Tiger Breath by making identifying a manufacturing partner a short-term objective that should come before prototype completion.

One long-term goal of Project Tiger Breath that cannot be understated is the desire to inspire new generations of globally-minded engineers. This intention is illustrated in the logic model found in the Appendix as Figure 1A. EWH along with other organizations have been able to accomplish this well. Ideally, the all results of Project Tiger Breath will not be easily measured in the evaluation. Some of them will come in the hearts of twenty-year-old men and women that travel with the devices to see the developing world for the first time. They will be seen in the jobs they choose, whether or not the pursue further education, and what projects they pursue in the future. There will probably not be a large enough cohort from the 2-3 design iterations at the partner universities to organize a study, but one possible future avenue of evaluation would to try and contact students affected by Project Tiger Breath and similar organizations to see what impact it made on their lives twenty years down the road.

Being grounded in the foundation of program theory and using rigorous programming and evaluation tools, Project Tiger Breath has potential to succeed through to implementation and effectual change. It will be a cross-cultural and transcontinental example of the human network working together to improve the lives of some of our most valuable members, children.



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## APPENDIX

Table 1. Review of Studies Discussed in the Systematic Review

(⊖: Not present ●: Present)

	Trait	The Skeeter	Recycled Incubators	Hand Scale	PhotoTx
Project Organization	University-based organization	●	●	●	●
	Advocated team leadership structure	⊖	⊖	●	●
	External funding source	⊖	⊖	⊖	⊖
	Long-term plan	●	⊖	●	●
	Partnership with non-university group	●	⊖	●	●
	Consider microfinance as funding	●	⊖	⊖	⊖
Design Objectives	Low-cost (<10% of commercial cost)	●	⊖	●	●
	Manufactured in target country	●	⊖	⊖	⊖
	Locally repairable	●	●	⊖	●
	Improvement upon available technology at the same cost	●	●	●	●
	Safe to use	●	●	●	●
	Durable	●	●	●	●
	Consistent	●	●	●	●
	Adaptable to varying power supplies	N/A	●	N/A	●
	Aesthetically pleasing	●	●	●	●
	Simple construction	●	⊖	●	⊖
	Stable in local environment	●	●	●	●
	Program Elements	Had previous design failure	●	⊖	●
Pre-design data collection		⊖	⊖	●	●
Laboratory testing		⊖	●	⊖	●
Multisite implementation		⊖	●	⊖	●
Phased implementation		⊖	⊖	●	●
Staff training		⊖	⊖	●	●
Accounted for device delivery		⊖	⊖	N/A	●
Evaluation	Quantitative data collection	⊖	●	●	⊖
	Qualitative data collection from staff	⊖	●	●	●
	Qualitative data collection from patients	⊖	⊖	⊖	⊖
	Plans for future development	⊖	⊖	⊖	⊖
	Seek FDA/CE approval	⊖	⊖	⊖	⊖

# PROJECT TIGER BREATH LOGIC MODEL

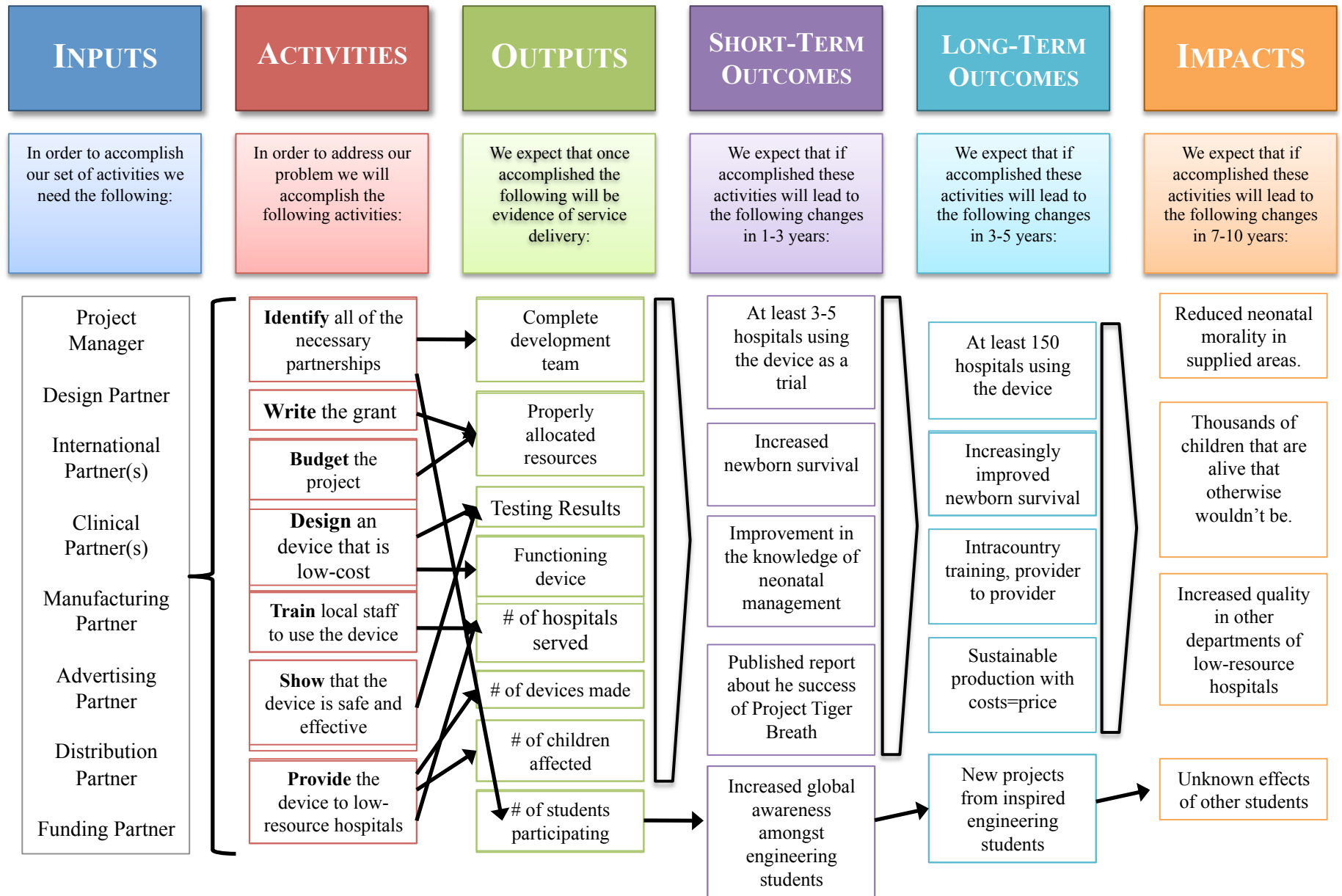


Figure 1A. Logic Model for Project Tiger Breath