

AEROVAX: Technology as part of a Social Movement

An Interactive Qualifying Project Submitted to the Faculty of WORCESTER POLYTECHNIC INSTITUTE In partial fulfillment of the requirements for the Degree of Bachelor of Science

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Abstract

This project, done in conjunction with the AeroVax Company, participated in the research and development process for a working model of a new medical device; an inhalable vaccination delivery system for use in the developing world. Our group conducted library research, semi-structured interviews, laboratory testing at Malvern Laboratories, and were participant observers in the new social movement for appropriate technology. After the completion of these tasks AeroVax gave presentations at the NEUSR, Respiratory Drug and Delivery Conference, FEMA and WPI's Venture Forum.

Executive Summary

Socially concerned innovators take into account the technological limitations of their clientele and user when designing a product. Additional barriers that must be taken into account include cultural and ethical guidelines and appropriate access to available markets. Proper health care is relatively expensive and not often a top priority for those living in poverty in the developing world. Therefore protective medical care has to be affordable to those at the bottom of the economic pyramid through innovation and intervention. Preventative healthcare is best viewed as a long-term investment, it has a high sustainable yield but is hard pressed to compete with things like food and shelter in the short run. A key part of the appropriate technology movement is emerging at places like WPI to foster innovation in areas that market forces tend to neglect due to low profit margins or a lack of resources by the people to be served.

A major theme of this paper will be to describe our current understanding of why efforts like the development of Aerovax, a system that allows clients to inhale a vaccine for a few pennies a dose, is necessary in today's market. This is more than a story about helping the world's poor. It is also an effort to address the flaws in US healthcare Research and Development effort serving the developed world's health care system. The current system does not just have gaps causing it to fail in its attempts to serve everyone. Lack of attention to the context of use has led to harm as well. For instance, disposable hypodermic needles are practical in the United States medical care system, but created new health care crises where they were exported to the third world. Their consequences in the developing world have created an international epidemic. This example illustrates the unintended consequences of technical innovation and dissemination that is not

attuned to the social and cultural context of its use. It is an extreme, but not an isolated example.

Most US biomedical research and development teams focus on developing products for the local market; often leading products that are overly expensive, difficult to manufacture, and difficult to utilize in rural villages. Developing countries seek solutions that are compatible to local culture, practical and inexpensive and Aerovax is an example of what can be done when one is designing with these considerations in mind.

This is the story of the AeroVax team's adventure in to the world of research and development for a start up company with a philosophy of social concern and appropriate technology as well as a capitalist requirement for finding profit. At the point where we enter the story, the goal is supposed to be prototyping for a final design and finding a first major client willing to provide a contract for our device. As the project progressed, it was no great surprise that we would be supporting the entry of Aerovax into a venture capital competition. With only a few days to prepare, the furious push to get ready to showcase the concept for a major potential client was the cause of great frustration and concern. The client was a U.S government agency, FEMA, and its responsibility was domestic disaster preparedness. This threw off our initial image of the context of application and required adjustment of many features. We lost sleep, but AeroVax went to Washington to present our concept and made a good impression. The interruptions would continue as we were called on to carry out testing, ultimately allowing the AeroVax to published an abstract for the Respiratory Drug and Delivery Conference and Proceedings. After the presentation, however, we were able to return to the third world context to finish the social aspect of our society and technology project. This involved understanding device

through the eyes of a rural person, a refugee in a UN camp and a resident of a third world slum. We presented our research at the New England Undergraduate Sociology Research Conference and received great feedback from our audience.

The experience of working with a start up company has presented the opportunity for personal consciousness raising and being a part of a social movement. We hope that in the long run our efforts will also have gained confidence, empowering the poor around the world by allowing them to preserve their own health, and that of their children, even when funding from international agencies and local political sources are unavailable. We like the idea that average people living on just a dollar a day can afford and deliver preventative medicine with a system like ours if trained properly.

The team was able to contribute to the company by turning the wheels of innovation and exhibited a wide range of expertise through contributions in their own respective fields. Goals and foci were subject to change as the project progressed due to the range of opportunities presented to AeroVax. In this sense, the team was able to adjust accordingly and contribute to the overall success of the company.

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Introduction

The AeroVax Company first began in 2006 as a group of six students from the Boston area coming together with one common goal, to create innovative medical devices that should exist, but don't. This collaboration sparked an initial interest of designing technology specifically for the developing world, as it is these locations that struggle with the most severe issues of contamination and lack of affordable technologies. The conditions of these poorer communities also present engineers with specific challenges due to their lack of resources, such as electricity and running water. The evolutionary process of this underserved market stalled, as many larger, global companies have recognize that the engineering problems are much more difficult; as well as presenting them with much lower profit margins. AeroVax, however, understands that a successful design for a vaccination system that encompasses all the components necessary for success in these developing worlds will provide an appreciable profit as well as encourage advancement of medical technology throughout all applications. This distinctive focus of AeroVax towards the underdeveloped regions has allowed the company to impact the global community as a social enterprise. As part of this movement, the AeroVax team has designed a product that acknowledges limitations that face these communities, providing a new technology that is practical to their daily life, their cultural and religious views, as well as a product that is affordable.

This paper focuses on three main limitations that are common throughout several regions of the world. The group determined that the lack of electricity, the issue of contamination, and the difficulty of reaching the most remote areas of the world were

important factors in their design. The main goal of AeroVax is to produce an inhalable mist vaccine as part of preventative health care. The mist is created by blowing a steady stream of air onto a solvent, which suspends the liquid in a cartridge and is breathed in by the patient (Hess, 2000). The system has been designed to allow two options for producing this mist, either by a pressurized canister of oxygen, or manually operated by a foot pump. These two options do not require electricity and are both efficient in causing droplet particles of the correct size for desired mist. This allows our product function properly in many different situations and scenarios.

Contamination is another problem that faces populations living in developing worlds. The basis behind the idea of an inhalable vaccine was to prevent the exchange of bodily fluids from one individual to the next. In the case of hypodermic needles, it is extremely easy to accidently stick a person with a contaminated needle (Reynolds, 1998). With the AeroVax system, there is no contact with human matrices. Our vaccine is inhaled through a paper mask that is placed over the nose and mouth, preventing any chance of contamination although still being disposed of as a potential bio-hazard. Finally, our product has been designed as a backpack, allowing portability and easy maneuvering throughout the desired regions of the world.

As our IQP group began its research for the project, the first step was to find literature that addressed these issues and it was an integral part towards our realization that we were a part of a larger movement of social innovation. We quickly recognized that this movement was not solely dedicated to medical advancement, as seen in the book <u>Gaviotas: A Village to Reinvent the World.</u> It was this book length study that enlightened us on the implications that face western engineers as they focus their efforts on

underdeveloped countries in an effort to encourage growth and change. The desire to create a self-sustaining village in the middle of a Colombian savannah caused much conflict as the native people preferred their simplistic way of life (Weisman, 1998). Another literary work that provided much inspiration in our project was entitled <u>Mountains Beyond Mountains</u>, which documented the life of Dr. Paul Farmer and his journey around the world. His dream was to cure the world, not by giving charity, but by "bringing life saving tools to those who need them most" (Kidder, 2003).

In order to spread the idea of our project, AeroVax was represented in four conferences, the New England Undergraduate Sociology Research Conference (NEUSR), WPI's Venture Forum, Federal Emergency Management Agency (FEMA) and the Respiratory Drug and Delivery Conference. The focus of the presentation at NEUSR was that of the social implications of our product, the impact it will have on those living in underdeveloped countries and what our group has done to research and understand the differences of these people. The other three conferences maintained a focus on technical components of the AeroVax device, the limitations it has been designed to overcome and the business plan that will allow it to be presented globally as a new medical device that will change the techniques of dispensing vaccinations around the world.

Literary Review

AeroVax has become an innovative participant in the progressive social movement for promoting health care in developing regions. Organizations such as Partners in Health, World Health Organization, and PATH along with the new start-up company AeroVax, are working synergistically to provide people in less fortunate living conditions with necessary preventative and maintenance medications. Vaccinations at a reasonable, affordable price are the key area of concern and the specialty of our company. The AeroVax system will see that vaccinations are not only brought directly to the developing and third world countries in a safe and cost effective manner, but will also provide these services in a way that is not disruptive of local customs, cultural philosophies and medical beliefs.

