Developing the Business Model for a Novel BioMedical Device and Evaluating Cross-Disciplinary Projects

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Abstract

According to the World Health Organization, approximately 15 million babies are born prematurely annually. A premature birth can carry significant health and mortality risks. To thrive, many of these babies require additional care from parents and medical professionals, including feeding. The most popular method to nourish premature babies is through enteral feeding pumps. The goal of our project is to work with biomedical engineering students to create a low-cost automatic feeding pump alternative and enter the Ghanaian market to improve the quality and efficiency of feeding premature babies in Ghanaian hospitals. Our industrial engineering team collected data, conducted expert interviews, and performed risk and market analysis, to determine the best avenues to pursue in terms of manufacturing, assembly, customer choice, and projected outcomes. Given the current prototype design of the feeding pump, our analyses determined it is most economical and less risky to manufacture product parts in the United States and assemble the feeding pump in Ghana. The results of the Business Model Canvas laid the groundwork for subsequent venture evaluation as the prototype is further developed. We also performed a process improvement analysis to evaluate and guide future opportunities for cross-disciplinary student project work. Our team recommends the use of agile methodology for meetings and deliverables, and an online software hub consisting of a central repository for all work and seamless communication between every team.

Authorship

This project was completed through a collaborative effort between project team members: Matthew Finn, Elizabeth Hagan, Salvatore Lombardo, Samantha Mendez, and Jose Andres Sanchez. Each group member had equal contribution to all chapters of the paper, working together to write, edit, and discuss all sections.

Acknowledgments

This project could not have been completed without the support and guidance we received from our advisor, Professor Renata Konrad, PhD, our sponsor, Professor Solomon Mensah, PhD, and his company, Therapeutic Innovations. We would like to thank the Biomedical Engineering MQP Team consisting of Akansha Deshpande, Joelle Hanley, Isablle Ting, and Julie Webster. We would also like to thank Adnrey Tetteh and Nathaniel Adibuer – biomedical engineering students from the University of Ghana. Finally, we would like to thank the WPI Foisie Business School professors for participating in interviews for data collection.

Executive Summary

Overview of Problems Addressed

Automatic feeding and drug delivery pumps are often too expensive for universal use in developing countries' healthcare systems. The vast majority of hospitals in these countries resort to using manual pumps which can be inconvenient to nurses and provides less consistent changing of formula. A lower-cost automatic device, one that is affordable and effective for hospitals, offers an opportunity to replace manual pumps and reduce errors, which in turn can decrease mortality rates. Introducing an automated device requires determining(1) whether healthcare systems are interested in such a product, (2) the support a country's manufacturing infrastructure can offer to produce automated pumps, (3) technical and financial feasibility of the product itself, and (4) costs and benefits associated with the implementation of these devices in hospitals. We answer these questions for the Ghanaian healthcare system. This project provides analyses of these factors and provides a roadmap for future action. In addition to these analyses, we have also taken our own experiences and addressed the opportunities and problems that large cross-disciplinary MQP project teams may face in a product development setting.

Background Information

A baby is classified premature if they are born prior to the 37th week of pregnancy. These babies face a higher risk of death due to complications such as undeveloped lungs, difficulty with regulation temperature, higher infection, among other complications. In Ghana, about 14% of babies are born prematurely, and these babies tend to need additional care and nutrition. To meet these needs, feeding and drug-delivering devices were developed. These pumps are designed to ensure that patients are receiving consistent amounts of nutrition eternally, which is necessary for premature babies. The problem with these medical devices is that they are too expensive for universal use in developing countries. Another concern involves Ghana's manufacturing infrastructure and whether or not the existing infrastructure can support a new medical device.

Objectives of this Project

The main goal of this project was to begin the development of the business model for the novel feeding pump device in the Ghanaian market. We identified three objectives to meet this goal.

1) Identify a possible supply chain through interviews and desktop research.

2) Establish and quantify the viability of the product through risk analyses(, cost-benefit analysis, economic evaluation, Monte Carlo simulation) and business analyses (BMC, PESTELE, Five Forces)
3) Generate a set of recommendations on how to proceed with this product to our sponsor, Therapeutic Innovations, and possibly a future MQP team.

Methodology

To accomplish the objectives, the team developed a project map. There are four areas of our work: (1) data collection; (2) risk analyses; (3) a business model, all leading up to (4) our deliverables. The main structure of this project revolved around the Business Model Canvas (BMC). The BMC helped the team cover each aspect of the project setting up a comprehensive canvas regarding the different key aspects of developing the novel feeding pump. To develop the BMC, the team first needed to collect as much data as possible to be able to complete our various analyses. Data collection was done by searching peer-reviewed publications, textbooks, and other sources accessed through the George C. Gordon Library at WPI. We also interviewed experts in Ghana and collaborated with the WPI Biomedical Team and WPI Professors in the Foisie Business School.

- The collected data informed our analyses: an analysis of Ghanaian market factors, product specific risk analyses, Monte Carlo simulations, and production analyses. Such analyses are necessary because of all the uncertainties in the development, production, and delivery of the feeding pump. For analyzing Ghanaian market factors the business team developed both a P.E.S.T.E.L.E analysis and a Porter's Five Forces analysis to better understand how healthcare and manufacturing systems in Ghana will be affected by national policies and regulations. This also helped the team analyse the feasibility of manufacturing in Ghana and selling to Ghanaian health services.
- Product specific analyses included a Failure Modes and Effects Analysis (FMEA) to identify the components or pieces of equipment in a production process that are most likely to fail. The FMEA also identified the components that will have the greatest impact on the product if failure occurs. A Product life cycle helped visualize how this product would progress through different stages: (1) market development; (2) market growth; (3) market maturity, and (4) market decline. Lastly, a Fault Tree Analysis qualitatively and quantitatively analysed the risk of failures within a critical system and its causes.

Significant uncertainty existed in the process of making forecasts regarding a new product's costs, revenues, and market demand. Rather than using an estimated, single point average for these uncertain variables to run predictions, the Monte Carlo Simulation technique was employed using an Excel add-in @Risk. Five Monte Carlo simulations were conducted to solidify our understanding of the uncertainty surrounding different decisions of our project:

1. **Cost-Benefit Analysis -** estimated production costs for all aspects of production (manufacturing, materials, assembly, and distribution) and potential demand projections.
2. **Simplified Cost-Benefit Analysis**. Analyzed a single pump's costs vs monetary benefit with the materials costs as the sole variable.
3. **Time to Market Prediction-** included Research & Development (R&D), testing (including prototyping), obtaining medical regulation approval, assembly, and distribution to hospitals.
4. **Detailed Cost-Benefit Analysis-** helped to further analyze how different stakeholders could be positively affected by a new and improved device.
5. **Decision Tree Model-** reflected the variability of decision alternatives the team can make regarding manufacturing and assembly locations.

The last simulation analyses conducted included manufacturing and logistical capabilities. With the development of a new product, there are many logistical and manufacturing considerations that are integral to successful production and distribution of the product. The team started off by researching a manufacturing plan that would be able to incorporate forecasting a demand, determining a production process, and monitoring and adjusting. Researching the supply chain of the healthcare industry played a vital part in the teams understanding of the feasibility of distribution of this device in Ghana.

- The final analysis developed an **economic evaluation model** to assess the Venture Survivability if a team or company were to produce this novel feeding pump. The economic evaluation compiled fixed and variable costs, (obtained from our data collection), involved in establishing the framework for manufacturing. The economic evaluation helped the team ascertain whether the profit made from this device over the course of ten years will justify the initial investment. Similar to the Monte Carlo Simulations this model is able to adapt to different scenarios based on different inputs, making it a useful tool to fully comprehend the process from idea to market.

Upon completing the four parts of our methodology, the results were analyzed and formed into a flushed business model proposal stemming from the Business Model Canvas. The BMC described the various facets of the venture and the progress into investigating them that has already been made.

The team also included process improvement suggestions regarding MQP cross-disciplinary MQP structure. The goal of this chapter is to self-evaluate how effectively this MQP worked, identify the obstacles faced over its tenure, and make the case to cement cross-disciplinary projects within the WPI MQP framework to fully harness the potential of the students, professors, and sponsors.

Analysis Results

Our risk and logistical analyses provided a solid understanding of the potential future avenues for this project. The main takeaway of our analyses is that it would be in the best economic interest to manufacture the feeding pump parts in the United States and assemble them in Ghana. This conclusion came from a thorough economic evaluation paired with a decision tree and Monte Carlo analysis. The economic evaluation also thoroughly examined potential future profits, pulling all the data we were able to collect about the pump and the market, estimating 10-year profit to be over $579,000. Other results focus on time to market, return on investment, part costs, and an understanding of Ghanaian market factors which are summarized in Chapter 4 Results.

Recommendations and Conclusions

The Business Model Canvas provides a foundation for future MQP teams to investigate and then build upon working on the development of an automated feeding pump for countries with a developing economy. This template is meant to evolve as product prototyping is completed. A recommended starting point for future work is making a patent decision and determining the financial plans. We recommended that further interviews be conducted and the data gathered to be included in our analyses for a more accurate development plan. Finally, based on our experience, the team concludes with recommendations for future cross-disciplinary projects and provides a Canvas page with helpful resources including agile methodology and communication options.

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Chapter 1: Introduction

1.1 Project Background

According to the World Health Organization (WHO), an estimated 15 million babies are born prematurely, and that number rises annually (World Health Organization, 2018). A premature birth is defined as a birth that occurs before week 37 of pregnancy (Centers for Disease Control and Prevention, 2019). A premature baby faces a higher risk of death and complications the earlier they are born. Globally, the leading cause of death in children under the age of 5 is due to complications from prematurity (Every Preemie Scale, 2015). About 60% of global preterm births occur in Sub-Saharan Africa and South Asia (Every Preemie Scale, 2015).

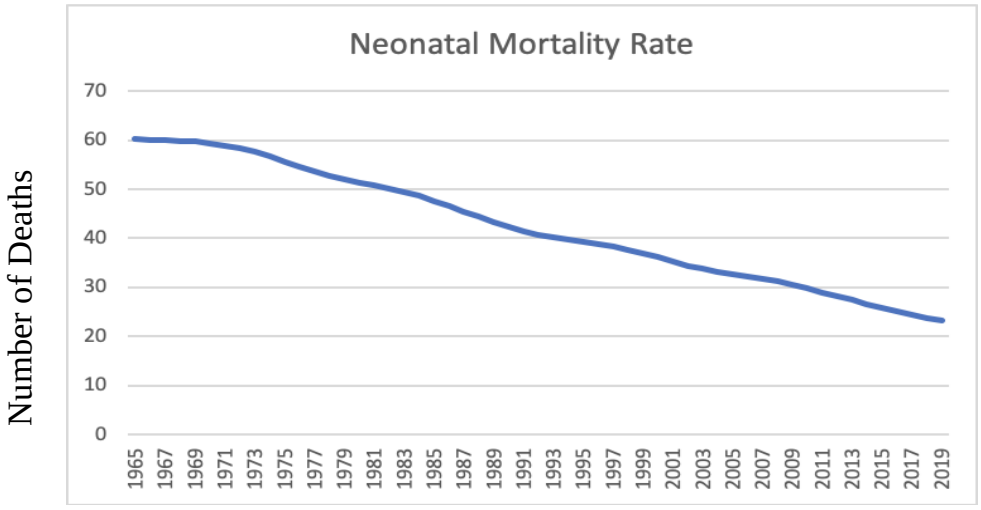


Figure 1.1: Trends in Neonatal Mortality Rates in Ghana (Child Mortality 2019)

In Ghana, about 14% of babies are born prematurely (Ghana Health Service, 2015), compared to 10% of babies in the U.S. (Centers for Disease Control and Prevention, 2019). In 2019, about 23 neonatal deaths out of 1000 births in Ghana occurred within the first month of life (Every Preemie Scale, 2015). The leading cause of death of premature babies in Ghana is due to preterm birth complications and infections. On a positive note, the neonatal mortality rate in Ghana has declined over the past five decades due to improved care plans, which can be seen in Figure 1 (Child Mortality, 2019).

The use of enteral feeding pumps is widespread across the globe for all ages, as these medical devices are considered the most accurate and effective mechanism to provide nutrition enterally. For premature babies, these pumps can provide the extra protein, calories, iron, calcium, and vitamins that they need to reach and maintain a healthy state after birth (White and King, 2014). The design of the pump typically allows for constant feeding necessary for

premature babies to thrive and thus many factors need to be considered in its production. Foremost, an accurate and consistent feeding formula is essential. Tube misconnection errors also must be minimized and the chemical composition of the casing used in the pump's manufacturing needs to be safe (Freijer, et al., 2014). Another design consideration is whether to create an open system pump or a closed system pump; both designs face cost and benefit tradeoffs and make for effective hospital use in different ways.

1.2 Project Problem Statement

Premature babies require additional nutrition in an efficient manner. Feeding and drug delivery pumps have been designed for this purpose; however, this medical device is too expensive for universal use in developing countries' healthcare systems. In partnership with two other student teams, this project is designing an alternative product to meet the market needs for feeding and drug delivery pumps for premature babies in Ghana.

Specifically, this report addresses the business aspect of producing such a product. What the project team is trying to establish is the technical, financial, cultural, and social feasibility of this new product in Ghana.

It is unknown whether or not Ghana's insurance programs, private hospitals, or any third-party support systems would be able to invest in a new feeding and drug delivery pump. Questions about logistics and competition raise problems for new device advancement. Another issue in Ghana is manufacturing. There is uncertainty with how Ghana's current manufacturing infrastructure can support the production of medical devices. Risks involved with the lifecycle of a new product in Ghana must be analyzed.

1.3 Project Goal

The overarching goal of this project is to develop a novel, low-cost feeding pump for premature babies in Ghana. This project has been broken down into three separate but collaborative teams: (1) a WPI-based biomedical engineering team (2) a University of Ghana biomedical engineering team, and (3) this WPI-based management engineering and industrial engineering team. This project team's goal is to develop the business model and short-term strategy for the Along with this, our team will use this project and others completed before as case studies to evaluate the role of cross-disciplinary MQPs. Currently, there is not a specific structure for these multi-department projects and therefore there may be value that is being lost.

1.4 Project Objectives

To meet our project goal of assessing the viability of a new feeding-pump for premature babies in Ghana, we identified the following three objectives:

1) Establish the viability of the product through various risk analyses and other quantitative business analyses.

2) Generate a set of recommendations on how to proceed on with this product to our sponsor, Therapeutic Innovations, and possibly a future MQP team.
3) Identify possible routes for the venture's supply chain through interviews and desktop research.
4)

1.5 Evaluation of WPI Cross-Disciplinary MQP Process and Structure

. A multi-year, cross-disciplinary project, such as ours, has the opportunity to benefit all parties involved with the MQP. For the students, the projects can mirror the working environments they will enter upon starting full-time. They may also find greater satisfaction in the impact of their projects while using many of the soft, and hard, skills they gained over the course of their studies at WPI. For the professors advising a cross-disciplinary project, such projects present an opportunity to invest in more complex, interdisciplinary projects. By having a structure that dedicates MQP teams to continue to develop specific ideas, professors are potentially able to increase research productivity. The university will also benefit because of the opportunity to potentially commercialize the promising products developed over several MQP projects . By joining an engineering or science discipline with a team from the Foisie Business School, the projects will gain the entrepreneurial analyses necessary to bring a product to realization. At the conclusion of this project, the team will reflect on all aspects of working across disciplines; what worked well, what did not, and how can WPI capitalize on this opportunity.

Chapter 2: Background

2.1 Ghana Overview

2.1.1 Economy

Ghana's economy has been growing steadily for the last decade. GDP growth in 2019 was 6.7% compared to the previous year's 5.4%. Over the past year, the service sector grew about 6% and private sector credit has also shown significant growth. Manufacturing makes up 10.44% of Ghana's GDP (Ghana-Manufacturing, n.d.). Health spending is 3.26% of GDP, compared to a worldwide average of 6.56%. Inflation is between 6-10% and is projected to remain around there in the future. One fiscal risk for Ghana is its tanking energy sector and this will be the main issue during the 2020 elections. Regardless, the nation's economy is on the rise and a 2019 increase in both imports and exports with the United States brings optimism for larger growth in the future (World Bank, 2019).

2.1.2 Population

Ghana has a population of 31.2 million people with an annual growth of 2.15%. Approximately 57% of Ghana's population lives in urban areas and the three most populated cities are Accra, Kumasi, and Tamale. The median age is 21.5 and life expectancy average is 64.9 years. The infant mortality rate is 30.8 per 1,000 births and the death rate of children under 5 years old is 44.7 per 1,000. The population will continue to increase as there are 3.9 births per woman while only 2.1 births per woman are necessary to keep the population stationary (United Nations, 2019).

2.1.3 Industries

Dominant industries in Ghana are mining, energy, tourism, and agriculture. The mining industry is responsible for over 5% of Ghana's GDP and the mined minerals comprises 37% of their total exports. Gold is the most valued mining mineral and accounts for 90% of mineral exports, other minerals include manganese, bauxite, and diamonds. Ghana's energy industry uses renewable energy sources, fossil-fuels, and hydropower. Ghana's Nzema project is the largest solar energy plant in the world, and has class 4-6 wind energy resources throughout the country. Ghana generates over 49% of their power from these renewable sources. Tourism is another main industry and is responsible for 4.8% of the GDP. Ghana attracts over 500,000 visitors who produce over $2 billion in revenue and around 360,000 employment opportunities for Ghanaians. The agricultural sector accounts for over 54% of the nation's workforce. The leading agricultural export is cocoa and additional crops are tobacco, cane sugar, rubber, palm oil, and cotton (Oxford Business Group, 2019).

2.2 The Ghanaian Hospital System

2.2.1 Hospital Statistics and Information

Ghana's healthcare system aims to, "improve access to quality, efficient, and seamless health services that are gender and youth friendly and responsive to the needs of people of all ages in all parts of the country" (Ministry of Health, 2014). District hospitals serve as the first referral placement, followed by regional hospitals which offer more specialized services rather than the general care provided at district hospitals. Beyond these public hospitals, there are also private and religiously affiliated hospitals. Most of the 1,800 public and 1,300 private hospitals are in urban areas, while the 200 religious hospitals are typically in rural areas and offer fewer services (Aetna, 2019). Some specialty care is offered at private hospitals, but many people need to travel out of the country for specialized services, such as surgeries (Aetna, 2019).

2.2.2 Health Insurance

The National Health Insurance Authority (NHIA) was established by the Ghanaian government under the National Health Insurance Act in 2003 (NHIS, 2020). The goal of this authority is to ensure access to basic healthcare services to all residents. Residents of the country may also belong to one of fourteen currently cleared private health insurance companies operating in Ghana (*Private Health Insurance - NHIS* 2020). As of 2017, 35% (10.3 million) of Ghanaian citizens were covered under the NHIS (Nsiah-Boateng & Aikins, 2018). The tax-financed service covers 95% of disease affecting the Ghanaian, minor surgeries, maternal care services, ear-nose-throat (ENT) services, general hospital admissions, and all emergency services (*Benefits Package - NHIS* 2020). Within the umbrella of maternal care services covered by NHIS is postnatal care, which, as of a World Health Organization ruling in 1970, extends services to the baby for up to forty-two days after birth (World Health Organization, 1970). Therefore, it can be reasonably assumed that the feeding/drug delivery tube this project intends to create has an avenue for acceptance within the Ghanaian hospital system without burdening the family of the recipient.

2.3 Overview of Biomedical Device Industry in Ghana

2.3.1 Government Regulations of Biomedical Devices

The Food and Drug Authority in Ghana was established in August of 1992 and was elevated to a Level 3 regulator by the World Health Organization (World Health Organization, 2020). Throughout all of Africa's 47 countries, only two: Ghana and Tanzania, have reached a Level 3 ranking. The Ghanaian FDA is closely modeled after the European Medicines Agency (EMA) and has become a hotspot for Indian and Chinese medical device companies as both nations vie for strong economic ties with the booming West African countries. (U.S. Department of Commerce, 2020) One major difference between the Ghanaian FDA and the EMA models is that all medical device approvals must go through the centralized FDA and not through another

certified regulatory body (Norman, 2016). The guidelines for medical device registration can be found in Appendices A through C.

2.3.2 Manufacturing Capabilities

Medical equipment is not locally manufactured for the most part, but entirely imported. Ghana has very limited local production of pharmaceuticals and even less manufacturing of equipment and devices; the country relies on imports for approximately 80% of its total healthcare pharmaceutical and equipment purchases (Geck). There is potential to resell the used equipment from the private health institutions, which are growing in number. There are a few local pharmaceutical producers producing generic medications such as painkillers and cough mixtures. All other pharmaceuticals are imported, mostly from Europe and India(Geck). Ghana has sought to introduce more private sector participation into the healthcare sector and the most dynamic growth and most exciting opportunities will be found in privately invested hospitals and clinics and in the non-state controlled portion of the pharmaceutical sector. Although U.S. products are highly regarded in Ghana, their higher price limits their market (Geck). Nevertheless, the prospect for increased U.S. pharmaceuticals and medical equipment and supplies to Ghana remain strong.

2.3.3 Sourcing

Ghana's health market is one of the largest markets in the Sub-Saharan African region and is expected to grow exponentially (Business Wire, 2018). In the past 20 years, there has been a growing presence of Chinese and Indian companies selling products to the health care sector, indicating the majority of healthcare products are imported (Healthcare Resource Guide: Ghana, 2018). Even though Ghana is a large healthcare market, it is lacking in reliable medical equipment (Bitran, 2011). This leaves many hospitals and doctors without a local source for medical devices. According to experts, there are four main factors that should be considered when selecting a supplier in Ghana: industry experience, product quality, local references in Ghana, and accreditation (Van Arsdale, n.d.).

2.3.4 Logistics

The Ghana Public Health sector operates a three-tier system for the management of health medicines and health supply distribution. The Central Medical Stores (CMS), the Regional Medical Stores (RMS) and the Service Delivery Points (SDP) together with the transportation network constitute the supply chain (Figure 2.1) The CMS unit is responsible for the receipt, storage, and distribution of all commodities procured by the Ministry of Health. Lower levels get supplies from the CMS through the pull or demand system (Raja). Health services in Ghana are provided by both the public and private sectors, including hospitals supported by faith-based organizations. The public sector, which is supported by the government accounts for over 70 percent of the institutions (Raja). As of 2009, the country has 1887 health

facilities, including three teaching hospitals and three psychiatric hospitals (Nsiah-Asare). Nine Regional Hospitals, 86 district hospitals, 11 polyclinics, and 927 health centers under the Ghana Health Service(GHS) represent about 55 percent of the total facilities (Nsiah-Asare).

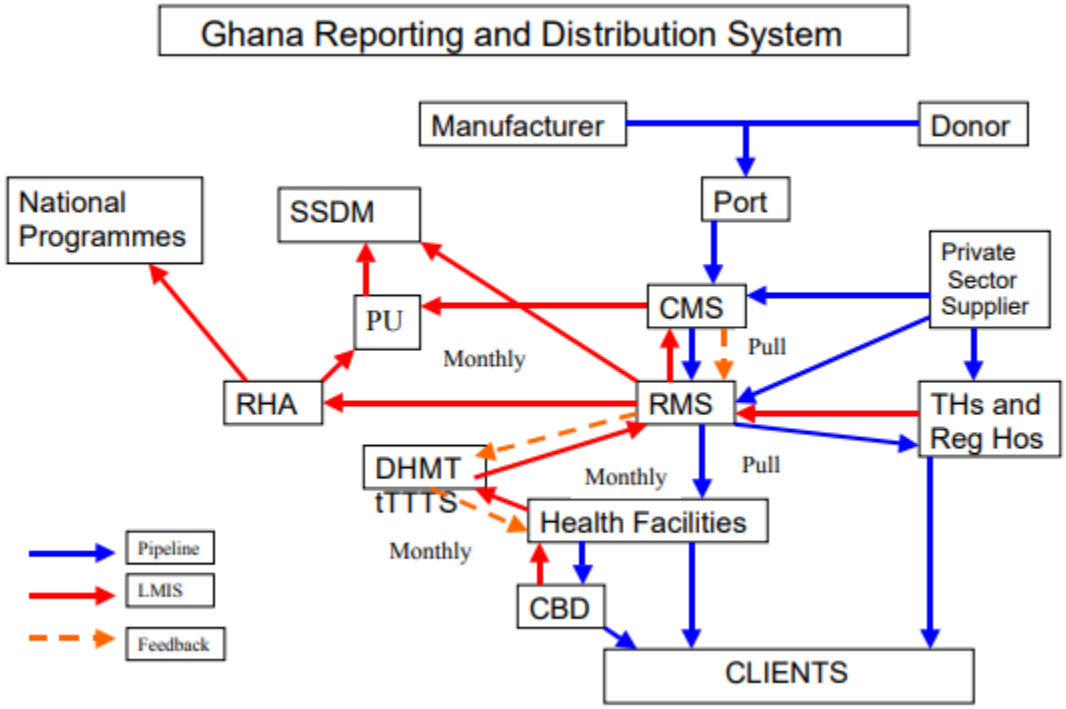


Figure 2.1: Structure of the pharmaceutical and health supplies logistics system in Ghana(Bossert)

2.4 Feeding and Drug Delivery Pumps

2.4.1 Device and Functionality

There are many integral features in the design of a feeding pump that are considered standard. Automatic priming and dose setting are important for device efficiency. A standard hospital pump must have advanced memory and continuing use of easily loaded feed. This allows for one-handed consistent pump setup (Philips, 2013). Another function of most feeding pump devices is flow rate selection. Being able to select the flow rate of the pump allows the user to give incremental increases in nutrient delivery. This is helpful because in critical care settings, it's important to maintain a balance between patient tolerance and the maximization of feeding volume. A common flow rate selection option is between 1-300mL and in 1mL increments. In pediatric settings, it's important that the flow rate is accurate within ±5% (White and King, 2014). The device is also often equipped with either a continuous or incremental feeding program, or sometimes both, depending on the patients' needs. A 24-hour battery is also standard (White and King, 2014).

