Project Title: Ambient Gas Plasma: A sustainable and viable tool for infection control in the developing world

Principal Investigator(s): David B. Graves, Douglas S. Clark, Hiroshi Nikaido and Lee W. Riley

Participants (students, major, year of graduation): Zhi Chen, undergraduate researcher (2011, ChE BS), Matt Pavlovitch, graduate student researcher (2014, ChE PhD), Sharmin Karmin, graduate student researcher (2015, ChE PhD), Matt Traylor, postdoctoral researcher (2010, ChE PhD)


Website featuring your work:

Press mentions of your work:

1. What new work has been done since your report to the Blum Center in October 2010? (If you need a copy of your last report to us, please let us know.) We are especially interested in hearing updates regarding field deployment or business development.

   1. Santhi Hariprasad, our Masters in Public Health (MPH) student collaborator has looked into the opportunities for AGP technology for maternal and newborn health. She made numerous recommendations and observations (that will form the basis of her ‘capstone’ report for her degree) and we are in the process of thinking about these ideas. For example, she notes the need for medical instrument and other disinfection/sterilization applications when mothers submit to a Caesarian section operation under less than sterile conditions. (I attach a copy of her report Ambient Gas Plasma: Maternal and Newborn Health Applications below (page 25), with her permission.)

   2. We developed and tested a novel AGP device (see photos and video in related document) that appears very promising for scaling and use in field conditions. This type of device could be used readily in the field because they are compact (easily hand-held), are very robust (designed for many thousands of hours of operation under high/low temperatures, humidity, rugged conditions, etc.), and they are commercially available throughout the world. They are based on inexpensive devices used for powering spark plugs for small scooters or motorcycles, etc. – known as capacitive discharge ignition (CDI) devices. The one we purchased was ~$50, and we had one small part (~ $5) made in our electronics shop (the trigger). They are designed to run from 9-12 volt batteries – so a motorcycle or car battery, or a solar-powered battery will work. (They can use an inexpensive power adaptor (like for many small devices) that allow use of ‘plug-in’ line voltage, too.)
3. We made numerous measurements of plasma-treated surfaces and more recently, plasma-treated water. The plasma devices can disinfect surfaces or water on the order of minutes. Moist surfaces are disinfected faster and more completely, we found, than dry surfaces.

4. We made measurements of the composition of plasma-treated water and discovered that the AGP device is leading to the formation of nitric oxide (NO) precursors in the water. As I discuss below, this composition measurement has changed our thinking about the project and suggests many possible applications. I detail some likely applications in the next section.

5. We made preliminary measurements of the effects of plasma-treated water on breast cancer cells. The results are not final, but it appears that the plasma-treated water will selectively kill breast cancer cells. There has been concern for about 30 years about the possible carcinogenic properties of nitrates and nitrites. There are many papers published within the last 5 years referring to the emerging, changed view on this. The general consensus now is that nitrites and nitrates are safe. Nevertheless, we made these measurements and found that in fact, plasma-treated water kills cancer cells. Similar results were reported in several other papers in the literature, as well.

2. What findings and/or conclusions (anticipated and/or unanticipated) have emerged? How have these influenced the scope or direction of your project?

1. In part because of the new scope mentioned above, based on the realization that plasma-treated water creates a solution that releases NO, we are currently considering the possibility to launch a start-up company. This idea was suggested by Jay Parrish, an MBA student at Berkeley. He became inspired by the possibilities of this technology. He headed up an entry based on AGP technology for the 2011 Global Social Ventures Competition at the Haas School. The entry made it into the semi-final round but did not make the finals. Nevertheless, we became convinced that a social venture-oriented business could be initiated based on this technology. I attach a copy of his business proposal (Hero Biomedical; page 4) although this will probably be revised if we decide to start a company.

2. The literature on nitrite ions and their biological and therapeutic importance is large and growing, and a proper summary is beyond the scope of this report. I will give only a very brief list of applications that have already been studied or are in clinical trials. I stress that one major advantage of the AGP-generated nitrite is that it can be done with only small amounts of electricity, water and air. It therefore offers the opportunity to achieve the therapeutic goals listed below without a supply chain.

3. The most likely near-term applications involve the use of the air plasma–treated water for disinfection of medical instruments and other critical devices; skin antisepsis; skin wounds and skin infections; protection against urinary tract infection in urine collection bags for urinary catheterization; protection against ventilator-associated pneumonia by adding plasma-treated water to the mouths and stomachs of intubated patients; and food disinfection/preservation. Other applications involving systemic applications to reduce blood pressure, or reducing ischemic/reperfusion injury will take more time and clinical trials.
4. The use of plasma-treated water as an infant formula supplement (breast milk contains nitrates and nitrites) and to augment other water-treatment (e.g. UVC or filtration) are other possible future goals.

3. What's next? What are you considering on your project's path towards scalability and sustainability? What do you need to make your project a success? What can the Blum Center do to help?

1. One important goal for next year is to help establish the range of different applications of AGP for a diverse set of developing world needs. There are many possibilities and each will take time to establish. Although we may start a company and look for investor support, there are many more aspects to consider and we hope to continue with Blum Center support.

2. One important way the Blum Center can help is to be able to discuss the prospects of this technology with Blum board members who might offer advice on starting and growing the company, and on the most promising directions to take. There are many possible paths and it is not completely clear at present which directions to pursue first.

4. Please share photographs (with captions and credits if possible) that we can use for our Board of Trustees and other supporters. Also, please share any stories or quotes from team members, partners or beneficiaries that demonstrate the impact, potential, and future needs of your work.