One of the organizations that is a major contributor to this global movement is Partners in Heath, a 501 (c)(3) non-profit corporation with a strong presence in Latin America, the Caribbean, Russia and the United States. PIH coordinates innovative programs to combat AIDS and women's health programs in both rural Haiti and urban Massachusetts, ground breaking tuberculosis treatment projects in the prisons of Siberia and the shantytowns of Lima, as well as health policy initiatives on a full global scale. All these interventions are made collaboratively by working carefully with local means and natural resources (Partners in Health, 2008).

The following few lines present the Partners in Health philosophy. This organization has provided great inspiration for the AeroVax system, and many of the core beliefs of their organization will be reflected AeroVax Mission Statement if it is ever formalized. "At its root, our mission is both medical and moral. It is based on solidarity,

rather than charity alone. When a person in Peru, or Siberia, or rural Haiti falls ill, Partners in Health uses all of the means at our disposal to make them well - from pressuring drug manufacturers, to lobbying policy makers, to providing medical care and social services. Whatever it takes. Just as we would do if a member of our own family or we ourselves - were ill." These few lines address all the necessary challenges that these charitable voluntary organizations face. The need to reach millions of people all over the world, the ability to respond immediately to ensure a full recovery for those who do fall ill, an accessible drug market that is available for continuous use, and finally, a philosophy that doesn't exclude or prohibit an individual or group from receiving the necessary help and protection to live a full life. It is under these principles that the development and design of AeroVax began. However, AeroVax has added one additional challenge to the list. It is not a charitable organization and must make its contribution to world heath care empowering the oppressed while making a profit. Although AeroVax is based upon a business plan geared towards a for-profit company, specified to narrowly focus on the needs of developing countries, the project team is working endlessly to keep these core social beliefs at the center of its design production mission (Partners in Health, 2008).

The practice of socially concerned innovation, a quality that the AeroVax reflects, is the inspiration behind the appropriate technology movement. Certain "at risk" groups are the focus of the innovators rather than a generalized consumer. The AeroVax system has practiced the process of identifying specific needs and then communicating with the people who are a representation of the group to be assisted. In our own case, the design team has interviewed three former Sudanese refugees from a Kenyan Refugee Camp to

gather a more complete understanding of one likely situation in which the device would be utilized. These ex-refugees provided insight on the medical practices in their camp, how the individual people in the refugee camp responded to and understood the practices of Western medical technology, and most importantly how they might react to a change in the way they receive immunizations. The Sudanese who were interviewed spoke of their own experience in the refugee camp and they each provided different opinions and answers to our questions. The conversations had with these men, Majok, Dan and John gave us incredible insight to their world, allowing us to envision a new system that is appropriate to this setting and the rural villages in Sudan that they originally came from, with elders and headman rather than UN representatives in charge.

A topic that was most strongly elaborated on was their memories of how accessible medicine and vaccinations were delivered to them while staying in the refugee camp. They spoke of the ways in which the vaccinations were received and who was able to receive them. As the refugees recollected the nine years spent in the camp, they were able to provide a vivid description of the medical center in which one had actually served. The refugee camp contained approximately 100,000 people, roughly the size of an average American city like Worcester, Massachusetts. Many of the health buildings had electrical service and were able to sustain refrigerators and other medical equipment necessary to provide adequate health care to the people. From their point of view, everyone in the refugee camp understood the benefits of western medicine, the importance of vaccinations and the necessity for routine checkups. Indeed, the people were given no choice in the matter if they wanted to be allowed to stay in the camp. The refugees recalled memories of people lining up for vaccinations when members from the

World Health Organization (WHO) stopped by to deliver their equipment. Hypodermic needles were used to give the vaccinations, however, they remembered that often times the clinic would run out of supplies and those people would have to wait for hours, or possibly return on a different day to get vaccinated. This dilemma was acceptable for a camp full of the unemployed, who had time to wait, but for those who held a job, or who had walked miles to get to a rural clinic, this was a serious implication. One could not let the limits of what could be kept cold on site limit the amount of vaccine available at the point of service. These people were extremely unlikely to return and were unlikely to receive the vaccine at all. These recollections helped the AeroVax team as they worked to design the structure and function of a system that could vaccinate more people at one time, and be less dependent on regular deliveries as well as avoid having the need for refrigeration by the limiting factor.

The book length case study that introduced the AeroVax team to the application of socially concerned innovation was entitled, <u>Gaviotas: A Village to Reinvent the</u> <u>World.</u> This nonfiction book described the process of creating a fully functional sustainable village from nothing but a barren wasteland not suitable for agriculture. This recollection also provided insight into the people and culture of Colombia, both urban white and rural native, and how they were individually affected by immigration of the concerned technologists. As engineers, scientists, visionaries and technicians began to flock the empty savannah of central Colombia, a land known as the Llanos, they each had one goal in mind, to create a self-sufficient and sustainable village in a region that has been unable to support people for over a hundred years. The project was soon underway,

but as quickly as it started, it began to encounter many unforeseen challenges (Weisman, 1998).

The first intersection of conflict occurred as the native Indians and the transplanted engineers disagreed over the nature and purpose of development. The first instance was seen as the scholars from the University of Bogotá received a rather large loan from the Inter-American Development Bank in 1962. Recognizing the Llano's need for development, a politician named Betancur met with a Guahibo Indian Shaman and asked him what sort of development would best help the struggling region. He anticipated such a response as "improvements like electricity. Running water. Sewers. Telephone and telegraph". He hoped to fund a large project that would give the bank good publicity, however, the Indian elders replied, "We know what we want to do with the money. We need new musical instruments for our band" (Weisman, 1998).

Betancur was taken aback by their response and assumed they didn't understand the nature of "development" and the generosity of the Bank's great gesture. Musical instruments are not a vital part of life; they do not create energy or purify water. They do not provide food for a village or education for the children. Betancur asked again and the Indian elders clarified "In our village everyone plays a musical instrument. On Sundays after Mass we all gather for a retreat, a concert in the church patio. First we make music together. After that we talk about problems in our community and how to resolve them. But our instruments are old and falling apart. Without them so will we". After this, Betancur began to understand the wishes of the elders, but continued to wonder how to justify the expense. Perhaps the value of a supportive community that addressed its real problems would be enough. Later, the Gaviotians would start their own orchestra and

understand the full power of musical harmony to create community and for the town of Gaviotas (Weisman, 1998).

In this example, the politician did not understand the desires of the natives in this particular region of the world. The lesson learned by Betancur can be related to the AeroVax system. With the purpose of traveling to remote regions of the world and encountering many different cultures, our system may encounter the same confusion from the locals as the bank loan did. Not every culture values preventative medicine as strongly as the Western World. In order to dispense our product to those cultures who are not initially interested, a balance between cultural backgrounds and medical advances must be reached. The AeroVax team has been taking those first steps by learning ways in which to integrate the device into specific regions, such as the Sudan, by taking to Sudanese.

The autobiographical account, <u>Mountains Beyond Mountains</u>, also examines the ideals behind socially motivated organizations and asks profound questions such as the role of professionals in the third world and the influence that they can have in those societies. The author of the book, Paul Farmer, is a doctor, a Harvard Professor, a renowned infectious-disease expert and an anthropologist. This modern-day Robin Hood found his calling in medical school: to diagnose and cure infectious diseases and to bring the lifesaving tools of modern medicine to those who need them most. This provided the foundation of Farmers life's work, set in cities and small villages all over the world. The phrase, "mountains beyond mountains", derives from a life based on hope and surmounting repeated challenges. This understanding is captured well in the Haitian

proverb; beyond mountains there is a mountain, once you solve one problem, another problem presents itself and so you must go on to solve that one too (Kidder, 2003).

The example of global responsibility set by Farmer represents a remarkable illustration of how to connect work in privileged settings with caring responses to social injustice in some of the most deprived parts of the planet. Farmer's mission is less about assisting the distant people in need, but is instead focused on repairing a broken world. One reason Farmer's written work is so useful is that it models the kind of rigorous global thinking that is necessary to make responses to a "broken world" both ethically and politically responsible, which is to say responsive both to the people they meant to help and to the contexts in which that help is offered. His approach clearly represents something different from both personal charity and traditional state-run development aid (Kidder, 2003).

Too often such charity is aimed at the 'needy' in ways that repeat the older imperial idea of 'civil mission'. Instead, by actually reminding us about the legacies of colonialism and imperialism, and by persistently highlighting other recent global processes that create local experiences of ill-health, Farmer's approach involves the "care of context" (Kidder, 2003).