2.4.2 Cost-Effectiveness and Value

The economic evaluation of feeding and drug delivery pumps focuses heavily on the quality adjusted life years (QALY) of patients and the clinical outcomes of the product (for a discussion on QALYs see Prieto and Sacristan, 2003. When analyzing cost-effectiveness for pumps, a comparison has to be made between open system and closed system pumps. Open system pumps often create less wastage of formula. These pumps give precise volumes of formula but the nurse has to change the container more often, usually every four to six hours. Open system pumps are also known to have reduced microbial safety (Bristol, Meer, et al., 2008). In contrast, closed pumps have preset feeding values, potentially resulting in wasted formula. However, they have 24-hour hanging times which requires less nursing work and are known to have more microbial safety (Freijer, Bours, et al., 2014). All factors considered, it is usually concluded that the need for increased nursing costs for operating open system pumps outweighs the initial larger cost of a closed system pump (Bristol, Meer, et al., 2008).

2.4.3 Overview of Feeding Pump Devices in the United States Market

In the United States, there are many different feeding pump suppliers and the devices come in various designs. Some pumps are made specifically for at-home use as well. These devices are cheaper and available for rent the majority of the time. Some are just for breast milk but most offer the delivery of any formulae. Pumps in the US almost always have a 24-hour battery life and options for continuous feeding (American Academy of Pediatrics, 2009). For example, a popular supplier is URS Medical. They supply the “Infinity Orange”, a pump made specifically for breast milk, the “EnteraLite Infinity”, a more versatile system for any nutritional delivery that can be brought home, the “Kangaroo Connect” which is brought home but manually controlled by a nurse in the hospital, and the “Kangaroo Joey” that includes new automated feeding and flush technology (URS Medical, 2020).There are more pumps and suppliers with a wide range of functions in the US, but the majority of the devices are designed for continuous delivery of any kind of nutrition.

2.4.4 Overview of Feeding Pump Devices in the Ghana Market

An example of a feeding pump used in Ghana is the Enteral Feeding Pump XB-400 (see Figure 2.2). This device offers a lot of similar features as many standard US hospital pumps. The device is portable and has an automated self-check function. It also has preset feeding volumes like the standard closed system pump in the US. This pump comes with advanced memory and flow rate selection, along with an accuracy of ±10% (Parecho Tech, 2016). For critical care settings in hospitals, these features are likely required universally for the safety and nourishment of premature babies.

Figure 2.2: Enteral Feeding Pump XB-400

2.5 Therapeutic Innovations

Therapeutic Innovations is a company our sponsor, Professor Solomon Mensah, co-founded and is currently the CEO. Therapeutic Innovations works to reduce the prevalence of illness and mortality due to inadequate or lack of medical devices. Therapeutic Innovations first started with a product they call the Airbab, this is a device that provides the adequate mix of oxygen and air at the right concentrations, humidity and temperature for preterm babies to assist in breathing. The idea and support for this project is attributed to Professor Mensah and Therapeutic Innovations.

Chapter 3: Methodology

3.1 Project Layout

To give the project structure, the following project map shows the progression from data collection through to the deliverables, categorized in four sections. Each of the sections are described in detail in this chapter. The data collection methods are used for analyses regarding the introduction of a new medical device in a market with a developing economy. These analyses then populate our venture survivability measurements and Business Model Canvas. The deliverables are then derived from the measurements and Business Model Canvas.

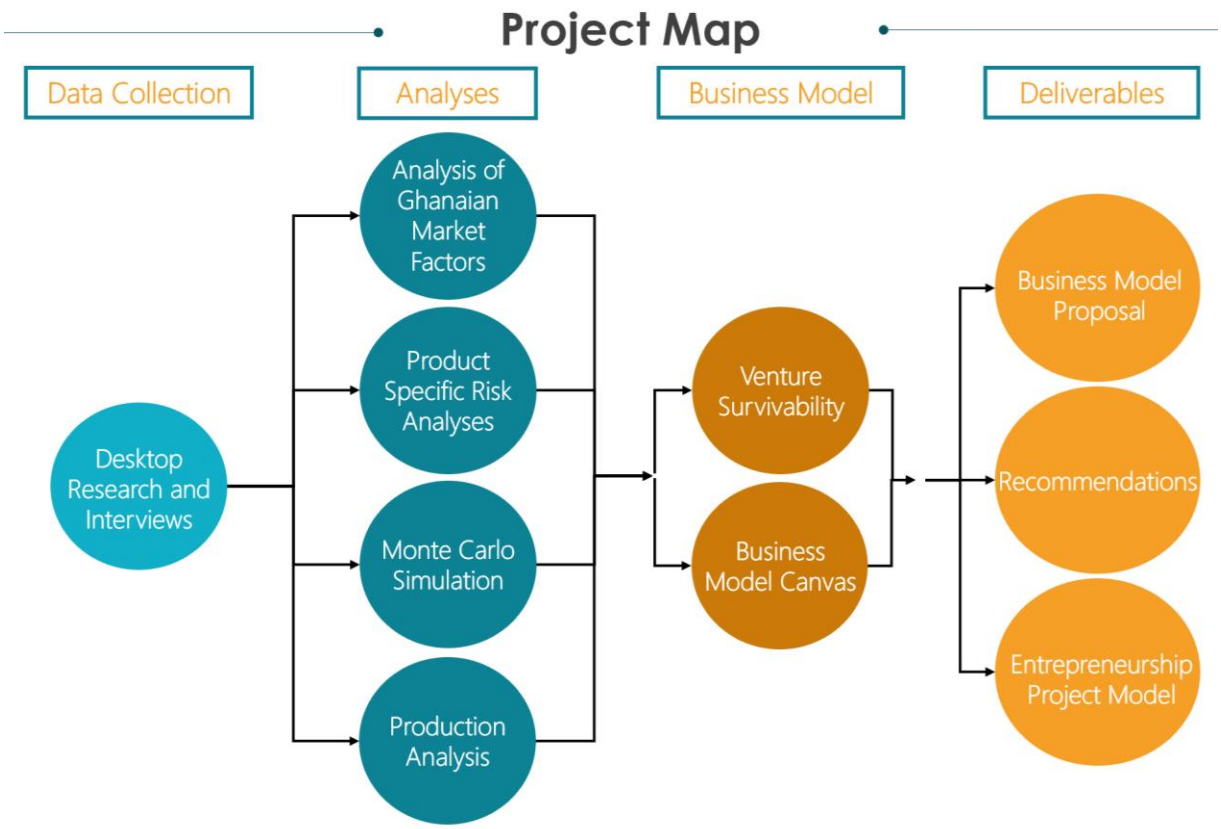


Figure 3.1: Novel Feeding Pump Project Map

3.2 Data Collection

3.2.1 Desktop Research

Throughout the project, data is being collected from desktop research. This research includes academic articles, textbooks, and other sources accessed through the George C. Gordon Library at WPI. Desktop research is being used to gather information on the Ghanaian market, various types of risk analyses, Monte Carlo simulations, as well as logistical and manufacturing processes. All information that is used for the project can be found in the Resources section of this paper.

3.2.2 Interviews

A portion of the team's data collection is coming from interviewing professionals in Ghana. This is to get a better understanding of how the factors in the pump's production and distribution are affected by nuances in Ghana's government, manufacturing industry, biomedical industry, and healthcare industry. 18 professionals are being contacted by email; the distribution of their positions are as follows: 7 medical distributors, 8 biomedical engineers, 1 medical practitioner, 1 medical officer, and 1 healthcare client relations professional. A total of 2 professionals completed interviews from the team over email; they were both biomedical

engineers. The remaining 16 were reached out to twice more, one and two weeks after the initial contact, but no more interviews were scheduled. The information that was received from the two completed interviews is relevant to the risk analysis and manufacturing and logistics analysis in this chapter.

For the second part of our project that dealt with the process improvement of cross-disciplinary projects, the team performed several more interviews. Professors and administration from WPI's Foisie Business school were interviewed to better understand how the requirements of WPI's large projects influence the potential structural changes that can be made to improve the success of these projects. They were also asked about how a product development team and a business team might align their goals and timelines to efficiently tackle a large problem in tandem. These discussions will be further reviewed in Chapter 6 and their results affected the project team's opinions on how future projects should be handled.

3.2.3 Collaborative Efforts with BME Teams

Data is also being collected from the two biomedical engineering teams. The WPI-based biomedical engineering team was able to provide data on the device itself; such materials the device might be made of. The team located in Ghana is able to supply the team with information on Ghanaian hospitals. Based on the data provided by the two teams, we will be able to conduct multiple analyses on the product's future.

3.3 Introduction to the Business Model Canvas

For this venture, the project team will use the Business Model Canvas (BMC) as a guide. The BMC was developed in 2004 by entrepreneur, Alexander Osterwalder, and has been widely accepted throughout the start-up community (Osterwalder, 2010).

3.3.1 Introduction to the Business Model Canvas

The BMC model breaks down a business venture into nine building blocks (see Figure 3.2):

1) Customer Segments - Who is this value being delivered to?
2) Value Proposition - What is the value being delivered?
3) Key Activities - How is the value generated?
4) Key Resources - What key information or financial resources do we need?
5) Key Partners - What partnerships can help us create value?
6) Cost Structure - What costs arise from this process?
7) Customer Relationships - What builds and defines the relationship with the customer?
8) Channels - How is this value delivered to the customer?
9) Revenue Streams - How is revenue generated?

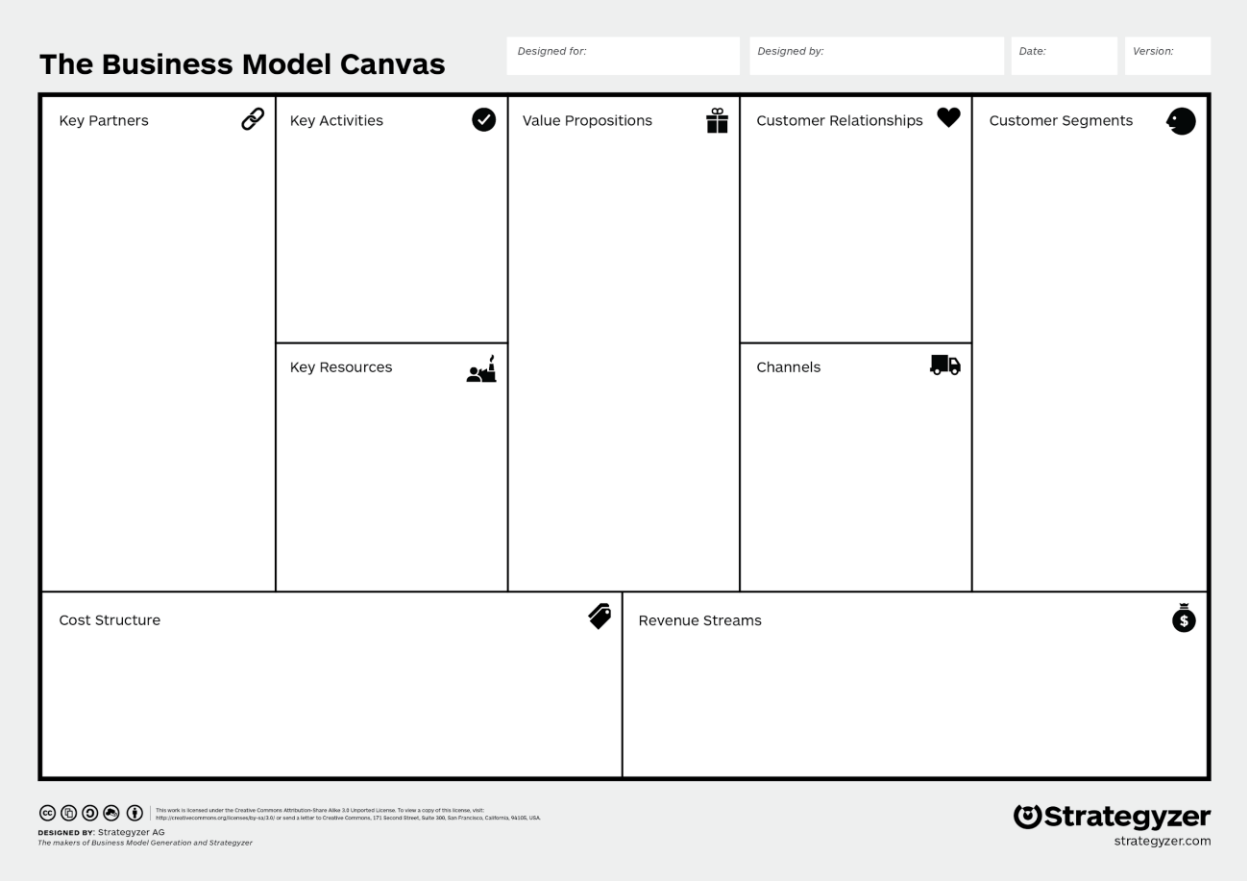


Figure 3.2. Blank Business Model Canvas (Business Model Canvas 2010)

By evaluating the venture of manufacturing a novel feeding pump for premature babies in Ghana through the BMC, the project group can be sure to cover each aspect of this project without leaving many unknowns. Each building block of the BMC can be evaluated independently but is most effective when thought of as a process. The project team is discussing the BMC at the beginning of each week to evaluate and further refine the idea. Each week the building blocks of the BMC are updated based on the previous week's research. This results in a sequence of BMC tracing the development of this project. Each building block of the BMC and initial thoughts our project group needs to evaluate is described below.

3.3.2 Building Blocks of the Business Model Canvas

1) **Customer Segments -** Identifying Customer Segments is the most important section of the BMC. Every other section can be derived by correctly identifying who you are working for. Our initial customer segments for this segments are:
   1) The Ghanaian Ministry of Health;
   2) Insurance companies and private hospitals in Ghana;
   3) Military hospitals in Ghana;
   4) Medical professionals handling the device;

5) The families in need of this product.

Through interviews with the professionals in Ghana outlined above, the project groups attempted to identify the needs of each of the five customer segments. The structure of the finalized business model is dependent on the constraints set by these various customer segments.

2) **Value Proposition** - The value proposition describes what value this product will bring to the customer. This evolves over time as the project group identifies the needs of the customer segments. The value proposition of the product is that it is a low-cost and highly effective alternative to the current feeding pumps used in Ghana. Currently in Ghana, there are no automatic feeding pumps in use in hospitals and the alternatives are manual or gravity-assisted feeding tubes. This is a very time-intensive task for the medical professionals handling the device and can also be subject to human error. This device will ensure accuracy and efficiency in delivering food and drugs to the premature babies. The value proposition may change as information is uncovered on the current system in use in Ghana as well as what the economic impact of this venture is.

3) **Key Activities** - The key activities describe how the venture generates value for the customer. This building block describes the steps taken to ensure the value proposition. Currently, the BME teams are designing the feeding tube with low-cost and high effectiveness in mind. While the product is still in development, this is the only key activity. The project team looked into over low-cost alternatives to meet this value proposition including; in-country manufacturing vs importing, hospital buying powers, and government incentives.

4) **Key Resources** - The key resources indicate what resources (information, technology, raw materials) that this business possesses that differentiates itself from others in the industry. Currently, this portion of the BMC is empty but as the product is developed will include patents and other monetary investments.

5) **Key Partners** - The key partners describe the various relationships this venture creates with individuals and organizations who play a crucial role in the success of the product. Currently, Professor Mensah can be seen as a key partner due to his insight and experience within the biomedical space with his firm, Therapeutic Innovations. It will be important for this project to develop key partnerships with individuals within the Ghanaian government, hospital systems, other biomedical firms, and eventually investment groups for this venture to come to fruition.

6) **Cost Structure** - The cost structure describes all the costs associated with this venture which need investigation. Below are ten costing areas we identified in which we expect costs will be accrued:
    1) Materials for Device
    2) Manufacturing
    3) Logistics
    4) Patents
    5) Quality Regulations
    6) Marketing
    7) Insurances
    8) Packaging
    9) Training
    10) Customer Support

7) **Customer Relationships** - This section describes how the company will build a good relationship with the customers. Customer retention is crucial for any company to survive. Besides creating a quality product, the project team will have to identify and understand the regulations and process of introducing a novel biomedical device in Ghana. By developing a smooth market introduction process, it is more likely that the device will be able to take hold in Ghana and therefore give the venture the opportunity to develop strong customer relationships.

8) **Channels** - This section describes the logistical aspect of delivering the product's value. For the end-user, this value will not change unless the product is radically altered. Currently, the product is meant to be used only in a hospital setting and administered by a medical professional. However, getting the product to that point will depend on a specific process which will be discovered through desktop research and interviews with biomedical professionals in Ghana.

9) **Revenue Streams** - Revenue streams describe how the venture makes money. This will depend on how the product is adapted into the Ghanaian hospital system. In the United States, hospitals buy the medical devices they need (*How do hospitals make purchasing decisions?* 2019). This process includes a committee of administrators and physicians who annually meet to make new purchases. In Ghana, the government makes the purchasing decisions for all nationally sponsored hospitals. While there are some private hospitals and military hospitals that control their own buying, the majority fall under the governments buying power.

3.4 Risk Analysis of a Business Venture

A thorough risk analysis is essential to this project because of the large number of unknowns related to the product and its future. It is important to identify all essential functions the product must perform, along with all team goals that will lead to success, and then identify each way these things may fail to perform (National Research Council, 2005). The quantitative risk analyses are listed below-

1. 3 Point Estimate
    a. Determines the optimistic, most likely, and pessimistic outcomes of the future of the product
2. Failure Modes and Effects Analysis (FMEA)
    a. Helps to identify every possible failure in the process
    b. Design, manufacturing, and assembly
3. Monte Carlo Simulation
    a. See 3.3.3
4. Decision Tree
    a. Differentiates between alternatives and identifies paths towards manufacturing and assembly location
5. Sensitivity Analysis
    a. Gain a better understanding of costs and demands with a result of operating profit
6. Fault Tree Analysis
    a. Determine what elements of production and logistical decisions may cause failure (Project Risk, 2020)

Such risk analyses are necessary because of all the uncertainties in the development, production, and delivery of the feeding pump. For planning purposes, grounded assumptions are made, and Therapeutic Innovations needs to be aware of the sensitivity regarding these assumptions.

The following is a list of **assumptions** the team is using. These assumptions are developed from our desktop research and interviews outlined in previous sections.

1) The product will be developed in time for the business team to perform analysis on the feasibility of its future success. There is a relatively short timeline for the prototyping and testing of the feeding pump and thus the business aspect of its product development is also restricted.

2) The Ghana healthcare system will be interested in the product. This is an issue that will be explored in interviews with professionals in the Ghana healthcare system in a future project. The project team has identified three potential hospitals in Ghana that will be contacted for either an email interview or a phone call interview. The team hopes that the interviews will result in detailed information about the current status of feeding and drug delivery pumps in the hospital and whether or not the project's product might be a good fit and effective addition to the

hospital. As much information as possible about the acceptability of the product into the Ghana system will aid in the risk analysis.

3) The team is also making the assumption that the product will be able to be manufactured. Different locations and methods of manufacturing will be looked into and the risks analyzed during this project. The key activities, resources, and partners that the project hopes to develop will be made more clear and quantified after an overall risk analysis.

3.4.1 Analysis of Ghanaian Market Factors

There are many external factors in Ghana that will affect the progression of this device into the market. The business team is developing both a P.E.S.T.E.L.E analysis and a Porter's Five Forces analysis to better understand how systems in Ghana, such as healthcare and manufacturing, will be affected by national policies and regulations. This also helps the team analyze the feasibility of manufacturing in Ghana and selling to Ghanaian health services. After a P.E.S.T.E.L.E and Porter's Five Forces analysis, a Product Life Cycle Assessment is conducted.

3.4.1.1 P.E.S.T.E.L.E Analysis

A P.E.S.T.E.L.E analysis is a framework that helps to analyze the external marketing factors that will affect the business venture (Professional Academy, 2005). The team is performing this analysis in tandem with the other quantitative risk analysis outlined above. The political factors (P) explored how the government intervenes in the economy. For this project, it is essential to analyze government expenditure as they play a large role in medical spending. Economic factors (E)were considered to determine how business should be done and how potentially profitable the product can be. Macro-economic factors in Ghana were reviewed to help project hospital demand. Next, social factors (S) in Ghana, like health, population, and age distribution aided the team's estimates of how many users are potentially available for the product. The technological landscape (T) in Ghana needed to be better understood by the team in order to make the right contacts in healthcare, manufacturing, and government. It also helped to understand how the distribution of products works. Sustainability and the limiting of a carbon footprint were also a priority when looking into manufacturing, material choice, and assembly. These are environmental factors (E) that will be specific to Ghana and better understood through the team's interview process. Some legal factors (L) that the team researched are health and safety regulations in Ghana along with product safety. The regulations were explored with further research and product safety will be analyzed alongside the BME team. Finally, ethical problems (E) that have the potential to be raised with this product development were discovered through research so that the project team can safely continue to progress Ghana in an ethical manner in all aspects of the venture (Professional Academy, 2005).

3.4.1.2 Porter's Five Forces

Following the P.E.S.T.E.L.E analysis, the team will perform a Porter's Five Forces analysis to analyze the industry's attractiveness and the likelihood of profitability. The forces are as follows: competitive rivalry, buyer power, threat of new entry, supplier power, and threat of substitution. The first aspect is competitive rivalry. The device that the BME team is developing has to directly compete in that it would be a novel addition to the Ghanaian healthcare system. However, there is indirect competition in the other methods that nurses use to provide nutrition to premature babies. For example, other methods to feed premature babies are currently in Ghana, and although they require more nurse interventions, they are cheaper. This was analyzed through data collected from interviews with healthcare professionals that the Ghanaian BME team in Ghana is conducting. The next aspect of the analysis is supplier power. For this project, inexpensive but safe suppliers in Ghana are the priority. Once again, the interviews were the main method for gaining this knowledge and analyzing options. The buyer power is in Ghana health services. The government takes the majority of the costs and so a top-down approach to buyer analysis needs to be taken in Ghana. The team looked at the Ministry of Health, health services, major regional hospitals, district hospitals, and remote clinics. The vast number of potential buyers needs to be broken down by feasibility and also how effective the device can be used in each area. The threat of substitution is relatively low for this venture, considering that the device appears to be a substantial improvement to how users currently provide nutrition for premature babies without automated pumps. Finally, the threat of new entry is a very broad issue with this project. The market, in this case, is Ghanaian healthcare and so the sector is tightly regulated by the government and Ghana health services. It was more important for the team to analyze how their particular device will enter, rather than the entry of current nonexistent competition.

3.4.1.3 Ghanaian Medical Device Regulations

All three project teams had to collaborate to ensure that the device is compliant with medical regulations in Ghana. This was performed first by collecting resources on regulations in Ghana and asking our contacted professionals about limitations, standards, and any design restrictions. The BME team designed a process to test the device, making sure it is compliant with the regulations that we will help outline for them. Furthermore, the teams had to work together to develop a quality assurance process so that the building of the device and the materials are all up to standard. This was an ongoing process through multiple sessions of device testing. The BME teams provided information to the business team regarding materials, design, and functionality for further analysis of regulatory standards.