I submitted a separate file (since it is a large file) containing photos and a video of the device. Comments and assessments of the prospects for the technology are elaborated in the two appended reports: Hero Biomedical is the GSVC business plan submitted by Jay Parrish and collaborators (page 4). His ‘impact value chain’ is summarized below:

![Impact Value Chain Diagram]

- **Inputs**
  - Investor Funds
  - Our People’s Efforts
  - Relationships with Our Partners

- **Activities**
  - Device Design and Manufacture
  - Working with the Graves Lab
  - Creating Valuable External Relationships
  - Marketing Efforts

- **Outputs**
  - Total Number of Devices Sold

- **Outcomes**
  - Less HAIs in LDC’s
  - Lives Saved
  - Productivity Gains by Healthcare Providers
  - Decrease in LDC HC costs

- **Less**
  - Less HAIs and Decrease in HC costs with Current Solutions

- **Impact**
  - Improved health care outcomes
**Ambient Gas Plasma: Maternal and Newborn Health Applications** is the HPM comprehensive exam submission of Santhi Hariprasad (page 25). Her Executive Summary:

Medical devices that use ambient gas plasma* (AGP) may be one way to combat the high rates of infection in developing countries. AGP reacts with the oxygen, water vapor, and nitrogen in the air to create microbe-killing chemical species. Professor David Graves and his team are creating a device that uses AGP technology to sterilize surgical instruments and/or disinfect environments. The most important benefits of the device are that it has a low per-use cost and can be used thousands of times without requiring any materials except a little water and electricity. One important application of this device is childbirth-related infections. Almost 4 million newborns and 350,000 women die each year from child-birth, and infections are a common cause of death. The market analysis I conducted resulted in several recommendations:

- There are several advantages to using the device in healthcare facilities rather than for home deliveries, including less chance of damage/loss and better targeting of complicated deliveries. Despite this, in areas with a weak healthcare system and high rates of home deliveries, use of the device by a Traditional Birth Attendant or Health Extension Worker may be more appropriate.

- Based on need, cesarean section rate, ability to pay, and feasibility, India and Tanzania are potential pilot locations.

- Making bulk sales and raising funds to subsidize the device for the poorest clinics are two strategies for keeping the cost of the device down.

- Outsourcing some of the organization’s functions and keeping others in-house may be ideal. Alternatively, creating open-source instructional manuals and trainings would make it possible for various organizations around the world to independently produce the device. This decentralized strategy would make the product more diffuse and adapted to local environments.

- The WE CARE Solar team is a natural partner given the organization's plan to partner with organizations that produce solar-powered medical devices.

- The AGP device has many characteristics that predict successful diffusion, including relative advantage, observability, and minimal need for infrastructure. Because it is a novel technology, communities will need to be educated about it. The social impact of the device can be amplified if socially-responsible production methods are used and the clinical trials for the device test additional public health interventions for reducing deaths from childbirth-related infections.

* Plasma, also known as the “fourth state of matter”, is ionized gas. The plasmas used in medical applications are room temperature, or “ambient.”
Executive Summary

Hero Biomedical

Quick Facts:

Management:
Jay Parrish, Ph.D. CEO
Brad Johnson, P.E. COO
Michael Greene CFO
Bauback Safa, M.D. CHIEF MEDICAL OFFICER
Professor David Graves FOUNDER

Industry: Healthcare, Medical Device

Business: Medical instrument sterilizer

Law Firms: Currently under review

Financing Sought: $2 M

Use of Funds: Start-up costs (equipment purchase, HQ procurement), marketing, and pay roll

Employees: 6 in Year 1 (4 G&A, 1 S&M, 1 finance)

Exit Strategy: Acquisition in Year 5 or 6 by a company such as Johnson & Johnson (Ethicon)

Contact Information:
Hero Biomedical
720 Bair Island Road, #106
Redwood City, CA 94063
Phone: 650-995-3872
Email: info@herobiomedical.com
Website: www.herobiomedical.com

Summary:

Hospital-acquired infections (HAI) are a major medical issue throughout the world. The most common HAI are from urinary tract infections, surgical site infections, lower respiratory infections such as ventilator-associated pneumonia, cutaneous infections, and infections resulting from the use of catheters.

In Least Developed Countries (LDCs), hospital-acquired infections are an unmet medical need of tremendous importance, with infection rates 3–5 times that of the developed world. With more accessible sterilization technology, lives will be saved, healthcare provider productivity will increase, and healthcare costs will decrease.

Strategy:

Hero Biomedical aims to develop a low cost ambient gas plasma technology that is expected to have a dramatic impact in fighting infections in resource-limited countries. Our device is a medical instrument sterilizer that effectively kills viruses, bacteria, and fungi safely and in rapid fashion.

Plasma is generated from conventional electrical sources and reacts with oxygen and nitrogen in ordinary tap water to create pathogen-killing reactive species like peroxide, hypochlorite, and nitrogen oxides. These species are lethal to pathogens, destroying >10^9 in minutes. In the process, surgical instruments or medical equipment are cleansed and infection is avoided. The goal of the process is to turn ordinary water into a disinfectant solution, quickly, cheaply, and on-site.

Market:

Analysis of LDCs reveals an average of 200,000 people/hospital. If we assume 750 million people live in LDCs, we have potentially $112.5 million in revenue:

| Population of Least Developed Countries | 750,000,000 |
| Average number of people per hospital | 200,000 |
| = Total number of hospitals | 3,750 |
| × Units sold per hospital | 100 |
| = Total Market for Units | 375,000 |
| × Price per unit | $300 |
| = Total LDC Market Size | $112,500,000 |

The device will sell for $300 and we expect to begin sales in Year 2. Our major markets are Haiti, Africa, and India. These projections are just for the Hero Plasma Sterilizer as currently described, and does not include other applications of the gas-plasma technology for which we may be able to lever the production and distribution channels this product develop.

Management Background:

Classmates from the Haas School of Business, UC Berkeley, Hero’s management team has over 50 years of experience combined in diverse specialties such as finance, operations, R+D, and medicine.

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</table>
The Problem

Hospital-acquired infections (HAIs) are a major medical issue throughout the world. Within industrialized nations, it is estimated that 5–10% of patients admitted to hospitals acquire infections after arriving for treatment.\(^1\) In the United States, these infections affect over two million hospital patients each year and result in 99,000 deaths. Annual costs attributable to HAIs are estimated at $4 billion per year in the U.S. alone.\(^2\)

![Figure 1. Common forms of hospital-acquired infections (HAIs).](image)

The most common HAIs are from urinary tract infections, surgical site infections, lower respiratory infections such as ventilator-associated pneumonia, cutaneous infections, and infections resulting from the use of catheters (Figure 1).\(^3\) The typical HAI manifests through poor or lax hygiene practices in medical facilities, or more disturbingly, when hospital patients have contact with infected surfaces or medical instruments. Infections occur mainly from bacteria, including methicillin-resistant \textit{Staphylococcus aureus} (Staph infection) and \textit{Mycobacterium tuberculosis} (TB). However, they can also occur from viruses, including rotavirus (diarrhea), influenza, and HIV or even from fungi such as \textit{Candida albicans} (yeast infection).\(^1\)

In Least Developed Countries (or LDCs, a UN classification), hospital-acquired infections are an unmet medical need of tremendous importance, with infection rates 3–5 times that of the developed
world. It is estimated that ~1 million people lose their lives to HAIs in LDCs each year. Patients who become infected require longer hospitals stays and antibiotic treatments, which increase overall cost to LDC healthcare systems. Overcrowding and understaffing in hospitals all challenge LDCs, which further compounds the HAI problem. Hidden costs arise as healthcare providers lose productivity while attending to the HAI afflicted.⁴

In LDCs, the need to decrease hospital-acquired infections is not being met. This is due to the high cost of sterilization equipment and limited supply chain access to disinfectants. Taking care to ensure that surgical instruments and medical equipment are properly sterilized is of the upmost importance in combating these infections, as 10–70% of HAIs are preventable.¹⁻³ With more accessible sterilization technology, lives will be saved, healthcare provider productivity will increase, and healthcare costs will decrease.