Although his tasks are of no small magnitude, Farmer is aware that the forces causing ill-health globally are much too big and too structural for any individual to be able to change them alone. The mapping of global mountains beyond local mountains is broken down into three movements. The first movement is found in collaboration. Farmer recognizes the need to locate his efforts at patient care within a context of engagement with his local community, their practical struggles and their own understandings of the

word. This concept helps to keep the culture of the village the same, working along side them to ensure they understand the benefits of how they are being assisted. The second movement is transnationalization, which works to understand the individual accounts of ill-health in terms of a broader context of local-global interdependencies. Different cultures have a different view of proper health and at many times the standards of health are much lower than that of the United States. It is in this movement that the discrepancies are minimized and everyone gets the same benefits. Lastly depathologization is the third movement and it works to criticize distorted accounts of disease that hide the history, culture, and political economy of the transnational context through a form of geographical accusation that blames the victim (Kidder, 2003).

Farmer removes a classical culturalistic excuse for double standards in health-care delivery and treatment: 'those sorts of backward people and places do not deserve top quality health-care.' Instead, he argues that no one should be treated like an outcast. Farmer's take home message was pretty simple: health is a birthright for everybody no matter where they live. By blaming the locals and pathologizing their society foreigners can let themselves and their own economic interests escape inquiry (Kidder, 2003).

A second goal of Farmer is to involve rethinking the dominant common-sense about globalization creating a global "level-playing field." This common-sense conception of globalization seems a lot less sensible. By acknowledging the uneven development represented by global relations it is possible to see what is wrong. Global interdependencies basically consist of linkages between the lives of people in different parts of the world. These linkages create bonds of fate between people in different parts of the world (Kidder, 2003).

Similar to the beliefs of Paul Farmer, the AeroVax system is following many of the same ideals. The AeroVax project is planning to reach members of the global community in the most remote regions of the world to ensure that they are being treated as humanely as everyone else in the global community and with the "best" and most appropriate technology. AeroVax is also working to establish a practice in which the dispensing of our vaccinations do not disrupt the daily life of the persons in a particular village as well as distort their cultural view of western medicine. We are trying to work with the local cultures to find a common link between our medical practices and their own. Such examples would be hiring men and women, or asking for volunteers in a particular community to help educate and deliver the vaccination to their own people, rather than rely on a United States volunteer to overstep their boundaries and come in as certified experts.

This difficulty of method delivery and cultural acceptance was further examined in <u>RX for Survival: A Global Health Challenge.</u> One of the major challenges for providing global health is the method of delivery to ensure safe and efficient transportation. Major cities in the United States are connected by highway, railroad and airlines. Many third world countries, on the other hand, do not have this infrastructure. Many of the villages are hundreds of miles away from other centers of civilization and many of those people cannot afford such luxuries as an automobile or even a bicycle. Public transportation is difficult and many times nonexistent. The director of UNICEF has recognized the dilemma of getting the vaccine to the patient, rather than the patient coming to the vaccine, quoting "we have to travel with them" (Hilts, 2003).

<u>Rx for Survival</u> describes this incredible lack of transportation and how that has affected the standards of health in many areas of the world as patients who fall ill continue to have trouble getting to a local hospital. It has been seen that this problem continues to prevent villagers from seeking the help they need in regards to minor health issues, problems which at first would have been easy to cure, but now will eventually worsen and become life threatening. A hospital worker in a desolate region quoted, "without mobility, health workers are almost useless." Although these issues are more directly involved with geographical limitations, it is the belief that the AeroVax system will be able to reach these people and vaccinate against some of the most life threatening infectious diseases in the area, before the condition becomes a life threatening epidemic (Hilts, 2003).

<u>Rx for Survival</u> also examines the way the vaccines are dispensed and administered. Maintaining the quality of the dispensed vaccine becomes a major challenge. Vaccinations have very specific expiration dates and workers must abide to specific criteria to ensure that the vaccines maintain their fidelity and work as they are expected to. Many times vaccinations are stored in a box and kept on ice, which rapidly thaws. Due to these conditions, it has been determined that the effective expiration date is often dramatically reduced to only two days. Due to the lack of education of many of the workers, this real expiration date (as opposed to the one that would be the case if refrigeration had been maintained) often goes unnoticed and patients receive inactive vaccinations. These improper conditions and poorly trained volunteers end up costing organizations millions of dollars each year even if the error is caught. This causes the cost of injected vaccines to rise and the impoverished people of developing countries continue

to refuse to purchase them, as they are perceived, not to work. Worse, an error not caught can lead to tragedy (Hilts, 2003).

It is AeroVax's goal to be able to prevent this type of situation in the coming years. The design that has been established will allow a single cartridge of the AeroVax system to have an expiration date of over two years without refrigeration, significantly more forgiving than using ice and having just two days to use it. This is due to the lyophilized form of the vaccine, a process that simply removes all the moisture, resulting in a dry powder. When the powder is mixed with a solvent, it then returns back to the original form. The training of workers and volunteers for the AeroVax is much simple than for hypodermic needles because everything has been pre-formulated (Hilts, 2003).

The significant epidemic attributed to contaminated syringes used to vaccinate people across the world is getting peoples attention as Researchers are reporting that disposable needles are doing more harm than good. A journal article entitled "Deadly Needles: Fast Track to Global Disaster" revisits this lasting problem. The number of patients contracting lethal diseases from contaminated syringes has skyrocketed and is now being reported upwards of 10 million infected people per year. Organizations such as the WHO conducted a study that revealed nearly 1.8 million people would die each year from contracted diseases due to the misuse of syringes. This number will consist mainly of children due to their weaker immune systems and inability to fight off the disease (Holding, 1998).

The contamination threat of injection is actually rivaling the benefits of having the device. Two medical anthropologists wrote, "Injections and syringes had become the symbol of modern medicine...a metaphor for everything fast and efficient." If the symbol

of medicine is being represented alongside the worst medical epidemic seen in decades, it is clear that this process needs to change. In fact, there was new technology that claimed to be the 'syringe of the future." It was a simple syringe that contained a retractable mechanism that prevents it from being used more than once. The public was informed of this easy, cost efficient response to the epidemic; however, this miracle syringe costs more, so it was never marketed for world use. The technological fix was tried and failed. Several such stories have reported similar findings; appropriate and inexpensive technology is available for use although it's just not being produced. Technological advances that are "attention grabbing and glitzy", however, are being manufactured even though they are inaccessible to the impoverished world. According to Rx for Survival, "health workers and engineers often overlook the importance of a simple, cost effective solution" (Hilts, 2003). The western educators often train their students to solve problems with advanced technology. Although these advanced solutions can generally solve the problem if used, they come with an overwhelming price tag. People living in third world and developing countries cannot afford this high price and even though organizations have attempted to lower the costs for the individual, it raises the cost for the organization, limiting the amount of available supplies. Clearly the old fashioned glass hypodermic needled designed to be sterilized by boiling for a specified time between uses, was better than the disposable for people in most places outside of the modernized world. Of course, the exception was the manufacturers, who made more money if their product as used once and discarded. The hidden cost, of destroying it after use, was shifted to the user and avoided when possible. Taking that cost into account would make it too expensive to sell, so the manufacturer did not insist on it (Holding, 1998).

As long as people in developing countries continue to demand hypodermic injections in the belief that it will keep them well, this epidemic will continue to spread. These accounts provide evidence that a new social movement needs to begin, one that the AeroVax system is proud to be a part of. The AeroVax team understands the harmful effects of the needle and undertook a socially concerned set of design criteria to make sure the technology changes in the right direction, driven by market forces rather than regulations. Our goal was to obsolete the hypodermic needle, especially in the disposable variety in the third world. With AeroVax's cost efficient method of vaccinating people through inhalation and absorbance, many prior health risks will be eliminated and the vast number of blood born diseases transmitted through needle contamination will be avoided.

Although the AeroVax team believes it has helped develop a product that will protect people all over the world, the issue of presenting it so as to be acceptable to people from many different cultures becomes a real problem. Another passage in the book, <u>Gaviotas: A Village to Reinvent the World</u>, reflects the power that the United States government has over other cultures and the distain that has come of it. In the early1900s, the beginning of the Panama Canal construction was underway. One resource that was directly impacted was a native, exotic species of tropical pine that had bloomed all over the Colombian land. What had once been a large part of the economy of Colombia only a few decades ago, suddenly was found to be a disadvantageous in the 1960s as "the Gaviotians debated among themselves whether it was wise to cultivate an exotic species. Some argued that the issue was political, not environmental… Had the United States not stolen the isthmus and installed a puppet government in order to dig

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their canal, these would still be native Colombian trees." Although this example is not relevant to health care, it still illustrates the power and strife that Western Culture has inflicted upon other areas of the world. What the United States believed to be one of the greatest engineering feats of the day, having an enormous impact on shipping across the two oceans, directly affected and destroyed a important natural resource of Colombia. The devastation of that local tree by the canal construction destroyed the last species known to naturally grow in the Llanos area. Upon reconstruction of the area, a related coastal tree had to be imported and meticulously cultivated to get anything to grow. Even so, the tree would not reseed itself and couldn't live without human intervention. This situation would never have occurred had the United States government not taken over that land for political and economic resources (Weisman, 1998).