3.4.2 Product Specific Risk Analyses

3.4.2.1 Failure Modes and Effects Analysis

An FMEA will identify the components or pieces of equipment in a production process that are most likely to fail as well as the components that will have the greatest impact on the product if failure occurs. With the BME team a FMEA table was created to analyze all aspects of the product. The FMEA procedure is effective when developing a new process or a process for producing a product. Through FMEA potential failures are being identified thus courses of action to counter the failures can be employed or processes could be revised and improved, effectively avoiding the failures and saving resources. An example of a FMEA table can be seen in Figure 3.3

Function/ Process	Potential Failure Mode	Potential Effects of Failure/s	S (Severity Rating)	Potential Causes of Failure/s	O (Occurrence Rating)	Current Process Controls	D (Detection Rating)	Critical Characteristic	RPN (Risk Priority Number)

Figure 3.3 - A Basic FMEA Table Template

Under the potential failure modes, the team will identify possible failures and their respective effects and potential causes by collaborating with the WPI Biomedical Team. A severity value is assigned for the respective failure mode on a scale between 1-10, which indicates extreme severity. Occurrence is scored on the same scale, with a 10 indicated. Likewise, detection employs a 10-point scale, with 10 indicating… failure is highly detectable, and a 1 indicating detection is low. Hard to detect failures should be scored high in detection. RPN is the product of severity, occurrence and detection (RPN=S*O*D). Critical characteristic is optional in many organizations because of its subjectivity (ASQ, n.d.). It is the measure of the overall impact of the failure to the organizations. It is usually scored “Y” or “Yes” if either severity or occurrence is at 9 or 10 and if detection is higher than 3. From this FMEA, actions plans can be formulated to prevent these failures (ASQ, n.d.).

3.4.2.2 Analysis of Product Life Cycle

Product life cycle is the process a product goes through from when it is introduced to when it is removed from the market. The product life cycle can be broken into four recognizable stages: (1) market development; (2) market growth; (3) market maturity, and (4) market decline (Levitt, 2014). Market development is when a product is first introduced to consumers and since the product was recently introduced, there is no demand or interest for the product. In this stage, sales are low and are slowly increasing (Sraders, 2019). In the market growth stage, consumers are buying more of the product thus demand is increasing. In the third stage, demand for the product reaches its peak and sales tend to slow down or even stop. In the last stage, consumers lose interest in the product and sales drift downwards.

The team began a product life cycle analysis by performing research on the medical device market in Ghana. This research includes reviewing the demand for drug delivery pumps and understanding the consumers' needs. The product life cycle also works in parallel with the life cycle assessment (LCA). To begin the LCA, the team started by defining the scope and goal of the device. This allowed for the team to identify the effects on the environment the device will have. After defining the goals, the team performed an inventory analysis. In this stage, the team assessed the effects of each inventory item on both environmental inputs and outputs. From there, the team completed an impact assessment by determining the effects of the materials analyzed in the inventory analysis stage. Lastly the team will evaluate the results from the inventory analysis and the impact assessment stages and will select the most sustainable process. It should be noted that LCA does not work well with products that are in the early development stage because these products do not have sufficient information to assess the potential environmental aspects (Sraders, 2019).

3.4.2.3 Fault Tree Analysis

A fault tree analysis (FTA) is a visual qualitative and quantitative risk analysis tool (PV, 2020). FTA uses Boolean logic to form a top-down logical diagram that identifies failures within a critical system and its causes. A fault tree is made up of a top event, basic events, and logic gates, symbols are shown in Figure 3.4 and 3.5. The top event is the undesirable failure being analyzed. Basic events are lower level contributors that cause the top event. Logic gates link the top and basic events and also display the relationship between them. An important factor in an FTA is the minimal cut set, which is a set of basic events that combined cause the top event (PV, 2020).

Steps in completing a fault tree analysis are:

1. Define the primary failure to be analyzed
2. Construct the tree
    a. Events connected by logic gates
3. Identify the minimal cut sets
4. Analyze the fault tree
    a. Quantitative and/or qualitative
    b. Calculate probability of failure
5. Mitigate the risk

Chart of Event Symbols

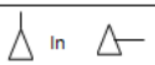
S.No	Event Symbol	Description
1		Primary or basic failure event. It is a random event and sufficient data is available
2		State of system, subsystem or component event
3		Secondary failure or under developed event, can be explored further
4		Conditional event and is associated with the occurrence of some other event
5		House event representing either occurrence or non-occurrence of an event
6		Transfer in and transfer out symbols used to replicate a branch or sub-tree of the FTA

Figure 3.4: Chart displaying various event symbols used in FTA (PV, 2020)

Chart of Gate Symbols

S.No	Gate Symbol	Description
1	 AND Gate	The output event occurs when all the input events occur
2	 OR Gate	The output event occurs when at least one of the input events occur
3	Priority AND Gate 	The output event occurs when all the input events occur in the order from left to right
4	 Exclusive OR gate	The output event occurs if either of the two input events occur but not both
5	 Inhibit gate	The output event occurs when the input event occurs and the attached condition is satisfied

Figure 3.5: Chart displaying various gate symbols used in FTA (PV, 2020)

3.4.3 Monte Carlo Simulation

Significant uncertainty exists in the process of making forecasts regarding a new product's costs, revenues, and market demand. Rather than using an estimated, single point average for these uncertain variables to run predictions, the Monte Carlo Simulation technique was employed to examine forecasted profits over a range of values. Single point estimates can severely limit a risk analysis as they aren't as effective at measuring change or assuming uncertainty. Single point estimates limit the user's potential for exhaustive analysis while a Monte Carlo provides a more comprehensive risk overview by incorporating uncertainty (Kenton, 2020). These simulations will help the team predict the probability of different

outcomes when uncertainty and variability are present which will help explain the impact of risk and uncertainty in prediction and forecasting models (Kenton, 2020).

The simulation addressed the uncertainty associated with various aspects of introducing a new product. Uncertain variables include the failure and availability of materials and the costs associated with different manufacturing options. The potential range for these variables were developed by collecting data and running the simulation. These variables constituted input into costing models which will be simulated to determine the probabilities of occurrences of outcomes, venture success, and failure (Kenton, 2020). The necessary data for costs were estimated from our desktop research and then probability distributions will be estimated. Based on the risks that the Monte Carlo Simulation will highlight, a probability distribution will be modeled for uncertain factors. Five Monte Carlo simulations were conducted to help bring a solid understanding of the uncertainty of multiple different decisions of our project; they are laid out below.

1) The first simulation that was run was a **cost-benefit analysis** for the costs from creating the pump to getting it distributed, and the revenue from its sales. This version used estimated production costs for all aspects of production (manufacturing, materials, assembly, and distribution) and potential demand projections.
2) The second simulation was a **simplified cost-benefit analysis** with fewer variables. Here, materials costs were the only input and the simulation was dealing with the analysis of a single pump's costs vs monetary benefit.
3) The third simulation was a basic **time to market prediction**. The factors that were used to estimate time to market were Research & Development (R&D), Testing (including prototyping), obtaining medical regulation approval, assembly, and distribution to hospitals.
4) The fourth simulation was a more **detailed cost-benefit analysis** that included multiple **benefit**s. These benefits were nurse opportunity costs, reduced bed days, and parent opportunity cost. Here, the team was analyzing benefits other than profit that the automatic pump could bring instead of the manual pump. This helped to further analyze how different stakeholders could be positively affected by a new and improved device.
5) Finally, a **decision tree model** using PrecisionTree was the input for the final Monte Carlo simulation to reflect the variability of decision alternatives the team can make regarding manufacturing and assembly locations.

The results of these analyses can be found in Chapter 4.

3.5 Production Analysis

3.5.1 Analysis of Manufacturing Capabilities

In order to fully analyze the manufacturing capabilities, the team constructed a decision tree. The purpose of the decision tree is to consider the most effective way to develop the

product. The team used the decision tree as a test to evaluate the expected value of each possible manufacturing and assembly location. For this test, we used the United States, India, and Ghana as manufacturing and assembly locations and the list of material provided by the Biomedical team to estimate cost.

3.5.2 Manufacturing Plan

With the development of a new product, there are many logistical and manufacturing considerations that are integral to successful production and distribution of the product. For the feeding pump, the team will create a manufacturing production plan. Production planning is a process within manufacturing that involves ensuring that sufficient raw materials, staff, facilities, and other necessities are available and prepared to be used in the making of the final product (International Finance Corporation). To develop this plan, the main steps involved are:

1. Demand Forecasting
2. Determining Production Process
3. Monitoring and Adjusting

Demand Forecasting

To know how many pumps need to be produced during a time frame, the demand of the pumps needs to be estimated. In addition to the Monte Carlo simulation, the team will also consider external events such as new market trends, changes in the economy, or updated health device regulations.

Determining Production Process

The team will determine the most efficient production process by comparing different production options, which for the feeding pumps are where to manufacture raw materials and where to assemble the feeding pump. For each option, we will make a process map flowchart (example in Figure 3.6) that accounts for sequenced/dependent tasks, task time, and cost. The risks and benefits of each option will also be analyzed.

Process Map Flowchart Example

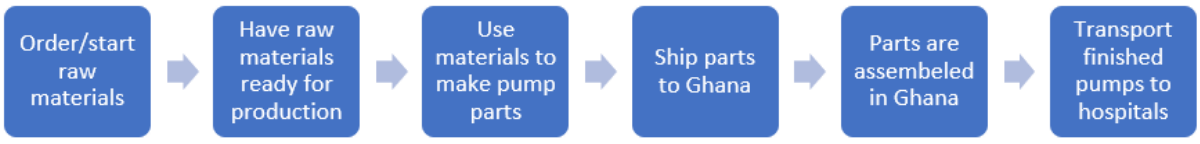


Figure 3.6: Example of Process Map Flowchart of US Manufacturing and Ghana Assembling

Monitoring and Adjusting

After the ideal option is identified, a master production schedule (MPS), material requirements planning (MRP), and assembling process can be developed. These will be used to monitor the process, comparing the process that was planned to the process that is actually taking place. If there are large differences or other problems are detected, the plan should be flexible enough to implement adjustments to correct and improve the process. This is beyond the scope of this MQP.

3.5.3 Analysis of Logistical Capabilities of Ghana

Logistic management is a part of the supply chain process that controls the flow and storage of goods, services, and information from the origin of the product to the point where the product reaches the consumer (Christopher, 2018.). Logistic management is important in the healthcare industry because it can affect when a product is available to consumers (Manamzor, 2018). Logistic managers should make the patient's safety their top priority when making choices on commodities.

3.5.3.1 Hospital Buying Power in Ghana Related to Logistics

Healthcare in Ghana is supplied by both private and public sectors with the Ministry of Health (MOH) having overall control of the system (Manso et al., 2013). The health commodity supply chain in the public sector is made up of two components, the Central Medical Store and a network of Regional Medical Stores, located in each of the 10 administrative regions of the country (Bossert, et al., 2004). Supplies are regulated through this supply chain and are distributed to their retrospective health facility through the country. Health facilities are expected to buy their supplies from their assigned Regional Medical Stores.

3.5.3.2 Flow Chart of Logistics in the Ghanaian Medical Device Market

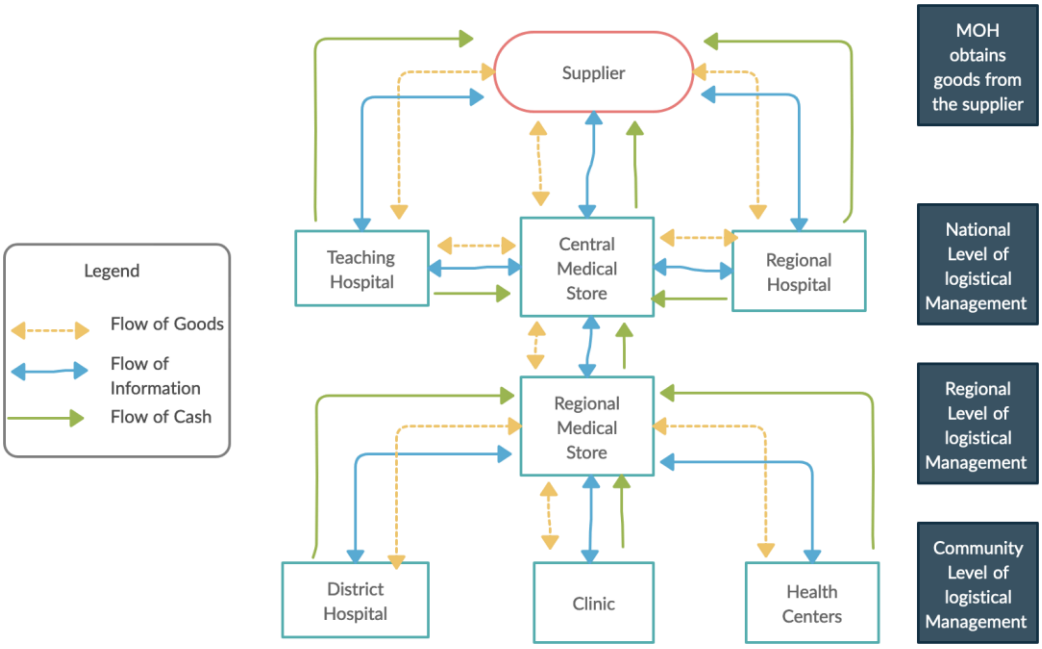


Figure 3.7: The supply chain of the Ghana Health Service (Manso, 2013)

The public health supply chain can be broken into four sections with MOH starting the chain by obtaining goods from the chosen supplier. Between each section is the movement of three different types of flow (goods, information and cash), which is important for logistical management. Figure 3.7 above shows how each section of the supply chain is connected to each other.

3.6 Venture Survivability Decision

The team focused on two evaluations for the feeding-pump. The first being an economic evaluation, which will value the fixed and variable costs of manufacturing novel feeding pump. This will help us ascertain whether the profit made from this device will justify the initial investment, hence making it worth investing. The other evaluation is a cost-utility analysis, which takes into consideration health state preference scores. This will help the team look at how this product is affecting the quality of life-years gained. Figure 3.8 shows the flow of basic types of economic evaluation that can be used in a healthcare setting. The team will create an economic evaluation as it provides a comprehensive outlook into all the fixed and variable costs of the novel feeding pump.

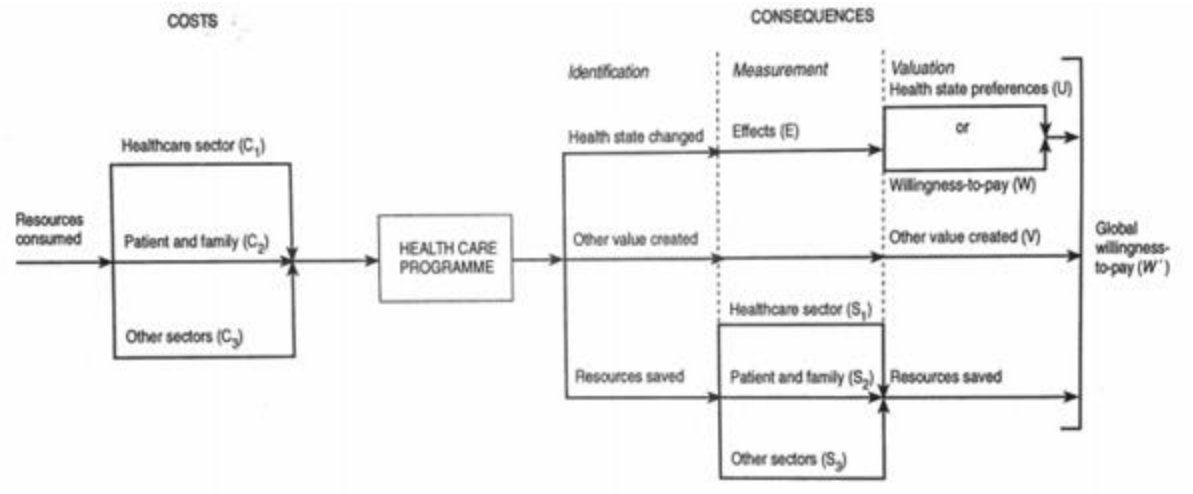


Figure 3.8: Basic types of Economic Evaluation (Drummond, 2015)

3.6.1 Economic Evaluation

The Economic Evaluation was composed of two types of costs: Fixed Costs and Variable Costs. Fixed costs are expenses or costs that are independent of the production output. Examples of fixed cost include rent, utilities, salaries, insurance, and equipment. Variable costs are costs dependent on the production output. Therefore, an increase in the number of units created and sold correlates to an increase of the variable cost (Drummond, 2015). The variable costs the team considered are the price for manufacture/assembly, transportation costs, direct labor, and utilities. The fixed costs that the team considered are rent, a one-time equipment purchase, and repair costs. This economic evaluation model will generate break even points based on a low, middle, and high price point that can be set as the selling price. There will be an initial, start-up, break even calculation and an after the first year break even calculation, due to not having the same start up costs for every year. This will help illustrate the differences in production quantities that will be useful for production planning and will affect the overall profit. A simulated 10 year operation time period will be created to simulate changes in demand or changes in price to ultimately present a comprehensive evaluation of the novel feeding pump. The team will conduct extensive research into these costs in the Ghana Market to create a model that will simulate a scenario based on the results of 3.5 Production Analysis.

3.6.1.1 Manufacture / Assembly

This cost will illustrate the cost per unit of the product. This includes the raw material, manufactured material and assembly cost. For the manufactured material the BME team has chosen to use injection molding for the plastic components as it is cheaper in mass quantities. A bill of materials will be shown once the BME team has finalized it, these components will be bought in bulk from outside sources. Assembly costs will be calculated based on the wages given the time it will take to assemble the product. In the model a total cost of manufacturing will be determined based on the amount of pumps needed to make a profit.

3.6.1.2 Direct Labor

To determine what our simulated labor force will look like, the team will research the typical labor structure of a company to determine quantities, job types, and importantly the wages. We will only take into consideration the annual income of these “employees”. Having a labor force is important because without them material would not be able to be assembled, manufactured or moved around the company, and we would not be able to satisfy demands.

3.6.1.3 Utilities

Utilities expense is the cost incurred by using utilities such as electricity, water, waste disposal, heating, and sewage. The team will research average kilowatt per hour consumption for operating a building where we will simulate housing our operations, for electricity costs. This will also include the costs of operating the machines. The second utility cost the team will consider natural gas, similarly calculated to the cost of electricity.

3.6.1.4 Rent

In the model rent will be the cost of paying for a space where our operations will be held. Having one location where all the logistics and manufacturing is handled greatly increases productivity and lowers costs. To determine the rent costs the team will research a variety of office buildings that would be able to accommodate the operations. The team will take into account, the total square feet, any included features that would be beneficial, what would be around this location (i.e airport, shipyard, etc), and importantly the overall price.

3.6.1.5 Transportation

Transportation costs will include importing raw material and the distribution of finished goods. This will be important to include in the model because it will fully cover the value stream of manufacturing this product from start to finish. The team will look into these costs from the point of the Ministry of Health since we are working with a medical device their channels will greatly help the distribution of the novel feeding pump.

3.6.1.6 Equipment

If manufacturing takes place in Ghana then the team will research costs of injection modeling as requested by Therapeutic Innovations. Injection molding was chosen because it has been the method Therapeutic Innovations has used, and since they expect a large demand it will be the most convenient way to reach this demand. The team will calculate the necessary quantities of machines or molds that will be necessary to achieve the calculated demand. In order to figure out the total cost of the necessary equipment the team will research several current industrial machines and determine if they would be fit for our production needs.

3.6.1.7 Repair

Similar to 3.6.1.6 Equipment, if manufacturing does take place in Ghana then the machines will need to be repaired at least once in the time period that will be simulated. Since the repair cost will be difficult to predict, a worst case scenario repair cost will be used. This repair cost will not be a repeating annual cost, it will be a one time cost after a determined number of years.

The results of this model can be seen: 3.6.1 Economic Evaluation

3.6.8 Cost-Utility Analysis

Cost-utility analysis (CUA) is a form of evaluation that focuses particularly on the quality of the health outcome produced or averted by either health programs or treatments (Drummond, 2015). In CUA, the incremental cost of a treatment from a particular viewpoint is compared to the incremental health improvement attributable to the treatment, where the health improvement is measured in quality-adjusted life-years (QALYs) gained (Drummond, 2015). QALYs simultaneously capture gains from reduced morbidity and reduced mortality and combine these into a single measure. The results are expressed as a cost per QALY. Currently, there are three main health status classification systems: Quality of Well-Being (QWB), Health Utilities Index (HUI), and EuroQol (EQ-5D). Figure 3.9 shows the function scales and its corresponding weights that can be used to identify and calculate the CUA of the team's product.

PART 1. Quality of Well-Being/general health policy model: function scales with step definitions and calculating weights.

Step no.	Step definition	Weight
	Mobility Scale (MOB)	
5	No limitations for health reasons	−.000
4	Did not drive a car, health related; did not ride in a car as usual for age (younger than 15 yr), health related, and/or did not use public transportation, health related; or had or would have used more help than usual for age to use public transportation, health related	−.062
2	In hospital, health related	−.090
	Physical Activity (PAC)	
4	No limitations for health reasons	−.000
3	In wheelchair, moved or controlled movement of wheelchair without help from someone else; or had trouble or did not try to lift, stoop, bend over, or use stairs or inclines, health related; and/or limped, used a cane, crutches, or walker, health related; and/or had any other physical limitation in walking, or did not try to walk as far or as fast as other the same age are able, health related.	−.060
1	In wheelchair, did not move or control the movement of wheelchair without help from someone else, or in bed, chair, or couch for most or all of the day, health related	−.077
	Social Activity Scale (SAC)	
5	No limitations for health reasons	−.000
4	Limited in other (e.g., recreational) role activity, health related	−.061
3	Limited in major (primary) role activity, health related	−.061
2	Performed no major role activity, health related, but did perform selfcare activities	−.061
1	Performed no major role activity, health related, and did not perform or had more help than usual in performance of one or more selfcare activities, health related	−.106

PART 2. Quality of Well-Being/general health policy model: symptom/problem complexes (CPX) with calculating weights

CPX no.	CPX definition	Weights
1	Death (not on respondent's card)	−.727
2	Loss of consciousness such as seizure (fits), fainting, or coma (out cold or knocked out)	−.407
3	Burn over large areas of face, body, arms, or legs	−.387
4	Pain, bleeding, itching, or discharge (drainage) from sexual organs – does not include normal menstrual (monthly) bleeding	−.349
5	Trouble learning, remembering, or thinking clearly	−.340
6	Any combination of one or more hands, feet, arms, or legs either missing, deformed (crooked), paralyzed (unable to move), or broken – includes wearing artificial limbs or braces	−.333
7	Pain, stiffness, weakness, numbness or other discomfort in chest, stomach (including hernia or rupture), side, neck, back, hips, or any joints or hands, feet, arms, or legs	−.299
8	Pain, burning, bleeding, itching, or other difficulty with rectum, bowel movements, or urination (passing water)	−.292
9	Sick or upset stomach, vomiting or loose bowel movement, with or without chills, or aching all over	−.290
10	General tiredeness, weakness, or weight loss	−.259
11	Cough, wheezing, or shortness of breath, with or without fever, chills, or aching all over	−.257
12	Spells of feeling, upset, being depressed, or of crying	−.257
13	Headache, or dizziness, or ringing in ears, or spells of feeling hot, nervous, or shaky	−.244
14	Burning or itching rash on large areas of face, body, arms, or legs	−.240
15	Trouble talking, such as lisp, stuttering, hoarseness, or being unable to speak	−.237
16	Pain or discomfort in one or both eyes (such as burnign or itching) or any trouble seeing after correction	−.230
17	Overweight for age and height or skin defect of face, body, arms, or legs, such as scars, pimples, warts, bruises, or changes in colour	−.188
18	Pain in ear, tooth, jaw, throat, lips, tongue, several missing or crooked permanent teeth – includes wearing bridges or false teeth, stuffy, runny nose; or any trouble hearing – includes wearing a hearing aid	−.170
19	Taking medication or staying on a prescribed diet for health reasons	−.144
20	Wore eyeglasses or contact lenses	−.101
21	Breathing smog or unpleasant air	−,101
22	No symptoms or problem (not on respondent's card)	−.000
23	Standard symptom/problem	−.257
X24	Trouble sleeping	−.257
X25	Intoxication	−.257
X26	Problems with sexual interest or performance	−.257
X27	Excessive worry or anxiety	−.257

Note: x indicates that a standardized weight is used.

Figure 3.9: Example of Quality of Well-Being Index (Drummond, 2015)

If the patient has multiple symptoms or problems, the one the patient finds to be the impactful is used. For example if a patient was asked to rate their health based on the given values of their symptoms if they had pain or trouble breathing that would be a specific value added to their score (Drummond, 2015). The scoring function is based on category scaling measurements on the random sample of the public. States worse than death were measured as a negative score. The value scoring weighted formula on the 0 (death) to 1 (perfect health) scale. From the selection of the scale determines the weight that can be imputed into the equation seen in Figure 3.10.

Calculating formulas

Formula 1. Point-in-time well-being score for an individual (W):

$W = 1 + (\text{CPX}wt) + (\text{MOB}wt) + (\text{PAC}wt) + (\text{SAC}wt)$

where wt is the preference-weighted measure for each factor and CPX is symptom/problem complex. For example, the W score for a person with the following description profile may be calculated for one day as:

CPX-11	Cough, wheezing, or shortness of breath, with or without fever, chills, or aching all over	−.257
MOB-5	No limitations	−.000
PAC-1	In bed, chair, or couch for most or all of the day, health related	−.077
SAC-2	Performed no major role activity health related, but did perform self-car	−.061

$W = 1 + (-.257) + (-.000) + (-.077) + (-.061) = .605$

Formula 2. Well-years (WY) as an output measure:

$WP = [\text{No. of persons} \times (\text{CPX}wt + \text{MOB}wt + \text{PAC}wt + \text{SAC}wt) \times \text{Time}]$

Figure 3.10: Example calculation example using QWB

Along with our interview of medical health professions, the team will work with them to analyze how this novel medical device will improve their quality of life in terms of this cost-utility equation.