Current Sterilization Solutions

Medical equipment sterilization in developed world hospitals is achieved through heat sterilizers such as autoclaves and steam systems or chemical sterilizers that use ethylene oxide, ozone, peracetic acid, or hydrogen peroxide vapor. Other methods include the use of hydrogen peroxide gas plasma, an example of which is the well-known Sterrad® system. These devices are readily available in the industrialized world, but in the developing world remain hard to obtain due to heavy fixed cost investment (e.g. Sterrad® >$100 K/machine), coupled with expensive maintenance and the costs associated with a specially trained workforce. Furthermore, the cleansing cycle of these devices usually lasts at least 30 minutes, which is less attractive in LDCs, where huge numbers of patients overwhelm hospital resources and time is precious. These machines are big, bulky and require a relatively high and consistent power supply, which can be spotty in LDCs. Furthermore some devices require a consumable for use, which means access to a supply chain that may be limited or closed to LDCs.⁵
Classic disinfectants such as alcohol (ethanol), alkaline glutaraldehyde solutions (Cidex®), and bleach are used more frequently in LDCs to meet this need. These low-tech chemical solutions are often used improperly, and are not often optimal for remote, rural, or temporary/emergency settings due to the difficulty of transporting and distributing them across undeveloped supply chains. Boiling water is the most common method in rural or extremely poor settings, but this has inconsistent effectiveness especially against some heat resistant bacteria and fungi.6

**Our Solution: the Hero Plasma Sterilizer**

*Hero Biomedical* aims to develop a low cost medical instrument sterilizer that uses plasma to effectively kill viruses, bacteria, and fungi safely and in rapid fashion, helping to mitigate the unacceptably high infection rate in developing nations. Our device is the **Hero Plasma Sterilizer**, named for the heroes that will be using it to save lives: healthcare professionals, first responders, and medics (our prototype is shown in Figure 2, applied to human skin with no damage). Our solution is small, fast, and inexpensive and does not require consumables or access to high-capacity supply chain infrastructure. Furthermore, it’s rugged, with off-the-shelf parts and completely reusable, requiring only ordinary water, air, and access to modest amounts of electricity.

**Figure 2.** The Hero Plasma Sterilizer prototype.
Our team is working through a collaborative effort with the Graves lab in the Chemical and Biomolecular Engineering Department at the University of California, Berkeley. Professor Graves has been working on gas plasma applications for over 25 years, and is considered a leading expert in the field. Plasma, known as the fourth state of matter, is simply a charged or ionized gas and is generated when an electrical current passes through the air, such as with a lightening bolt (like in our logo). It’s application as a medical equipment sterilizer is well accepted in the scientific community. Currently, Professor Graves and his group of outstanding graduate students and postdoctoral researchers are optimizing an operational prototype for a variety of applications.

The goal of this device application is essentially to turn ordinary water into a sterilizing solution, quickly, cheaply, and on-site. The device is a shallow tray that contains water, with the plasma-generating electrodes arranged over the top of the tray (see Figure 3 for a schematic). Healthcare providers submerge surgical instruments and medical equipment that require cleansing into the tray. The device generates gas plasma from a standard 12 V battery or an electrical outlet. The plasma ionizes and dissociates oxygen, water vapor, and nitrogen in the air to create pathogen-killing reactive species, such as hydrogen peroxide and nitrogen oxides in the water. The degree of sterilization depends on the conditions, and precise data on killing rates must be established, but published reports using similar devices have seen pathogen destruction of $10^4$–$10^6$ with exposures as short as tens of seconds. In the process, surgical instruments or medical equipment are cleansed and infection is avoided. Preliminary results of toxicity to humans have shown no issues. The water in the tray maintains its sterilization capacity for several hours and can be reused or disposed as normal waste (post-treatment pH = ~2.5).
We envision the device will run off standard rechargeable batteries with power on the order of 5–10 watts. With LDCs in mind, the batteries will have the ability to be charged through standard sources, foot pumps, or solar-powered systems. The device is being designed with ease of use and simplicity in mind. No specialized training will be needed to operate the device effectively. The **Hero Plasma Sterilizer** is currently in the prototype stage and will require approximately 12–18 months of development to achieve a product.

Once operational, our team intends to deploy the technology in healthcare facilities within LDCs. The solution will be positioned as a substitute or complement to existing sterilization products. However, this device could be used in other areas where access to hygiene is lacking such as field hospitals or refugee camps. The value to society is potentially huge, given the unmet medical need in this area. The potential patient populations are massive with the much higher rate of HAIs in LDCs. If the solution...
works as advertised, then it will be easily scalable and applications for the industrialized world will manifest, including military and domestic first-responders, providing a positive revenue inflection. Other applications are already being discussed within *Hero*, including a hand-held version for directly applied wound treatment.

**Development Plan**

We have a two-year development plan, from incorporation to product launch (Figure 4 is a timeline of our key milestones). The first step is to identify legal counsel in order to incorporate the business, which will most likely take the form of a C-corporation. After incorporation, the company will need to establish the appropriate licensing agreements with the University of California, Berkeley Office of Technology Transfer. Once those agreements are in place, the company will establish a headquarters and begin the process of hiring design engineers. These hires will likely come from graduate students and postdoctoral researchers in the Graves laboratory who are already familiar with the technology and its applications.

![Figure 4. Timeline of key milestones.](image)

After hiring design engineers, the bulk of Year 1 efforts will be developing a product from the operational prototype already in place. Throughout the process, we will constantly seek input from LDC medical practitioners and other key opinion leaders in order to provide the best solution imaginable. Once we have the finalized product, we will seek the necessary regulatory approvals in our target markets if needed. We plan to hire a medical device regulatory specialist either as a consultant or on a full time basis.
to help guide us through these processes. Provisional patents applications may be filed as is appropriate at this stage to protect any IP we generate.