Though there were many other hurdles to clear throughout the project of building Gaviotas, the village eventually took off as both a new environmental and technological center associated with innovative and appropriate technology pumps, windmills and solar panels. It became well known to the world and received both national and international funding. As native people began to join in as technicians, the negative connotation that the locals had given the project quickly diminished. "They became known as el grupo de Gaviotas, identifiable everywhere by their white caps and tee shirt with a logo showing Gaviotas's namesake" (Weisman,1998).

The engineers of the AeroVax system are hoping for the same response that Gaviotas got. Other organizations have worked for years to receive the same response as el grupo de Gaviotas, being recognized wherever they go. With the hopes of worldwide

acceptance, AeroVax aspires for the same level of acceptance, recognition and respect as a pioneer and role model in the field among other global medical organizations.

Ultimately the Gaviotas project was about sustainable development. But one question always loomed in the back of their minds, how you can best define development. This was later answered, "not by the amount of paved kilometers of road per citizen... by the number of hospital beds per capita. No, for them development means making people happy...before you spend your money on roads and factories, you should first be sure that those are what your citizens really need." Western medicine can be arguably called the most advanced in the world, technologically, but it performs poorly in terms of keeping people well with long, happy lives and protecting its children so that they survive to age five. Hence, it is no surprise that we are a poor role model and not every society wants to be incorporated into our way of life. This presents an unusual problem, as the AeroVax system really has no place in such a system but needs to find a niche to get development capital. Then it must be locally defined as beneficial and worth adopting in totally different parts of the world (Weisman, 1998).

Similar to the sustainable development of the Gaviotas project and the new undertaking of the AeroVax, economics has played a vital role in the accomplishment of many great ideas. <u>Small is Beautiful</u>, by E.F Schumacher, investigates the true importance of world economics and its application in both developed and underdeveloped countries. As our AeroVax system continues through the process of innovation, this underlying concern for marketing and distribution throughout the world must remain a focus of attention. As with any company, the goal of both creating job

opportunities and bringing in a profit must be considered at each step of the process. (Schumacher, 1973).

Schumacher's book examines how the civilized man came to view economics and then compare it to the ideals that the world should live up too as we enter "the era of the learning society." This concept encourages mankind to observe the pre-economical ways, and by finding the flaws proceed to create a new, improved structure to take its place (Schumacher, 1973).

The first error that was focused on was centered on the idea that "the problem of production has been solved." Economists have attributed this problem to scientists and technologists, stating "the illusion of unlimited powers, nourished by astonishing scientific and technological achievements, has produced the related illusion of having solved the problem of production." As technology improves, it often masks the underlying issues of a society, such as the lack of total coverage of health care, or universal poverty stemmed from a lack of jobs in certain locations around the world. These are concerns that must first be addressed before flashy new innovative ideas can claim to solve all the worldly problems related to production and distribution. The AeroVax system is scheduled to be outsourced to developing areas that need the products and are capable of maintaining quality and efficiency, while providing individuals with new job opportunities and the hopes for a higher standard of living. This may not be the place where one could turn out the most units quickly. The AeroVax system is also planning to recruit workers to help distribute the vaccines to the villages and cities of underdeveloped countries. Since the training is simple enough to require at most literacy, rather than a nursing degree, it will provide opportunities for more jobs as well

Ultimately we are proposing a new system to help improve the standard of living in one area, while improving the standards of health care in another (Schumacher, 1973).

Another flaw that was noted about the pre-economic principles was the issue of availability and accessibility to new innovations and advancement. Too much time and money was being spent on marketing products to local consumers, wealthier individuals and easily accessible areas. The other countries around the world with the greatest need for help were continually being ignored and forgotten. This created an unequal distribution with regards to health care and technological advancements between the wealthier areas of the world and the poorer areas. If everyone deserves the same human privileges, such as health and education, the cost and quality of the necessary tools to accomplish this must be reasonable enough for everyone to afford. The AeroVax system is working to improve this market distribution flaw by reducing the overall cost of vaccinations for all areas of the world, and maybe have the wealthier areas subsidize the less wealthy in a sliding price structure. This system will provide an equitable and comprehensive way to distribute medical assistance at a cost all people can afford. AeroVax is also working with government agencies such as FEMA and WHO to make sure that even those people in areas that can't afford vaccinations still have the opportunity to get vaccinated (Schumacher, 1973).

Conscious policy adjustments and partial subsidy can address the unequal distribution of health, as the developed world is focusing on a new approach to economics. E.F Schumacher quotes "wisdom demands a new orientation of science and technology toward the organic, the gentle, the non-violent, the elegant and the beautiful." This quote sums up the direction he hopes economics will take in the coming years. As

he wrote in <u>Small is Beautiful</u>, the world has not yet adopted economics "as if people mattered" and still views people as abstract consumers. The social conscience revolution is still to come; however, his philosophy is in tune with the logic by which we developed AeroVax. Even though this book was published several decades before the idea of AeroVax began, we are still fighting the same principles that began many years ago to influence the movement toward a new, more inclusive, economic logic (Schumacher, 1973).

Social Innovation

Social innovation is the ideas, concepts and strategies that meet the needs of society. Social innovators identify problems based on practical needs, and generate a solution that is compatible with the local cultures (Mumford, 2002). The product of innovation did not necessary represent the advancement of technology. What it represented was the establishment of connections between different parts of the society.

The challenges of global health could be met by the concept of social innovation. In the context of global health, the solution to the challenge must be inexpensive, and able to meet the environmental constraints (Beardsley, 2007). International health workers often found that their advanced medical equipment becomes ineffective on inadequate in third world countries. This was because most of these technologies were researched and developed in Western developed worlds and was designed to operate there. The operating procedures of this equipment often required high intensities of illumination, impossible without reliable electricity and clean water supplies. These requirements were simply impracticable in many parts of the developing world. It is hard to accept the idea that building roads in Africa is faster and effective if you use a hundred shovels rather than one bulldozer. However, the evidence is abandoned that this is time. Abandoned bulldozers rust by the side of the roads completed by hand; colossal machines rounded useless by the luck of a \$20.00 replacement part, and a staff able to diagnose the problem and arrange for repairs before the rest of the idled system succumbed to the elements. Further more, many local people wanted the jobs so much they would bring on buy their own shovels, saying to take it by of their wager, so in the end they would own it and could build other roads with their village neighbor before the paid work was done.

2.8

The cost of these foreign technologies was another major concern. The income for average person in African countries is approximately \$360 a year (Behram, 2003). This translated into \$30 a month. A regular MRI procedure cost \$75.64 (Sethi, 2002). This was more than two times the average monthly income for an individual. The high cost of medical testing procedure often led to delay in diagnosis. In the case of SARS, Chinese officials admitted that many infected patients delayed diagnostic tests because they were concerned about the costs of examination (Cao, 2004). A few of these patients boarded the airplane with minor symptoms. Immediately, these passengers transmitted the disease to several nations. Among these nations were Singapore and Canada, two of world's most developed countries.

Governmental programs often try to lower the cost of medical procedures by subsidizing the expense or providing funds, also in the name of "research". The goals of these programs were to increase the accessibility of care to the poor, and help to develop treatments or vaccines for illnesses. This approach often led to products or services with high price tag for the government, but low quality of service for the people in need of the service. It is also short sighted to encourage government charity interventions into the matter to become systematic circumvention of the market in the name of research on volunteer community service by expensive professional who can't sustain the effort. Companies in the private sector compete against each other by lowering the cost and increasing the quality in health care as well as other fields. Governmental funds often disrupt this competition; and therefore increase the cost and lowered the quality of the resulting product.

Social Business

Muhammad Yunus, Nobel Peace Prize 2006 winner, proposed the concept of social business. He suggested solving poverty problems by combining the traditional nonprofit organization model with the for profit business model.

"Social Businesses seek to profit from acts that generate social improvements and serve a broader human development purpose. A key attribute of social businesses is that an increase in revenue corresponds to an incremental social enhancement. The social mission will permeate the culture and structure of the organization and the dual bottom lines - social and economic will be in equal standing with the firm pursuing long term maximization of both"(Fleischer, 2001).