3.7 Project Final Deliverables

The final deliverables of this project are an in-depth Business Model Canvas that allows either another project group or our sponsors to continue building this venture and a preliminary decision as to if the feeding pump venture will be successful and sustainable in Ghana. To reach these deliverables, the project group will need to develop the ability to sufficiently track the progress throughout the project, create a fully-encompassing final presentation to deliver our decision, and a thorough recommendation chapter for future groups to follow.

3.7.1 Tracking Updates to the Business Model Canvas

To track the Business Model Canvas's evolution throughout the course of the project, the project team used the online tool Canvanizer to continuously update the BMC. This tool allows the project team to add, delete, and edit various ideas from the BMC and automatically adjusts the scale of the BMC. With the ability to color-coordinate various ideas, the same BMC can be used for overlapping alternatives.

3.7.2 Business Model Proposal and Alternatives

Upon completing the methodology, the results were analyzed and formed into a flushed business model proposal stemming from the Business Model Canvas. This outline described the various facets of the venture and the progress into investigating them that has already been made. Section 4.1 will also include alternative business model options that should be considered if this

venture is to be pursued. The goal with section 4.1 is to allow whomever continues this project to either pick up where this project team has left off, or make a strategic pivot to better the position of this venture.

3.7.3 Examination of Cross-Disciplinary MQP Structure

In the final chapter, the process of the cross-disciplinary MQP will be evaluated and recommendations will be made. These recommendations will come from three main sources:

1) Reflection on the efficiency of this project;
2) Findings from other University-based cross-disciplinary projects;
3) Interviews with WPI Administration, Faculty, and Staff.

3.8 Gantt Chart

The project timeline was 21 weeks spanning three academic terms. The Gantt chart in the appendix illustrates the key activities for each term. The Gantt chart will be a good measure of the team's progress throughout the project. Methods the team will use to assess the feasibility of a new feeding pump in Ghana include: product reliability, Monte Carlo simulations, logistics and manufacturing, product lifecycle, cost-benefit analysis, risk analysis, a Business Model Canvas, and finally a project template.

Chapter 4: Results

This chapter contains the results of multiple analyses and interviews as described in Chapter 3. At the time of writing the feeding pump was in the initial stages of prototyping . Accordingly this chapter is written summarizing the results to date, with the intent of laying a foundation for subsequent business teams to move the project forward. We envision a business-based MQP team continues this project, but it could also be an analyst for Therapeutic Innovations.

This chapter also includes information about the MQP process improvement initiative which can be found in Chapter 6.

4.1 Feeding Pump Business Model Canvas

Shown in Figure 4.1 is the final Business Model Canvas developed through this project. It outlines the information gathered throughout the interviews, desktop research, and ideas proposed for Therapeutic Innovations and subsequent MQPs team to investigate. This Business Model Canvas describes two strategies that share many similarities. The strategies are distinguished by their colors in the graphic.

1) Develop this device and pursue as a start-up - Yellow Blocks
2) Develop this product, patent, and then lease it to an established biomedical company - Blue Blocks

Figure 4.1: Novel Feeding Pump Business Model Canvas

Both strategies will need the feeding pump to continue through the validation and verification process and possibly animal testing. They both share many of the same blocks of the BMC, however, the “Channels”, “Customer Relationships”, and “Key Activities” would be nullified if a “patent and lease” approach was taken. Below the findings in each section of the Business Model Canvas are described and differentiation between these two strategies are discussed in the Sections 4.1.5 and 4.1.6.

4.1.1 Value Proposition

There are three ways in which this product would deliver value to the Ghanaian market and fill the need desired by the customers:

1) Reduces human error associated with feeding pumps;
2) Increased ease of use for medical professionals;
3) Offers a low-cost alternative to current infant feeding-pump products.

The first and most important value this product can deliver is the limitation of human error in the feeding of these premature babies. Currently, the process of feeding the premature babies relies heavily on the nurses to correctly measure and feed each child, and with every child needing something different, this creates variation in which problems can occur. Limited availability of the feeding pumps in Ghana has led to the adoption of this manual process in most cases. A device which enables automated feeding reduces the risk that a feeding measurement will be incorrect. Reduced risk of mis-measurement leads into the second value, the ease of use for medical professionals. Currently, the feeding process consumes a considerable amount of the nurses and medical professionals’ time. Accurately measuring and carefully feeding the premature babies multiple times a day can be exhausting for the staff and create a strain on them when there are other patients who need attention. This device will allow free up staff time for other tasks. Lastly, this product can deliver the previous two values while costing a fraction of automatic feeding pumps that are currently on the market. This value will be the differentiator in enticing the customers.

4.1.2 Customer Segments

There are three customers that have been identified who would benefit from this device:

1) Premature babies requiring feeding and care;
2) Medical professionals using the device
3) The Ghana Ministry of Health

The needs of each of these customers is considered as the product is being designed and tested. The needs of the segments align with the value being delivered from the feeding pump.

The first customer, the children receiving nutrition from this device, are in need of a device that can guarantee their safety as they are being fed. The removal of potential human error is the value that addresses this need. The second customer segment, medical professionals, are in need of a device that is easy to use and can save them time. The final customer segment is the Ghana Ministry of Health (MoH). While they too have similar needs to the previous two segments, they also desire this device to be a low-cost alternative to what is currently available since they have the purchasing power for the nation's hospital systems.

4.1.3 Customer Relationship

To appease and maintain these customer relationships, the teams moving forward should develop a plan to provide training on how to use the device. This will allow the team to develop personal relationships with the medical professionals who will be using the device to keep them satisfied with the product. This will also allow the MoH to feel comfortable using the device in their hospitals.

4.1.4 Channels

While much of this section was done using desktop research, if a start-up strategy was used, it would make the most economic sense to manufacture and assemble these devices in Ghana (See Section 4.5). The distribution networks in Ghana still need to be examined and understood and contacts need to be made with manufacturers within the country.

4.1.5 Revenue Stream

There are three separate revenue streams that can be identified through the two different business models.

1) Start-Up Approach

For the start-up approach, revenue will be generated by securing contracts with the Ghana MoH and other private hospitals and insurance companies in the country. These contracts will specify the number of devices hospitals need produced. Earlier on in the process, teams should look into grants and funding opportunities to develop this product; or outside investment into the start-up, so the company can be established in Ghana.

2) Patent and Lease Approach

If the decision is made to pursue the patent and lease approach, the teams working on this device should look for grants through universities or state/federal agencies. Such funding will allow for the device to be developed and initial testing to be completed. Once the product is developed, proven it works, and a patent has been filed, it should be leased to an established biomedical company that has the pathways created to grow the product and deliver its value to

the customers in Ghana. The lease method will generate a percentage income for the patent holders for the revenue being created by the device.

4.1.6 Key Partners

The key partners for this product differentiate depending on the strategy taken by the teams moving forward.

1) Start-Up Approach

There are many key partners for this product to be successful in the Ghanaian market. First are the initial investors in the product. This may come from WPI or private investors but their guidance and financial support will be the first steps in allowing this product to undergo further development and start expanding on the business front. The second key partner would be an audit contractor so that as this product undergoes testing, Therapeutic Innovations or the MQP team can be aware of what is necessary to be approved by the Ghanaian FDA. From here, the key partners become the Ghanaian FDA and Ministry of Health. Building relationships within these two institutions will ensure the product is fairly reviewed, and if given clearance, negotiations can begin on using the device in Ghana. Lastly, if the product is approved, then building significant relationships with contract manufactures and the companies within the supply chain are needed to allow for the product to be manufactured and distributed without any hiccups in the process.

2) Patent and Lease Approach

In the patent and lease approach there is only one key partner and that would be the company to which the product is leased. That company will take control over the growth of the product; however, a relationship needs to be maintained if the device needs upgrades from either obsolescence or general improvements.

4.1.7 Key Activities

There are two key activities that the teams moving forward must do to differentiate themselves and meet the Ghanaian FDA standards for a biomedical device:

1) Total Quality Management Systems
2) Post-Market Surveillance

The first key activity, total quality management systems, means that the teams must develop a system to check the quality of the feeding-pump and assure the device meets the standards for the Ghanaian market. A functional quality management system is a requirement of the Ghanaian FDA (see Appendix A) as in most regulating bodies in the biomedical industries. The second key activity, post-market surveillance, allows the team to make changes to the device

in response to what is happening in the hospitals. While the device may work in a controlled setting, when out in the field, issues will be revealed that will require the device to be upgraded.

4.1.8 Key Resources

There are two key resources for this venture. First is identifying the best materials to source to generate the lowest-cost, the highest value device possible. Material investigation will take place later in the manufacturing process as the demand for this device rises and the venture is in a position to expand. A second key resource is a patent. Protecting the intellectual property for this product is a crucial step once the novel device is tested and shown to work. Without this, larger companies can design the exact same instrument and, utilizing their established pathways and relationships, make this venture obsolete.

4.1.9 Cost Structure

The final box in the Business Model Canvas describes the sources of costs for this venture. For both strategies, there will be costs in pursuing a patent. This will include filing fees and all the designing and testing that goes into the development of the device. After these costs, the start-up will accrue most of the costs from the sourcing and manufacturing of the device. This will include all contract manufacturers and the costs associated with starting an assembly for the device in Ghana, if it is decided that assembly will happen in Ghana. The entire supply chain will end up under the "Cost Structure" umbrella once it is designed.

4.2 Interview Results

Table 4.1 summarizes the results of the two completed interviews. Both interviewees were biomedical engineers in Ghana and a summary of their answers to the 11 questions asked are below.

Question	Interviewee #1	Interviewee #2
What kind of devices do you make or work with?	Life support devices like Incubators, Radiant Warmers, Anaesthesia units, Ventilators etc. Diagnostics Devices like Chemistry and Haematology Analysers, X-Ray Units, CTs etc and Therapeutic Devices like Infusion Pumps, Syringe Pumps etc	Currently, almost all medical devices being used in Ghana are imported. Except a few protective clothing such as operating theatre gowns, surgical face mask and head covers. In Ghana we work with almost all the devices in the medical equipment industry you can think of and in your imagination, ranging from diagnostics, rehabilitation, therapeutic, to life support, surgical tools, medical furniture, non medical furniture and others.
Are your devices imported from another country?	Yes	Yes our devices are imported from countries in Asia, Europe, and North America, as for example USA, China, Japan, Korea, Spain, UK, Turkey, Germany, The Czech Republic and the rest.
Who are your top suppliers?	Dragger, General Electric, Mindray, Dometic.	In Ghana we have suppliers of medical equipment who are not manufacturers. They

		may include the following who function as Turn Key contractors who builds health facilities and equips them as well: Vamed Engineering GmBH. Euroget De Invest. Universal Hospital Group. There are others who are just supplies only and may include the following: Beautiful Creation Company, Limited, Herona, Hanisa, Cteq, Younfa, Baron, ADB, Philips Medicals, GE
Can you tell me who buys your medical products?	mostly the Government buys medical devices for hospitals and most Hospitals also buy medical devices for their own use	The Ghana Government buys the equipment needed for the public Health sector.
How do regulations affect the operations of a biomedical company in ghana?	They serve as check and balance on biomedical companies by ensuring quality devices are sold to hospitals for use to ensure patient safety	Regulation accounts for the supply of good quality medical equipment by biomedical companies in Ghana. By regulations, international standards are adhered to by these companies and any company that flouts laid down regulations is blacklisted from trading in this sector.
How do you interact with hospitals?	Servicing and maintaining their medical devices	There are management, administrative and technical reporting structure through which we interact with hospitals. The technical outfits usually will channel all important communications in writing through their management requesting us to offer a service to them through our management system, and when received we respond to the request appropriately.
Can you please describe the medical device industry in Ghana and how it is regulated by the government?	The Ghana FDA and Standards Board are the main regulators of the medical device industry in Ghana. In Ghana, we do not produce medical devices.	The medical equipment industry is mainly made of supplies that buy finished medical products from manufacturers and retail them to customers that need them. So there are lots of middle men in the supply chain making the industry expensive. Sometimes, inferior devices maybe supplied by these middle men, though not widely spread. When this happens, they are quickly detected and delft with immediately.
Are most medical devices made in or out of country?	Most are made out of the country	Most medical devices are made outside the country.
Would it be more beneficial to develop our product within Ghana or outside of Ghana?	It would be more beneficial to develop your product within Ghana using local materials	It would be more beneficial to develop your products outside Ghana because: You may be challenged with non availability of raw materials. Land acquisition procedure is cumbersome to enable you start up a manufacturing plant. Renting or hiring office premises could be very expensive. Sales of your product could be a daunting task if market environment is not well researched to find good customers base. Hiring of workforce could be expensive. Paying utilities services such as electricity, water, telephone could be challenging. You may be crediting your products to potential buyers, and it may take you long periods of time to get paid. The foreign currency exchange environment

		is not stable and may affect you investment. Generally the cost of doing business in Ghana is high.
How does the Ministry of Health decide what devices to use and which not to?	Through the standardization of medical devices	Decision to use or not to devices by the Ministry of Health depends on Disease patterns, as for example, malaria, glaucoma, hypertension Type of health service being offered, e.g. surgery, diagnostic, therapeutic Level of health service, e.g. primary, secondary, tertiary levels Availability of health professionals to use the device, e.g. eye specialist. Dermatologist, laboratory technologist.
If our group achieves in creating a safe, lost-cost replacement device for the current standard in Ghana, what are the next steps we would take to develop a working partnership with the Ghanaian government?	Contact The Ghana FDA and Standards Boards	Sign memorandum of understanding with the government (work out the details to suit your project)

Table 4.1 Interview Results

The most important takeaway from these interviews related to considerations regarding the location of the manufacturing and assembly of the product. The two interviewees seem to disagree on whether it would be beneficial to develop the product in Ghana. The first engineer spoken to seems to think that using local materials in Ghana would be the ideal option. The second disagrees, for the following reasons:.all the necessary materials might not be available in Ghana; it is relatively difficult to start a manufacturing plant because of the current difficulties with land acquisition;, hiring a workforce could be expensive; and as the engineer stated, “generally, the cost of doing business in Ghana is high”. These remarks were a significant consideration in the project team’s manufacturing and assembly recommendations.

4.3 Porter’s Five Forces

The first aspect is competitive rivalry. The device that the BME team is developing has to directly compete in that it would be a novel addition to the Ghanaian healthcare system. However, there is indirect competition in the other methods that nurses use to provide nutrition to premature babies. For example, other methods to feed premature babies are done manually by the nurses rather than automatically. This was analyzed through data collected from interviews with healthcare professionals. The next aspect of the analysis is supplier power. For this project, inexpensive but safe suppliers in Ghana are the priority. Once again, the interviews and market research were the main method for gaining this knowledge and analyzing options. The buyer power is in Ghana health services, regional hospitals, private health care facilities, etc. The government takes the majority of the costs and so a top-down approach to buyer analysis needs

to be taken in Ghana. The team investigated the Ministry of Health, health services, major regional hospitals, district hospitals, and remote clinics. The vast number of potential buyers needs to be broken down by feasibility and also how effective the device can be used in each area. The threat of substitution is relatively low for this venture, considering that the device appears to be a substantial improvement to how users currently provide nutrition for premature babies without automated pumps. Finally, the threat of new entry is a very broad issue with this project. The market, in this case, is Ghanaian healthcare and so the sector is tightly regulated by the government and Ghana health services. It was more important for the team to analyze how their particular device will enter, rather than the entry of the current nonexistent competition. Figure 4.2 shows the results from the Porters 5 Forces analysis.

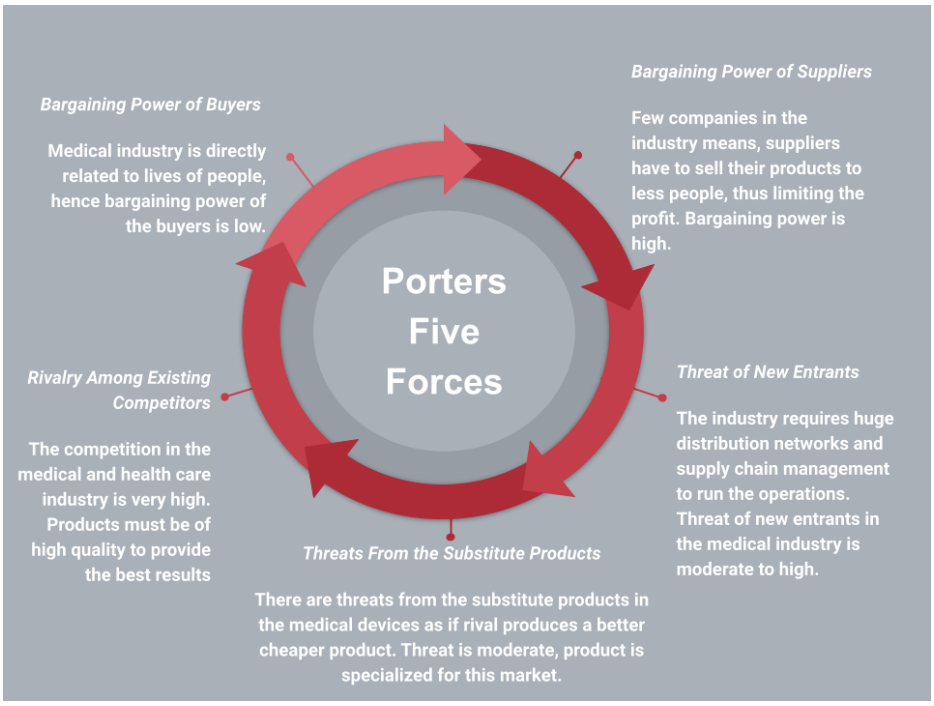


Figure 4.2: Porter's Five Forces Diagram

4.4 P.E.S.T.E.L.E. / SWOT

The following graphic, Figure 4.3, summarizes Ghana's political, economic, social, technological, environmental, legal, and ethical factors into the categories of strengths, weaknesses, opportunities, and threats based on their influence on this project.

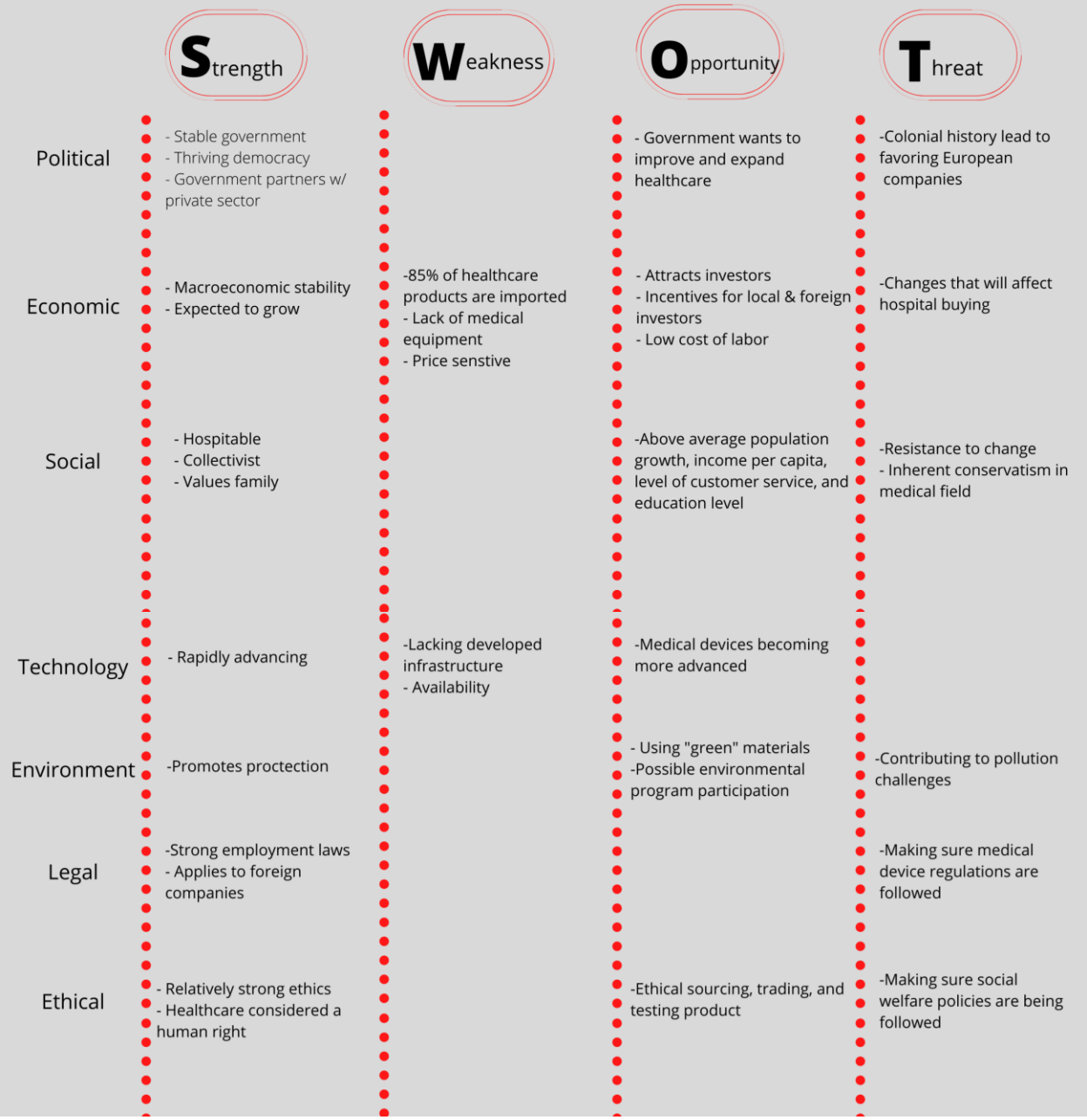


Figure 4.3: P.E.S.T.E.L.E./SWOT analysis of Manufacturing an Automated Feeding Pump in Ghana

4.5 Monte Carlo Simulations

The results of five Monte Carlo simulations are outlined below with screenshots from Microsoft Excel's @Risk add-in for both inputs, outputs, and results of the simulations.

1. **Cost-Benefit Simulation with multiple costs and multiple benefits:**

Figures 4.4 and 4.5 contain the inputs and results for a Monte Carlo simulation that estimated multiple costs and multiple benefits from the perspective of a 1-to-1 (1 baby to 1 pump) situation. These benefits were different from the other simulations as they accounted for unique stakeholders. The nurse opportunity cost was considered to analyze what else the nurses could be doing if not regularly checking up on the baby's formula or manually pumping. The reduced bed days are also accounted for and add up to a large sum in a Ghanaian hospital. Finally, the parent opportunity cost was considered because both the reduction of bed days and less manual work would create a significant benefit to the parent of the baby. The results show the predicted Future Value and Net Social Benefit of the business venture. The simulation results for Future Value show anywhere from -$23,282 to $24,489 with a mean profit of $1,146. This is a baseline value that will evolve over time as one-time costs disappear and more pumps are in use in hospital systems.

