Product Development of a Device for Manufacturing Medical Equipment for Use in Low-Resource Settings

by

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Submitted to the Department of Mechanical Engineering in Partial Fulfillment of the Requirements for the Degree of

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ABSTRACT

The objective of this paper is to describe the product design of a device that can be used to create medical supplies on-site in clinics in low-resource settings. The machine uses purely mechanical elements to cut and fold cardstock paper in order to fabricate aerosol masks for the treatment of asthma. The devices will be mass manufactured by larger firms and then distributed through the Ministry of Health to hospitals, clinics, and health posts across Nicaragua. An assessment of the market needs was conducted, and a target customer profile was developed. Alternative mask and device designs were explored and evaluated based on their financial costs, probability of user acceptance, and appropriateness to the design context. Feedback was obtained by doctors in Nicaragua as well as a few professionals working in the field of global health technologies. The use of this product will reduce dependency on imported medical supplies and solve some of the issues concerning lack of resources and incomplete healthcare coverage.

Thesis Supervisor: Maria Yang, Assistant Professor of Mechanical Engineering and Engineering Systems

Acknowledgements

The author would like to thank D-Lab for providing a framework for approaching technologies for the developing world. Amy Smith and Victor Grau Serrat provided valuable information about design strategies and assessing customer need during their class at MIT, D-Lab Design.

The author would also like to thank Jose Gomez-Marquez for his mentorship. Gomez-Marquez provided the author with information about appropriate medical technology projects, as well as insights into successful dissemination processes and the value of creating networks and community partnerships.

Prof. Maria Yang also gave extremely valuable advice, encouraging the author to look at the design of the product from all different angles. This allowed the author to incorporate the human, environmental, and economic factors of the design context into the physical design in order to create not only a product but a dissemination plan as well.

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Chapter 1: Introduction

This paper introduces the idea of a device that facilitates on-site manufacturing of medical supplies in low-resource settings. The design context, challenges, and strategies will be discussed as well as the author's ideas for how to design, manufacture, and disseminate the product. The content of this project will be focused on Nicaragua and other poor countries in Latin America, where the author has more first-hand experience.

Chapter 2 discusses the background of the problem and gives a context for the design. It describes the process for procuring medical equipment in developing countries and the problems that arise from the current system of using donated equipment.

Chapter 3 talks about the objective of the project and details the customer need and design specification.

Chapter 4 is focused on design strategies for designing a product for healthcare professionals in low-resource settings.

Chapter 5 is the physical design of the mask template and the manufacturing device. It includes reasoning for design choices and steps for how to use the product.

Chapter 6 is a collection of feedback from contacts in Nicaragua and a selection of professionals who have done global health technology projects in developing countries.

Chapter 7 details a marketing and distribution plan for disseminating the technology to the target customers, healthcare workers in Nicaragua.

Chapter 8 concludes the paper, proposing next steps and discussing the potential impacts of this device if it were to be implemented.

Chapter 2: Background

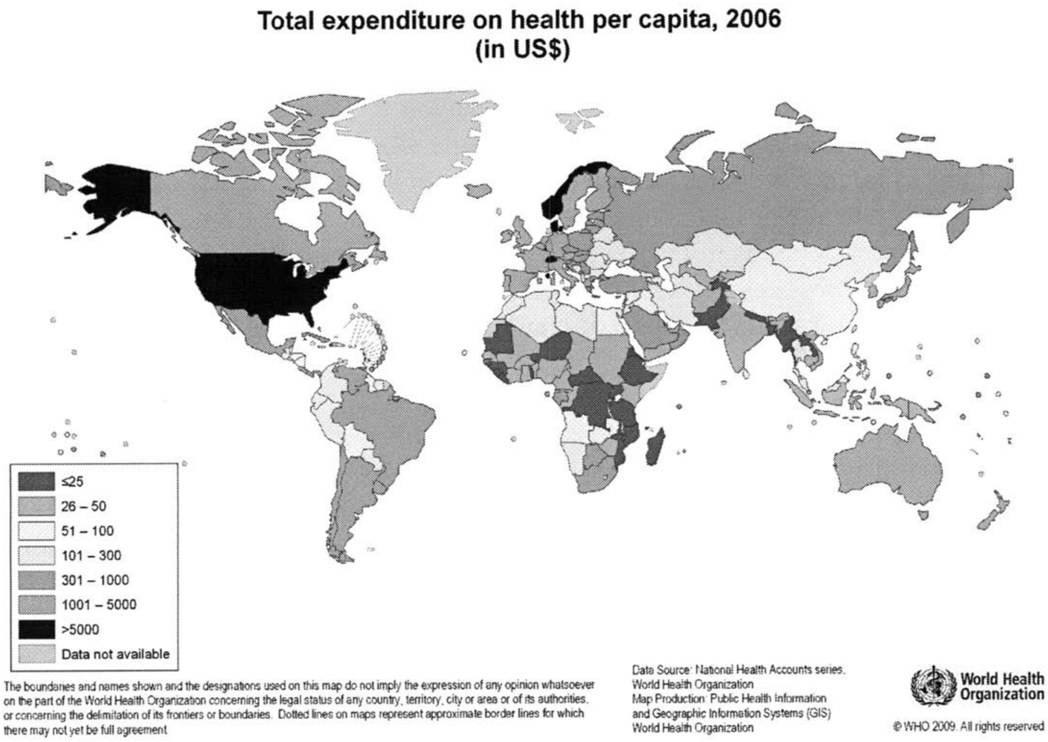

Figure 1: Total Expenditure on Health per Capita, 2006. World Health Organization (WHO)

As of 2006 between $50 and $100 were spent per capita on healthcare in Nicaragua. This is less than one-fiftieth the amount spent per capita in the U.S. Many countries in Latin America, Africa, and Asia are trying to emulate the standard of care set by the U.S. and Europe, while working with a fraction of the resources available in richer countries.

Access to medical equipment in the developing world

Currently, the end user of the majority of medicines and equipment is a minority of the world population. The World Bank reported in 2005 that 88% of sales in the pharmaceutical industry were to North America, Japan, and Europe, with 11% to Asia, Central and South America combined and less than 1% in all of Africa. Data for expenditure per capita on medical equipment is difficult to find but there has been a reported 100 fold difference between Sub-Saharan Africa and the U.S. (Date)

Hospitals in the developed world often have whole divisions in charge of researching and purchasing new equipment. In countries such as the U.S., equipment is available in catalogs with costs displayed upfront, and clinics have the option of choosing between a variety of models to suit their needs. Users are also often allowed a free evaluation trial to test out the equipment before they commit.

In developing countries, the acquisition of equipment is different. More than 95% of medical equipment in public hospitals is imported (Malkin 571) and because of economic constraints, most of equipment is donated. This causes a range of problems. First of all, because equipment is donated from many different countries and programs, the devices are often incompatible with each other so if a Japanese incubator breaks down and all the repair crew has are German spare parts, the machine sits un-used. Since the equipment is random, there is no uniform distribution of equipment across a hospital or healthcare system. Therefore healthcare personnel needs to go through more training in order to operate all different versions of the devices. Medical devices created for richer settings also tend to include unnecessary features that drive up cost and complexity of repair. For clinics in the developing world, reliability and durability is often weighed more heavily than accuracy. (Nimunkar)

Under the current system, medical personnel and healthcare management professionals have little flexibility to decide which equipment would lead to more efficient and higher quality care. In developing countries, hospitals and ministries of health often have to either outright purchase equipment or receive donations, both of which do not allow a trial period. Meanwhile in richer countries there are more options to rent or lease equipment without committing. When medical equipment is donated, doctors have no choice over which equipment they receive and therefore their care is dictated by whatever is donated. Since they are not exposed to the options that are available, technological advancements, such as dual-chamber syringes that could be cheaply mimicked in Nicaragua, remain in the richer countries.

The money saved through donations is more than offset by the "hidden" costs of medical equipment. Beyond infrastructure, a large portion of medical equipment goes unused due to lack of "consumables." The disposable components that are taken for granted in richer settings such as plastic masks, are often washed to extend their use, adding to cleaning costs. Diabetes, a prevalent disease in Nicaragua, requires expensive paper to run the tests. Other costs are due to batteries, repair, calibration test equipment, warranty service visits, computer dependency, and training of principal users and technicians. Some estimates place annual maintenance costs at 6-15% of the initial cost. (Date)

The following photos are from a repair shop near a hospital outside of Estelí, Nicaragua. All of the broken equipment was sent to this shop to be repaired. If they could not fix it on site, the repairmen would send it to Managua, which was often the only place were spare parts could be found. Many medical devices across the world sit un-used because a small part is broken and users either cannot diagnosis the problem, do not know how to fix it, cannot find the correct part, or do not know of suitable alternatives.