Concurrent to the design efforts, we will need to establish a production process. We will hire a production engineer to execute this phase. We feel we can translate our design shop into an initial production facility to meet early demand. However, as we progress in the business and customer demand increases, we are prepared to seek an outsourcing partner for production. Our core competency is the design and marketing of the Hero device, so it is likely that an aggressive production ramp will require some level of partnering for production and distribution. As will be described in the subsequent section, marketing efforts will begin almost immediately after incorporation.

Marketing and Distribution Plan

Market analytics: Our estimate of the total addressable market is approximately 300,000 hospitals worldwide, plus a fluid number of non-governmental organization (NGO), military, and other first-response medical installations, based on an extrapolation from lists of hospitals and clinics per country. Large portions of these hospitals are in developed world nations where solutions exist, so our serviceable market is smaller. We have therefore identified Haiti as our ideal starting point for sales efforts beginning in Year 2, given its close proximity to the U.S., international financial, NGO, and media focus, and arguably the least effective healthcare system in the Western Hemisphere. Haiti has 28 hospitals and >100 clinics serving a population of 10 million.9

According to The World Bank, the U.S. GDP in 2009 was $14.1 trillion with approximately 17% spent on healthcare.10 The U.S. spends $4 billion on HAIs, or ~0.03% of GDP. If we assume that Haiti spends an equivalent percentage of their GDP-adjusted healthcare bill on HAIs, we can estimate a current spend as follows. Haiti’s 2009 GDP was $6.69 billion and it spent 5.3% of GDP, or ~$350 million on healthcare.10 Haiti has 4 times the U.S. HAI rate, so it spends ~0.11% of GDP dealing with these
infections or ~$7.5 million/year. If we assume that 40% of HAIs are preventable (median of the 10–70% range reported in literature), then our immediate market opportunity is $3 million in Haiti ($0.75–5.25 million range). At $300/device, that equates to 10,000 potential sales in Haiti (we will assume 100 devices sold/hospital). We estimate that we can deliver approximately ~$15 million of discounted value to Haiti’s healthcare system, given a 100% adoption rate. To the extent that we can demonstrate precisely how many lives saved or improved our product can deliver, we can capture a very small portion of that value-add as revenue and still be profitable, given our $100 per unit estimate of variable cost and low fixed costs.

| Population of Least Developed Countries | 750,000,000 |
| + Average number of people per hospital | 200,000 |
| = Total number of hospitals | 3,750 |
| × Units sold per hospital | 100 |
| = Total Market for Units | 375,000 |
| × Price per unit | $300 |
| = Total LDC Market Size | $112,500,000 |

Table 1. Least Developed Countries market size.

In order to estimate worldwide market size, we identified a metric in our analysis of hospitals per country. In a country like the U.S., there are 312 million people and ~8400 hospitals, which equates to ~36,000 people/hospital. Likewise, people/hospital for Haiti is 10× that of the U.S. at ~360,000. Our analysis of LDCs revealed an average of 200,000 people/hospital. Therefore, if we assume 750 million people live in LDCs, then Table 1 indicates we have potentially ~$113 million in revenue. Of course this does not include other potential sources of revenue in the developed world (vide infra).

Marketing plan: Our focus is developing this product, and to partner with the most effective production and distribution channels possible to ensure that it helps as many people as possible.
Given the necessity of hands-on marketing to reach such a dispersed client base, an early priority will be to hire a LDC sales and marketing expert. Extra consideration will be given to candidates with experience and contacts in markets where we perceive the greatest need for our device, i.e. Africa, Asia, Haiti, etc. This person will work along with the team to establish our brand by attending and presenting at scientific and medical conferences, and medical device vendor shows. We will work with contacts in both the NGO community and relevant government agencies, both U.S. and foreign, to get the necessary visibility and acceptance to drive sales.

In order to understand our revenue assumptions, we now describe our marketing timeline in detail. The Haiti market appears attractive as a starting point for several reasons. First, it is easily accessible from the U.S. and has a large existing NGO infrastructure. The media focus on Haiti in the U.S. and around the world will help our overall marketing strategy, and this will in turn allow us to gather and focus appropriate resources. It is also a small country, which can therefore act as a test-bed from which we can derive quantitative results that demonstrate our ability to save and improve lives. Finally, and most importantly, the need for better sterilization solutions is clear and present in Haiti.

Our first clients will be medical NGOs, such as Doctor’s without Borders. NGOs offer the prospect of smaller sales with a shorter sales cycle (versus enterprise sales directly to hospitals and governments), which allows for momentum building. Furthermore, the global reach of some NGOs will allow for marketing via word of mouth. Notably, the existence of an onshore U.S. NGO presence allows for the groundwork to be laid before going to Haiti. The next step in our marketing plan is to move into Haitian hospitals and clinics, which should be an easier opportunity once we have established success on the ground in Haiti. We make a conservative estimate of 100 device sold in Haiti in Year 2.

<table>
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<th>Units Sold/Year</th>
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We will then expand to Latin America and rest of the Caribbean. Geographically, this is an easy expansion within the same hemisphere. While these more developed countries face less of a stark need for our product, a notable urban/rural disparity of wealth and access to healthcare still affords us opportunity to add value. A simultaneous new vertical for us will be marketing to the first responder community in U.S., primarily EMT’s, Search and Rescue, and remote rural clinics. Once we have revenue coming in the door and have adapted our product and strategy for the currently unforeseen contingencies that will arise, we will broaden our effort by hiring additional marketing staff to cover other market opportunities, such as Sub-Saharan Africa and India which are excellent long-term target markets based on size and need. Table 2 shows our projected sales by region, including the key Africa and India markets and other markets of interest. Please note that these projections are just for the **Hero Plasma Sterilizer** as currently described, and does not include any other applications of the gas-plasma technology for which we may be able to lever the production and distribution channels this product develops.