Discount Rate		1	2	3	4	5				Discount Rate	
7%		1.0000000	1.0666667	1.1377778	1.2136296	1.2945383				min	3%
										most likely	5%
Benefits										max	12%
nurse opportunity cost		$ 533.00	$ 548.99	$ 565.46	$ 582.42	$ 599.90				**nurse OC**	
reduced bed days		$ 23,625.00	$ 23,625.00	$ 23,625.00	$ 23,625.00	$ 23,625.00				triangular distribution	
parent opportunity cost		$ 1,575.00	$ 1,622.25	$ 1,670.92	$ 1,721.05	$ 1,772.68				min	300
										most likely	500
										max	800
TB		$ 25,733.00	$ 25,796.24	$ 25,861.38	$ 25,928.47	$ 25,997.57				**reduced bed days**	
PV TB		$ 25,733.00	$ 24,183.98	$ 22,729.73	$ 21,364.40	$ 20,082.51		114,094		triangular distribution	
PV ALL		$ 25,733.00	$ 49,916.98	$ 72,646.70	$ 94,011.10	$ 114,093.61				min	10125
										most likely	20250
one time costs										max	40500
materials		$ 93.00	$ -	$ -	$ -	$ -				**parent OC**	
manufacturing		$ 46.00	$ -	$ -	$ -	$ -				triangular distribution	
assembly		$ 37.00	$ -	$ -	$ -	$ -				min	675
distribution		$ 12.00	$ -	$ -	$ -	$ -				most likely	1350
										max	2700
ongoing costs											
administration		$ 775.00	$ 813.75	$ 854.44	$ 897.16	$ 942.02				**materials**	
lab		$ 7,088.00	$ 7,123.44	$ 7,159.06	$ 7,194.85	$ 7,230.83				triangular distribution	
NICU		$ 16,537.00	$ 16,619.69	$ 16,702.78	$ 16,786.30	$ 16,870.23				min	70
										most likely	83.41
TC		$ 24,588.00	$ 24,556.88	$ 24,716.28	$ 24,878.31	$ 25,043.07				max	125
PV TC		$ 24,588.00	$ 23,022.07	$ 21,723.29	$ 20,499.10	$ 19,345.18		109,178		**manufacturing**	
PV ALL		$ 24,588.00	$ 47,610.07	$ 69,333.36	$ 89,832.46	$ 109,177.63				triangular distribution	
										min	35
										most likely	41.7
FV		$ 1,145.00	$ 1,239.37	$ 1,145.10	$ 1,050.16	$ 954.50				max	62.5
Net Social Benefit		$ 1,145.00	$ 1,161.90	$ 1,006.43	$ 865.30	$ 737.33		4,916		**assembly**	

Figure 4.4 Cost-Benefit Simulation #1 Results

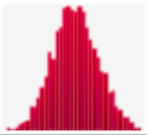
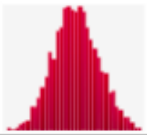
Detailed Statistics				
Output	Future Value	Net Social Benefit	Total TB-TC	Return On Investment
Function	skOutput("Future Value")	tput("Net Social Benefit")	skOutput("Total TB-TC")	"Return On Investment")
Graphs				
Cell	CBAIC31	CBAIC32	CBAIC33	CBAIC36
Statistic				
Minimum	-$ 23,282.00	-$ 23,282.00	-$ 23,282.00	-60.68%
Maximum	$ 24,489.00	$ 24,489.00	$ 24,489.00	163.11%
Mean	$ 1,146.00	$ 1,146.00	$ 1,146.00	8.58%
Mode	-$ 8,546.00	-$ 8,546.00	-$ 8,546.00	2.48%
Std. Deviation	$ 7,885.71	$ 7,885.71	$ 7,885.71	34.67%
Variance	62,184,361	62,184,361	62,184,361	0.1202
Skewness	0.0910	0.0910	0.0910	0.7990
Kurtosis	2.7199	2.7199	2.7199	3.7624
Errors	0	0	0	0
Percentiles				
1%	-$ 16,120.00	-$ 16,120.00	-$ 16,120.00	-49.86%
2.5%	-$ 14,051.00	-$ 14,051.00	-$ 14,051.00	-44.85%
5%	-$ 11,646.00	-$ 11,646.00	-$ 11,646.00	-39.39%
10%	-$ 8,967.00	-$ 8,967.00	-$ 8,967.00	-31.80%
20%	-$ 5,580.00	-$ 5,580.00	-$ 5,580.00	-20.86%
25%	-$ 4,319.00	-$ 4,319.00	-$ 4,319.00	-16.55%
50%	$ 941.00	$ 941.00	$ 941.00	3.81%
75%	$ 6,393.00	$ 6,393.00	$ 6,393.00	28.17%
80%	$ 7,961.00	$ 7,961.00	$ 7,961.00	35.32%
90%	$ 11,643.00	$ 11,643.00	$ 11,643.00	55.15%

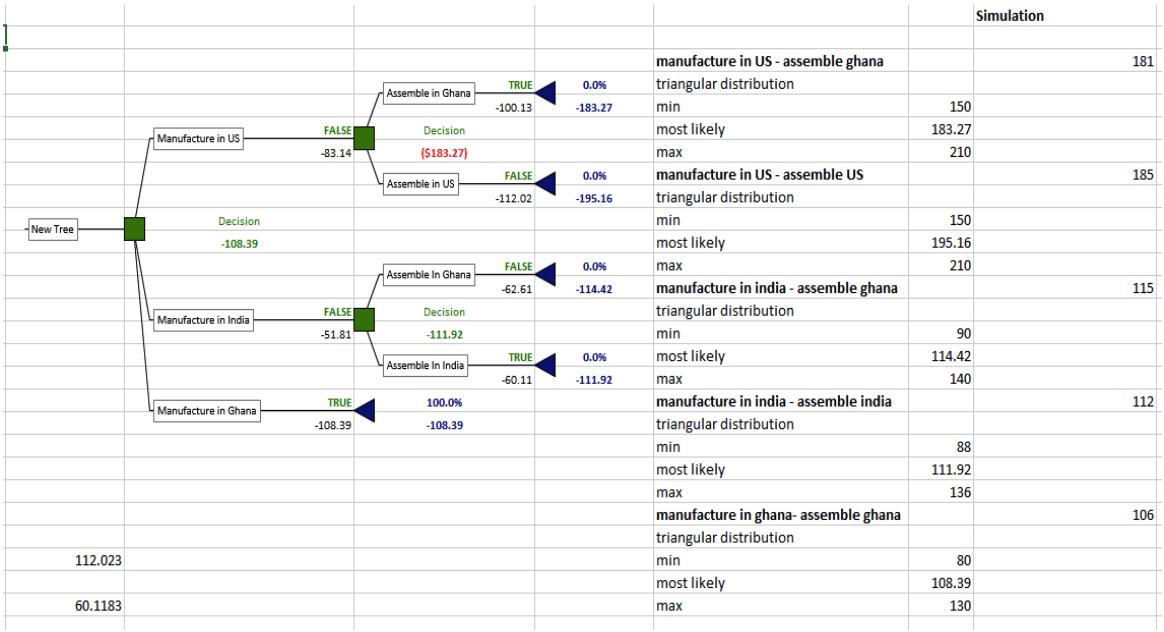
Figure 4.5 Cost-Benefit Simulation #1 Results

Decision Tree Simulation:

Figure 4.6 and Table 4.2 are two screenshots of Excel inputs for a Monte Carlo Simulation for a PrecisionTree decision tree and then the summary statistics results in a table from that simulation. Details regarding the decision tree can be found in Section 4.8.1. In this analysis the team used Monte Carlo simulation to explore uncertainty regarding:

- manufacturing in the US and assembling in Ghana;
- manufacturing and assembling in the US;
- manufacturing in India and assemble in Ghana;
- manufacturing and assembling in India;
- manufacturing and assembling in Ghana.

The costs for each option are considered below and the decision tree calls for the manufacturing and assembly to take place in Ghana.



		Simulation
manufacture in US - assemble ghana		181
triangular distribution		
min	150	
most likely	183.27	
max	210	
manufacture in US - assemble US		185
triangular distribution		
min	150	
most likely	195.16	
max	210	
manufacture in india - assemble ghana		115
triangular distribution		
min	90	
most likely	114.42	
max	140	
manufacture in india - assemble india		112
triangular distribution		
min	88	
most likely	111.92	
max	136	
manufacture in ghana- assemble ghana		106
triangular distribution		
min	80	
most likely	108.39	
max	130	

Figure 4.6 Decision Tree Monte Carlo Simulation

Summary Statistics									
Input	Cell	Graphs	Function	Minimum	Maximum	Mean	Std Dev	5%	95%
manufa cture in US assem...	Sheet1! O3		RiskTriang (N5,N6,N7)	151.213	209.894	181.092	12.277	159.917	201.016
manufa cture in US assem...	Sheet1! O8		RiskTriang (N10,N11,N1 2)	150.363	209.321	185.053	12.767	161.626	203.278
manufa cture in india assem...	Sheet1! O13		RiskTriang (N15,N16,N1 7)	91.038	139.151	114.807	10.212	97.758	131.977
manufa cture in india assem...	Sheet1! O18		RiskTriang (N20,N21,N2 2)	88.747	135.332	111.973	9.802	95.570	128.340
manufa cture in ghanaassem...	Sheet1! O23		RiskTriang (N25,N26,N2 7)	81.178	129.683	106.131	10.241	88.396	122.638

Table 4.2 Decision Tree Monte Carlo Simulation Results

Simple Cost-Benefit Simulation:

Table 4.3, Figure 4.7 and Figure 4.8 are from the most basic cost-benefit simulation that the team performed. The first figure lists the prices for each part required to build a pilot feeding pump. These prices are estimates from the WPI biomedical engineering team and are subject to change. The demand was then estimated from discussions with the BME team, and the benefit for this simulation is profit. The demand in this simulation was set to be conservative to analyze at which point the process may break-even. The mean profit from the results is $3,050 and the standard deviation is $855.

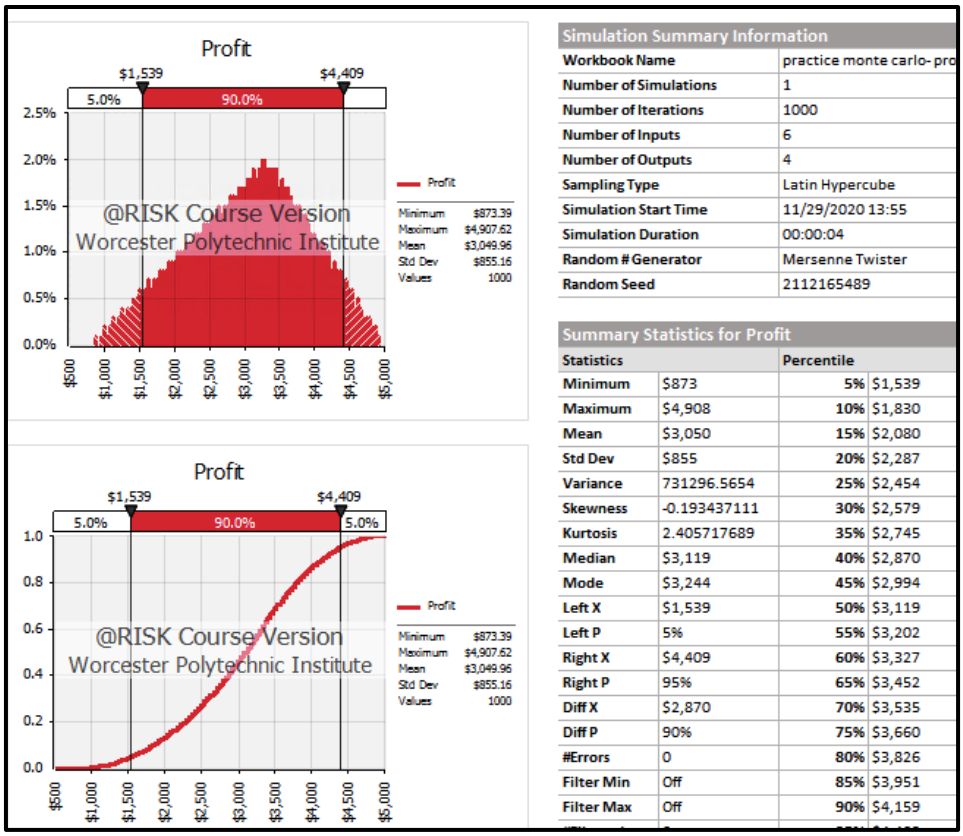
Ultrasound sensor	$8.39 (2)
AtMega1284p	$30
LCD Display	$7.03
Memory card	$14.99
IV Valve	$2.40
Feeding bag	$3.89
Administration port	$3.97
Tubes	$4.35

Rough Estimate for total: $83.41

Table 4.3 Cost Estimate for Parts of Pump

Practice Monte Carlo Simulation					
Cost-Benefit Analysis					
Cost Data				**triangular demand distribution**	
Unit cost	$ 83.41			minimum	20
unit price	$ 125.00			most likely	80
				maximum	120
Simulation					
	Demand	Revenue	Cost	Profit	
	73	$9,125	$6,089	$3,036	

Figure 4.7 Cost-Benefit Simulation #2 Monte Carlo Inputs



Simulation Summary Information	
Workbook Name	practice monte carlo- pro
Number of Simulations	1
Number of Iterations	1000
Number of Inputs	6
Number of Outputs	4
Sampling Type	Latin Hypercube
Simulation Start Time	11/29/2020 13:55
Simulation Duration	00:00:04
Random # Generator	Mersenne Twister
Random Seed	2112165489

Summary Statistics for Profit			
Statistics		Percentile	
Minimum	$873	5%	$1,539
Maximum	$4,908	10%	$1,830
Mean	$3,050	15%	$2,080
Std Dev	$855	20%	$2,287
Variance	731296.5654	25%	$2,454
Skewness	-0.193437111	30%	$2,579
Kurtosis	2.405717689	35%	$2,745
Median	$3,119	40%	$2,870
Mode	$3,244	45%	$2,994
Left X	$1,539	50%	$3,119
Left P	5%	55%	$3,202
Right X	$4,409	60%	$3,327
Right P	95%	65%	$3,452
Diff X	$2,870	70%	$3,535
Diff P	90%	75%	$3,660
#Errors	0	80%	$3,826
Filter Min	Off	85%	$3,951
Filter Max	Off	90%	$4,159

Figure 4.8 Cost-Benefit Simulation #2 Monte Carlo Results

Cost-Benefit Simulation for Monthly Production:

Figures 4.9 and 4.10 show a simulation that considered multiple costs in the monthly pump production process: manufacturing, material, assembly and distribution. The outcomes are profit and return on investment, and the main input being demand. The results of this simulation show a mean monthly profit of $11,666 and a mean return on investment of $259.26. In future months, base payments that are considered costs in this simulation will be decreased, and some

changed to 0. We also assumed demand would rise over time.

Practice Monte Carlo Simulation						
Cost-Benefit Analysis						
Cost Data				**triangular demand distribution**		
Unit cost	$ 150.00			minimum	50	
unit price	$ 200.00			most likely	250	
				maximum	400	
manufacturing costs	$1,000.00					
material costs	$2,000.00					
assembly costs	$1,000.00					
distribution costs	$ 500.00					
total	$4,500.00					
Simulation						
	Demand	Revenue	Cost	Profit	ROI	cost of investment
	233	$46,600	$34,950	$11,650	$ 258.89	$ 4,500.00
Summary Stats						
minimum	2900					
maximum	19800					
average	11666.7					
standard deviation	3585.5972					
5th percentile	5450					
95th percentile	17450					

Figure 4.9 Monthly Cost-Benefit Simulation Inputs

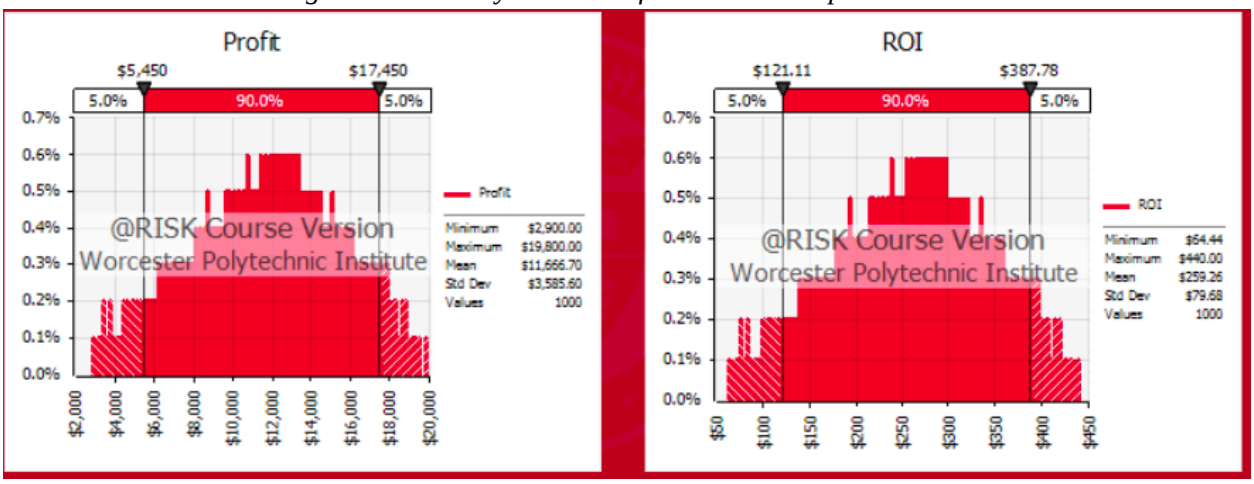


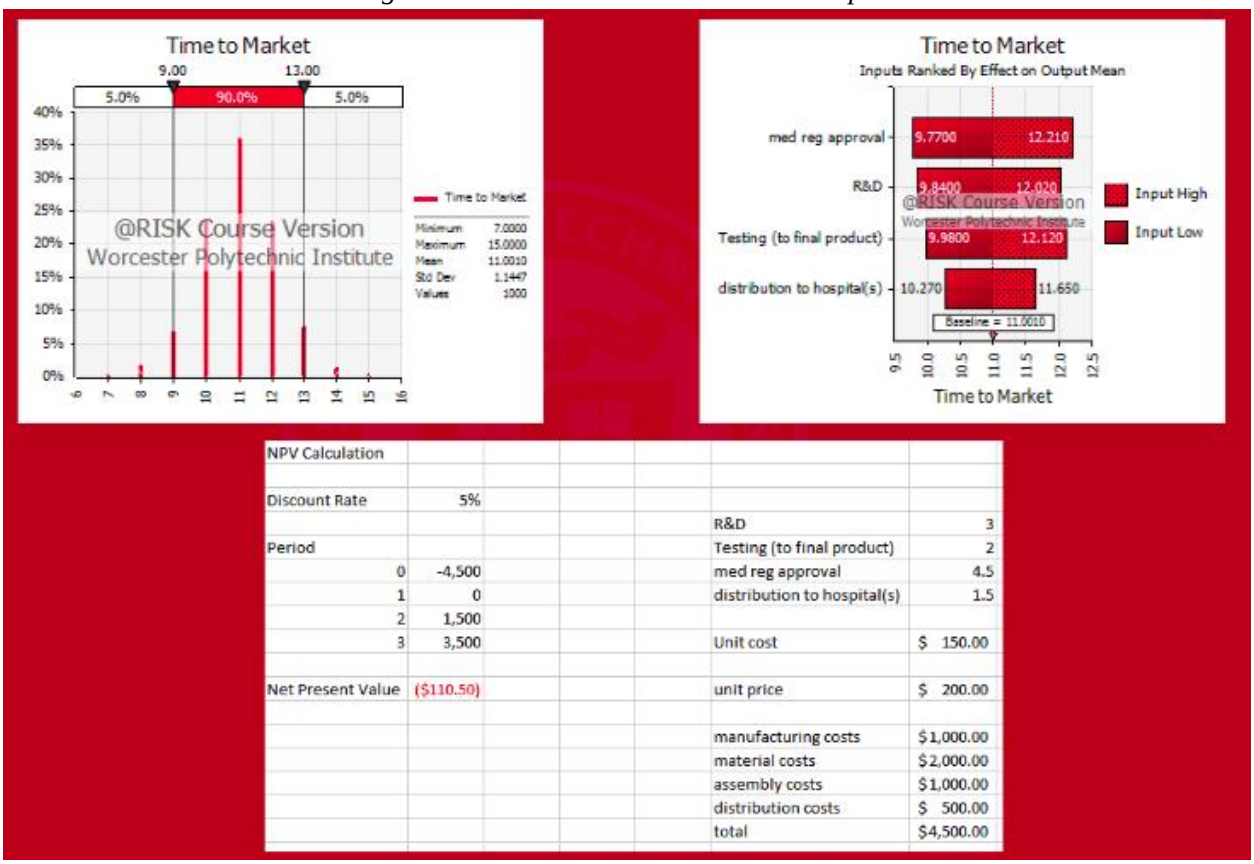
Figure 4.10 Monthly Cost-Benefit Simulation Results

Time to Market Simulation:

Figures 4.11 and 4.12 show a time to market estimate for the life of the pump. The factors (R&D, Testing, getting medical regulation approval, and distribution to hospitals) are iterative in this case, meaning one has to be completed before the other begins. The mean time to market from the simulation results is 11 months. The standard deviation is 1.14.

Practice Monte Carlo Simulation				triangular demand distribution	
Time to Market				minimum	2
				most likely	3
				maximum	4
				triangular demand distribution	
Inputs (months)				minimum	1
R&D	3			most likely	2
Testing (to final product)	2			maximum	3
med reg approval	5			**triangular demand distribution**	
distribution to hospital(s)	2			minimum	3
				most likely	4.5
				maximum	6
Outputs				**triangular demand distribution**	
Time to Market	12			minimum	0.5
				most likely	1.5
				maximum	2.5

Figure 4.11 Time to Market Simulation Inputs



NPV Calculation				
Discount Rate	5%			
			R&D	3
Period			Testing (to final product)	2
0	-4,500		med reg approval	4.5
1	0		distribution to hospital(s)	1.5
2	1,500			
3	3,500		Unit cost	$ 150.00
Net Present Value	($110.50)		unit price	$ 200.00
			manufacturing costs	$1,000.00
			material costs	$2,000.00
			assembly costs	$1,000.00
			distribution costs	$ 500.00
			total	$4,500.00

Figure 4.12 Time to Market Simulation Results

4.6 Sensitivity Analysis

A sensitivity analysis illustrates the tradeoffs between the cost and demand for the feeding pump using a basic Excel Sensitivity simulation. The left hand side of Figure 4.13 list assumptions, and user-inputted profit and losses. The right hand side of Figure 4.13 are predictive outputs based on demand, once again estimated from discussions with the biomedical engineering team. From observing the table on the right in Figure 4.13, a monthly demand for 25-200 pumps would generate negative operating profit if the price of the pump is between $100 and $150. The cost and demand combinations that result in a net positive operating profit under this simulation are: cost of $175 and demand of 150-200 and a cost of $200 with a demand of 100-200 products.

SENSITIVITY ANALYSIS									
Assumptions									
Pumps Sold	100				Demand				
Price per Pump	$ 200.00			$ 2,000.00	25	50	100	150	200
Cost per Pump	$ 150.00		Cost	$ 200.00	-1750	-500	2000	4500	7000
Manufacturing	$ 1,000.00			$ 175.00	-2375	-1750	-500	750	2000
Assembly	$ 1,000.00			$ 150.00	-3000	-3000	-3000	-3000	-3000
Distribution	$ 1,000.00			$ 125.00	-3625	-4250	-5500	-6750	-8000
				$ 100.00	-4250	-5500	-8000	-10500	-13000
Profit and Loss									
Revenue	$ 20,000.00								
Cost of Sales	$ 15,000.00								
Gross Profit	$ 5,000.00								
SG&A	$ 3,000.00								
Operating Profit	$ 2,000.00								

Figure 4.13 Sensitivity Analysis

4.7 Logistics

Interviews revealed (see section 4.2) that most medical devices and supplies are imported from other countries. These devices are purchased by the Ghanaian government and are supplied to hospitals. Before the devices are given to the hospitals, the Ministry of Health (MOH) decides whether or not the device is needed based on several criteria, the main criteria being the demand and need for the device.

4.8 Manufacturing

Ghana v.s. U.S. Analysis

Most medical devices in Ghana are imported or donated to hospitals (Mensah S 2020). The devices that are used in the hospitals are mainly purchased by the Ghana Health Services, which is a subsidiary of the Ghanaian Government. Devices are typically imported due to the lack of advanced medical equipment and manufacturing capabilities, so manufacturing in Ghana may result in a lower quality product or present difficulties with acquiring raw materials. If the

manufacturing were to take place in Ghana, the benefits would include being independent from international suppliers and supply chains, ease of transportation, lower production costs, and supporting local Ghanaian markets and businesses. Manufacturing in the US and exporting to Ghana would be more expensive and relying on international relations is risky, but the quality of the product could be guaranteed. It is important to ensure that the costs of US manufacturing would be low enough for the product to still be reasonably priced in Ghana, which may not be realistic.

Most of the mentioned benefits and risks are also applicable to the product assembly. Assembling in Ghana would be less expensive, would support the Ghanaian economy, decrease transportation time of the finished products, and decrease potential chance of damage in transportation. Assembling in the US wouldn't necessarily produce a better-quality pump as it would with the manufacturing. Assembly is relatively simple, so both locations would be capable of producing the same quality. US assembly costs more with no effect on the finished product and products would be more likely to get damaged during the long transportation

Demand Forecasting: Based on the Sensitivity Analysis and Monte Carlo Simulation, the team is going to assume that the demand forecast is 100 pumps in the first month of production, and if all pumps are sold then the demand estimate can be increased for future months.

Production Process: Figure 4.14A contains a Process Map Flowcharts for options of manufacturing pump components in the US and assembling the final product in Ghana, and Figure 4.14B shows the same for manufacturing the components in Ghana and assembling in Ghana. The times for each task were estimated on general manufacturing times and how long travel will take to various locations.