The traditional nonprofit organization model could be seen as a waterfall. These organizations collected money and resources from donations, and put them toward different services. This method is often ineffective because resources gathered at great cost only go out, but do not circulate and come back in as well. The quantity and quality of the services heavily relied on the donations. These varied year to year and a shortage of donation often resulted in limited coverage of people in need of the organization's service, at precisely the time more people needed service the most during economic depression. This strategy is conservative but inefficient as you take in much more than you give out in immediate services. It is suitable when the goal is to maintain the organization first and deliver sources secondarily.

A business model is neither a waterfall nor an icebox. They need to get in the loop and flow of money, and go where the action is. The high profit in unessential products

attracts many companies away from meeting pressing needs. The goal of private businesses is to maximize the return for their investors. This business model could effectively lower costs and increase the quality and quantity of products, but it sever only those who can afford the product, and following affective demand not absolute need. Private companies invest millions of dollars annually in researching beauty supplements and diet drugs, but leave essential health care product such as vaccines untouched. This process gradually enlarged the gap in health cares between developed world, and the underdeveloped world, until we reached the present unhappy state of affairs.

The concept of social business calls for bringing the competitive business model to the mission of achieving global health. Social business was profit oriented in the sense of providing services without relying on a continuous flow of donations after the original startup grant. Companies in the social business community develop their products for a market in developing countries. This development process accounts for constrains that were not a factor in western countries. The developed products are sold in an affordable price range. Different from traditional business where gross income profit were toward the investor, social businesses put the profit marginal income into improving their products and further lowering the price. This would effectively achieve global health without meeting the constraints of traditional nonprofit organization or the profit requirements of the private sector.

AeroVax, A Socially Concerned Innovative Company

Five social innovators from Worcester Polytechnic Institute and Massachusetts Institute of Technology with majors in business, management and business founded AeroVax during 2006. The goal of AeroVax is to develop a vaccine delivery system that is suitable for use in developing countries. AeroVax itself is running on the model of social business. The company does not setout to maximize profit for its investors by exploiting the markets in the developing world. It looks for a balance between providing affordable vaccination technology to the developing world, and becoming self-sufficient at the price they can afford.

The founding of AeroVax provided a snapshot of the movement of social concerned innovation in major institutions. Engineering oriented institutions tend to follow the market forces. Social innovation did not occur due to low profit margins, and lack of investment from the business sector. Those with the greatest need, often people in the developing world, are least likely to be served unless someone volunteers to do so, based on some other motivation or potential gain, such as getting academic credit.

AeroVax's social business model is the company's greatest advantage. This model allowed the company to continue providing medical service to the poorest people without being interrupted by the shortage of funding. Many young people have a passion to improve the living quality in developing world, but often constrained by lack of opportunity on financial means. AeroVax will attract talented minds with passion to improve health care quality in developing world.

The revolutionary business model of AeroVax might be a shortcoming in terms of convincing the market to use this new vaccine delivery system. It is not as good as investment to the traditional venture capitalists, but it is attractive to certain specialized

capital funds looking for socially concerned opportunities rather than maximum return. It might also threaten the traditional syringe and needle suppliers that have been in the vaccination market for years. The problem is not so much the traditional market is modernized nations, but the loss of contracts from the United Nations, World Health Organization and national health agencies in developing nations. The concept of social innovation is to develop products based on practical needs, and make it affordable to those at the bottom of the society. This requires moral extensive communication and collaboration between the development team and people from the developing world.

The Role of Research and Development in IQP

A group of passionate students from Worcester Polytechnic Institute joined forces with Jose Gomez Marques, Vice President of AeoVax to develop a vaccine delivery system with social innovation approach. Jose was aware that the original MIT team was incapable to finish the design and turned to his classmate at WPI to form the second product development team. Unlike the first team, this one could arrange to their academic credit worth three courses per student for worth on an approved technology project. Professor John Wilkes agreed to advise both Jose's MQP project and own IQP projects and linked them in a common effort. Hose would be doing a group dynamics study of five R&D teams, only two of which he would manage directly. We would participate in his study, as "participant observers" writing diaries on the experiment. Cognitive styles fill out indicators and reporting on matters of changing moral and engagement. He would later look for patterns in levels of conflict innovation, productivity, contributions and satisfactions across the five teams in his study.

The successful development of Aeovax system would demonstrate the feasibility of introducing of new medical technology to developing countries. The final product would be world-class in quality, but affordable by the people at the bottom of the economic pyramid. We would strive for a working design that can be marketed different parts of the world without major modification. This was a challenging technical task.

Our competition did not seem to be a twist. Most of the current biomedical R&D units focused on developing products for the U.S. market. These products will later export to European countries with little modification to fit into local cultures. While the U.S. and European cultures are similar in many ways, the differences in cultures between the U.S. and developing countries often limit the effectiveness of medical devices transferred to foreign lands. The current development method of major pharmaceutical companies concentrates on improving the currently available products, and resolving problems that have already been solved with original designs. This often keeps the price high, and prevents developing countries from adapting the technologies. Developing countries seek for simplest solution that solves the problem with the lowest cost. In short, the market we want could be taken if we succeeded in our task and a follow up team at WPI or MIT designed the production lines. Production would probably be in India or Pakistan so the next team should be made up of people from the country where the plant should be. They must not assume support infrastructure or levels of skill scare and expensive in that land that would be taken for granted here.

Client Statement

The goal of the specific R&D mission that we undertook is to design a cartridge specifically for use in third world countries. This cartridge allows medicine to be mix internally, and should be compatible with commercially available air compressors and nebulizer masks. Safety for both users and operators are primary goal in the design. The device should be robust in the face of changes in surrounding environment, and relatively simple to maintain and assemble in developing countries. The cost of the cartridge should be kept under \$0.15. Product must be adorable at the bottom of the economic pyramid.

Difficulties and Solutions

Implementing U.S. designed medical devices for both production and use in third world countries was a difficult task. This was due to the difference in culture and technology gaps between two worlds. For this reason, many successful U.S. made medical devices have failed to work and solve problems in developing countries. Sometime they were not adapted to condition but more often lead to a high price tag. The IQP team considered the difference between cultures while still in the process of design. We were told that this method while seemed reasonable, even essential, was fundamentally different from the traditional engineering method of identifying and using the "bad" design. We were influenced by efficiency criteria but that was not the most important considerations.

Lack of understanding of the local culture has often led to problems in introducing new medical devices to foreign countries. Medicine was often being

considered as gift from God. New medical devices were treated as part of the dark art of wizards in many cultures. The challenge for the IQP team was to design a medical device that is compatible with not one but many cultures, and that would have to include those with spiritual rather than material interpretation of the disease. The final objective is to allow people at the lowest level of the economic pyramid to receive quality preventative health using AeroVax system.

The living standard for individual families in developing countries plays an important role in the deployment of AeroVax. Health especially preventative medicine is not the first priority for many families in developing countries. Food, housing and education have higher priority than preventative health care. A product that designed for developing countries must take in to account the consideration of cost in family budgets. The IQP team was required to look at the cost of AeroVax cartridge through the eyes of local families. Most of the rest of the system is reusable and can be authorized over thousands of doses, but the cartridge cost must be carry by few dozen families.

The availability of technology in developing countries limited the design complexity and places of AeroVax cartridge. The cartridge is intended to be built and maintained by local contractors who will get the medicine in bulk powder form. IQP team limited the complexity of the design to meet the technological support limitation. Simple to build and simple to fix were two objectives set by the IQP team.

Analysis

The group initially met D term 2007. Jason Hu and Julie Hickman had already met to discuss the AeroVax IQP opportunity. The group then met with John Wilkes, a Sociologist and Associate Professor in the Social Science and Policy Studies Department, the Project advisor to discuss how the group could take advantage of this unique opportunity. The key would be to take an MQP like technical task which would contribute to an appropriate technology startup company's survival and use that experience to see how society is influenced by science and technology and can be taken in new direction by a social movement. The next introduction was to Jose Marguez-Gomez, a co-founder and current Chief Technical Officer (CTO) of AeroVax. As project sponsor he was able to enlighten the group on his philosophy, on how one can impact the socio-economic world beyond the laboratory and machine shop through technical innovation. A third member, Jonathan Shoemaker, joined the AeroVax team after hearing about the project. The three joined forces and decided to stay separate from the three other people who wanted to work with AeroVax in other capacities. Hillary Stinnett and Chris Rollins formed a testing team and branched off from us, and later and made their own decisions. Laura Saltzman would work alone. Initially our team decided to focus on the engineering design and the prototyping of the cartridge, following by product testing and quality assurance. Given the team's background this endeavor seemed appropriate and attainable. Jason and Jonathan have bioengineering backgrounds and were to lead the design process while Julie with her background in biochemistry, would be leading the particle and vaccine testing. Julie would also be working as the team's liaison between our team and that of Chris and Hillary. They were scheduled to complete their work in B

term. It also seemed possible that Julie and Laura could join forces and continue testing as she joined the team during C term if that was not complete at that time.