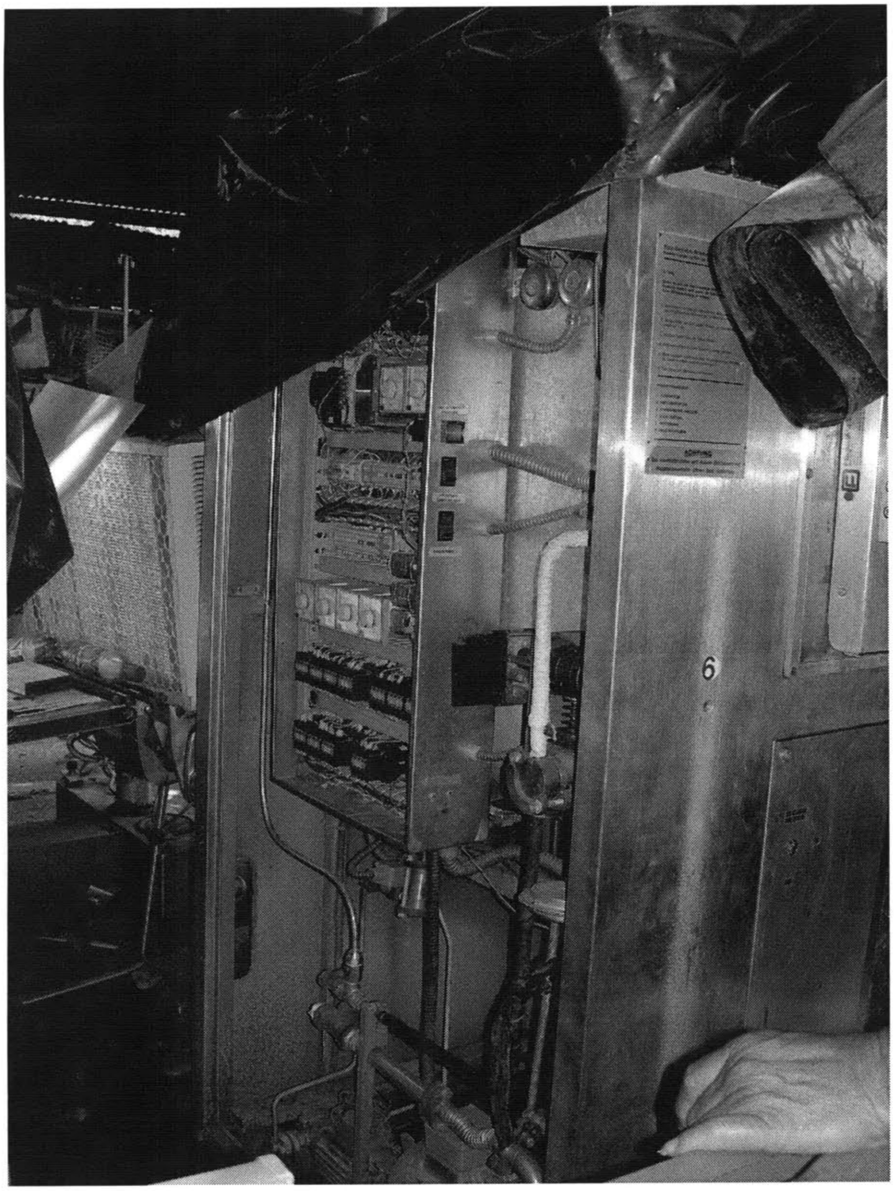

Figure 2. De-commissioned autoclave, Esteli, Nicaragua. This autoclave was sitting in a yard because the repairmen were unable to find the parts to fix it

Figure 3. A broken centrifuge that could be re-used if it was connected to a different power source

The World Health Organization and the Pan American Health Organization have deemed medical equipment coverage in Nicaragua insufficient. As of 2000, 82% of medical equipment was located in hospitals but only 73% were in working order. Other healthcare centers possess 18% of the equipment. Sixty-one percent of health posts have refrigerators, 28% have ice chests, and 82% have thermal containers for vaccines. (PAHO 2007) Less than two thirds of health centers have radio and telephone services.

While some clinics in Nicaragua have access to health technologies, there are inequalities in care due to geography, socioeconomic status, gender, and ethnicity. As only 6.3% of the population is insured, out of pocket expenditures are debilitating for the majority of the rural poor. Lowering procurement, maintenance, and transportation costs of certain pieces of equipment, will hopefully cut costs to the consumer and allow healthcare clinics to spend resources on other materials or programs such as vaccines and training staff.

Local manufacturing capabilities

In the poorest nations, there is almost no local production of medical equipment (Pena-Mohr) and those that do exist are controlled by multi-national corporations. There are some local manufacturing capabilities that have been developing, such as the pharmaceutical industry in Nicaragua. The laboratories are third-tier producers but they need to import all of their raw materials. There is also some importing between Latin America countries. Peru for example produces low-complexity equipment while importing more complex equipment from the European Economic Community, Japan, the United States, Argentina, Brazil, Chile, and Colombia. Even where local pharmaceutical production exists, only half of the people in Peru with health problems can access the necessary medications due to financial hurdles. Many developing countries, including Nicaragua and Peru have a dense area of resources located around major cities, with very little infrastructure connecting its resources with the rest of the country. Improving local manufacturing capabilities would allow healthcare workers in these areas to fabricate materials without the need of financing large-scale infrastructure projects.

There are some companies that are realizing the potential of marketing goods to developing countries but the progression is slow. The majority of the medical device sector sees the industry as low volume, high-margin instead of high volume, low-margin which contributes to inflated equipment costs abroad. There are companies that are making a difference by creating lower cost supplies but management of health technology continues to be an issue in many developing countries. In 2003, the WHO reported that while a lot of money was being spent on medical equipment, the recipients were not receiving the proper care because of holes in technology management.

Producers in Pakistan, India, and China have begun creating lower cost devices using similar design principles as their competitors but they are able to infiltrate markets in lower-income settings by reducing manufacturing costs. This project would go further to create certain pieces of equipment even closer to the end user.

People have already recognized the strength of providing healthcare workers with cell phones and ICT diagnostic equipment to cut down on transportation times and costs. This technology would follow a similar strategy. It is difficult for a centralized hub to know the needs of the periphery clinics without constant communication. Even if the supplier knew what they wanted there would be extra costs and delivery delay.

Thesis Inspiration

The author decided on this thesis topic because there is a large need for local manufacturing of medical equipment in the developing world. The author chose to focus on creating equipment to address the treatment of asthma in Nicaragua, because it is a prevalent issue worldwide.

Asthma in developing countries

According to the WHO, 300 million people suffer from asthma. 255,000 people died of asthma in 2005 and over 80% of these deaths occurred in low and lower-middle income countries. Asthma is the most common chronic condition among children (WHO). Asthma is exacerbated by pollutants, tobacco smoke, and inadequate ventilation and there has been high rates of occupational asthma due to workplace conditions.

The Global Initiative for Asthma developed a set of guidelines for standardized methods of diagnosis and treatment of asthma. A group of researchers conducted a survey spanning asthma sufferers in 11 Latin American countries and found that only 2.4% met the GINA criteria for asthma control.

According to a GINA report, 5.2 million people in Central America suffer from asthma, but this percentage is much higher in other regions. Most asthma patients receive treatment in hospitals or clinics, and the rate of hospital admission due to asthma has increased drastically over the past few decades. In Mexico, for example, admission rates increases by a factor of ten over the past forty years.

There are different methods of administering treatment for asthma, but the most common treatment in developing countries is the use of an inhaler or nebulizer. Parents will often bring their children to the nearest hospital as often as once a week, and the child will sit by the nebulizer, breathing in the aerosolized medication for around twenty minutes at a time. The aerosol masks are designed to hold the medication by the patient's face while they slowly breath it into their lungs, but it is not meant to act as a barrier between the patient and the environment, as a surgical mask is supposed to do.

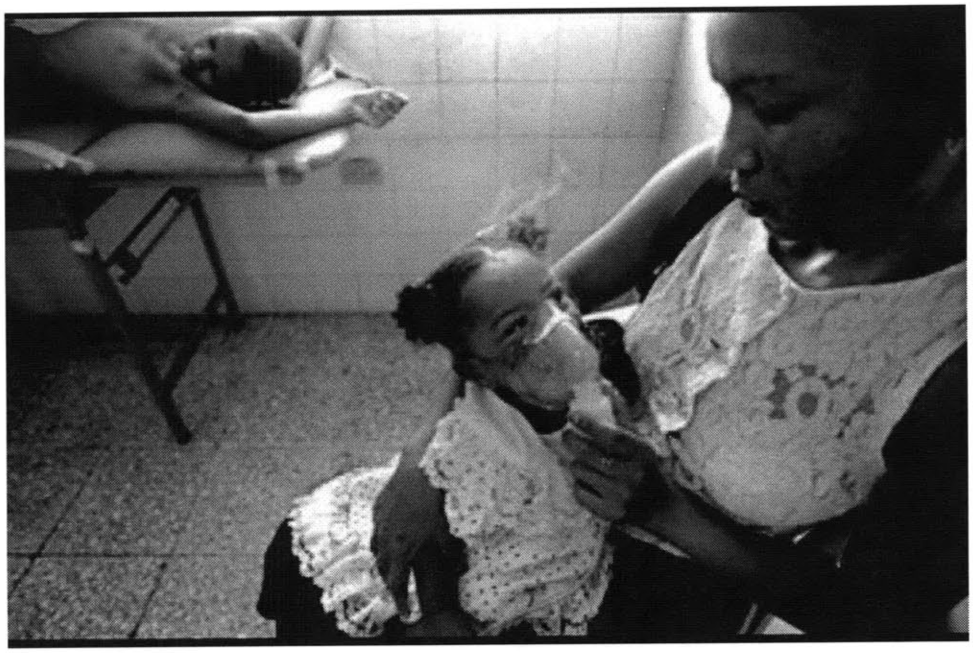

Figure 4. A girl using a nebulizer in the Dominican Republic. Photo Credit: Global Links Annie O'Neil

Aerosol mask use in Nicaragua

Asthma medication and the equipment to administer it is cost prohibitive for many families, so they travel to nearby hospitals for nebulizer treatement. In these cases, if a clinic has a nebulizer, they may crowd a couple of children around one nebulizer to treat a larger number of patients more quickly. Field observations of the nebulizer ward in the children's hospital, La Mascota, in Managua, Nicaragua revealed some drawbacks of dealing with donated equipment. The doctors and nurses have to deal with multiple types of nebulizers, all of which require a different set-up of tubing. The time spent assembling a nebulizer detracts from the diagnosis and treatment of patients. Therefore, if healthcare professionals could fabricate their own devices, and make them standardized, then they could focus on treatment instead of worrying about finding another mask or looking for a clean one that fits with the rest of the setup.