Figure 4.14A: Process Map Flowchart of US Manufacturing and Ghana Assembling

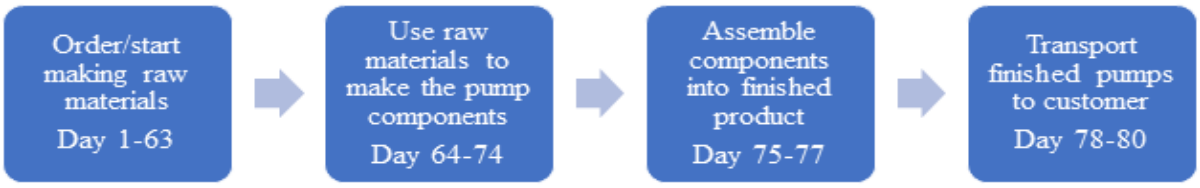


Figure 4.14B: Process Map Flowchart of Ghana Manufacturing and Ghana Assembly

Monitoring and Adjusting: The master production schedules are in tables 4.15A and 4.15B, followed by material requirements planning information, and the assembly process. These tables contain a suggested Master Production Schedule which shows the estimated time producing the pump will take. Data for these tables was obtained from the World Bank. Actual times could be subject to change according to specific manufacturers' cycle time, which is calculated by the following equation (Bragg, 2020): Manufacturing cycle time = Process time + Moving time + Inspection time + Queue time.

Master Production Schedule (US Manufacturing, Ghana Assembly):

Activity	Shortest Duration (days)	Longest Duration (days)
Order raw materials	30	60
Make components	7	10
Ship to Ghana	7	20
Assemble final product	1	2
Transport to customer	1	2
Total	46	94

Table 4.15A: MPS US, Ghana

Master Production Schedule (Ghana Manufacturing, Ghana Assembly):

Activity	Shortest Duration (days)	Longest Duration (days)
Order raw materials	37	63
Make components	7	10
Assemble final product	1	2
Transport to customer	1	2
Total	46	77

Table 4.15B: MPS Ghana, Ghana

Material Requirements Planning: Each task must be completed before the next task can begin. The longest duration times in the MPS shows the latest each task can be completed and should be used to plan when materials will be ready and needed.

Assembly Process: Figure 4.16 is for a general feeding pump and the team anticipates the parts needing to be assembled for this product are similar to the ones in Figure 4.16. Assembly may alter based on the actual components the BME team chooses.

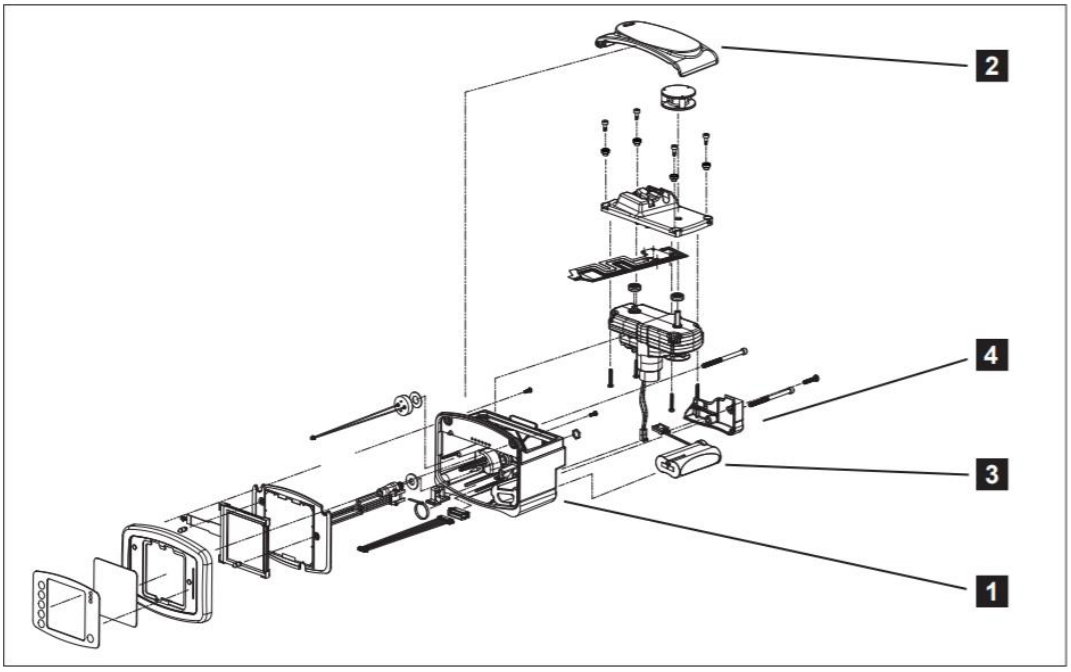


Figure 4.16: Pump Assembly Overview (Operating Manual, Kangaroo Joey Enteral Feed and Flush Pump with Pole Clamp)

List of Components:

1. Flush pump
2. Main door
3. Battery pack
4. Battery door

Unnumbered components: A/C power adapter, pole clamp, electrical plugs, ultrasound sensor, LCD display, memory card

Components not pictured: Feeding bag, tubes

4.8.1 Decision Tree

Based on information provided by the WPI Biomedical team, the decision tree found in Figure 4.17 was created. The purpose of this decision tree was to evaluate which location is the best for manufacturing the device. The numbers in the tree represent the cost of the device depending on where the device is manufactured. These costs are based on the bill of materials given to the team from the WPI biomedical team. Since the numbers used in the tree are costs and the decision tree represents cost as negatives numbers, then the lowest number is the best decision. In this case, the best option would be to manufacture and assemble in Ghana.

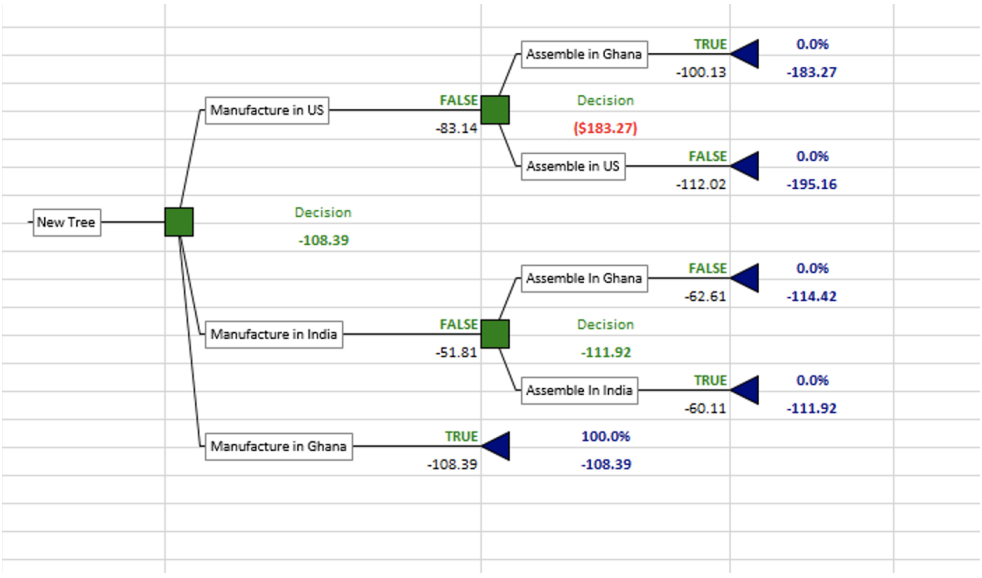


Figure 4.17: Manufacturing and Assembly Decision Tree

4.8.2 Economic Evaluation

After extensive research and collaboration with the WPI BME team we were able to input costs into an Excel model, all calculations are in US dollars. As detailed in Section XYZ the team looked into both fixed and variable costs related to manufacturing and distribution of the pumps. From the results of section 4.8.1 Decision Tree, it was decided to outsource the manufacturing of materials in the United States and import them to Ghana where final assembly can take place. With these results and our research outlined in section 3.4 we were able to still construct a model that can be used to visualize the feasibility of this venture.

Figure 4.18 shows the annual labor costs of 7 workers in Ghana (one manager, and 6 workers). To simulate a real business operation the team decided to include a manager that would oversee the workers and their assembly of the medical devices. The data for this was obtained from looking at the national average salaries in Ghana for specific job types (“Ghana Salary.”).

https://www.averagesalarysurvey.com/ghana			GHS -> USD	$ 0.17	12/9/2020
	Ghana salary by field				
Manager	$ 124,821.00	GHS			
Worker	$ 26,539.00	GHS			
	$ 21,219.57	USD	$ 10.20	per hour	
	$ 4,511.63	USD	$ 2.17	per hour	
Work Hours	8				
Work Days	5				
Working weeks	52				
Labor	Quantity	Total			
Manager	1	$ 21,216.00	$ 124,800.00		
Workers	6	$ 27,081.60	$ 159,303.53		
	Total Labor	**$ 48,297.60**			

Figure 4.18: Calculation of Labor Costs

The next cost we looked into were transportation costs of moving the product to medical stores or hospitals. The Ghanaian Ministry of Health gives an estimated cost of logistics for their supply chain based in different regions (Raja). These costs also include the importation of our material. Using @Risk we were able to add variability to this cost to replicate the fluctuation of prices, on average the cost is $20,276.95 for the year.

Transportation Costs						
https://www.who.i	GHS		USD			
Ashanti	$	196,864	$ 33,466.88		Normal	
Central	$	15,189	$ 2,582.13		$ 20,276.95	$ 13,216.48
Greater Accra	$	126,901	$ 21,573.17			
Upper East	$	214,821	$ 36,519.57			
Upper West	$	105,846	$ 17,993.82			
Western Region	$	56,036	$ 9,526.12			
	Transportation Cost		**$ 22,642.40**			

Figure 4.19: Average Transportation Costs

The BME team, at the time of writing, decided to mold the plastic parts necessary for the assembly of the device. The equipment needed for injection molding include machines and specially made molds for each component. In this case the device needs three plastic parts ranging from small (less than 5 grams or 0.01lbs) to large (no more than 10 grams or 0.02lbs). Since the team decided to simulate manufacturing in the United Stand and assembly in Ghana (Section 4.8.1 Decision Tree), there will be no equipment costs. The material that will be used is Polypropylene since it has a lower cost per pound, and it is medical grade plastic (BMP Medical). Polypropylene is sold for $0.0369 per pound, and will use this cost to calculate the cost of one unit.

https://www.3dhubs.com/guid	https://www	https://www.too		
Plastic Injection Mold	Quantity	Price	Total	
Machine	0	$ -	$	-
Mold	0	$ -	$	-
			$	-
	$ per lb			
Polypropylene	0.0369			
https://www.bmpmedical.con				
https://resource-recycling.cor				

Figure 4.20: Price per lb of Polypropylene (Guest Authors)

To calculate the utilities cost we took the national average consumption of both electricity and gas to operate a 600 m^2 building ("Ghana Electricity Prices."). Again, since there is no need for equipment, the electrical consumption of the machines was not calculated. The total utility costs summed up to be $4,942.74 per year.

Utility Cost	$ per kWh	kWh per hour	Quantity	Hours	Days	Weeks	**Total Cost**
Injection Machines	$ 0.26	2.97	0	8	5	52	**$** -
Lights	$ 0.26	1.48	1	24	7	52	**$ 3,370.74**
	$ per mmbt	mmbtu per montl	Service	Month	**Total Cost**		
Natural Gas	$ 7.00	15	$ 26.00	12	**$ 1,572.00**		

Figure 4.21: Price of kWh ("Utilities - Ghana Investment Promotion Centre (GIPC)")

We gathered data from rent by taking a sample of office/warehouse spaces that are currently available in Ghana, from this we choose one in particular based on the spacing needs for the just assembly and material storage. This location also included some utilities and had an ideal location near the Accra airport.

Rent	Adjiriganor Office	Tema Freezone Wa	Spintex-Accra Warehouse
Price per m^2	$ 24.00	$ 7.00	$ 4.00
Size m^2	600	1000	900
Total	$ 14,400.00	**$ 7,000.00**	$ 3,600.00

Figure 4.22: Price of Rent (Taken from various sources)

The WPI BME team provided our team with an estimated bill of materials which will be used to calculate the cost per unit. The bill of material had to be estimated at the time of this model because their team had to make design changes, however their goal was to keep the total cost under purchasing material to be $10. The cost per unit is important because we are able to calculate the profit that will be achieved from selling at high demands.

Polypropylene	$	0.04	
Total lbs		0.5	
Cost for injection molded part	$	0.018	
Assembly per	$	2.89	
Material per	$	10.00	Bought in bulk
Manufacture(imported)/Assembly	$	12.89	

Figure 4.23: Total Cost of 1 Unit

Figure 4.24 shows all the variable and fixed costs combined for production. We established three desired price points: a minimum price ($30), a maximum price ($60), and a middle price (average of max and min) that this pump should cost. The revenue was calculated by multiplying the price per pump with the pumps sold and the total cost was calculated by adding all the fixed and variable costs together. The pumps sold was adjusted to be able to obtain a wide range of demand, like mentioned before this changes the revenue obtained.

Manufacture/Assembly	$	12.89					
Direct Labor	$	48,297.60					
Utilities	$	4,942.74					
Rent	$	7,000.00					
Transportation	$	22,642.40					
Equipment	$	-					
Repair	$	-					
Price / Pump @ Min	$	30.00					
Price / Pump @ Mid	$	45.00					
Price / Pump @ Max	$	60.00					
		50					
Pumps Sold		500		550		600	
Revenue @ Min	$	15,000.00	$	16,500.00	$	18,000.00	$ 19,
Revenue @ Mid	$	22,500.00	$	24,750.00	$	27,000.00	$ 29,
Revenue @ Max	$	30,000.00	$	33,000.00	$	36,000.00	$ 39,
Variable Costs	$	29,089.07	$	29,733.73	$	30,378.40	$ 31,
Fixed Costs	$	60,240.34	$	60,240.34	$	60,240.34	$ 60,
Total Cost	$	89,329.40	$	89,974.07	$	90,618.74	$ 91,
Intersection @ Min		0		0		0	
Intersection @ Mid		0		0		0	
Intersection @ Max		0		0		0	

Figure 4.24: Calculations of Break Even

These calculations yielded a break even graph that shows the amount of pumps that need to be sold at a specific price in order to begin generating profit. Anything below the dotted cost line will not generate profit and anything above will. Having the three different price points allows the teams to analyze and modify certain costs based on where they would want their idea production. For instance if we decided to go ahead and sell these pumps at $45 the break even point would be located around 2600 pumps with a revenue of $117,000.00 and a total cost of $116,405.40.

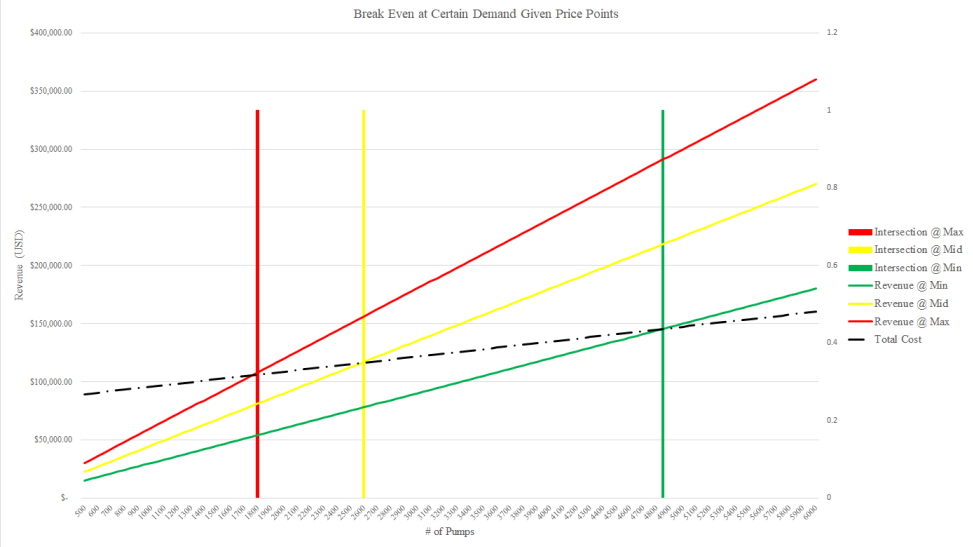


Figure 4.25: Break Even Graph

With the different forecasted demand points the team was able to create a projection of profit over the time period of 10 years, as seen in Figure 4.26. This helps project the longevity of this product and analyze its profit generation to determine if the initial investment is worth it. The team decided to use the minimum selling price of $30 to construct this projection as this is the ideal price the WPI BME team would like to sell the novel feeding pump for. To complete an actual profit we were recommended to at Value-Added Tax.

Year	1	2	3	4	5	6	7	8	9	10
Manufacture(imported)/Assembly	$ 12.89	$ 12.89	$ 12.89	$ 12.89	$ 12.89	$ 12.89	$ 12.89	$ 12.89	$ 12.89	$ 12.89
Direct Labor	$ 48,297.60	$ 48,297.60	$ 48,297.60	$ 48,297.60	$ 48,297.60	$ 48,297.60	$ 48,297.60	$ 48,297.60	$ 48,297.60	$ 48,297.60
Utilities	$ 4,942.74	$ 4,942.74	$ 4,942.74	$ 4,942.74	$ 4,942.74	$ 4,942.74	$ 4,942.74	$ 4,942.74	$ 4,942.74	$ 4,942.74
Rent	$ 7,000.00	$ 7,000.00	$ 7,000.00	$ 7,000.00	$ 7,000.00	$ 7,000.00	$ 7,000.00	$ 7,000.00	$ 7,000.00	$ 7,000.00
Transportation	$ 22,642.40	$ 22,642.40	$ 22,642.40	$ 22,642.40	$ 22,642.40	$ 22,642.40	$ 22,642.40	$ 22,642.40	$ 22,642.40	$ 22,642.40
Equipment	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -
Repair	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -
Selling Price	$ 45.00									
Production Inc	0	-1500	0	0	0	0	0	0	0	0
Forecasted Demand	5850	4350	4350	4350	4350	4350	4350	4350	4350	4350
Revenue	$ 263,250.00	$ 195,750.00	$ 195,750.00	$ 195,750.00	$ 195,750.00	$ 195,750.00	$ 195,750.00	$ 195,750.00	$ 195,750.00	$ 195,750.00
Total Cost	$ (158,308.74)	$ (138,968.74)	$ (138,968.74)	$ (138,968.74)	$ (138,968.74)	$ (138,968.74)	$ (138,968.74)	$ (138,968.74)	$ (138,968.74)	$ (138,968.74)
Profit	$ 104,941.26	$ 56,781.26	$ 56,781.26	$ 56,781.26	$ 56,781.26	$ 56,781.26	$ 56,781.26	$ 56,781.26	$ 56,781.26	$ 56,781.26
Value-added tax (VAT) 12.5%	$ (13,117.66)	$ (7,097.66)	$ (7,097.66)	$ (7,097.66)	$ (7,097.66)	$ (7,097.66)	$ (7,097.66)	$ (7,097.66)	$ (7,097.66)	$ (7,097.66)
After Tax	$ 91,823.60	$ 49,683.60	$ 49,683.60	$ 49,683.60	$ 49,683.60	$ 49,683.60	$ 49,683.60	$ 49,683.60	$ 49,683.60	$ 49,683.60
Cumulative Profit	$ 91,823.60	$ 141,507.21	$ 191,190.81	$ 240,874.42	$ 290,558.02	$ 340,241.62	$ 389,925.23	$ 439,608.83	$ 489,292.44	$ 538,976.04

Figure 4.26: 10 year Profit Projection

Due to the initial cost of investment the model calculates that the profit after tax will be $91,823.60 at a forecasted demand of 5850 pumps. After the first year the forecasted demand is able to decrease to account for a possible decrease in demand or a possible decrease in production. The last row of figure 4.26 shows the cumulative profit for every year. For posterity this model can be modified to simulate other outcomes or variables.

4.9 Fault Tree Analysis

Figure 4.27 is a Fault Tree Analysis of the pump, which depicts reasons why the pump may not be operating correctly and identifies the cause of the problem.

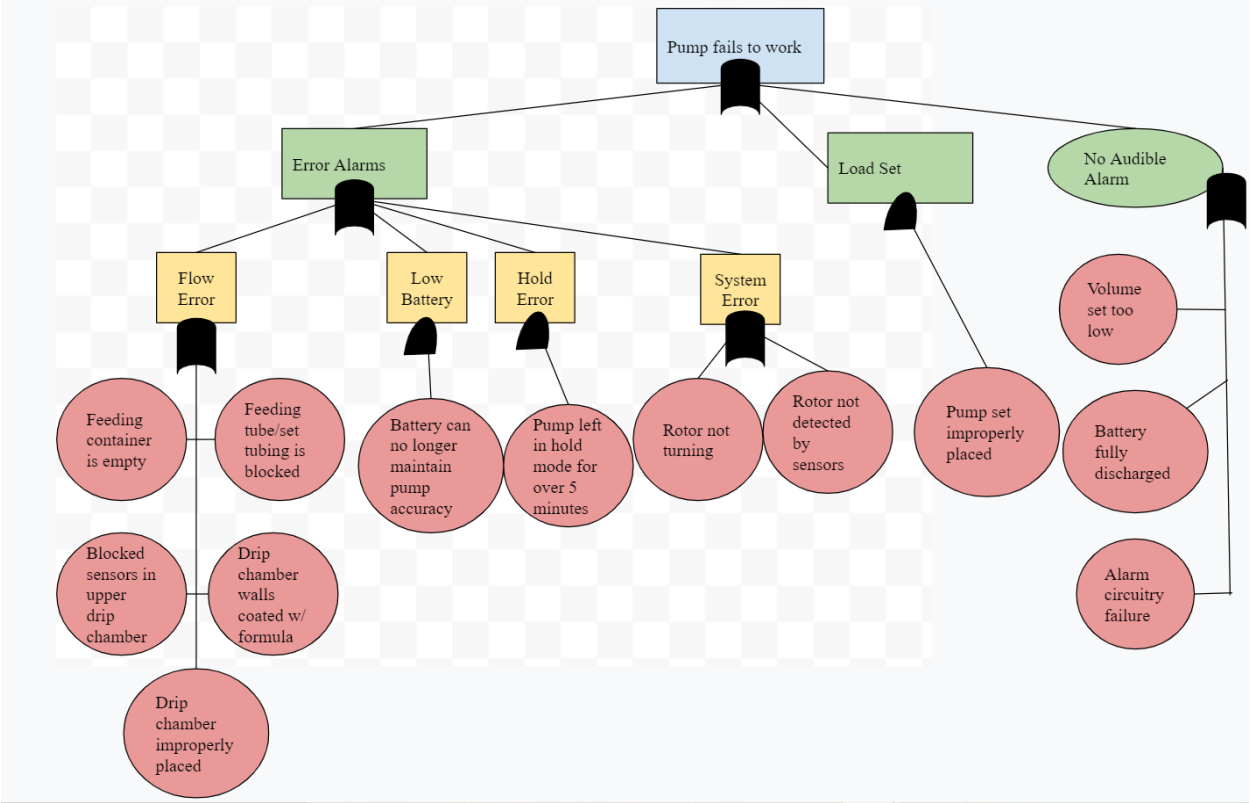


Figure 4.27: Fault Tree

4.10 Failure Mode and Effects Analysis

With the help of the BME team, we were able to create an FMEA to help analyze aspects of the product. Figure 4.28 shows a table with possible failures and effects of the pump and their ratings (calculated from section 3.4.2.1 Failure Modes and Effects Analysis). From this table we can see that regulating the temperature of the formula has the biggest risk as it has the highest risk priority number. In terms of the highest severity, administering the specific volume of formula is ranked the highest as it is the most important aspect of the medical device's function. From this analysis both teams will be able to determine if the product will be stable enough to introduce into the market.

Specification	Failure Mode	Effect	Severity Rating (1-10)	Cause	Frequency (1-10)	Detectability (1-10)	Critical	Total
Administer specific volume of formula/drug	Device fails to administer correct amount of formula	Malnutrition or over feeding. Overdose. Death.	10	Electrical malfunction	2	4	yes	80
Temperature regulation of formula/drug	Device fails to administer at body temperature	Body temp of child could be lowered	4	Electrical malfunction	3	9	yes	108
Operating Temperature	Device does not operate between 50-100 degree F	Device malfunctions	6	Electrical malfunction	1	8	yes	48
Low battery alarm	Alarm does not sound	The device will die. Malnutrition in child	8	Electrical malfunction	1	8	yes	64
Pump error alarm	Alarm does not sound	The device stops pumping or pumps incorrectly. Malnutrition or over feeding. Overdose. Death.	8	Electrical malfunction	1	6	yes	48
Memory log	Log does not hold memory from device	Memory for the device is not accessible or stored.	1	Electrical malfunction	5	1	no	5
Alarm if tube is blocked	Alarm does not sound	Malnutrition	9	Electrical malfunction	1	5	yes	45
Low food alarm	Alarm does not sound	Malnutrition	7	Electrical malfunction	1	7	yes	49
Alarm if drug/food temperature goes too far out of body temperature	Alarm does not sound	Body temp of child could be lowered or heightened	4	Electrical malfunction	1	9	yes	36
	If the device falls off ring stand/table	The device may break, stop working, crack, not administer nutrients/drugs correctly	7	Falling off table/stand	1	9	yes	63

Figure 4.28: FMEA Chart

Since production of these products will reach thousands, each specification are vital to understand when designing the assembly process to limit any risk of failure and maintain the proper quality.