**Financial Plan**

We are initially targeting $2 million in funding to finance the business for 5 years. We will seek non-dilutive funding through various sources including SBIR grants. In addition to our non-dilutive fund raising efforts, we will concurrently request Series A funding to reach the cumulative $2 million target. In turn, we will grant investors a negotiated percentage of company ownership.
We will use these funds primarily for initial start-up costs such as legal fees for incorporation at $2–3 K and licensing/IP fees at $20–25 K/year. Equipment purchases are still being quantified, so we will assume $50 K/year in the pro forma statements. HQ procurement is targeted for a Bay Area location with life sciences critical mass, such as Mission Bay’s 409 Illinois incubator building, which gave us a quote of $6/square foot/month including overhead (i.e. power/gas, internet, phone, janitorial service, and some scientific overhead). Quotes for space were as low $2/square foot, but these did not include overhead. We would likely need only 1000 square feet of space or less, so for the sake of the pro forma statements we assume the high $6/sq. ft. quote @$72 K/year, which assumes all overhead expenses as well. As our venture moves forward, we will need to add production capability (included in COGS), marketing ($100 K/year), and regulatory expenses ($100 K/year). We assume salaries for 4 full time employees @ $1400 K/5 years including benefits and 2 part time/consulting employees @ $200 K/5 years without benefits. Initial pricing of the device will be set at $300 and COGS will be $100. Based on our marketing projections, we expect an S-curve based sales model, with revenue ramping from $30 K in Year 2 to $3 M in year 5. Our pro forma financial statements are shown in Tables 3–5.

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<td>Legal/Tech Licensing</td>
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<td>$25,000</td>
<td>$25,000</td>
<td>$25,000</td>
<td>$25,000</td>
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<tr>
<td><strong>Expenses</strong></td>
<td>$580,733</td>
<td>$581,333</td>
<td>$590,333</td>
<td>$590,333</td>
<td>$595,333</td>
</tr>
<tr>
<td><strong>Total Profit</strong></td>
<td>($580,733)</td>
<td>($561,333)</td>
<td>($470,333)</td>
<td>$9,667</td>
<td>$1,404,667</td>
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**Table 3.** Pro forma income statement.

<table>
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<tr>
<th>(At Year End)</th>
<th>Year 1</th>
<th>Year 2</th>
<th>Year 3</th>
<th>Year 4</th>
<th>Year 5</th>
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</thead>
<tbody>
<tr>
<td><strong>Assets</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Cash</td>
<td>$1,369,267</td>
<td>$757,934</td>
<td>$237,601</td>
<td>$197,268</td>
<td>$1,551,935</td>
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<tr>
<td>Equipment</td>
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<td>$50,000</td>
<td>$50,000</td>
<td>$100,000</td>
<td>$150,000</td>
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Table 4. Pro forma balance sheet.

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<tr>
<th>Total Assets</th>
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<td>Liabilities</td>
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<td>ST Debt</td>
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<td>0</td>
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</tr>
<tr>
<td>LT Debt</td>
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<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Accumulated Depreciation</td>
<td>$50,000</td>
<td>$50,000</td>
<td>$100,000</td>
<td>$150,000</td>
<td>$200,000</td>
</tr>
<tr>
<td>Total Liabilities</td>
<td>$50,000</td>
<td>$50,000</td>
<td>$100,000</td>
<td>$150,000</td>
<td>$200,000</td>
</tr>
<tr>
<td>Shareholders’ Equity</td>
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<td>$757,934</td>
<td>$187,601</td>
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Table 5. Pro forma statement of cash flows.

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<thead>
<tr>
<th>Cash Flow From Operations</th>
<th>Year 1</th>
<th>Year 2</th>
<th>Year 3</th>
<th>Year 4</th>
<th>Year 5</th>
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<tr>
<td>Net Revenues</td>
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<td>$20,000</td>
<td>$120,000</td>
<td>$600,000</td>
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<td>Less: Total Costs</td>
<td>$580,733</td>
<td>$581,333</td>
<td>$590,333</td>
<td>$590,333</td>
<td>$595,333</td>
</tr>
<tr>
<td>= Total CF From Operations</td>
<td>($580,733)</td>
<td>($561,333)</td>
<td>($470,333)</td>
<td>$9,667</td>
<td>$1,404,667</td>
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<tr>
<td>Cumulative Cash</td>
<td>($580,733)</td>
<td>($1,142,066)</td>
<td>($1,612,399)</td>
<td>($1,602,732)</td>
<td>($198,065)</td>
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<table>
<thead>
<tr>
<th>Cash Flow From Investments</th>
<th>Year 1</th>
<th>Year 2</th>
<th>Year 3</th>
<th>Year 4</th>
<th>Year 5</th>
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</thead>
<tbody>
<tr>
<td>Equipment Purchases</td>
<td>($50,000)</td>
<td>($50,000)</td>
<td>($50,000)</td>
<td>($50,000)</td>
<td>($50,000)</td>
</tr>
<tr>
<td>= Total CF From Investments</td>
<td>($50,000)</td>
<td>($50,000)</td>
<td>($50,000)</td>
<td>($50,000)</td>
<td>($50,000)</td>
</tr>
<tr>
<td>Cumulative Cash</td>
<td>($50,000)</td>
<td>($100,000)</td>
<td>($150,000)</td>
<td>($200,000)</td>
<td>($250,000)</td>
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</table>

<table>
<thead>
<tr>
<th>Cash Flow From Financing</th>
<th>Year 1</th>
<th>Year 2</th>
<th>Year 3</th>
<th>Year 4</th>
<th>Year 5</th>
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<tr>
<td>Series A Investment (or other)</td>
<td>$2,000,000</td>
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<td>0</td>
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<tr>
<td>Cumulative Cash</td>
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<td>$2,000,000</td>
<td>$2,000,000</td>
<td>$2,000,000</td>
<td>$2,000,000</td>
</tr>
</tbody>
</table>

| Net Cash Flow              | $1,369,267 | ($611,333) | ($520,333) | ($40,333) | $1,354,667 |
| Total Cumulative Cash Position | $1,369,267 | $757,934 | $237,601 | $197,268 | $1,551,935 |

Exit Strategy

Our exit strategy is to be acquired in Year 5 or 6 by a company such as Johnson and Johnson’s Ethicon division. A comparable acquisition occurred in late 2005 when Stryker Corporation acquired PlasmaSol Corporation (an ambient gas plasma-based sterilizer company) in a merger for $17.5 million. Other potential acquirers include Stryker (NYSE: SYK), Steris (NYSE: STE), or TSO? (TSX: TOS). The value proposition for an acquirer will be our revenue stream, sales channels, and the company’s technology, both present and future applications thereof.