A clinic in Masaya, a relatively wealthy suburb of the capital of Nicaragua, Managua, serves 81,000 people, some of whom live in very rural areas. A nurse in the clinic said that they get 20 to 30 patients per day who need to use the nebulizer and it takes one hour to clean the masks. Patients sometimes need to wait up to one hour for clean masks to be available. One mother who lives four blocks from the clinic said that her daughter has an asthma attack every two weeks and she needs to visit the clinic every time. In rural areas, the percentage of the population that lives more than two hours' walking distance from a hospital is 33%, 22% for health centers, and 10% for health posts, and 26% for health clinics. Even in Managua, 13% lives more than 30 minutes walking distance from a health unit, which combined with treatment delays in busy clinics is a major problem. Allowing healthcare professionals to manufacture asthma masks on site would reduce treatment delays, allowing more patients to be treated. Reducing the infrastructure needed to provide nebulizer treatments would also allow more rural clinics to administer the treatment, reducing transportation times and costs for rural patients. Since the population is so dispersed, there are already challenges in providing universal access to healthcare. Only 0.5% of the 7,099 communities in Nicaragua have more than 15,000 inhabitants, with 97.5% having fewer than 2,500. (PAHO 2007) The high degree of population dispersion calls for a dissemination model that works through local channels to allow communities to fabricate the materials they need.

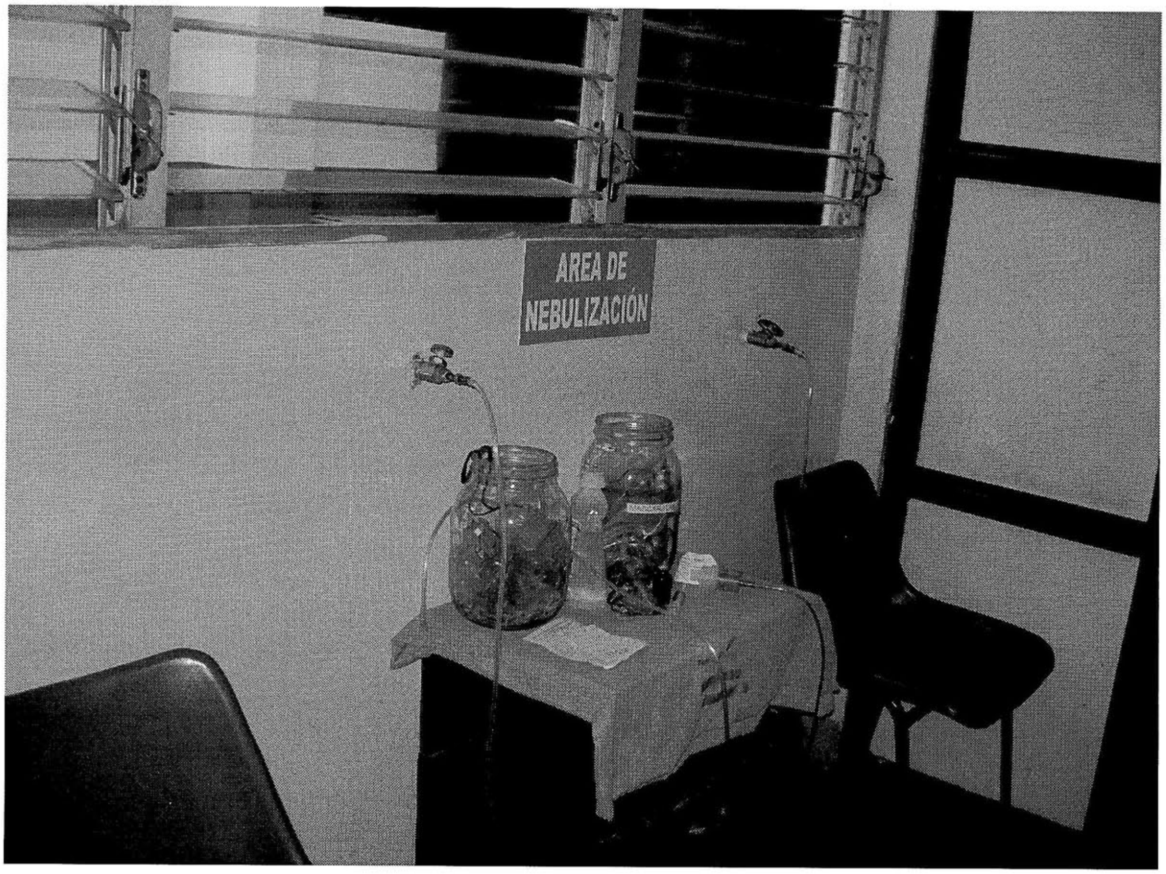

Figure 5. Nebulization Area of a Hospital in León, Nicaragua

This photo was taken of a hospital in León, Nicaragua. This is a typical set-up of how patients receive nebulizer treatments. The medication is aerosolized via pressurized air which is dispensed by the valves attached to the walls. Each patient is given a plastic aerosol mask.

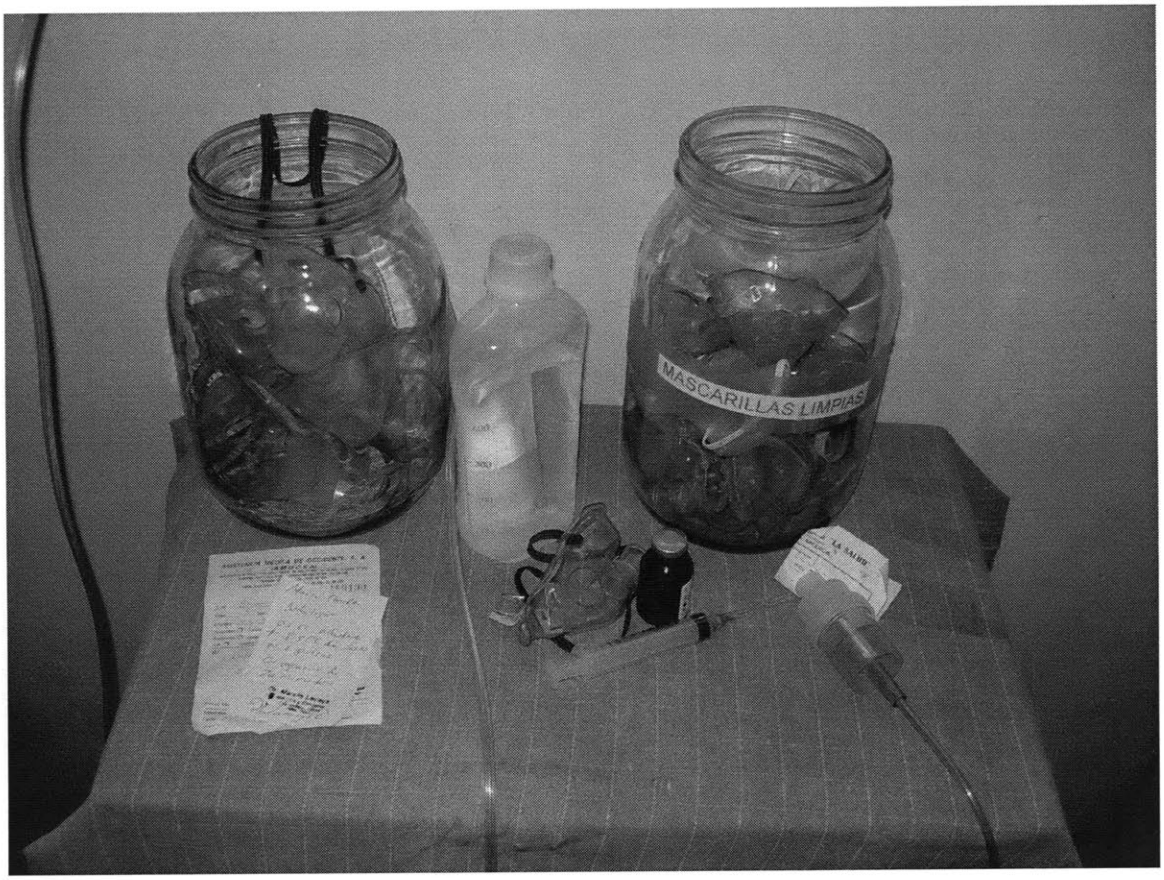

Figure 6. Aerosol Masks in León, Nicaragua

These jars are marked with labels that read "clean masks" and "used masks." Speed of care is restricted by the number of masks and the time it takes to clean them. In this case, there is a possibility of re-using a used mask, which could spread infection.

The Inspiration: Respira Design Spacer

A group from Stanford developed a design for a low-cost spacer made out of paper. Through field work in Mexico, they noticed that while the health centers had access to inhalers and the proper medications, they lacked spacers which are required to delivery medication to children. Inhalers require the user to inhale quickly and deeply once they are activated, which is difficult for a child during an asthma attack. Spacers allow the child to breathe in the medication over time, allowing more to reach their lungs. Typical plastic spacers cost around $50 plus distribution costs. The design team was able to reduce the unit price to 25 cents.

The spacer is fabricated from a flat sheet of paper which the user fold easily on-site. Since the design is created from a flat sheet, they can be shipped hundreds at a time, further reducing costs. The group plans to ship the unfolded devices to the doctors directly.

Figure 7. Girl using a Respira Spacer in Mexico. Credit: Respira Design

Chapter 3: Objectives

Scope of Design

This thesis is an attempt to address a specific but prevalent problem and to fill a niche in the medical equipment industry. Right now, health programs in developing countries have access to donated supplies or what they can afford. They have no control to choose what equipment they need and if they happen to have more patients than anticipated, health care quality can be jeopardized. This technology would provide healthcare workers with flexibility and allow health centers to produce exactly what they need when they need it, which will reduce wasted resources, labor, and distribution costs.

The purpose of the thesis is to introduce a method to manufacture aerosol masks on site. This design method may be applied to other devices, allowing clinics to manufacture a variety of products to meet their medical equipment needs. As 97.5% of the communities in Nicaragua have fewer than 2,5000 inhabitants, the dispersion of the population calls for more localized production to free up development funds.