The first meeting with Professor Wilkes shed light upon the project. The most attractive feature to working for this team was the information that a NCIIA (National Collegiate Inventors and Innovators Alliance) grant was given to WPI and Jose to support this research worth \$500. This money was supposed to be used to develop a proposal and compete for \$5000 of support, but Jose adapted an existing proposal to submit to this contest and never spent that money. It was held for reserve by WPI for the duration of our project in case we needed it. If the money was untouched it would be used to reimburse AeroVax for the cost of working up a proposal. While the team never actually saw that money, it was a driving force in our commitment by reassuring us that there was a genuine need for the product and outsiders were interested in it. This further propelled the groups' intention to help the world. This project was not just going to be a typical oncampus IQP project that was an exercise resulting in only a report in the library, but more of a global awareness experience with the potential for a strong impact on the world. While the team talked primarily about doing R&D to help AeroVax succeed, Professor Wilkes was more concerned with team dynamics and the social aspect of the design process. He reminded us that this was neither an MQP nor a service project. It was participant observation study of the society-technology interface. This approach served to protect us as well that way the project was a success as a study of the R & D process as impacted by the socio-economic setting whatever the outcome of the technical work. The team attempted to predict the outcome of the group experience in terms of conflict, cooperation and innovation based on our own personality mix as measured by MBTI

scores. We noted that we had certain complementary advantages as a group, but were all the same in some respects as well- and that was to be expected. We were all attracted to a change the world for the better – socially concerned technology project.

MBTI

The purpose of the Myers-Briggs Type Indicator (MBTI) personality inventory is to make the theory of psychological types described by C.G. Jung understandable and easy to apply in peoples' lives. The goal of knowing about personality types is to understand and appreciate differences between people. In her book <u>Gifts Differing</u>, Isabel Myers claimed that all MBTI types are equal, there is no best type; rather each type is part of a system that describes situation based strengths and weaknesses. The MBTI instrument is one of the most widely used instrument for understanding normal personality differences and the most popular offering of the Consulting Psychologists Press (CPP). Because the indicator explains basic patterns in human functioning it is a great tool for team building and problem solving; both of which are necessary in the mechanical design process (Myers, 1995).

In our case it revealed that we had a common way of making decisions (F), but in other ways we were complementary. These common F qualities increased the odds of cooperation and good communication with the team since F's prize harmony and tend to be able to see things from the perspective of others and do not put abstract principles of justice over the ability to make a good decision that benefits all parties to the common endeavor. It does not have to be a fair and equal partnership in terms of work load as long as it's a win-win situation. Chris and Hilary were different from our group on the decision making dimension (T) and from each other on all other dimensions. They were

more likely to have to work at managing internal conflict, and fostering communication and seeing things from the standpoint of the other as well as dealing with work load inequalities. Justice, not harmony is key in T decision making and subjective features like empathy are viewed a source of bias to be ignored as much as possible by "objective" decision makers. This attitude combined with the changes of having an introvert and an extrovert, a structured and a flexible task environment preference and differences in what information is worth processing- the most tangible clear evidence are the intuitive clues about what is going to end up being important made conflict more likely for them rather than us. We too had differences on the other dimensions to deal with but in general it was 2:1 on each and we knit together in a way that had reasonable balance.

At the first team meeting with Jose, Jose was able to fill the team in on the previous research conducted by the company founders at MIT, as well as other student groups that were receiving academic credit for their work, and to suggest or provide basic project objective. Jose showed the team a detailed presentation of what the product should consist of and what still needed to be accomplished. Jose had already presented this project in corporate forums and had both a business plan and proposal based on considerable knowledge. It was interesting to note how Jose explained that the finished product would fit into the larger picture, and told the team, that we would play a significant role in the company. Serving as a "coach" and "manager" Jose would try to work equally well with these two very different teams.

Jose was to be a great resource as he often worked with the team as a fourth group member rather than a supervisor; allowing the team to explore all of their options and not to do work based solely on the foundation provided by MIT summer interns who were

previously assigned to work on the design. Jose's initial cartridge vision involved modeling the cartridge after a telescoping design and from there the group began the second wave of the design process on this key element.

Important take away remarks from the team's initial meeting with Jose also included some warnings about working with a start-up company looking to reach major market status. The plan could change as opportunities were identified. Company confidentiality was important to the sponsor and advisor as they were crucial in terms of patent applications and intellectual property, the current main asset of the company. The team planned to use The Global Medical Device Group; an online resource and project manager that were password protected and allowed for the sharing of files, research and any other means of group communication. Deadlines, to-do lists, and suggested readings were important things to post in an effort to foster better team communication and production.

The team's design goals began with the development of a design for the cartridge of the AeroVax system. As part of the design team effort it was necessary to do essential background research on the existing products in the field and how they work. There were not a lot of competitions but there were some.

The team's project is essentially a project within a project. While the student team focused their efforts into engineering and design they also served as part of the research study group analyzing group dynamics in Research and Development teams. The team planned to tie together the relationship between society and technology and the interface between science and the third world. At one level, in the broadest of terms, the team

envisioned their goal as that of the AeroVax Company, i.e.: Save the World from infectious diseases, through developing a cheap and fast vaccination process.

Beginning at the start of the 2007-2008 academic years the team created a timeline with appropriate deadlines and completion dates. The team's initial overall goal was to have a prototype developed by the end of first term and to allow for testing in the second. If things worked out according to the schedule, the team would be able to hand over the design to Chris and Hillary for continued testing in B term or Laura if it were in C term. Working as part of a team with two missions it was necessary to continue background research into several markets. Who would be the end user? Where was production to take place? What are the environmental implications? In the bluntest of terms, what is "overseas"? Should we have Asian villages, Latin American Barrios or African Refugee camps in mind? The team planned to interview and survey three Sudanese men for their input on design, marketing, technology and application of our technology to reduce the risk faced by people living in refugee camps. The Sudanese people were available to the group through the efforts of Professor Wilkes. Coming over to Worcester in the early 1990s these men were from Southern Sudanese villages attacked by government sponsored militia forces during a revolution. These three men (then boys) were refugees in a Kenyan Camp for nine years previous to their relocation to America, and in many cases the fate of their families was unknown. They lived because they were out tending flocks of animals when the villages were attacked. They were interested in the project and agreed to help if they could.

Engineering

Initial background research began with preliminary designs and investigation into the existing drug delivery market. The most important stating place would be to consider the feasibility of what AeroVax was trying to create. Nebulizers already exist on the open market, yet these products would not be worthy of patent potential or have already been protected as intellectual property. A nebulizer is a device used to administer medication to people in form of a liquid mist to the airways. Vaccines typically need to be kept cold and can only be stored for a temporary length of time. Doctors generally prefer to prescribe inhalers for their patients rather than the nebulizers due to low cost and the ease of training concerning its use.

The team conducted a series of membrane testing experiments using water balloons to serve as the separating membrane of the cartridge. With food coloring mimicking the lyophilized vaccination, the team added water to proceed with the reconstitution process. This activity was the team's first real introduction to the design of the cartridge. While identifying the A + B mixing process, experimentation allowed the team to experiment with the properties of a membrane.

As the team's first true technical teamwork activity took place we began to build bonds among team members. The team investigated how to break the membrane, why the membrane broke, what made membrane easier to pop, fullness, and the correct order in which to add the vaccine (powder/water on top?). Work was completed in the Biology and Biomedical Engineering laboratories in Salisbury Laboratories. Under loose guidance of Professor Mike Buckholt, the team used PVC piping and the aforementioned fruit punch to mimic the cartridge. As many good design teams do, the team failed to met the initial design criteria on the first try. Although the first idea was dropped, a specific

design criterion was developed in accordance with the original design idea building on experiments that were developed previously by MIT students. It is surprising how long it took us to face up to the problems in the original design concept we were given and be openly critical of them.

Although the team was only to focus on the cartridge, it is necessary to know the workings of the entire product in order to develop a true understanding of our component. Jose created a sketch up design for the AeroVax system. This allowed the team to visualize the process, develop expectations and put the whole project into perspective. While to some extent, the idea of an end vision may help accomplish the long term goal, the team felt as if early exposure to the prior design mockup had limited their imagination, we felt as if we were restricted to work within that system and its specifications. This process also foreshadowed what was to come, when the focus changed to redesigning the entire system, not just the cartridge.