Critical Risks
Device Risks: The most obvious risk is the inability to create a working model that can be manufactured cheaply on a mass production scale. Additionally, the device involves creation of ultraviolet (UV) light as well as potentially toxic gases such as ozone (O₃) and nitrogen dioxide (NO₂). Both UV light and toxic gases are produced in low quantities. The concentrations of these gases and the flux of UV will have to be determined during product development to ascertain whether exposure toxicity is an issue. The device must be shown to be electrically safe, but this is likely a minor issue given intended product design which uses validated commercial rechargeable batteries as its power source. The sterilization method must show compatibility with a wide range of medical equipment including glass, plastic, cloth, tubing, etc. Finally, the device may not be approved by regulatory agencies in target countries or require extensive and costly further testing.

Marketing Risks: Developing the intended marketing channels in resource-limited countries may be difficult. Furthermore, future competition may impact our revenue projections. The subsequent section describes the competitive environment.

Gas Plasma Device Competitive Landscape

In our survey of the competitive landscape, we performed an IP analysis using a U.S. Patent Office search. This analysis revealed 58 issued patents and 34 patent applications using the search term “plasma sterilizer”. A similar WIPO search yielded 10 PCT applications. In each search, hits were analyzed for relevance and it was found that Hero has freedom to operate.

In the sterilization space, several companies around the world sell hydrogen peroxide gas plasma devices, with the Sterrad® device being the most well known. Other plasma-related sterilizers exist in the developed world marketplace. In 2005, a company called TSO₃ (TSX: TOS) received FDA approval for their STERIZONE® 125L ozone sterilizer. Other applications of gas plasma used in medicine include a low temperature surgical ablation system known as Coblation® from ArthroCare (Nasdaq: ARTC). The
company had over $300 M in revenue last year. ERBE sells an argon plasma coagulation device used primarily to control bleeding. Additionally, Peak Surgical sells a similar solution known as the Plasmablade®. These technologies are mostly sold in developed or emerging nations.

We estimate there are at least 50 academic groups in the world working on gas plasma technology for medical use. However, these groups are generally targeting developed world applications. One such example is a gas plasma hand sanitizer under development in Germany that was recently featured in a New York Times article. We are confident that even if competition in this area arises, we have a superior business plan and a first-rate team that will allow us to achieve the dominant market position.

The Hero Team

Hero’s management team has over 50 years of experience combined in diverse specialties such as finance, operations, R&D, and medicine. The Founder of Hero is David Graves, Ph.D., who is currently a Professor of Chemical and Biomolecular Engineering at the University of California, Berkeley. David is considered a world expert in plasma technology and is the device expert. David serves as the first member of our Board of Directors.

Jay Parrish, Ph.D. is the founding Chief Executive Officer of Hero. Jay is presently a Research Scientist with Gilead Sciences, Inc. where he has used his expertise in infectious disease to bring several products forward. Jay has been involved with several life sciences and medical device start-ups, either in an advisory role or as a principal.

Bradley Johnson, P.E. is Hero’s Chief Operations Officer. Presently, Brad is an Engineering Manager with Incline Village General Improvement District and is an expert in water treatment and purification.
Michael Greene is our Chief Financial Officer and our commercialization expert. Michael is currently Vice President of Institutional Equities at Morgan Stanley, where he has gained experience in business development and financial markets.

Bauback Safa, M.D. is our Chief Medical Officer. Bauback is a surgeon and Chief Medical Officer at Zipline Medical. Bauback has extensive experience in conducting surgery in LDCs and knows what sterilization solutions are needed.

With the exception of David, all the principals are in their final semester of the part time MBA program at the Haas School of Business, University of California Berkeley. After incorporation, each of the part time principals will make a decision whether to leave his present role for a full time role within Hero. The needs of the business will help dictate these decisions. The organizational chart for the initial formation of the company is shown in Figure 6.

**Figure 6.** The *Hero* Organization.
As stated before, to further complement the team we envision several early hires including design and production engineers, an LDC market professional, and a regulatory specialist.

Social Impact Assessment

—Our social value proposition is as follows:

*Hero Biomedical* aims to develop a low cost ambient gas plasma technology that is expected to have a dramatic impact in fighting infections in limited resource countries. Our device is a medical instrument sterilizer that effectively kills viruses, bacteria, and fungi safely and in rapid fashion, mitigating the unacceptably high hospital-borne infection rate in developing nations.

—Our theory of change is as follows:

If a device such as the *Hero* reduces hospital infection rates, then lives will be saved. In addition, the cost to LDC healthcare systems will be reduced, and healthcare providers will see increases in their productivity as they are freed to help other needy patients.

We are assuming that hospital-acquired infections, in addition to the obvious human cost and loss of life, cost hospitals time and money. We are assuming countries want to solve this problem. We are assuming that our product delivers healthcare providers productivity gains.

—Our impact value chain is as follows:
Figure 5. The Hero Plasma Sterilizer Impact Value Chain.

Shown in Figure 5 is our Impact Value chain. This describes how we achieve the desired result of improving healthcare outcomes in LDCs by reducing the number of HAIs. Our key value creation comes from making and selling the device, and from having healthcare providers utilize it to reduce HAIs. From this Value Chain, we are able to calculate a social net present value (NPV) for the Hero device (Table 6).

In order to calculate our social NPV (i.e. social impact), we made some key assumptions. First, we used data obtained from The World Bank throughout our calculations in order to stay consistent. Next, we normalized all data to the per capita GDP of the U.S, while factoring into our calculations the 2-fold increase in population for LDCs vs. the U.S. We assumed that the HAI rate in LDCs was 4 times that of the U.S. Next, we assumed the average HAI infection in the U.S. costs ~$2000, which includes hospital costs, healthcare worker’s salaries, treatment, and overhead. Since anywhere from 10–70% of HAIs are preventable, we assumed a mean of 40% in our calculations. Furthermore, we assumed that the Hero device could reduce 10% of the preventable HAIs (or 4% of total HAIs). Finally, we assumed a 10% discount rate for our perpetuity calculations, and that device revenue is the total discounted lifetime amount.

<table>
<thead>
<tr>
<th></th>
<th>U.S. (data)</th>
<th>Least Developed Nations</th>
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</thead>
<tbody>
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<td>Population (2009, World Bank)</td>
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<td>750,000,000</td>
</tr>
<tr>
<td>GDP (2009, World Bank)</td>
<td>$14,860,000,000</td>
<td>$544,000,000,000</td>
</tr>
</tbody>
</table>
Table 6. Quantification of the *Hero* Device Social NPV.