One of the trade-offs in the design was deciding how much technology vs. labor inputs would be required. This device is meant to be an intermediate solution between mass manufacturing in a factory and cutting and folding masks by hand. The device cuts down the time required to create equipment, which will aid healthcare workers where labor is tight. By not relying on electricity and by maintaining a simple design, healthcare centers around the country will be able to create disposable medical products regardless of their level of resources or training.

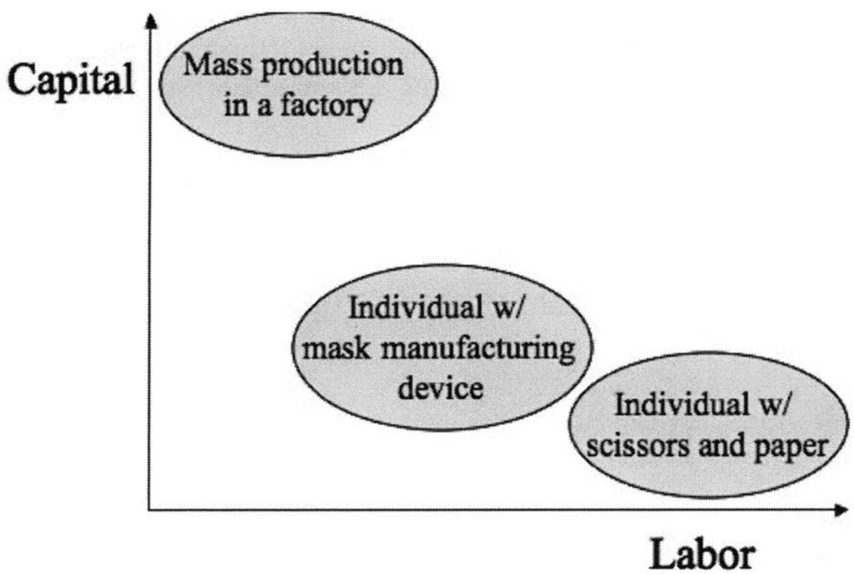

Figure 8. Capital vs. Labor Input Required for Different Mask Manufacturing Options

Creating a machine that stamps and folds standardized patterns would also help alleviate some quality concerns and ensure that all clinics are working with the same mask design. The precedent the machine sets will also allow the creation of more complex shapes, which would be difficult to fabricate by hand. Another large factor for avoiding strict labor is to create a job market and to ensure trust in and therefore adaptation of the product. The author sees a large potential to tap into the small business sector to also manufacture medical goods. The introduction of a mechanized process would allow a local producer to create and distribute masks to all of the surrounding hospitals and health clinics.

While time may not be an issue in some areas, it is in understaffed hospitals. In Nicaragua, the number of doctors has been increasing since the 1990s while the number of nurses, nursing auxiliaries, and technicians are declining due to budgetary constraints that limit the ability of schools to offer training. (PAHO report) Therefore, doctors are often required to take on duties traditional reserved for nurses or assistants, increasing the demand on their time. In 2004, there were 3.8 doctors and 3.1 nurses per 10,000 people. (PAHO 2007) The Ministry of Health implemented staff reduction policies in the 1990s which resulted in a decrease of staff of 18% between 1990 and 2003. (PAHO 2007)

Many of the reports of the preference of labor over machines is because machines are more capital intensive. Therefore the goal of this project is to design a machine that is not capital intensive.

The final use of the product is a question of the most appropriate distribution and management system. This will probably vary between countries and regions. In some settings it may be more cost-effective for the clinic to hire someone within the practice, or outsource production, while in others it may be more important to have direct access to production. The device will be designed however to allow doctors to fabricate masks on-site in their clinics.

The setting chosen for this design iteration was low-resource settings Latin America where the author has more experience. The design could be adapted to other communities' needs and conditions. The scale of this project was inspired by the ideas laid out by E.F. Schumacher in his book "Small is Beautiful" which describes the benefits of smaller scale industries to promote development.

Design Requirements

Customer Need

The target customers are doctors, nurses, and healthcare workers in clinics where disposable plastic aerosol masks are too expensive. These are often clinics that are severely understaffed, underfunded and underequipped.

Design Specification

In general, there are a few factors that have shown to correlate with the success adoption of a new technology, which were outlined by the U.S. National Research Council in 1982. The product should,

- Meet the felt needs of the users as perceived by the users (not the creators)
- Be technologically reliable
- Financially viable
- Have organizational support for purchase, installation, repair and maintenance.
- Other factors: integration with existing technology, clear functions, adaptability to existing methods of distribution, and compatibility with existing work organization and values.

Healthcare professionals in the target settings need a device that is:

- **Fast:** to maximize doctor patient interaction time
- **Intuitive**: does not require a steep learning curve
- **Cheap:** more cost effective than plastic masks and manual labor in the long-term
- **Environmentally Sustainable**: Needs to withstand heat, be easily cleaned, and not harmful to the environment at the end of its product lifecycle
- **Culturally Adaptable:** Needs to look high-tech yet still be simple so it is easily fixed
- **Regionally Adaptable:** Needs to run without an electrical power source to function in clinics across the country
- **Easily Repairable:** Materials and spare parts or units must be locally available

Chapter 4: Design Strategies

General Design Strategies

Relocation of Technologies

The right technology may be already available but not known to users. It may have been discarded by another sector or user because it did not fit their functional requirements but it could work well in a different setting.

Upgrading of Outdated Technologies

Sometimes older technologies can be an important source of inspiration in design for low-resource settings. Innovative projects have resulted from the mixing of new and traditional technologies, ex. Micro-hydroelectric power.

Downscaling of Modern Technologies

Sometimes modern technologies can be replicated for a cheaper cost by reducing scale and complexity of features, or by choosing different materials or manufacturing methods.

Completely New Technologies

Oral re-hydration tablets are an example of a new technology that has significantly cut the death rate from diarrhea in developing countries. Solar panels are another example.

Design for Healthcare Professionals

As the end users or customers are healthcare professionals, there are specific design considerations. Doctors will reject equipment if it (a) increases workload, (b) creates new opportunities for error or (c) reduces efficiency without providing offsetting benefits. These professionals are pressed for time and will not use equipment unless it is an improvement over what they already have.

The device must also operate in a specific setting. In hospitals or clinics, technologies need to be considered part of an entire system of workers, patients, and other devices. It needs to be easily operated in the midst of a clinical environment. It also needs to be intuitive to the user to be used by people of a variety of levels of training. "A well-designed interface between human and machine conveys to the user the device's purpose, operational modes, and controlling actions" (Wiklund).

Dr. Matthew B. Weinger, an anesthesiologist, professor at Vanderbilt University and user chair of the Association for the Advancement of Medical Instrumentation Human Factors Committee, described the best-loved products. These products are "ones that make the caregivers' jobs easier, enabling them to spend more time with their patients and less time making the devices work properly... [they also] give healthcare professionals confidence in their ability to render safe and effective patient care" (Wiklund). Therefore the goal of this product is to provide doctors with not only the tools to succeed but with the confidence that they will be able to provide quality care to their patients. The product should also work with the user's previous experiences and look like the other equipment they are accustomed to.

In designing an effective product, it is important to understand the needs and capabilities of the target user. Many of the medical devices on the market today are designed more with the interests of the engineers in mind than those of the doctors. The key is to bring the most important features to the surface, while allowing advanced users access to other options. As products are harder to understand as complexity increases (and users are more likely to miss a step), the author's goal is to develop a simple design that requires minimal user input and calibration. Also, since people are reluctant to admit that they do not understand a piece of equipment, they will either misuse the device or not use it.

Design for Low-Resource Settings

In the developed world where funds are not as large of a barrier, healthcare providers prioritize safety, often going for disposable products. Equipment is also designed with the assumption that the healthcare setting will have reliable access to utilities such as clean water and electricity. Conditions in the developing world are different, therefore their priorities differ from those of richer countries. A successful design needs to take into account the target user's preferences which means a change in mindset. When evaluating potential health technologies, lower-income countries are dealing with cost-constraints and extensive training in proper equipment use is difficult. Designs also need to be reliable in settings where they will be exposed heat, humidity, dust and insects.

"Appropriate technology" is a phrase that has come to have many different definitions. While it tends to be associated with "low-cost," the cheapest alternative is not necessarily the one that will have the most impact. Some examples of alternative medical products that are appropriate in their context are solar-powered vaccine fridges and bicycle pump nebulizers. In 1976, the USAID defined appropriate technologies as those that take advantage of abundant factors, such as labor and local resources, while being economical in the use of capital and highly trained workers. It also stated that appropriate technologies should be replicable in small modules which are easily operated and repaired by the local population. The definition has grown and developed but the general idea is that appropriate technologies are created by designers who are mindful of the economic, social, political, and environmental context of the community they are designing for. Appropriate technologies have also come to mean "capacity-building," in the sense that a community will be able to grow because of this technology addition.

In order for a technology to be accepted and successful, the user needs to take ownership of the device, as well as operate and maintain it. Studies have shown that people are more invested in technology if they pay a small price for it. Therefore the combination of having a small investment plus a device that can be fixed in the local community should contribute to adaptation.

In this case, it will require a change in behavior which is a challenge. A large factor in successful adaptation is whether the community feels that the technology addresses an issue of high priority. Therefore consultations will need to be carried out with each individual community in order to determine which types of products they need the most and therefore which "templates" would be introduced first.

Distribution Channels

Most goods are transported around Nicaragua via trucks, cars, and bicycles so devices would need to be compatible with transportation networks.

Looks Matter

The device should be culturally acceptable, which means that the physical form and the behavior required by the user should fit into the local culture. Users are also more likely to accept a new technology if it looks exciting. Therefore, the form factor must be relatable but also sleek to encourage use.