In order to complete some preliminary background research into the feasibility of the production of some designs that the team had begun to develop, a visit to the U-Mass Medical Machine Shop was planned. On the trip we learned about the cost of making the product, time of production, and the necessary prerequisites for production. Based on the price of \$90 an hour, Jose decided to develop a 3-D printing instead of machining due to costs. The manager of the machine shop was very helpful, explaining that he has worked on similar projects and had the medical device experience to support us going forward.

One of the most important topics of discussion were availability of materials and what materials to use for a product that would be sent overseas. We had to keep in mind the environment of its use as well as how feasible production would be in a less

developed nation, than the USA. Clearly the local resources and expertise were sufficient to proceed. The fact that the machine shop does work for local companies as well as with the medical school, the team felt as if this project was headed in the right direction; it was doable and it would be successful in prototyping. The challenge would be designing for developing nation production facilities that might not be as sophisticated as the ones available to us here in the USA.

In terms of the biological testing the team's chance of reaching its objective was not as optimistic. Negative feedback was received from the Chesapeake labs. The first real roadblock of the project had been encountered, and we were disappointed. Did this mean we no longer had a chance to impact the real world, and the project would become an academic exercise? The Labs continued to state that the project device would never be able to be tested with real attenuated vaccines. Maybe it could be tested overseas, but credibility depends to some extent on USA approval. The United States Food and Drug Administration develops most of these regulation guidelines, thus making the testing section of the device considerably more difficult than coming up with possible design concepts.

With this conflict in mind the team attempted to discuss alternatives of lyophilized vaccines, and working with the reconstitution factors. Lyophilized vaccines are harder to come by than expected. Most companies wanted to use their own existing vials; as adaptation to the team's requirements were a hindrance on their production lines. Glass vials were preferred by the producers, but would not feasible with our application. Testing of the measles vaccine remained difficult due to restrictions on who could work

with the potentially dangerous strain of virus. Companies that did want to assist us in the team's testing program didn't have any other pseudo-vaccines to offer.

A major gap that would limit the testing side of research was that there is no means of conducting real life testing into lung tissue. The team would have to rely on previous research to get the point across that the process would deliver enough vaccine to work. We came to understand that the validity of our testing might be questionable and contribute little to the AeroVax Research and Development program that was a disappointment.

The first opportunity for the team to develop a mock up system came earlier than expected and deviated from initial plan for concentrating on the cartridge design. The WPI Entrepreneur Venture forum became an important opportunity for AeroVax. The team was asked to create the full system rather than just the cartridge, in order to present at WPI's entrepreneurship forum, and in the most basic form be a prop for an elevator sales pitch. The team was excited about this surprising turn of events.

We spent three days in the lab transforming a simple toolbox into a workable concept. Group trips to Home Depot to find parts and late nights in the laboratory setting resulted in team frustration due to time constraints. The team was told only five days before a completed product had to be displayed. This event marked the team's first exposure to dealing with other entrepreneurs and the concept of how to get money to start a business. The team encountered difficulties, conflicts, and design constraints as the processes of producing under later deadlines continued throughout the project. In addition to the team's continued work with Jose, meeting other key members of the AeroVax community was necessary for product completion. On Friday night we met Esmeralda,

the MIT management major that co-designed the concept for the MIT IDEAS competition. This was the first time we had worked with her and her pride and excitement about AeroVax were infectious. She even seemed excited to be able to work with us. The experience was eye opening in that it shed light on what other people expect of themselves and the "support staff", meaning us. Then had to deal with the fact that the team did not place first, though we thought we deserved to win and so did other observers. Jose was led to protest the behavior of a few seemingly biased judges. One can only speculate about why some people really did not want to this MIT-WPI entry, which had already won a prize at MIT, win another one at WPI.

Jason and Julie attended a seminar at MIT to speak with other innovators some were in school at MIT and others were there to recruit students to help their companies with projects or products. The pair learned about other creative ideas that were being developed in the movement to produce medical innovation appropriate for use in the third world. The most important piece of advice obtained was that some innovations will never work and fail before given the opportunity to be tested; but do not hesitate to create those ideas, for they are stepping stones in the right direction, and will be reconfigured or inspire other innovations that will be put to use.

Jonathan and Jason attended the viewing of <u>Invisibles</u>; a series of short films examining the world's overlooked problems and the people who suffer from them. The film documents health care in the third world, and the declining status of medical and health care available in those locations was sobering. CIMIT, the Center for Integration of Medicine and Innovative Technologies may have been the most influential broadening and consciousness raising experience that the team took part in. Held in Boston, the

CIMIT consists of a whole collaboration of people to advance medicine, ranging from innovation and design processes to product development. Jonathan, the only member of the team to attend, met with Dr. Kris Olson, head of Global Health and Mass General who does a third of his clinical work overseas in post tsunami Thailand still, domestically he does innovative research inspired by that experience. For example, Olson has developed a neonatal incubator that can be built from used Toyota car parts. He wants to develop a movement to bring basic medical technology to the third world. Dr. Olson has agreed to mention the AeroVax product at any opportunity the chance is given to foster the medical innovation movement.

Main players in the field were acknowledging that our project was a good illustration of the things that need to be done to make the developing nations a healthier place. That was a gratifying affirmation of our work, but also put pressure on us to get the remaining financial and technical obstacles out of our path.

The largest and most significant step in product redesign came when we were asked to develop a prototype for FEMA. The consultant Booz Allen wanted to see a more in depth development of a prototype than we had produced for the WPI competition, one that could be used domestically for use in response to a natural disaster. They had interesting insight in the idea that when the US infrastructure breaks down and electricity is gone and the risk of infectious disease grows- intervention using equipment designed for third world conditions makes considerable sense. FEMA also has to plan for bioweapon terrorist attacks. The team was given four long hard workdays to develop this full-scale prototype. The team initially dropped the ball on ordering the external hard

case, and that may have been the first instance in which Jose was disappointed with our work.

On our side, the team was upset with the way that the process was moving along in fits and starts, responding to events rather than unfolding according to any kind of plan much less our original planed that we signed on for. With limited information about the potential implications of this tremendous opportunity, the team felt uncomfortable spending company money on a carrying case, not having a vision of the final product. So we balked, actually just, hesitated but failed to ace at a key moment. We were slow to emphasize image, splash, and presentation over content, but in the world of resource competition it has to look good as well as be good. So we neglected a "detail" that was something considered important by "management." Jose wore several hats but in this case he was the boss and had authorized the resources we failed to use. The FEMA presentation was completed but Jose felt he had to explain essentially apologize for the lack of a suitable hard case for storage under the condition disaster preparedness would require. It seemed to go well anyway but his confidence was not at its usual high level and he worried inordinately about this lapse. We had not come through; he tried to fix it when he should have been honing his delivery and message. This was not the last that we would be called on to jump into a breach.

The next time the team was notified of an opportunity with little time to act. We were returning from winter break and found out about the opportunity to present an abstract to the Respiratory Drug and Delivery Conference. The tests were not yet done and had to be completed 18 hours before hand. The testing was to be completed at Malvern Laboratories in Southborough, with the use of their laser technologies to

measure particle size. Although everything worked as scheduled it was difficult to adjust to meet the given timeline. Using baking soda and water as pseudo vaccine the team operated a foot pump and compressor ultimately showing that the particle size of the aerosolized mist yielded the same results. So the technology appropriate for third world application was good enough. Also, premixed and cartridge mixed vaccinations yielded similar results. So, we could go into the field with the dry mix not yet activated, mix it at the time of use in our cartridge, power the delivery with a foot pump and get results that would be comparable to having premixed, refrigerated vaccine delivered in a clinic using a compressor. The idea was feasible, and the results were going to publication.

The AeroVax team was disappointed to find out that while we were running around putting out fires, Hilary and Chris had dropped the ball with testing and had done little or nothing else for AeroVax. Nothing was achieved, and they complained about not being able to work well with Jose, due to a lack of clear focus. We were surprised to find out that they considered him distant, unavailable and not clear about what he wanted, unable to provide necessary resources.

By contrast, we were smothered with attention, in daily contact, all too clear about changing objectives, expectations and why the priorities had changed. We were running hard to try to keep up, and ended up doing part of their job too, while they were discouraged and wondering what to do with them. If only they had asked, we would have put them to work.