If LDCs keep their current HAIs solutions in place, that is the *Hero* device is not deployed, then sum of costs to their healthcare systems and value of lives lost approaches ~$1.2 billion per year. We achieve value in two ways: by reducing overall cost to healthcare systems and by saving lives. To that end, it is clear from Table 6 that the *Hero* device will have a very valuable impact for these nations and their citizens. In LDCs, we calculate nearly $1 billion in lifetime savings to healthcare systems and almost 100,000 lives saved per year, which is shown as discounted sum of A + B. If the $112.5 million cost of the device is subtracted (375,000 units at $300/unit), we achieve a highly positive social NPV of $819 million.

References

2. For CDC guidelines and methods for HAI reduction, see: [http://www.cdc.gov/hai/](http://www.cdc.gov/hai/)


AMBIENT GAS PLASMA TECHNOLOGY:

MATERNAL AND NEWBORN HEALTH APPLICATIONS

SANTHI HARIPRASAD

HPM COMPREHENSIVE EXAM

APRIL 4, 2011
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EXECUTIVE SUMMARY

Medical devices that use ambient gas plasma\(^2\) (AGP) may be one way to combat the high rates of infection in developing countries. AGP reacts with the oxygen, water vapor, and nitrogen in the air to create microbe-killing chemical species. Professor David Graves and his team are creating a device that uses AGP technology to sterilize surgical instruments and/or disinfect environments. The most important benefits of the device are that it has a low per-use cost and can be used thousands of times without requiring any materials except a little water and electricity. One important application of this device is childbirth-related infections. Almost 4 million newborns and 350,000 women die each year from child-birth, and infections are a common cause of death. The market analysis I conducted resulted in several recommendations:

- There are several advantages to using the device in healthcare facilities rather than for home deliveries, including less chance of damage/loss and better targeting of complicated deliveries. Despite this, in areas with a weak healthcare system and high rates of home deliveries, use of the device by a Traditional Birth Attendant or Health Extension Worker may be more appropriate.

- Based on need, cesarean section rate, ability to pay, and feasibility, India and Tanzania are potential pilot locations.

- Making bulk sales and raising funds to subsidize the device for the poorest clinics are two strategies for keeping the cost of the device down.

- Outsourcing some of the organization’s functions and keeping others in-house may be ideal. Alternatively, creating open-source instructional manuals and trainings would make it possible for various organizations around the world to independently produce the device. This decentralized strategy would make the product more diffuse and adapted to local environments.

- The WE CARE Solar team is a natural partner given the organization’s plan to partner with organizations that produce solar-powered medical devices.

- The AGP device has many characteristics that predict successful diffusion, including relative advantage, observability, and minimal need for infrastructure. Because it is a novel technology, communities will need to be educated about it. The social impact of the device can be amplified if socially-responsible production methods are used and the clinical trials for the device test additional public health interventions for reducing deaths from childbirth-related infections.

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\(^2\) Plasma, also known as the “fourth state of matter”, is ionized gas. The plasmas used in medical applications are room temperature, or “ambient.”
BACKGROUND

INFECTIONS IN THE DEVELOPING WORLD
Infectious diseases cause about 25% of all global deaths each year, mostly in developing countries. i Six of every ten deaths in low resource countries are caused by infectious disease, while in developed countries, only one in ten are. ii

The disproportionate deaths in developing countries are caused by unsafe water, lack of sanitation, insufficient hygiene, and low vaccine coverage, as well as other factors. Health-care associated infection is three times as common in low resource countries as it is in the US. Inadequate sterilization of surgical instruments and medical supplies is an area of concern - surgical-site infections are most common type of healthcare associated infection. iii In many developing countries, more than 50% of injections are done with needles that are re-used without having been sterilized. iv

AMBIENT GAS PLASMA TECHNOLOGY
Technologies using ambient gas plasma (AGP) may be one way to combat the high rates of infection in developing countries. AGP reacts with the oxygen, water vapor, and nitrogen in the air to create microbe-killing nitrates and nitrites. These are some of the same chemical species that are present in breast milk and protect newborns from infection. v The chemicals created by AGP destroy drug-resistant bacteria, fungi, and viruses. Exposure to ambient gas plasma has been shown to lead to 4-6 log bacterial reduction after 10 minutes of exposure. vi

Scientists have started creating medical devices based on AGP technology. A device has been developed at the Max Planck Institute that can sanitize hands within seconds. The device is currently in clinical trials. vii About 50 groups worldwide are studying the medical uses of AGP, but most of these groups are focused on technologies for the developed world. viii

Professor David Graves of the University of California at Berkeley is looking into the uses of AGP technology in the developing world. This work is partially supported by funding from the Sustainable Products & Solutions Program (SPSP) and Blum Center for Developing Economies at Berkeley. His work, and any start-up company that resulted from it, would have the following mission, vision and value:

---

3 Plasma, also known as the “fourth state of matter”, is ionized gas. The plasmas used in medical applications are room temperature, or “ambient.”
**Mission:** To develop technologies using Ambient Gas Plasma that have a positive impact on the health of people in low resource countries.

**Vision:** Creating of a set of products and processes that are widely used and have a demonstrable impact on infection rates.

**Value:** All people have a right to safe healthcare.

While safe healthcare is an end in itself, it also has the indirect effect of increasing people’s use of health care. When infections are seen as a common outcome of visiting health care facilities, people avoid going. ix

There are many potential uses for AGP technology in the developing world. A plasma-creating device could be used for skin antisepsis, pre-operative skin preparation, sterilization of hypodermic needle and surgical supplies, disinfection of surfaces, water and air, wound healing. While various devices may be developed in the future, the first project of Graves Lab is a device that creates a sterilization solution that can be used on medical supplies and surgical instruments. A schematic is below:

![Figure 1: AGP Device Schematic
Created by Professor David Graves](image)

This AGP device would hold several surgical instruments and water. It could use a standard rechargeable battery. To avoid the need for electricity, the device could be recharged using solar power or a foot pump. The cost of the device is estimated to be $100 US.

It would take 20-30 minutes to sterilize the surgical instruments within the device. The water within the device may then have antiseptic properties for as long as a month and could possibly later be used to disinfect surfaces, hands, or surgical sites.
At this point, the device is in development. It will take at least one more year to finish developing the product, and then clinical trials will be undertaken to get appropriate approvals. A team of Berkeley MBA students submitted a business plan for this device to the Global Social Ventures Competition.
The potential uses of AGP technology in the developing world are broad. The scope of this paper is childbirth-related infections. I chose this focus for several reasons. First, caesarean sections are very common – they are the most common major surgery in Sub-Saharan Africa. Second, as described below, childbirth-related infections result in a high burden of morbidity and mortality. Third, understanding the potential impacts of this device on childbirth-related infections will help the team make partnerships with and apply for funding from organizations that focus on this area.