Design for Manufacturing

Design for manufacturing will depend on the distribution plan. Larger firms would be able to take advantage of economies of scale and conduct extensive quality and reliability testing. However, the economic incentives for larger private firms to invest in this technology is small. Firms with these capabilities are either located in foreign countries which does not address the import reliance issue, or if they are located in the country, there are other higher return products they could pursue. The author is not against the involvement of large private firms in manufacturing and distributing products for the developing world, but given the slow response so far in investment in medical equipment abroad, a more local focus may provide faster results because they are closer to the demand.

Therefore, this technology is focused on smaller-scale manufacturing units, capitalizing on local skills in order to fabricate and repair the devices closer to the end user's location. Considering the liabilities involved with fabricating medical products the best option would be to work with a medium sized manufacturing unit. The Ministry of Health could more easily regulate products released by one manufacturer than by hundreds of individuals. The design itself would consist of relatively simple parts that could be replaced in the nearest city or by a metal shop, reducing the dependency on Managua for repairs.

Leapfrogging

Numerous case studies have shown that developing countries have diverted from the traditional development path set by the United States and European countries. Cellphones have spread rapidly through Africa, Asia, and Latin America because they require less infrastructure than landlines. While the medical equipment system works in the United States, the high capital required to establish local plants, pay for licensing for the use of technologies, and the infrastructure costs required to emulate the systems in richer countries is virtually insurmountable. Being restricted to a set model of how medical equipment manufacturing and distribution systems should work severely limits product innovation. The best design for addressing medical equipment issues in Nicaragua may not look at all like the current standard.

Benchmarking

Plastic Aerosol Masks

Unlike surgical masks, the target product is an oxygen or aerosol mask, used in this case to deliver medication from a nebulizer to the lungs of an asthma patient. While the focus of this thesis is asthma care, the same mask design is used in a variety of applications. Aerosol masks are also used in the administration of oxygen, anesthesia, and any other gases for medical purposes. Plastic oxygen masks were developed because they were cheaper than non-disposable alternatives, because the flexible material was more comfortable to patients and provided a closer fit, and because the see through material would allow healthcare professionals to more easily monitor the patient. Below is a photo of a aerosol mask manufactured by PARI used in the treatment of asthma. The shape and size of masks varies among manufacturers but the general function is similar. This shape was taken as the basis of the mask template described in Chapter 5, but the design could easily be altered if a community preferred a different design.

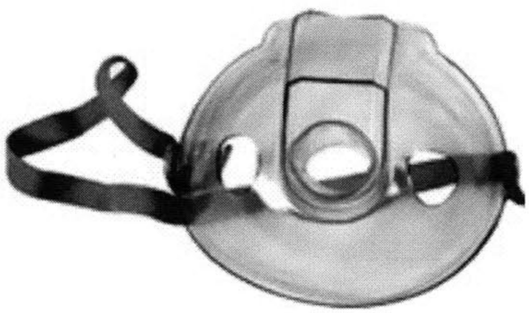

Figure 9. PARI Aerosol Mask. The basis of the mask template

Local Manufacturing of Medical Products

There is already locally manufactured medical equipment in many developing countries. Examples include: wheelchairs, hospital beds, delivery tables, bicycle-drawn ambulances, crutches, and surgical instruments some of which are sold to hospitals in developed countries. In terms of available materials and manufacturing processes in Nicaragua, access to materials and tools increases the closer one is to the capital. There are markets, workshops, and hardware stores to purchase equipment or contract manufacturing support. What is lacking is high-precision manufacturing, due to the high financial and human capital required to build such a plant in Nicaragua.

Some physicians and nurses outside of the capital have learned how to cope with aging or non-existent equipment by adapting their practices, sending equipment to be fixed locally, or by modifying local resources to perform a similar function.

Chapter 5: Physical Design

Mask Template

The main inspiration for the design was an aerosol mask. This is a rather complicated design to cut, fold, and construct by hand so it seemed to be a good candidate for a more automated manufacturing process. A simplified paper model was designed from a plastic aerosol mask. See Appendix A. for a template of the paper mask design.

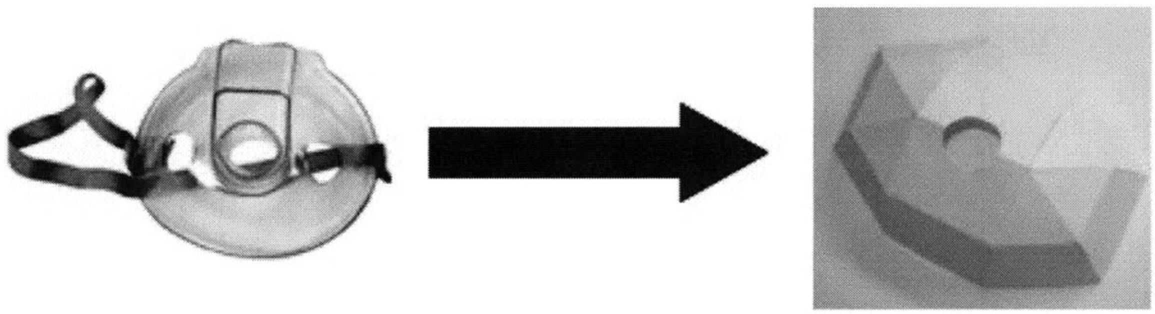

Figure 10. Plastic Mask and a Simplified Paper Replica

When designing lower cost versions of existing supplies there are tradeoffs to consider. Healthcare professionals and patients are concerned about where products lie on a plot of cost versus user acceptance. Richer hospitals may value user acceptance higher than cost, while low-resource settings will accept a simpler version if it is more affordable than the original. A number of reports have shown that users in developing countries are less likely to adopt a new product if they feel they are getting the "cheap" version. Therefore, the design needs to be simple enough that it will drive down costs while minimally compromising the user experience. While any mask design will need to be tested for its effectiveness at delivering an aerosol treatment, it is wise to stay as close as possible to proven designs. Many of the products that fail to be successful do so not because they are ineffective but because they were not adopted by the consumer. The medical industry has a lower rate of early adoption than other sectors because the of the field's focus on standardization and quality control of life-saving products. Therefore, the device will more likely be adapted if changes from the status quo are incremental rather than drastic.

Making the design too simple will also replicate what many doctors are already using when they have no other option. There are MacGyvers all across the developing world who are using their ingenuity to save lives given the resources they have. There was a doctor in Nicaragua who was in a rural village, treating a baby who was having an asthma attack. All they had was an inhaler, which is different for small children because it requires them to time their breathing in order to obtain all of the medication. The doctor took a plastic cup, cut a hole in it and created a homemade spacer, allowing the child to breath in the medication, which ultimately saved the baby's life. It is extremely important for healthcare professionals around the world to have that mindset and to be willing to improvise in order to save lives. No device will be able to replace the value of quick thinking in extreme circumstances and the design and education about suitable alternatives is extremely important. This project focuses on the step in between the plastic cup and the donated masks, where costs can be cut but extreme affordability is not crucial.

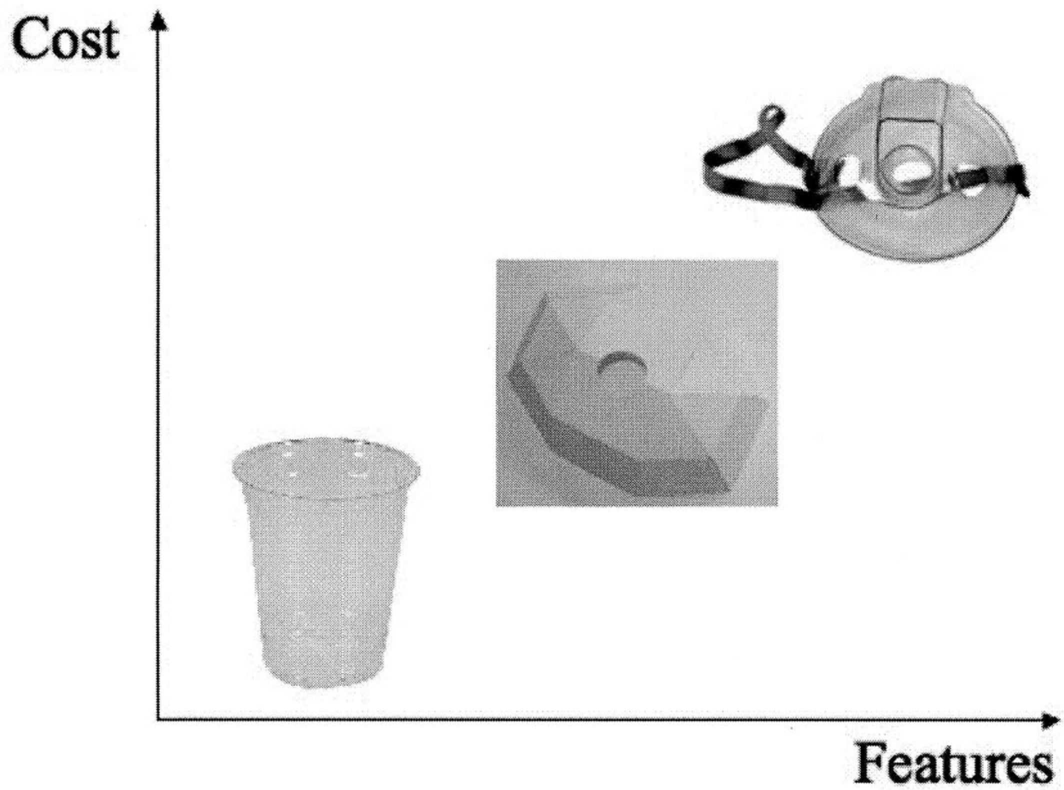

Figure 11. Cost vs. Features of Different Mask Options. Features can be thought of as another measure of "user attractiveness." This mask design has a similar level of features as the plastic mask at a cost/unit comparable to the plastic cup.

Costs vs. Benefits

The goal of the design is to minimize extraneous costs in order to maximize the value of the resources the healthcare clinic has.