Chapter 5: Recommendations

This MQP centers on analyzing WPI BME's automatic food and drug delivery pump in terms of (1) production, (2) market introduction, and (3) market feasibility. After analyzing our results and conclusions, the team developed a series of recommendations regarding (1) how to move forward with the introduction of the pump and (2) future work needed.

5.1 Interpreting the Results

Where to Manufacture:

From the decision tree analysis, the pump should be manufactured and assembled in Ghana. However, this option is not the final recommendation.. The decision tree helped the management team compare manufacturing and assembly options, but does not require more comprehensive analysis to address the "where to manufacture/assemble" question .

Where to Produce:

Based on the SWOT analysis, our production analysis, and information gathered from interviews - the team recommends the best production option is to manufacture the pump components in the US and assemble the final product in Ghana. This option provides the highest quality of pump materials, while creating assembly job opportunities in the local Ghanaian community. Assembly in Ghana mitigates the risk of product damage during transportation to the hospitals by eliminating the need to ship the final product from overseas. Manufacturing in the US will be more expensive but even with that added cost, the price of our pump is significantly lower than other pumps available.

Production Volume:

The economic evaluation conducted provides an estimate to the feasibility of a full scale operation. The model indicates a positive economic outcome from outsource manufacturing in the United States and Ghana assembly selling the automatic drug and food pump. To successfully make profit from the pump, it would be necessary to scale up the manufacturing. This would require a factory or automated production system that could produce pumps at a high rate. If the demand of 5850-4350 pumps as estimated by the model (LINK) are maintained, a company will be able to overcome the fixed and variable costs of this medical device. An injection molding process is able to meet these projected, annual demands, at a lower cost per unit than 3D printing.. While this model analyzes financial costs of the pump, a more in depth analysis can be created with applied values generated mainly from interviews or concrete numbers. There is uncertainty regarding our cost estimates for instance: the amount of workers needed, transportation costs, utilities costs, and rent costs. With these uncertainties we recommend to add these necessary variabilities to generate a more comprehensive evaluation. However, with the data presented to use the team does believe that there will be a demand that can fulfil the projects at the same time generating profit.

5.2 Project Limitations

The potential of this project was largely limited by the limitations encountered in data collection and subsequent analyses. The first and most prominent limitation was the lack of data from expert interviews. The team identified, contacted, and planned to interview well over a dozen experts in Ghana that would aid in data collection in the fields of manufacturing, nursing, logistics, and hospital administration. However, the responses from the professionals were severely limited. This topic is further discussed in section 5.3.1 "Additional Interviews".

The next limitation was an academic timeline misalignment between this project team and the biomedical engineering project teams. The BME product development process is ongoing. This business team was unable to obtain the necessary data and information needed for the risk analysis, cost-benefit analysis, or logistical analysis as at the time of writing, the biomedical teams were in the early stages of development. This hindered the business analyses and left for a significant amount of best-guessing and estimating when it came to product-related analyses. This limitation hinders the accuracy of the data used in the business team's reports.

Another limitation was the lack of connections in the Ghanaian market. During the project's initial phases, it appeared that the teams would be able to utilize a strong Ghanaian presence in order to gain hands-on experience inside Ghanaian hospitals and possibly with logistics-related professionals. In particular, one team member from the WPI biomedical team was to travel to Ghana, but because of COVID-related restrictions she was not able to do so. As such, we did not have the necessary strong connection to contacts in Ghana to help in the data collection or risk analyses.

The final limitation, albeit a subjective hindrance, was structure. This project team's deliverables and end-goals were not clearly laid out at the project's start, and so constant adjustments and evolutions became a hindrance to the project's success. This was largely due to the differences in academic timelines between the business and biomedical engineering teams. We acknowledge misalignment between teams is a reflection of product development-related initiatives; however, the constraints of different department academic calendars made the necessary collaborations difficult. The lack of a clearly laid out path to success impeded the team's progress and made for a regularly pivoting set of deliverables.

5.3 Guidance for Future Project Teams working on the Feeding Pump

5.3.1 Additional Interviews

To acquire more accurate data reflective of doing business in Ghana, further interviews are needed. The project team was able to interview two Biomedical Engineers in Ghana, but there are several more fields that would have given relevant information for the benefit of the product's future.

1) Manufacturing professionals in Ghana would be helpful to get in touch with for material, assembly, and supply chain matters. It is important to understand the nuances of

Ghanaian manufacturing and how it might differ from logistical processes in the United States.

2) It would be in a future team's best interest to interview Pediatric Nurses and/or Registered Physicians. Information is needed on the current processes of feeding and nourishing premature babies. If a caretaker can outline the process of using the manual feeding tubes and be asked about how their productivity might increase if they had access to automatic pumps, the team could better define the benefits of their venture. It would also be extremely helpful to get specific metrics, like the time it takes to change a manual pump.

3) Another field that a business team would benefit from interviewing is Strategic Relations for supply chain analysis purposes. These professionals may better understand the logistics and supply chain systems in Ghana and also know who to contact for things like materials and plant pricing. This type of interview could acquire a broader understanding of doing business in Ghana and help a team make high-level logistics decisions.

4) Medical Device Engineer. More guidance may be needed in the design and prototyping phases of the product development and a professional that understands the requirements of a medical device and how it is created.

5) Medical Distributors would also provide information needed to assess the feasibility of the pump. The business team needs to understand where the product is moving to and from and a distributor may give an effective overview of how the current processes work in the Ghanaian medical world. Then, the team can make better estimates of a timeline to market.

5.3.2 Additional Analyses

Further product-specific and risk analyses are needed to obtain a more accurate understanding of the future of this product development. Product lifecycle, disposal, and reliability analyses are necessary to understand the entire value of the pump. Mean time to failure, and mean time between failure, are two important metrics that the team required more data to accurately calculate. These metrics are helpful to price the product as its lifetime is important for buyers to consider when comparing devices. Another form of analysis that would help make informed decisions about the product's future is a decision tree. A more comprehensive decision tree is needed to understand the options that the teams have going forward. Factors needing to be considered are customer choice (competitive products), cost structures, and material choice. In addition to these decision trees, fault tree analysis could be included to illustrate how a product design could fail. This would give the team a more exhaustive understanding of the potential results of each logistical decision.

5.3.3 Device Verification and Validation

For the pump to continue its development past the prototyping phase, it will need to go through verification and validation (V&V). This process, outlined in Figure 5.1, explains how the device needs to show expected functionality from micro-components and whole-device standpoints.

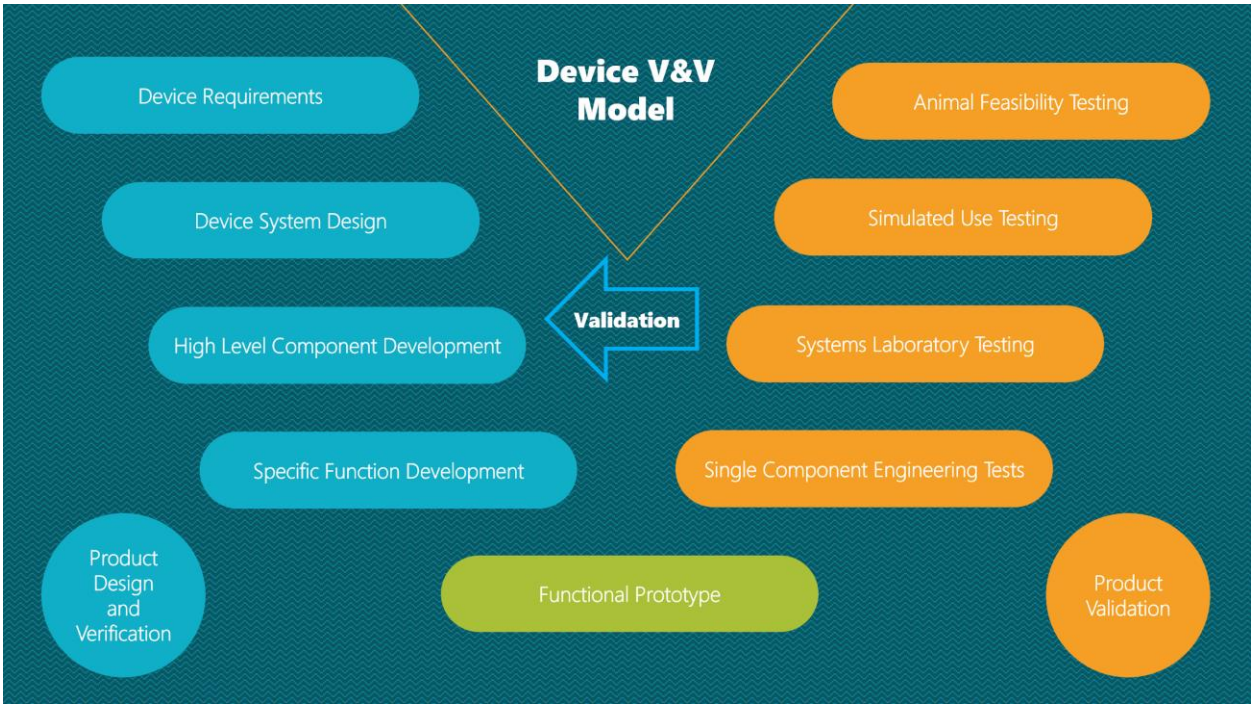


Figure 5.1 Device Verification and Validation Model

At the conclusion of the BME groups project for this academic year, a functional prototype should be completed. Moving forward, the business team should work in with the BME team to design the parameters for the next steps in the V&V Model: :

1) Individual Component Engineering Tests;
2) Systems Laboratory Testing;
3) Simulated Use Testing;
4) Animal Feasibility Testing.

Each step is described in detail below.

Each of these four steps will validate the design of each component of the pump and how the components function as a system. The BME team and business team will work together to determine the metrics for testing at each level.

Single component engineering tests, requires the device to be broken down into its most basic components and run individually. Specifically, the pump can be broken down into the following components:

1) Testing the Arduino board for software compatibility;
2) Testing the photoresistor with a digital multimeter for sensitivity readings;
3) Testing the stepper motor with an ohm meter for electrical output;
4) Testing the pinch valve to determine use to failure;
5) Testing each component for lifetime functionality;
6) Testing each component for shelf-life functionality.

Systems laboratory testing. Once the individual components have been tested and their standards identified, they can be coupled for more complex functions such as:

1) Testing the Arduino board and photoresistor to accurately count drips;
2) Testing the Arduino board and roller clamp to automatically close;
3) Testing the pinch valve and stepper motor to open and close on command;
4) Testing each system for lifetime functionality.

After these systems have been deemed satisfactory, the entire unit can be tested to simulate its use in the field – the step referred to as Simulated Use Testing.

Finally, the device must go through the Functionality Testing step. Here, the device will need to be tested for lifetime, functionality in different environments (controlling for temperature and humidity), and shelf-life functionality; how long the device can be idle between uses. This testing step will need to determine the frequency of device routine maintenance; and if a particular component's lifetime changes when coupled with other components. After all this, the device, since it will be invasive, may need to undergo animal testing as a pre-clinical study before moving onto clinical studies with humans.

5.3.4 Agile Methodology in Cross-Disciplinary and Product Development-Related MQP Projects

In this section we provide recommendations regarding how to effectively work across cross-disciplinary MQP teams related to product development.

WPI has a history of cross-disciplinary MQPs. For example, Professors Frank Hoy and Walter Towner advised a solar technology commercialization project. Professors Helen Vassallo and Walter Towner advised a project exploring techniques for cross-disciplinary success. Professors Marko Popovic, Frank Hoy, and Jerome Schaufield advised a project about remanufacturing a robotic arm with both applied physics and management engineering students.

Professors Sarah Jane Wodin-Shwartz and Walter Towner advised a project about a biodegradable alternative to the single use cup with both mechanical engineering and business students. Professors Guillermo Salazar and Walter Towner advised a project on the construction of a parking garage with both civil engineering and management engineering students. See References for links to all these projects.

While delving into the specifics of past cross-disciplinary MQPs is beyond the scope of this MQP, we offer recommendations for these types of projects based on (1) our experiences and (2) data collected from interviews with faculty, including some faculty who advised the aforementioned projects.

Recommendation 1: Use of Agile Methodology.

After interviewing business school faculty with industry experience, the team recommends that project meetings be held in scrums, or at least with an agile style. The following is a review of what should be focused upon, especially inside of meetings. In this context, the agile thought process will focus on iterative development, the weekly evolution of requirements and solutions, and frequent meetings for accountability and predictability (What is Agile?, n.d.).

Recommendation 1.1 Communicate Goal and Timelining Setting

Before beginning working together, teams should focus their efforts on goal setting. All teams involved have to have goals directly aligned so they may be able to accomplish their deliverables in tandem. Rules of engagement should be established in early meetings and the avenues that each advisor and professor have in mind should be clearly stated. As much as possible, teams should outline their entire timeline at the very start of the project, and communicate it to the other team. This information should be brought to an early meeting to see if the teams' timelines line up and to know everyone's key dependencies.

Recommendation 1.2 Communication Channels

Teams would benefit from a clear, open dialogue and must establish a mechanism for these dialogues. Communication software discussed in Chapter 6 may help with this decision. The software used, such as Microsoft Teams or Slack, should have a central repository where each member can keep their work. In projects involving students from multiple disciplines, each team would benefit from becoming familiar with the other team's technical capabilities and design techniques. This can be an early area of preparation and it will help with understanding each other's languages in future meetings.

Recommendation 1.3 Meeting Procedures

Meetings across all teams should be handled with agile methodologies in mind. Daily standups can be utilized to keep each member on track. These meetings are 10-15 minutes in length and used to check in with teams and see if there are any issues that might be hindering the day's work. The weekly meetings are called sprints. Everything that is going to be delivered in the next week is discussed. The agile-related focus here is on a framework called "story work". Each action item is a story, and each story has an owner. At the sprint, every story owner will discuss any blockers to their story and workarounds will be brainstormed. Potential risks are highlighted and contingency plans are made. The sprint is when time estimates for stories will be made, but throughout the week and during the daily standups, members should continuously check on the accuracy of their time estimates. Logs are taken of all this information and work is clearly laid out and delegated (Rehkopf, n.d.)

Recommendation 1.4 Continued Documentation

With these meeting logs, another benefit to the teams is that they are continuously writing their reports. Each story is detailed and a burn-down chart, which shows how efficiently users are working through their stories (Rasmusson, n.d.) is already made for the teams to show things like risks, solutions, the speed of the teams, how everything is coming together, and retrospective thoughts. This will act as a significant time-saver for student project teams when it comes to the writing phase, giving the students more time to work on the actual development of their project.

5.4 Business Model Canvas Implications

The Business Model Canvas was a great tool to begin developing what this venture may look like in the future. Through it, our group is able to identify the areas where a subsequent business team should investigate and build. The Business Model Canvas is meant to evolve over time, and accordingly the next team should continue to build upon our template.

5.4.1 Patent and License vs. Patent and Produce

One of the first decisions needing to be made by the next business team is whether the venture should follow one of two approaches outlined in the Results Chapter:

1) Patent and License, or
2) Patent and Produce.

These approaches will determine the goals of the business team moving forward. For both alternatives it is necessary to patent the device. One goal of the business team should be to understand the necessary documentation for filing for a patent in the US and Ghana. Preparing this documentation will allow the BME team to focus on the verification and validation process outlined in Section 5.3.3. Once a patent has been filed for, and granted, the two alternatives

differ vastly. The first alternative is to license the patent to a larger company who has the means to establish connections within Ghana, and has the financial capability to support the production and manufacturing. In this situation, the business team will need to develop a market analysis for the product, as well as some financial forecasting to entice the larger biomedical device companies. This situation could be very financially rewarding for the university as a portion of the revenue from every product sold would go back to WPI.

The second alternative patent and produce, moves this venture forward as a start-up. This will require the business team to complete the following tasks:

1) Determine the financial backing of the venture;
2) Develop connections within the Ghana market;
3) Understand the supply chain for the pump;
4) Build relationships with the Ghanaian MoH and other purchasing parties in collaboration with Therapeutic Innovations.

While this alternative is perhaps more time consuming, the entrepreneurial set up will be a much more academically rewarding project.

5.4.2 Determining the Financial Backing of the Venture

To continue to move this venture forward, the business team will need to identify how it will be supported financially. The costs of a start-up are significant and development of this venture will need multiple financial streams. Some ideas of places to begin searching are:

1) Grants from either Federal, State, or private organizations, such as WorcLabs in Worcester.
2) WPI investing directly
3) Outside Investments - Venture Capitalists, Crowdfunding

Chapter 6: Evaluation and Opportunities for Cross-Disciplinary MQPs

6.1 Introduction

As this MQP reaches its conclusion, it is important to reflect on the manner in which our accomplishments were reached. The goal of this chapter is to self-evaluate how effectively this MQP worked, identify the obstacles faced over its tenure, and make the case to cement cross-disciplinary projects within the WPI MQP framework to fully harness the potential of students, professors, and sponsors. For this paper, a cross-disciplinary MQP refers to projects *in which two or more teams from different academic departments work collaboratively towards the same goal*, as was attempted in the project outlined in this paper. It is important to note that the MQP must meet a student's major degree requirements, but two teams (such as in our case), could be working on the same project but approaching it from a different facet. The goal is for these MQPs to build year after year and to grow, much like a start-up is developed year-over-year. An example of a popular WPI MQP developed over the course of several years is the *WPI Mascot Robot* project, with initial advisors Holly Keyes Ault, Michael A. Gennert, and Gillian Margaret Smith. This project acknowledges that it would be impossible to complete within a one-year venture and lays the framework for future MQPs that will progress the robot. To quote the team's abstract, "Future MQP teams will further develop the robot, and it will serve as a continuously evolving platform to showcase the traditions and experiences at WPI" (Dietz, 2020). This project work exemplifies a multi-year, multi-discipline WPI MQP to which we reference in this chapter.

6.2 Obstacles Faced During this Project and Recommendations

This section will address the obstacles faced during this MQP and recommendations solutions to address said obstacle. The largest obstacles the team faced were: (1) the communication between teams; (2) the project structure, and (3) the understanding of the goals of the cross-disciplinary MQP. While these were the obstacles faced during this project, it is also recommended that all the WPI Project Centers continue to, or begin to, track the success of the cross-disciplinary MQPs moving forward.

6.2.1 Communication Tools

Several tools and software exist that have the potential to increase the productivity, communication, and fluidity of a multidisciplinary operation. Some aspects of a project that can be streamlined through tools and software are: shared documents; shared research; integrated timelines; group chats; and action items. Several examples of widely accepted software for large

teams are Microsoft 365, Slack, Asana, Trello, Podio, Ryver, and Flock (Fearn, et. al., 2020). The software that our project team would recommend for WPI MQPs is Microsoft 365.

Microsoft Teams is Microsoft 365's large team software application that consists of several other features of Microsoft 365. When you set up a Microsoft Team's group, a SharePoint online site, an Exchange online mailbox and calendar, and a OneNote notebook are all created. In addition, other Office 365 applications like Planner and Power Bl are connected (Serdar, 2020). Assigning tasks is relatively straightforward with the assignments tab on Teams. There is also an option to create smaller teams that are part of the larger team. This breakdown is ideal for multidisciplinary organizations that are working on a project. MS Teams also has a section for files, where members can store and group files for others to view and edit. A chat bar exists which can be broken up into smaller groups. From the Teams application, you can select many of Microsoft 365's other software and applications, making Teams a convenient hub for Microsoft users.

MS Teams would be ideal for a product development-related project at WPI because of its power to hold an entire project in one application. WPI already uses Microsoft 365 and the linkages to Microsoft Teams would be seamless. The shared documents, timelines, and chats would help for constant communication between multiple project teams, and the online video or audio meetings are right there in Teams as well.

This project team would have benefited from the use of Microsoft Teams for a few reasons. The business and engineering team's timelines were quite different, and constantly changing. This was a challenge for both teams and having integrated timelines in the same software that we communicated in and met in would have been helpful. Also, sharing documents and files in real-time of findings, research, models, and writing would have helped the teams better document one other's work and stay on top of any updates. The shared calendar also would have helped schedule meetings and view the availability of project members. Overall, Microsoft Teams should be strongly considered for any large WPI project.

6.2.2 Project Structure

One consideration for projects that include both a product design team and a business or logistics-related team is the structure and timeline of the teams' deliverables. This became a concern for this project as the timeline for product development did not line up with business objectives and longer-term goals. Projects have different durations. For example, in our case, the business team's project was to be completed in 21 weeks, in contrast to the 28 weeks of the engineering team. As will be discussed in this section, varying project durations serves as another reason as to why there needs to be a defined structure at the beginning of the project.

6.2.2.1 Project Schedule

Business analyses may have to be delayed until a point where the product design has progressed enough to provide sufficient data for the business team. This is a recommendation based on the limitations identified in Section 5.2 Limitations. Specifically, risk, costing, benefit,

and feasibility analysis are more accurate when a product is in a prototyping or testing phase. Because of the different schedules in the engineering and business team, this team was required to develop a number of assumptions about the product, and estimate data parameters. The reliance on data between teams suggests that the timeline of these types of projects be restructured. In addition to this, it's important for the business team to be included in the initial stages of the project. This is because the planning, organizational timeline, business goals, and strategies need to be set early on and would be enhanced by collaboration between engineering and business teams.

Considering WPI MQPs specifically, the terms and credits must be considered before multi-team projects like this begin planning their timelines. This team completed a three-term project with one full course requirement met each term, while the product development team completed a four-term project, with one-half course credits being completed in the first and fourth terms. The result of this structure was the pace of the business analysis was ahead of the product development, requiring estimations and assumptions - while the analyses were data-driven, the data itself is uncertain relying heavily on assumptions and estimations. One proposed solution for this issue is to structure the business team's project the same way as the product development team's, with four terms and the first and fourth being half-credits. This may allow for a more feasible timeline when it comes to deliverables that require collaborative data between both teams.

6.2.2.2 Project Management

As the project develops, it is important that there is a level of project management from the students that keeps all the teams on the same page. If a defined "project manager" role is not assigned to the team, the responsibilities of a project manager could be distributed and kept in mind as the MQP progresses. One important step is developing a project-wide Gantt chart and defining goals that each team needs to meet individually. This information can be shared on MS Teams or the project management software of the team's choice. A 2016 WPI MQP by student Morgan Hopeman titled *Cross Disciplinary Project Management* looked at how to be an effective project manager on a team that involves multiple disciplines. Morgan found that "creating a value proposition, axiomatic design decomposition, Gantt and PERT charts, and risk and failure analysis" were all important aspects to project management (Hopeman, 2016). Along with this, there should be an exchange of information between teams and inclusion of all team members in steps such as customer discovery and design. Strategies for this efficient exchange of information can be found in Section 5.3.4. *Agile Methodology in Cross-Disciplinary and Product Development-Related MQP Projects*.

6.2.3 Compatibility of the Teams

Project teams are a key factor in the success of a project and having an effective team can lead to project success, while an ineffective team can lead to project failure. Some success metrics that a team can look towards are a working prototype and data-supported cost

effectiveness analysis that drives new recommendations. It is important to view teams not as just people assigned to a common project, but as a group of people who are working independently and collaboratively to reach a project's goal.

6.2.3.1 Preparations

For the Foisie Business School and collaborating departments to have their cross-disciplinary MQP projects be successful there needs to be complementary aspects of each major to the respective project. The combination of majors should complement the overall project research, and development through the application of methods from the team's major. For this to be able to happen preparation is required from all teams to stay on track with each other's needs and goals as referred to in the previous section of 6.2.2 Project Structure.

6.2.3.2 Advisor Collaboration

Each individual project team is required to have an academic advisor in their major. It is important that these advisors are constantly in touch with one another regarding timelines, deliverables, project updates, and the progress of the students in the teams they are not advising. Combined with proper student project management, this advisor collaboration will help the teams perform in parallel by ensuring that each team's work is in line with the advisors' views of where the end deliverables should be headed. To do this, communication tools, such as those identified in Section 6.2.1 should be used and advisors should have access to all documents from every team. In addition, it would be helpful for the advisor of one team to participate in the meetings of the other teams - weekly or monthly. This will help share information across teams, as well as advisor input, to aid in the direction of future work. Another idea is to share meeting minutes or have minutes posted in brief bullets at a central location in a shared software. This project team believes that increased advisor collaboration would have benefited the fluidity of work across each team in this venture.