Although most of the work had already been completed, by our team – including the testing- the AeroVax team hoped to have considerable collaboration between teams. That was not to be in part because Chris and Hillary changed direction when it was clear that

testing with virus was out of the question. Hilary turned her project into a literature review of medicine and health care beliefs and practices in South America, and Africa, (implicitly compared to the USA) so as to have something tangible to report on when her project was scheduled to end. She had no intention of dragging out her "poorly managed" project relationship with Jose and was determined to take control and end on time. Chris, on the other hand, really tried to save the original project, cared about AeroVax and wanted to make a contribution. He decided to let his project run late and ultimately did a different study on how to raise WPI consciousness about the health care issues of the USA and developing nations. He documented the impact of a thirty minute documentary that motivated 10% of its viewers to want to do a project like AeroVax and got most of the rest aware and concerned about the issue. Though they were not ready to take personal action on the matter they might well vote, invest, by or donate money to an organization with goals like that of AeroVax.

Although helpful to further our knowledge of total impact of the AeroVax experience and the future goal of saving the world one breath at a time, the AeroVax team had already contributed to the literature review. It was compensation to Jose, that while the second team contributed little directly to the technical side of developing AeroVax, they were a wonderful story in contrasting team dynamics for his MQP. The theory about which team would struggle with conflict and fail to communicate worked perfectly. As Professor Wilkes worked to salvage their projects worthy of three courses of credit that contributed something to AeroVax he did something that upset us. The one part of the project that had been stable was our plan to study how spiritual cultures would interpret using the AeroVax system.

In effect, he gave away that part of our project to Hilary after we had started identifying care studies to read. Regrouping once again, we shifted to looking into the literature Jose had found inspiring and ended up studying the medical wing of the appropriate technology movement, and economic reasons why AeroVax was not produced by the Biomedical industry. We got the better end of the deal with Hilary taking over part of what we had planned to do on the cross cultural side. When forced to shift our attention to the alternative technology movement content of the project everything came together for us. It is likely that the original literature review would have just been an interesting intellectual exercise to balance the technological side of our project. This way we did a real study of the society-technology interface.

Laura was the one most interested in cross cultural issues and most likely to feel preempted by Hilary, but she had lost interest in AeroVax as a focus and wanted to get into cross cultural comparative study more generally.

To our surprise, we were the AeroVax team, only 3 out of the 6 original recruits that carried the company through a turbulent time of design change, testing protocol adaptation and fundraising efforts when no one from MIT was available. On the other hand, we did not achieve our original objectives we had instead kept the company going. However odd that felt to us, we were told by our advisor that it was not unusual. Indeed, a 50% participation and success rate for R & D teams is not bad at all. Now it was time to try to understand the key to our success in terms of group dynamics and MBTI theory.

Group dynamics

The following were the results from the MBTI instrument and an interpretation follows.

Jonathan – ESFJ Julie – ENFP Jason – IN (F) J

According to a study conducted by Stanford University, the following MBTI results typically fill the following roles:

Anchor \rightarrow ISTJ Task Master \rightarrow ET Visionary \rightarrow (E) NT (P) Facilitator \rightarrow EF

Note the emphasis of having T-types in the team to anchor and envision, and Ftypes are just supposed to harmonize the high conflict potential between ISTJ and ENTP. The team has determined other ways to balance a team. Look at what our high functioning tem was made up of:

Jonathan, according to the MBTI results, is a warm hearted, talkative, popular, and conscientious individual, who often acts as born cooperators, and active committee members. These individuals need harmony and may be good at creating it. They are always attempting to do something nice for someone, and work best with encouragement and praise. Their main interests are in things that directly and practically improve (save) people's lives.

Julie, according to the MBTI results, is warmly enthusiastic, high spirited, ingenious, and imaginative individual, who is able to do almost anything that interests them. Quick with a solution for any difficulty and ready to help any one with a problem, these individuals often rely on their ability to improvise instead of preparing in advance, and can usually find compelling reasons for whatever they want. Jason, a little bit more difficult to describe by the standards of the MBIT, is best fit as an individual who succeeds by perseverance, originality and a desire to do whatever is needed or wanted. They typically put their best efforts into their work. Quietly forceful, conscientious, and concerned for others they are respected for their firm principles. These individuals are likely to be honored and followed for their clean convictions as to how best to serve the common good.

Professor Wilkes told us of a study in which a WPI MQP team intended to see if the Stanford results could be replicated at WPI. There was one major difference in the results, that INTJ-types can anchor a team as well as an ISTJ and conflict less with ENTP-types. On its face, ours was a group that would be attracted to a worthy cause, and interested in more than dollars and cents. We were also complementary in a way that fit the general idea of the Stanford roles, but deviated at the level of specifics. What we had was a person who was 3/4th CEO type (ESTJ) but worked well with a facilitator since he was the EF-type. In short, we had a soft touch anchor helping create the harmonious environment we all needed to function at our best. We had no ISTJ or INTJ anchor, but we did have people with a strong need for closure and specifics, Jonathan and Jason. INFJ and ESFT types, respectively, passed the stabilizer and anchor role back and forth. Then when it came time to re-envision, trouble shoot and improvise, Julie and Jason would take the lead for a while, and Julie sometimes worked well beyond her field training on the technical side making it happen to meet the deadlines. On an all F-type team, no official facilitator is needed, just a task master. In our case that was Jose.

One can't understand the dynamics of their team without knowing that there was another "member" and he was an ENTJ. Jose is an enlightened T-type who respects the

F-type and doesn't micromanage. He knows that you motivate an F-type by showing them, have confidence in them, and will be there for them <u>BEFORE</u> you load on stress and high expectation. Then they will move heaven on Earth for you to avoid letting them down. As for himself, he expects no praise and encouragement in advance. However, if and when he comes through, he wants the recognition, credit and reward to which he is justly due. So, he was the insider-outsider we respected who needed us, but also trusted us and gave us great responsibility and had confidence in us. We let him down once, and while that was bound to happen, no one yelled or screamed, a look of disappointment burned like a whiplash because we were joined in a common cause and cared for one another (Myers, 1995).

So, our team is sort of a refutation of the emphasis on the T-type to anchor and innovate- if you ignore Jose's role. If you ignore instead the fact that he was not always physically present but always in tough, is older but still a WPI student, our "manager" but also our peer and we were doing the job he did on the last round of the project, then our team fit the theory rather better.

> ENTJ – Jose INFJ- Jason ENFP- Julie ESFJ- Jonathan

This was a team with a strong need to finish things that they never got to finish and needed to accomplish what they set out to do. However, we accepted the judgment and explanation of those who said that for a startup you can't be sure what is going to matter most, so you have to adapt, and we did, as a team, not individuals, and can look back on a considerable string of accomplishments that leave AeroVax in a stronger position, more likely to succeed, it was when we began our project.

While no single person emerged as the individual team leader, each member had learned to take the lead when needed. Each member was reliable when called upon. Although deadlines passed frequently and tasks changed daily, all aspects of the commonly acknowledged goals were accomplished when needed; if one member was not able to complete their own task, others helped out. Meetings were scheduled weekly and whenever all team members were available conducted to as not to exclude any team member. Jose also contributed to the group dynamics by being a large big part of the design team. He focused the team's research, design and testing. Jose became a great leader by presenting and endorsing the team's ideas to Professor Wilkes, and kept the team organized through online project management and provided clear goals and objectives throughout the term.

However, Jose did frequently change his corporate objectives as new opportunities arose. Each member of the team played their own role and knew when to give up leadership when a topic was not among their special strengths or personal abilities.

Initially the team members were to keep a journal in order to track changes and how we meshed as a group throughout the process. The journal was to document obstacles, feeling, successes, difficulties etc throughout the year. Besides reflecting on our or achievements and struggles the journal served to help Jose complete his portion of his MQP study, by documenting the team dynamics and how they changed over time. It became increasingly difficult to keep up with the Journal entries in the hectic terms. The journal became more of event documentation and a retrospective view of the process over

time. It refreshed our memories about what we were doing and how we felt about it as the project proceeded form one phase to the next.

Conclusion

At the conclusion of our project, our group was satisfied with the results and progress. Information was gathered, introducing us to the new social movement and making us aware of its existence. To encourage the future development of the project, we would establish a set list of goals, making sure that each deadline is reached and the target focus remains clear. Although our group was able to produce prototypes of our device that launched our product onto the medical scene, it was very different from the original plan. This caused lots of confusion and frustration resulting in strain amongst the group. Even though the group ultimately failed at its original goal, developing a working model of the cartridge we feel that we far surpassed our expectations.

Due to patent applications pending and protection of intellectual property, the engineering team was not able to present any detailed design of the products. Any suggestions or comments concerning the technical aspects of the device should be directed to:

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