Cost of the Device:
Financial cost is proportional to template complexity, to materials, and to degree of automation (device complexity)
Labor cost (and opportunity cost) is due to time spent creating the masks.
Plus maintenance costs: paper, etc.

Cost of current medical masks:
Cost to patients: 1 hour wait time, possibility of infection
Cost to clinic: Time of personnel (opportunity costs), procurement costs (time lag, lack of choice or other options, portion of donated supplies or budget)

The key to user acceptance is to demonstrate why the switch is beneficial to the clinic. The point is not to provide them with another piece of equipment that needs to be serviced, but to introduce capacity building that will allow hospitals to accomplish more while spending less money and resources. By decreasing mask costs they can increase the quality of patient care and may be able to add in features that the original masks lacked such as infection warnings. The demand for aerosol masks is large and could be increasing in the developing world. Asthma rates have been rising due to pollution. There has also been a lot of research recently in breathable vaccines and aerosol treatments for other diseases, which would also increase the demand of aerosol masks. These applications include inhaled insulin to treat diabetes (also a large health problem in Nicaragua), aerosolized gene therapy to treat lung disease, as well as aerosol vaccines for influenza and measles.

There is very little insurance coverage in Nicaragua, which means that patient expenditures supplement governmental expenses. These expenditures are so high that people in rural areas will often refrain from seeking treatment because they are unable to pay. Therefore, reducing financial costs in any way possible would reduce the load on the consumer and/or redirect funds to other areas of need.

The exact cost vs. benefit line will differ depending on the circumstances communities face and therefore more specific market research will need to be conducted before a price point is established.

Device Design

Fabricating a paper mask by hand requires:

1) Tracing the template
2) Cutting out the shape by hand
3) Folding
4) Adhering the edges together to complete the mask.

Testing showed that the first three steps are the most time consuming, therefore the device's functional requirements will be to cut a pattern and fold it.

Cutting

Copying the method that a human would use (scissors) is impractical in this case due to the issue of controls. While using some kind of moving blade would afford more design flexibility, the costs of implementing such a device is prohibitive and unnecessary in a context that values standardization.

The use of a die would be expensive initially, but costs would be reduced as device production increased. As there are no controls involved, incorporating a die would be less expensive than a computer controlled blade. It would also decrease the time spent cutting as all of the cuts could be completed at the same time. The features of the die would need to be sufficiently large as to avoid the material being caught in the die, compromising the folding step, and leading to a need to clean the device of smaller scraps.

Folding

The advantage of using a machine instead of a human to fold the mask is that multiple folds may be created at once. There would be a negative of the final shape in the bottom of the device and a lever would push the cut paper into the mold, where the normal forces would cause the paper to bend into a mask shape. Then the user would be able to remove the folded mask and add tape to complete the manufacturing process.

Casing

The device itself will be at maximum around the size of a desktop printer, depending on the number of templates it is equipped with. The device will also be completely contained as to protect the blade and crevices from dust collection when not in use. The blades will also be covered when the top is lifted, to avoid user injuries. To ensure smooth cuts, the device will include clips to secure the sheet of cardstock during fabrication.

Building the Device

The manufacturing plan will depend on a cost/benefit analysis performed by the country or community in need. The design is simple enough to be created in a local workshop, but it may be more cost efficient to manufacture the machines abroad or in a Nicaraguan factory if they have the required capabilities. In busier clinics, such as in Masaya, doctors see 20-30 patients per day, in which case they would prefer a device that saves them time. In settings where the flux of asthma patients is not as high, the doctors could use a simple paper stamp to quickly cut the shape and then fold the masks by hand. Therefore, two models could be marketed, depending on the throughput levels desired and the clinic's access to manpower.

Manufacturing Masks

Ideally the device would be placed on a countertop or mounted to a wall similar to dispensers in clinics. The user would place a sheet of paper in the device and punch a design. Then the user would press on another button to fold the paper, and the third step would be adhesive. As the two most time consuming steps are cutting and folding, a device that simplifies the first two would save the healthcare worker a considerable amount of time. With this device, the entire process would take a few seconds.

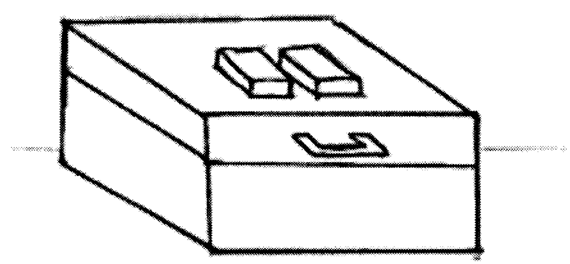

Figure 12. Drawing of the Mask Manufacturing Device

To operate the device:

1) The user opens the lid upward and places a sheet of cardstock on top of the cutting surface.

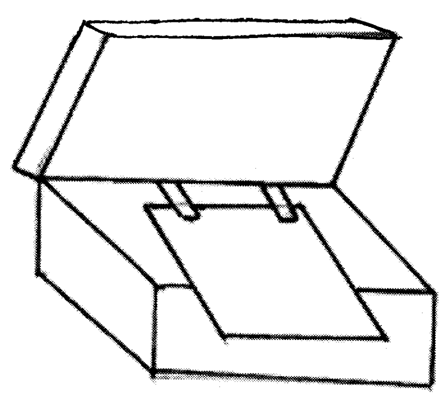

Figure 13. Step 1 of the Mask Manufacturing Process

2) Then the user closes the lid and presses on the first button which would cut the cardstock.

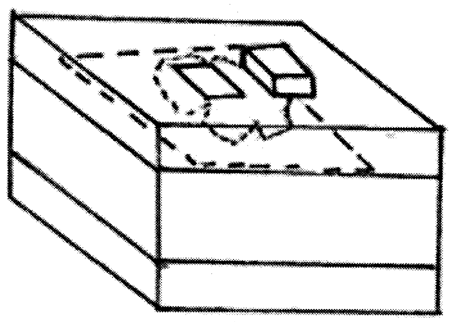

Figure 14. Step 2 of the Mask Manufacturing Process

3) When the shape is cut, the user presses the second button which folds the cut-out into a familiar mask-shape.

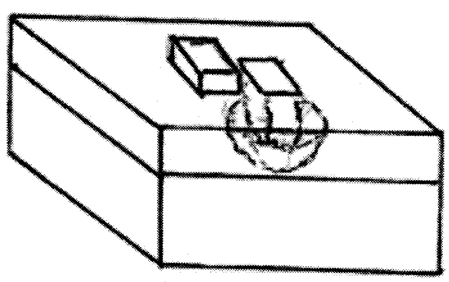

Figure 15. Step 3 of the Mask Manufacturing Process

4) When the shape is folded, the user can then tape the open edges together, saving considerable time that would have been spent either washing or cutting and folding masks.

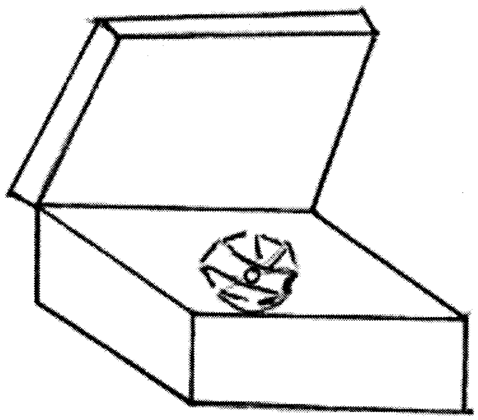

Figure 16. Step 4 of the Mask Manufacturing Process

Chapter 6: Feedback

Local Feedback

The author worked in Nicaragua during the summer of 2009 with Jose Gomez-Marquez on a project with Innovations in International Health funded by the Inter-American Development Bank. When doctors were shown a mock-up of a paper mask, they were exited about the possibility to reduce cost and increase access of Nicaraguan clinics to essential medical supplies. A mock-up was also shown to students at CIES, the school of public health in Managua, as well as to visiting professors from the school of pharmacy and doctors from Estelí, with positive responses.

Respira Design: Santiago Ocejo Torres

Santiago Ocejo Torres, a M.D. from Mexico and a member of the design team, stressed the importance of patient safety in the realm of manufacturing paper medical devices, *"One of the things that we are being very careful, is related to the concept you are talking about having the users "build" their own device. As is always very important in medicine, patient safety should always be our first priority. In order for them to be able to build a "life-saving" device, we should be quite confident that what they are building, actually satisfies the safety and efficacy requirement for any medical device. Even though is a paper-made device, it does have a lot of engineering behind (valves, seal, specific paper). It would be great to have them build it under really stringent quality levels. That would be a great goal to achieve. In the mean time, we need to assure that those paper devices are made correctly."*

Chapter 7: Marketing and Distribution Plan

Healthcare System Structure in Nicaragua

The distribution plan will vary depending on specific country politics, resources, and existing networks. To develop a plan for Nicaragua, it is crucial to understand the structure of the healthcare system and the key players in order to determine how this product will fit in and who should be responsible for distributing it. The healthcare network is large, but not sufficient to reach the entire population. A 1998 report from the Pan American Health Organization stated that the Ministry of Health has 873 healthcare units, serving around 3 million people, or a little over half of the country's population.

SILAIS (Sistemas locales de atención integral de la salud) is the integrated healthcare system of Nicaragua. There are 17 SILAIS (one per department) that organize the healthcare providers within their region. They are in charge of overseeing care and managing resources. There are 1,039 outpatient care units and 32 public hospitals in Nicaragua, the majority of which are located in Managua. However, the majority of visits, 75% in 1995, are to primary health clinics where less attention and finances are paid. The number of patient visits has been growing and is expected to continue to grow as health education improves.

While there is a private healthcare sector, the Ministry of Health is the main healthcare provider. The Ministry of Health has undergone a process of reform in the recent years, including "institutional reorganization" (PAHO) with the goal of improving its regulatory capacity, the management of healthcare services, the integration of data systems, and increasing coverage.