6.2.3.3 Team Dynamics

Understanding the dynamics within a project team is vital to ensure that a team is functioning effectively and efficiently. Important aspects of a project team are team development, clear expectations of members, diversity in members' background, and effective problem-solving skills. Members should collaborate and work together, and trust that one another will uphold their responsibilities. This can be reached through introductory exercises during the project's initial phases. It is important for members to value the diversity amongst the rest of the team and use problem-solving approaches to overcome obstacles. The hope here is that this large team dynamic experience will be a valuable aspect of each student's education and leave them better suited for professional work with different disciplines. A study in 2006 by the American Society for Engineering Education looked at the benefits of interdisciplinary projects compared to traditional academic structures (Juisto and DiBiasio, 2006). In their experiment, the authors wanted to establish if interdisciplinary projects increased readiness for two aspects of the

student's life: self-directed learning (SDL) and life-long learning (LLL). What the researchers found was "The research demonstrates the success of one experiential learning environment in promoting SDL/LLL" (Juisto and DiBiasio, 2006). Such findings support the importance of these kinds of projects and enhances the idea that establishing effective team dynamics for successful collaboration will allow students to reap the benefits of such projects.

From our interviews with Foisie Business School faculty, we found that effective project teams share common characteristics of having a clear understanding of project objectives, clear expectations of roles/responsibilities, a high degree of cooperation and collaboration, and a high level of trust. These characteristics come together to form a high functioning team that is committed to the project objective, communicates effectively, and depends on each other for overall success.

6.3 Benefits of Cross-Disciplinary MQPs

Cross-disciplinary MQPs can be a mutually beneficial project for WPI, the advisors, and the students. Each party has something to gain, whether experimentally, or financially, from working on a long-term cross-disciplinary project. These MQP projects require students to draw on their experiences and apply theory they have learned during their time at WPI by building upon a previous group's progress. By joining the project at a different project stage (e.g. conception, development, prototyping), each team will have a different experience and need to identify the applicable material from their education. Having MQPs that build upon themselves will let students see the value of a long-term venture with multiple groups of students over time.

6.3.1 University Commercialization Incentives

One enticing benefit of cross-disciplinary MQPs for WPI is the potential to commercialize the products and discoveries developed through these projects. The goals of the MQP are to demonstrate knowledge applicable to an academic major, effective communication and understand the social, cultural and ethical dimension of a project ("Major Qualifying Project"). If teams of undergraduate engineers, scientists, and business students are dedicated to a project and continuing to develop it, after a few years, all the necessary steps would have been taken to commercialize the product. This project is an example of that; while a working prototype of a low-cost feeding pump and the estimated economic models associated with it have followed an academic exercise, neither would pass in the real world as a sustainable business. As the project moves into the next academic year, it is anticipated that a new BME team will progress through the V&V model outlined in this paper, leading them towards animal testing; and a new business team will either identify a sustainable supply chain to pursue, or a larger company to partner with while helping file for the products patent. Both of these projects, once completed, will move the pump closer to becoming commercialized.

6.3.2 Research Application and Exploration

Faculty gain from these cross-disciplinary MQPs because of the breadth, and possibly depth of research that can be conducted, and subsequently applied. Many faculty members pursue research projects; however, they could be limited by either time or the number of graduate students and research assistants they can support. By allocating portions of development to the MQP teams, their research activities can be expanded At the same time, the MQP teams will work towards real world application of the research, bringing the project to eventual realization.

6.3.2 Student Gains

Many students attend WPI for the project-based learning that takes place during their four-year studies ("Project-Based Education."). The Major Qualifying Project (MQP) is the main project where the culmination of all material from classes come together demonstrating knowledge appropriate to your specific major. As stated on the WPI's website: "The MQP helps you put the theory of what you've learned into practice to tackle real-life scenarios and issues, often sponsored by corporations or other external organizations. You will see that the skills acquired over your undergraduate years will be your foundation on which to build your life's work" ("Major Qualifying Project"). From talking to alumni about their time at WPI, the best way they were able to get the most out of their major was to connect it as much as possible to a real world application, in terms of structure, content, and delivery. Just like internships and co-op, students obtain practical experience in a specific position by applying theoretical material they have learned in school. In contrast to an internship or co-op, an MQP is typically an unstructured problem providing an opportunity for students to develop skills in problem definition, project organization and ownership.

Working with a cross-disciplinary team provides an opportunity to better reflect the working environment most students will find themselves post graduate, one in which different departments are working on the same project, but with different goals in mind. As such, a cross-disciplinary MQP gives WPI students an edge in the career search, as still undergraduate students are exposed to an environment similar to one which can be found in industry. It is more impactful for students to be the owner of the design, theory, prototype, or research than to work on something that hasn't already been done before. MQPs demonstrate that a group of students is able to complete designs, research or analysis. Cross-disciplinary projects will foster these types of projects due to the diversity that combining two different disciplines; adding a management or a business component to any project is beneficial, particularly if external stakeholders are involved.

6.4 The Opportunity with Cross-Disciplinary MQPs

WPI is uniquely positioned to capitalize on all training, knowledge and expertise their students have obtained through project-based learning with the implementation of cross-

disciplinary MQPs. By summating a WPI education into a project with real world implications, students will better understand everything they have learned and leave more satisfied having been a part of a high-impact project. While conducting research is important and should remain part of these cross-disciplinary MQPs, there is the possibility to couple this with the excitement of entrepreneurship and bring WPI's impact to the rest of the world. An example of one of these projects is a 2019 MQP titled *A Biodegradable Alternative to the Single-Use Cup*. This MQP went so far as to analyze the cup's ability to enter the market and there is opportunity for entrepreneurship (Herrman et. al. 2019). We hope that future projects take on challenges similar to this in hopes that WPI can more regularly produce new products and innovations from student work.

Our project team has compiled a Canvas module (Canvas Course Name: WPI Multidisciplinary Team Project Template: Module: MQP Tools) in the WPI Commons with various tools that we believe would be helpful for a large MQP team to utilize for success throughout the project. This module includes things like tips, guides, modules, worksheets and agendas. A screenshot of the Canvas page can be found below, in Figure 6.1.

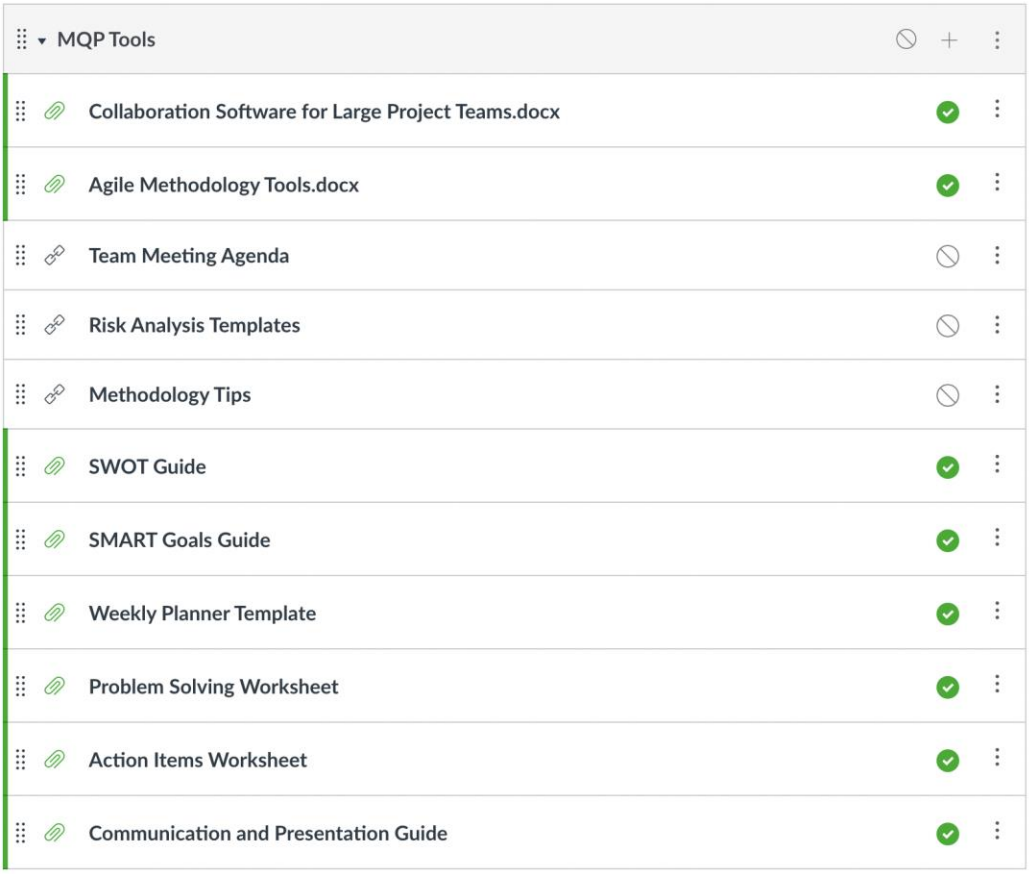


Figure 6.1 MQP Tools Canvas Module

7 Reflections of Industrial Engineering Majors

7.1 J. Andres Sanchez

Our team designed a process to support implementation of a novel automatic food and drug delivery pump that a WPI biomedical engineering team (BME) is designing. This included a risk analysis of a business venture, a production analysis, and a venture survivability decision all implemented into a Business Model Canvas (BMC). With the help of our sponsor Professor Solomon Mensah, we focused our project on establishing the framework in order to support the novel feeding pump to market. We established clear objectives and evaluation criteria in which our project was framed. Our methodology was directly connected to our objectives, which were the constituents of our overall goal. The risk analysis of a business venture involved an analysis of Ghanaian market factors (P.E.S.T.E.L.E, Porter's five forces, and Ghanaian medical device regulations), product specific risk analyses (failure mode and effect analyses, product life cycle, and fault tree), and lastly several Monte Carlo simulations. Since this device included a lot of variability and unknowns we decided the best way to tackle this was using @Risk, an Excel plugin, that would simulate variability. Much of the decisions in terms of what would be implemented were constrained to our assumptions influenced by our sponsor. In our production analysis, we investigated manufacturing capabilities, established a manufacturing plan, and discovered the logistical capabilities of Ghana. The next step was to create an economic evaluation in order to comprehensively illustrate the profitability and success. The foundation of setting up the model came from all previous analyses. The team followed a sequence of design/device analyzes to make sure that we could move further in our goals. In the end we were able to compile these findings into the BMC that will be passed down to future groups in order for them to build on what we have already established.

The team faced many constraints, some due to the organizational nature of the project and others due to the difficulties of not being able to have the usual in person meetings due to the COVID-19 pandemic. On the organizational side, our team consisted of five members from the Foisie School of Business, another four members from the WPI Biomedical Engineering Department, and two more students from the University of Ghana. Additionally, while we had our overall team goals it was hard to stay on the same timeline due to the difference in curriculum. While we were ready to start the majority of our analyses and models the WPI BME team had just started researching medical device designs and oftentimes did not have the answer to our questions. Especially when building the economic evaluation we needed to set a bill of materials (BOM) and a price at which they would be comfortable selling the feeding pump for. Since their design continuously changed, as normal, so would their BOM. In which case we established numbers that the BME team wanted to achieve. In our eyes our biggest constraint was to fully understand the impact this device would have in Ghana. We wanted to make sure that social, political, ethical, and especially health and safety was considered into our analysis. To overcome this we met with our sponsor and advisor as much as we could in order to make sure we were on the right path, and to get his opinions on several ideas. We did not want to go

off our assumptions of Ghana and what would benefit them. The Ghana team, interviews, and the extensive research we conducted also aided in this.

One key experience our team gained during this project was the difficulty of completing a project with several parties that have different objectives and needs. Working on a tight timeline of 14 weeks with these barriers was difficult, especially when our team was waiting on information from other parties. We were able to adapt our thinking to meet the needs of ourselves and of what others wanted. One technical skill our team developed in the way to work off a canvas, or a temple that outlines what steps need to be taken in order to achieve something, in our case it was the BMC. In Industrial engineering we see this in the 5S, DMAIC, Lean, and even Six Sigma. These tools all have a structure that is followed to make the end goal easier. Applying the BMC made it easier to understand what analysis needed to be completed to gather the right information to support this project, and now it will be used for other teams to pick up on. It also forced us to quantify our different project goals and prioritize them. These skills will be useful in our future careers when we are undoubtedly required to complete various projects. The team believes that the best experience from this project was teaching us how to learn. This team had a lot of different backgrounds and skills, but we were able to learn what was needed for our certain parts and complete our analyses. From our experiences, it is vital to constantly alter processes to keep up with the change. Without constantly gaining new knowledge about areas of the different topics outside of one's expertise, it is impossible to understand why certain processes function the way they do, and effectively design new ones to repair previous pitfalls.

7.2 Samantha Mendez

The purpose of our project is develop a business model that supports the implementation of a feed and drug delivery pump in a new market. For this to be accomplished, the team had to perform many risk analyses, such as a SWOT analysis. We also had to run analyses, such as a decision tree, in order to assist the decision making process. The risk analyses allowed for the team to apply many IE concepts such as optimization to our project.

One of the main constraints of this project is the effect of the Covid-19 pandemic. Due to the pandemic, the team was unable to have someone from WPI in Ghana. This would have definitely could have helped the team with aspects of the Business Model Canvas, such as customer discovery. It also could have helped with finding hospital contact in Ghana. If the pandemic never happened then the project could have been different. Another constraint is the issue with time. Since this project has three different teams involved, it was a challenge for us to find a time to set up a zoom meeting with everyone involved.

My mindset during the completion of this project completely shifted from the initial thought that everything would have run smoothly. As the pandemic progressively became more serious our intentions to have proper contact in Ghana were quickly demolished. With that said, the idea to have time to communicate and understand the needs of the local people was unattainable as well. This made it difficult for me to perform at my maximum potential due to

the fact that I wasn't personally connecting with the project. With the current situation, I've learned the importance of team building skills, since this project has lasted three quarters while regular WPI courses only last one quarter. This allowed us as a team to learn each other's strengths and weaknesses helping us grow stronger as a team. WPI taught a course involving Monte Carlo simulation which I attended but the professor was unable to reach past the tip of the iceberg. This projects allowed me to fully use a Monte Carlo simulation and apply it to the real world. To be able to overcome the learning endeavors I will apply the different concepts I've learned during this project, such as the Business Model Canvas.

Appendices

Appendix A: Application Form for the Registration of Classes II-IV Medical Devices

FOOD AND DRUGS AUTHORITY FDA GHANA Your Well-being, Our Priority.	FOOD AND DRUGS AUTHORITY	DOC. TYPE: FORM	
		DOC NO.: FDA/MDD/FOR-04	
		Page 1 of 7	REV. NO.: 02
TITLE: APPLICATION FORM FOR THE REGISTRATION OF CLASSES II-IV MEDICAL DEVICES			

APPLICANT'S CHECKLIST	CHECKLIST	FDA'S CHECKLIST
☐	Cover Letter	☐
☐	Signed Declaration	☐
☐	Certificate of Analysis of Finished Product	☐
☐	Real/Accelerated Stability Data	☐
☐	Manufacturing License	☐
☐	Free Sale Certificate	☐
☐	Sterility Certificate	☐
☐	Device Description and Features	☐
☐	Device Verification and validation	☐
☐	Software Verification and Validation	☐
☐	Pre and Post Clinical Study Reports	☐
☐	Risk Analysis Report	☐
☐	Biocompatibility Study Report	☐
☐	Contract Agreement (where applicable)	☐
☐	Other Documents (where applicable)	☐

Page **1** of **7**

APPLICATION FOR THE REGISTRATION OF A MEDICAL DEVICE
(*TO BE SUBMITTED IN ONE HARD COPY, ONE SOFT COPY*)

A. COVER LETTER

Addressed to:
THE CHIEF EXECUTIVE OFFICER
FOOD AND DRUGS AUTHORITY
P. O. BOX CT 2783
CANTONMENTS, ACCRA,
GHANA.

B. DETAILS OF APPLICANT

Name: .....

Postal Address: .....

....

....

.....

Fax: .....

Tel. No.: .....

E -mail: .....

Website: .....

C. DETAILS OF MANUFACTURER (*FOR AUDIT PURPOSES)*

Name: .....

Postal Address: .....

.....

.....

.....

Location Address: .....

....

.....

Fax: .....

Tel. No.: .....

E -mail: .....

Website: .....

Contact Person: .....
Tel. Nos.: .....

D. DETAILS OF LOCAL AGENT

Name: ....

Business Address:

.....

.....

.....

Fax: ....

Tel. Nos.: ....

E-mail: .....

Website: ....

Contact Person: ....

Tel. Nos.: .....

Certified Copy of Power of Attorney (where applicable, to be attached)

E. DECLARATION

I/We, the undersigned, hereby declare that all the information contained herein is correct and true.

Name: .....

Position: .....

Signature: .....Date: .....

Official Stamp:

F. DETAILS OF THE MEDICAL DEVICE

i. Generic name: ……... ii.

Brand name: …… iii.

Model/Series (*If applicable*): …… iv.

Family (*If applicable*): ……

v. Commercial presentation: ……...

vi. Country of origin: ……

vii. Any special storage condition applicable to the device:

……

……

…… ix.

Intended use of the device

……

……

……

……

……

x. Select Global Medical Device Nomenclature(GMDN) Categories

01 Active implantable device
02 Anaesthetic and respiratory devices
03 Dental devices
04 Electro mechanical devices
05 Hospital hardware
06 In vitro diagnostic devices
07 Non-active implantable devices
08 Ophthalmic and optical devices
09 Reusable instruments
10 Single use devices
11 Technical aids for disabled persons
12 Diagnostic and therapeutic radiation devices
13 Complimentary therapy devices
14 Biologically derived devices

15 Healthcare facility products and adaptations
16 Laboratory equipment
17 Others

xi. Description of the device. (Applicable GMDN description. Otherwise, provide a short description of the device)

……
……
……

xii. Class of the medical device:

Class I .....
Class II .....
Class III .....
Class IV .....

xiii. Basis of classification of device

……
……
……
……

APPENDIX I

1. Details of manufacturing procedure and documentation
   a. Give a brief summary of the manufacturing process.....
   .....
   .....
   .....

   b. Attach documents showing analytical control procedures performed during the manufacturing process …….....

   c. Attach relevant Certificates for the quality of the finished products (sensitivity, specificity, sterility, pyrogen test, etc)
   .....
   d. Attach the final analytical report and authorization for the release of the finished product
   ……..

SECTION	NAME OF AUTHORISED PERSON	ADDRESS	QUALIFICATION

QUALITY CONTROL			
PRODUCT PACKAGING			
PRODUCT RELEASE			

f. State the estimated shelf-life of the Medical Device

.....

g. Attach stability data and justification on which shelf-life has been predicated

.....

h. Provide details of the source of starting material and characterization of the antigen used in the manufacture of the diagnostic test kit if the device is a rapid diagnostic test (RDT).

.....

.....

APPENDIX II

1. a. Has an application for the registration of the device been made in any other country?

YES ☐ NO ☐

If YES, list the countries

....

....

b. Has the device been registered in the country of origin?

YES ☐ NO ☐

If YES, attach a copy of certificates of registration in respect of such a device issued by the appropriate authority established for the registration of Medical Devices in the country.

.....

c. Has the registration of the device been rejected, refused, deferred or cancelled in any country?

YES ☐ NO ☐

If YES, provide details.

.....

.....

.....

2 . Is the device manufactured in countries other than the country of origin?

YES ☐ NO ☐

If YES, provide details and list manufacturing plants from which imports can be made.

.....

.....

Attach 4 (four) copies of labels*, package inserts and packaging materials proposed for marketing the product in Ghana.

*The text of labels and written material should conform to the existing labeling regulations (LI 1541).

Appendix B: Guideline for Registering Software as a Medical Device

FOOD AND DRUGS AUTHORITY

GUIDELINE FOR REGISTRATION OF SOFTWARE AS MEDICAL DEVICE

Document No. : FDA/MCH/MDD/GL-RSAMD/2017/03

Date of First Adoption : 1st November, 2017
Date of Issue : 1st December, 2017
Version No. : 01

Remainder found at: FDA/MCH/MDD/GL-RSAMD/2017/03

Appendix C: Guideline for Registration of Medical Device

FDA/MCH/MDD/GL-RMD/2013/01

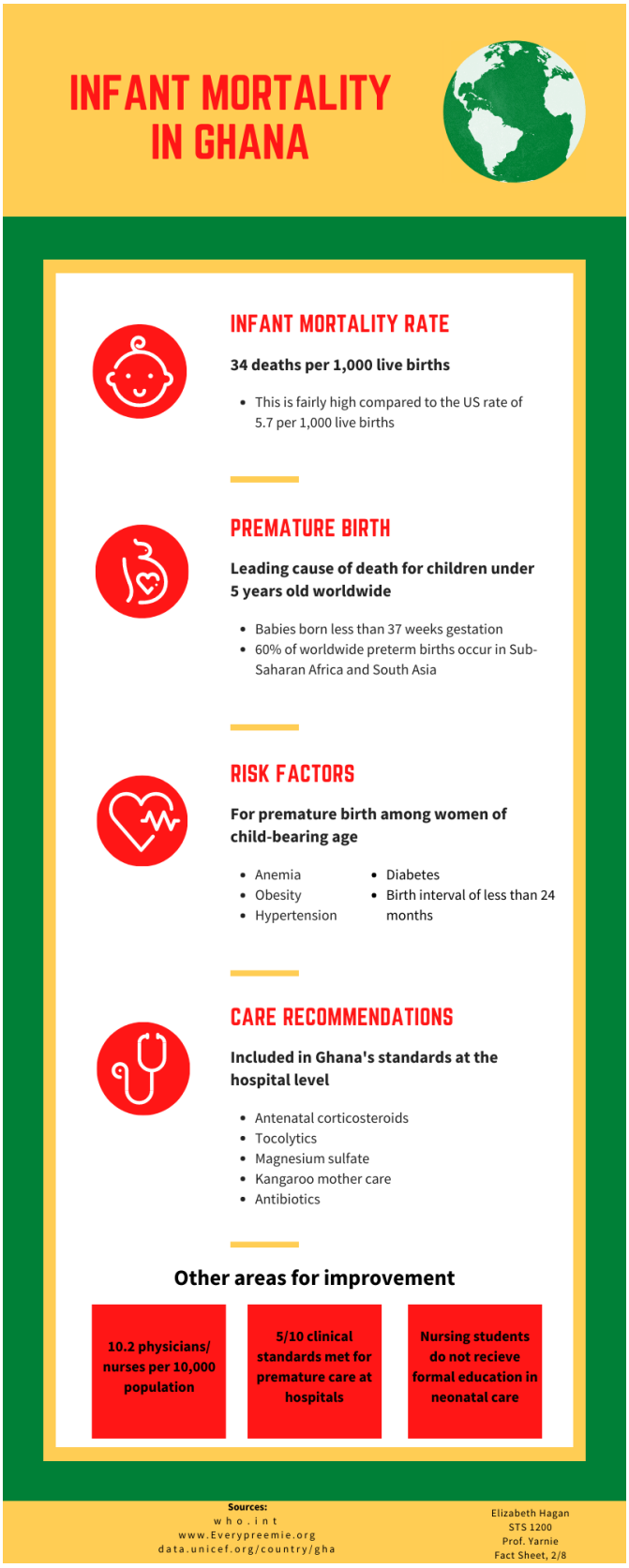
FOOD AND DRUGS AUTHORITY

GUIDELINE FOR REGISTRATION OF MEDICAL DEVICE

Document No. : FDA/MCH/MDD/GL-RMD/2013/01 **Date of First Adoption :** 1st February, 2013
Date of Issue : 1st March, 2013
Version No. : 01

Remainder found at: FDA/MCH/MDD/GL-RMD/2013/01

Appendix D: Ghana Infant Mortality Infographic



Appendix E: Gantt Chart

Week 1 to Week 7

	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7
	9/06-9/11	9/14-9/18	9/21-9/25	9/29-10/2	10/5-10/9	10/12-10/16	10/19-10/23
Background Research on Ghana							
Meetings with Ghana Contacts							
Meetings with BME							
Interviews / surveying							

Week 8 to Week 14

	Week 8	Week 9	Week 10	Week 11	Week 12	Week 13	Week 14
	10/26-10/30	11/2-11/6	11/9-11/13	11/16-11/20	11/23-11/27	11/30-12/4	12/7-12/11
Meetings with Ghana Contacts							
Meetings with BME							
Interviews / surveying							
Product Reliability							
Monte Carlo Simulation							
Logistics + Manufacturing							
Product Lifecycle							
Cost-benefit analysis							
Risk Analysis							
Business Model Canvas							
MQP Evaluation							

Week 15 to 21

	Week 15 2/1 - 2/5	Week 16 2/8 - 2/12	Week 17 2/15 - 2/19	Week 18 2/22 - 2/26	Week 19 3/1 - 3/5	Week 20 3/8 - 3/12	Week 21 3/15 - 3/19
Meeting with BME							
Business Model Canvas							
Creation of MQP Process improvement							
Economic Evaluation Creation							
Presentation of Results							
Presentation of Recommendations							

Resources

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Foise Business School Interviewees:
Professor Francis Hoy
Dean Debera Jackson
Foisie Business School Undergraduate Policy and Curriculum Committee
Professor Robert Sarnie

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