Challenges

"Despite the progress made in enhancing the organization of the public health services system, problems persist, notably the shortage of medical and non-medical supplies, infrastructure and equipment deficiencies, unplanned growth of the units, lack of technical-administrative guidelines, unmet demand for some services, saturation of hospital capacity, and low productivity and inadequate distribution of human resources"
–Pan American Health Organization Report, 1998

The Ministry of Health has been undergoing reforms, but the main problems still facing healthcare units are: (1) shortages of basic products (i.e. drugs, linens, clothing, and replaceable materials), deteriorating infrastructure, and lack of doctor motivation due to extremely low salaries. A report from the Pan American Health Organization stated that evaluations showed that the major factors hindered Nicaragua from achieving its Millennium Development Goals, objectives including reducing hunger and improving child and maternal health, are "high transaction costs, dispersion of resources, [and] lack of linkage with local initiatives." The Ministry of Health provides quality care to a large portion of the population, but given the challenges the country's healthcare system is facing, focusing on empowering the periphery should hopefully lead to greater capacity and take some administrative pressure off of the central government.

There are definitely challenges in implementing a project of this sort in terms of sharing of knowledge and coordination between the potential actors. Physicians and researchers in Nicaragua have been studying public health issues, but most of the research that has been conducted is not formally published nor widely distributed. There are also no regulatory policies for the introduction of new technologies, technology assessment, or information management (PAHO 2007).

The Role of the Government

Appropriate technology has traditionally been thought of in terms of micro-intervention or devices that are delivered to a specific family, firm, or community, without a national plan of its adoption. Recognizing the potential of grass-roots operations, governments in developing countries have enacted programs to support micro-firms in their pursuits. A device meant to provide value locally could be distributed nationwide by coupling it to the health networks within Nicaragua.

Involving the Ministry of Health in some way will be important in assuring the acceptance of new technology, as equipment and processes are currently approved by a central authority of healthcare professionals. After the machines are manufactured, either abroad or within the country, depending on local capacity, they will be distributed to hospitals, clinics, and health posts throughout Nicaragua. The most likely vehicle to achieve widespread access and acceptance is to work with the Ministry of Health to launch an initiative to promote on-site manufacturing, while working with the established networks of both the Ministry and NGOs working in Nicaragua to physically distribute the devices. As this is a medical device, it comes with the obstacles of a life-saving product, but it also has the benefits of a built-in distribution system. Therefore, if the Ministry of Health sets policies that state that locally manufactured products are supported and encouraged, they can use their resources to set a new nation-wide standard in medical equipment fabrication.

A national development strategy is important in order to compete with traditional methods of medical device procurement. The Ministry of Health and other influential doctors, nurses, and healthcare workers would need to support an initiative for locally manufactured equipment in order for clinics around the country to support the idea of on-site manufacturing. This would require strong leadership and the ability to create a clear vision, as well as be able to convince their supporters that local manufacturing will contribute to social and economic development in the region while reducing constraints on the healthcare system. Strong leadership has been influential in public health issues, such as Senegal, Uganda, and Thailand who have communicated on television and radio, and made public appearances on how HIV/AIDS is transmitted and how to prevent it.

The general marketing plan is to advertise this device through the Ministry of Health and local universities. A small group of doctors will test run the machine and report their reactions and recommendations for improvements. Following the pattern of technology dissemination among hospitals in the U.S., the doctors would ideally act as "ambassadors" for the device and recommend it to their colleagues. Besides word of mouth, medical technology fairs could be established to showcase new technologies. This could be coupled with current conferences of healthcare professionals such as the "Congreso de Trabajadores de la Salud," held annually in Managua. Establishing a relationship with universities and doctors is also a possible source of R&D. As they develop ideas for improving the provision of healthcare they can modify and create new patterns that can be incorporated into the device, allowing the lead users to have an impact on future design iterations.

Working with local healthcare professionals, as well as the Ministry of Health and NGOs who have the resources and connections to develop, test, and disseminate these devices would help get this product to the end user as quickly as possible. It would also be a sustainable dissemination plan because the initiative to pursue the technology would originate from local actors instead of being solely driven by a foreign entity.

The Role of NGOs and Communities

NGOs could play a large role as a distributor in areas the public health system does not cover. In areas where it is unpractical to have a separate machine in every health post, the masks could be manufactured in a central clinic and then transported via NGOs to rural areas of extreme poverty. There are multiple public health programs run by NGOs that are aimed at increasing education and focusing on services for women, children, and adolescents, such as family planning, prenatal and puerperal care, growth and development monitoring, immunization, management of childhood illness, and sexual and reproductive health. There has also been a number of disease prevention and control programs that focus mostly on HIV/AIDS and tuberculosis. These groups have experience working with diverse communities and can more easily recognize and respond to the needs of the community. According to a PAHO report, the Ministry of Health has registered 90 nongovernmental organizations that offer health services. International NGOs have experience implementing programs in other countries and often already have integrated dispersion and communication networks between their main offices and smaller communities. They also often already have the backing of the community, the government, and potential funders. Therefore, working with an established organization makes the dissemination of ideas and products more efficient and would allow the product to reach the intended user more quickly.

Smaller communities in Nicaragua are already managing local development projects such as improving the drinking water supply, construction of latrines, energy projects, and so on. Therefore, a more decentralized dispersion of medical equipment will not necessarily sacrifice management, rather it will allow communities to decide which products they have a greater need for, and adapt that design iteration accordingly.

Ultimately the device would be tested first in a single community and then "scaled-up" by increasing distribution of the device to other regions in order to increase the impact of the device. User input from the first trial run would be used to refine the device in further iterations and for different settings.

The Role of Small-Scale Firms

Depending on the demand of the clinic, they will either have one device on-site in the nebulizar ward so doctors will be able to fabricate more masks exactly when they need it, or they will outsource production. Nicaragua has high levels of unemployment and migration, but this product could be used by a local entrepreneur to create a small business. An individual could create a business around creating a supply of masks and delivering them to local clinics. This would probably require some kind of regulation by the Ministry of Health to ensure quality and avoid the possibility of extortion, but with the proper control it could create a new sector for employment.

The general trend in production is toward giantism because it takes advantage of "economies of scale." However, according to some development scholars, large-scale production is only economical in the presence of high-density markets and highly efficient, low-cost transportation systems. In developing countries, small-scale producers in the informal sector are a large part of the economy. Even in response to "capitalist firms," producers of the means of production continued to be important. In the case of Nicaragua, where the population is dispersed and transport is associated with delays and poor coordination, it would not be economical for one large firm to produce and distribute cheap masks around the entire country. Small scale production can also require less materials, capital, and energy to create the same product.

The power relation implications of the fabrication structure this device would create are important to consider. Instead of a central distributor, the supply of medical equipment would be in the hands of the owner of this device. This will probably lead to concern over the control of quality and meet some resistance by people who are adverse to disturbing the existing system. The most successful solution would probably be to locate manufacturing of these systems in a nearby city, where quality can be more easily regulated, and then distributed to other regions where masks can be fabricated on-site. Since Latin America has a long history of large-scale production, mass production is associated with modernization so it will be a greater challenge to convince the government that this format is better than a local factory. The costs and benefits of large versus small scale operations combined with the local need should push governments towards a less traditional answer.

Looking Forward

A successful implementation in Nicaragua would open doors for dissemination to other countries. The Ministry of Health has multiple connections with other Latin American Countries and they often hold conferences to present their research findings. The physical design of the device could be adapted to different countries and settings, depending on which type of equipment is in demand and if a more portable or fixed, centralized distribution system is required.

Ultimately, a culture of local manufacturing could grow and eventually follow the model established in India, where Trivitron is working with three foreign medical equipment companies to build a 25-acre medical equipment technology park in Sriperumbudur. The company aims to create equipment for developing countries, and fifty percent of the goods they manufacture will be exported to Africa, the Middle East, and developing Asian countries.

Chapter 8: Concluding Remarks

Next Steps

The next step in this project would be to create a working prototype with which to collect user feedback, both in the Boston area and in Nicaragua. Some issues to address with user testing are:

- Ease of inserting paper and removing finished product
- Whether it is intuitive to use
- How much force is required to cut through the cardstock
- Whether the process is repeatable irregardless of user inputs (for example: strength and angle of applied force)
- Perceived benefit of a folding device vs. folding by hand
- Aesthetics
- Whether the device is enjoyable to use

Once a prototype is created that satisfies the functional requirements, it will be tested abroad in the target setting. The same questions and observations will apply, accompanied by others:

- User reaction
- Who would use the device
- If it withstands the local environment
- Which products do they need the most?
- Would they rather have a larger device with multiple patterns to create a manufacturing center or a more portable device for manufacturing individual types of supplies?
- Would they use the masks if they were created using this device by a local enterprise?

After the reactions of local doctors are measured, it would be necessary to gain feedback from government and NGO workers in order to determine what is the most feasible plan for dissemination the technology. Questions to consider include:

- What will the pricing strategy be?
- Who decides which health centers will receive the first batch of devices?
- What level of regulation will be necessary and how will it be carried out?

Future Design Iterations

In terms of the design for the aerosol mask, there are possible improvements that would increase the mask's level of features and by extension attractiveness to healthcare professionals and patients. There are coatings that could be incorporated to either kill bacteria or allow colormetric testing of airborne diseases. A spray function could be incorporated into the manufacturing device to automatically add an infection alarm. The design could also include a breathing indicator that alerts healthcare professionals of any problems.

Future design iterations would focus on creating patterns for different devices. Below is a discussion of two possible areas besides drug delivery where this technology could be useful: diagnostics and public health records.

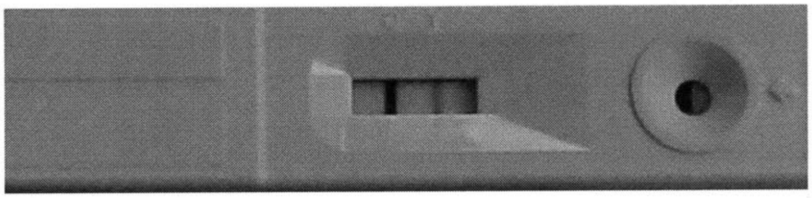

Figure 17. Pregnancy Test Holder from a Pharmacy in León, Nicaragua

The figure above is a photo of a pregnancy test similar to one that was sold in a pharmacy in Leon, Nicaragua. For scale, the device is about the length of the palm of your hand. The user is required to dispense a few drops of urine onto the circular application pad and then wait for the results. Beyond the obvious difficulty of administering this test in a home setting, the instructions were written entirely in English. Other pregnancy tests more commonly used in the United States require the user to place the cap back on the urine application site. While uncomfortable for the user, a better design that removed the need to touch anywhere near the sample site would be important for a clinical setting when testing blood. The lateral flow strip is the crucial part of this diagnostic tool but the user interface is far from perfect. Doctors could modify the design using sheets of cardstock or bendable plastic to create one that better meets their needs.

The design below is for a lateral flow strip diagnostic holder. The holder is more user friendly because the user never needs to touch anywhere near the application site. The flexibility of the holder would allow the doctors to administer any type of lateral flow test they desired using the same casing design. Such as design would also be more environmentally friendly because it would require less or no plastic, therefore reducing waste and energy. Appendix B includes a template for this design.

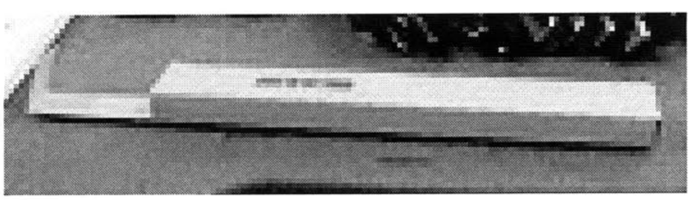

Figure 18. Lateral Flow Strip Test Holder with Improved User Interface

Appendix C is a template for a "Diagnostic Booklet." This diagnostic tool is basically a collection of lateral flow tests, arranged in a grid. The grid format allows healthcare professionals to more easily recognize diagnostic patterns, which can help them identify possible diseases more quickly. There are also implications for public health. As the human brain is better equipped to deal with visual images rather than words or numbers on a medical chart, this format would aid healthcare workers in spotting recurring patterns in a population.

Potential Impact of this Device

Decentralizing manufacturing of medical equipment would combat mass migration to cities as well as unemployment. Since workplaces could be created in places where people are right now, migration to urban areas would be curbed, and because capital costs to producing this equipment are low and human capital required is relatively low, multiple workshops could be created.

There is a sentiment of frustration and hopelessness among healthcare centers that are lacking supplies and manpower. The Ministry of Health is facing too many constraints to provide quality equipment to every health post and to maintain it, which means the doctors, nurses and healthcare workers are often left to figure out how to deal with the lack of supplies themselves. Creating paper aerosol masks for the treatment of asthma may seem like a small contribution, but the aim is to introduce the idea that there are alternatives to the status quo of medical equipment procurement. Hopefully this will empower communities to not only decide what they need and when, but to be able to fulfill those needs instantly and improve patient care.

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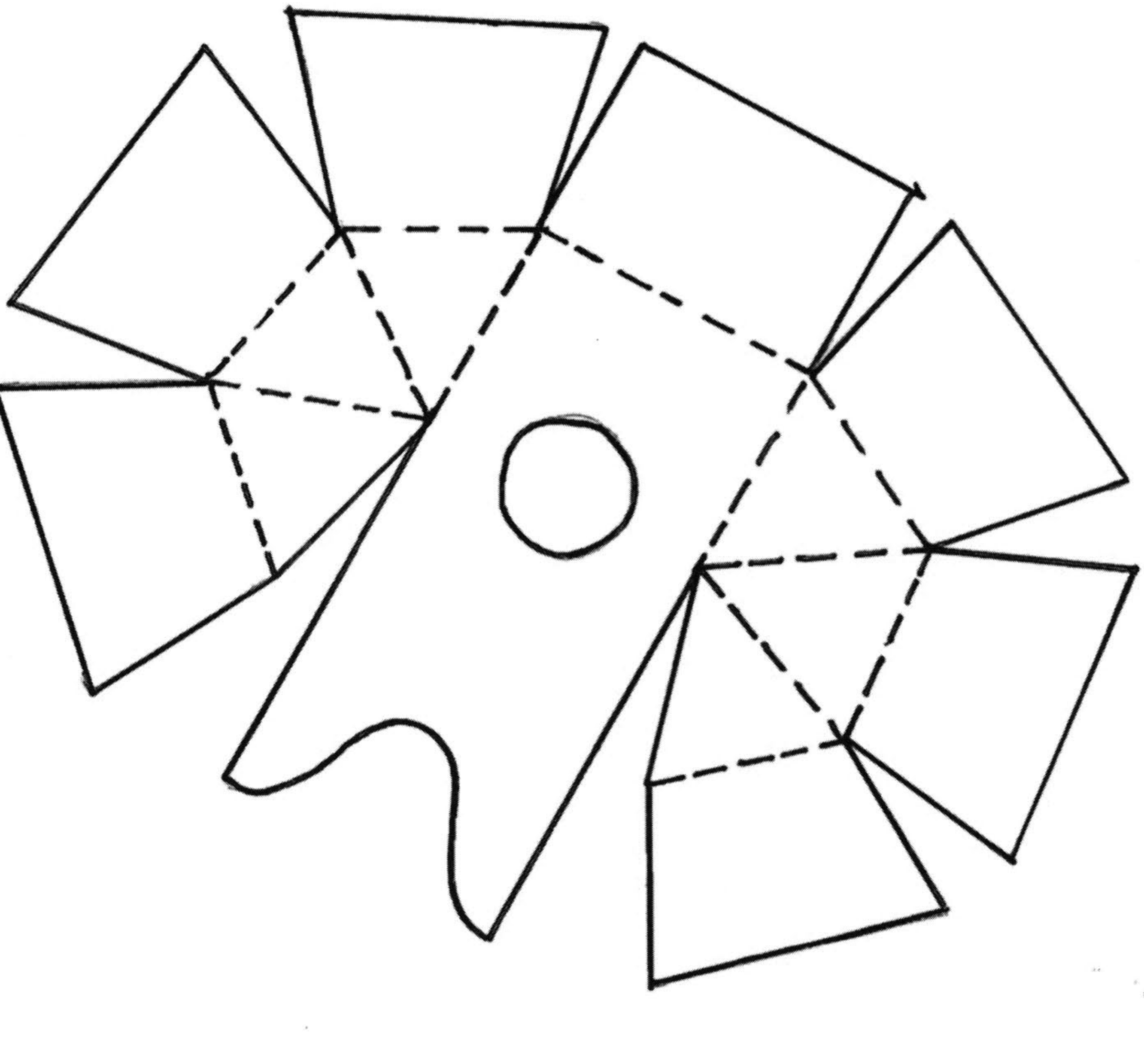
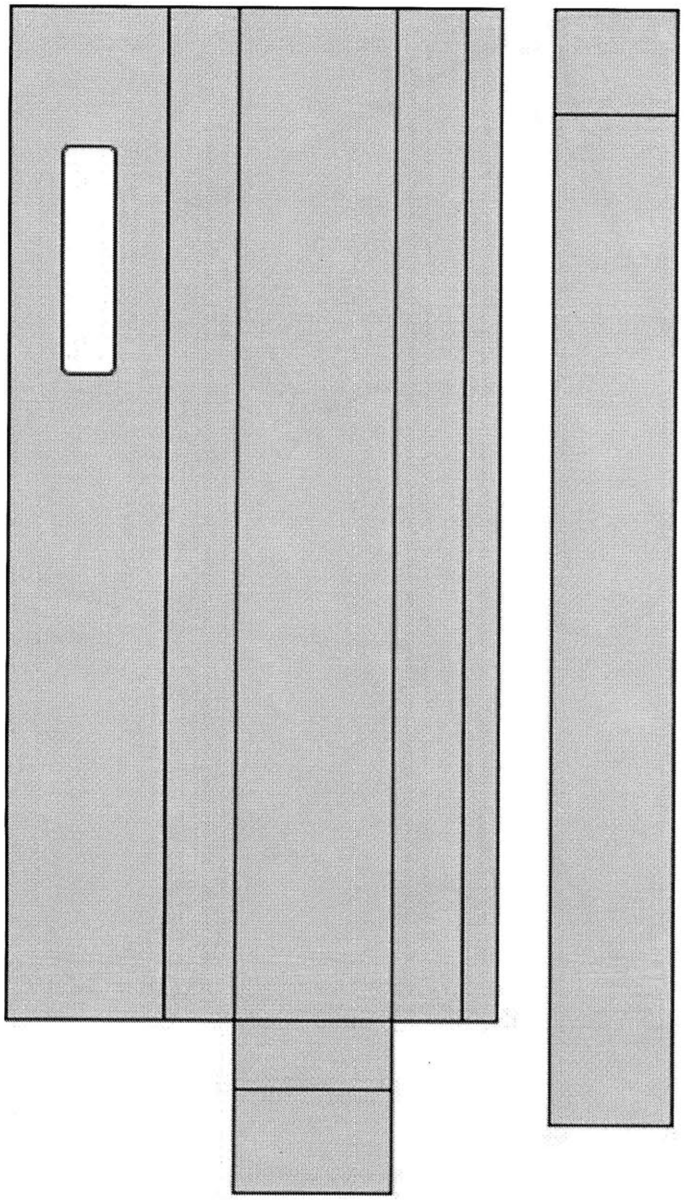
Appendix A. Paper Mask Template



Appendix B. Lateral Flow Strip Test Casing



Appendix C. Diagnostic Booklet Template