MATERNAL AND NEONATAL INFECTIONS

Maternal Infections:
Ninety-nine percent of maternal deaths are in developing countries. The Maternal Mortality Ratio (MMR) in the US is 17 deaths per 100,000 live births while it is 629 per 100,000 births in west Sub-Saharan Africa. In total, about 350,000 women die from pregnancy and childbirth each year. This accounts for 15% of the deaths of women of reproductive age. Infections are a significant factor, causing about 10% of maternal deaths in Africa. (See Figure 2) And, for every woman who dies from an infection, there are many more who suffer from serious infections, even if they live.

Risk factors for the development of maternal sepsis include “home birth in unhygienic conditions, low socioeconomic status, poor nutrition, first pregnancy, anemia, prolonged rupture of membranes, prolonged labor, multiple vaginal examinations in labor, caesarean section, and multiple pregnancy.” But, the most important risk factor of all is cesarean section.

According to one study, the most common bacteria causing maternal infections are E. Coli, S aureus, and Proteus spp. Recommended strategies for decreasing maternal mortality due to infections are hygienic deliveries, treatment with antibiotics, and Vitamin A supplementation.
Neonatal Infections:
Each year, almost 4 million babies die in their first month of life. 99% of these deaths are in low and middle income countries. \(^{xviii}\) UN Development Goal number 5 is to reduce the mortality rate for children under five years of age by two-thirds between 1990 and 2015. \(^{xix}\) Since 25% of all deaths of children under five happen during the first month of life (the “neonatal” period), focusing on the health of newborns in developing countries is an effective strategy for working towards this goal. \(^{xx}\)

Infections are both the most common cause of newborn death as well as the most preventable cause. Globally, 38% of newborn deaths are due to infection \(^{xxi}\), but in countries with the highest neonatal mortality rate (NMR), infections cause about half of all newborn deaths. (See Figure 3). Some of the most important strategies for preventing neonatal infections are tetanus toxoid vaccinations for pregnant women, clean childbirth practices, improved hygiene and umbilical cord care, and early and exclusive breastfeeding. \(^{xxii}\) Clean delivery practices alone could prevent 6-9% of newborn deaths in sub-Saharan African countries. \(^{xxiii}\)

The most important risk factors for neonatal sepsis are prematurity, premature rupture of membranes during delivery, maternal fever during labor, low birth weight, and difficult labor (obstructed labor or birth asphyxia). \(^{xxiv}\) Looking at Figure 3, it is apparent that the common causes of neonatal mortality have
interact with each other. The most common pathogens found in newborn infections are S aureus, coagulase-negative staphylococci, Klebsiella spp, E coli, and pseudomonas spp.\textsuperscript{xxv}

\textbf{A CLEAN DELIVERY: POTENTIAL USES FOR AGP TECHNOLOGY}

According to Zaidi et al,\textsuperscript{xxvi} some of the most important reasons for unhygienic deliveries in the developing world are:

- Lack of essential equipment and supplies (soap, washbasin, clean water, obstetric instruments, gloves, sterilizers, medications, cord clamps)
- Failures in sterilization/disinfection or handling/storage of multi-use resuscitation instruments, equipment and supplies, delivery surfaces, leading to contamination
- Re-use of disposable supplies without safe disinfection/sterilization procedures

\textit{Figure 3: Causes of Neonatal Mortality}

Many of these problems could be ameliorated by the availability of a sterilization/disinfection method appropriate to low-resource settings. Below, I describe the elements of a clean delivery, the current cleansing methods, and the potential uses of AGP technology.

**Clean Vaginal Deliveries:**
The WHO has set forth six principles for a clean vaginal delivery:

- Clean hands.
- Clean perineum.
- Nothing unclean introduced into the vagina.
- Clean delivery surface.
- Clean cord-cutting instrument.
- Clean cord care (including cord ties and cutting surface)

In developing countries, soap and clean water can be used to clean the birth attendant’s hands and the mother’s perineum. A new plastic sheet or a washed rubber mat can be used as the delivery surface. For the clean cord-cutting instrument, a new or boiled razor should be used, though a new razor is preferable. A clean cord tie must be used as well.

Obtaining sufficient clean water to use for washing can be a challenge in developing countries. Alcohol-based antiseptics are easy-to-use solution to this problem. However, replenishing alcohol-based antiseptics requires a functioning supply-chain.

Alternatively, the AGP device could be used to clean the birth attendant’s hands, the mother’s perineum, the delivery surface, and cord-cutting instrument. The device could be used thousands of times without requiring any additional materials. It is also expected to have a much cheaper per-use cost than alcohol-based antiseptics. Professor David Graves estimates that it will cost 19 times more to clean an umbilical cord with an alcohol-based antiseptic than it will with the AGP device once. (See Appendix B) But, the AGP device has a much higher up-front cost than alcohol-based antiseptics, an important consideration in the developing world.

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4 “Clean” refers to an environment in which strategies have been used to reduce the number of microorganisms that come in contact with the patient. Sterilization aims to destroy all micro-organisms.
Clean Cesarean Sections:
Before a cesarean section, the surgical site must be prepared. Currently, the recommended pre-operative skin antiseptic is a chlorhexidine-alcohol preparation. The AGP device could be used for this pre-operative skin cleansing, and as mentioned above, would cost much less.

Sterile surgical instruments must be used for the surgery. This is a challenge in rural health centers. Boiling water is one method that is commonly used, but this does not kill all microbes and is not recommended by the WHO. Chemical sterilants can be used, but this is expensive, requires a supply chain for distribution, and involves a complicated and time-consuming process. A study in Mexico showed that facilities often do not expose their surgical materials to chemical sterilants for the recommended amount of time. Central hospitals have expensive electric autoclaves for high-heat sterilization. But, these break down, and staff at rural health centers have to travel far to use these machines. If a woman comes to a rural health center for a cesarean section and no sterilized instruments are available, the choice is to either move forward using unsterile instruments or to turn the woman away.

Scientists at Innovations for International Health (IIH) at MIT have created a solar-powered autoclave engineered for low-resource settings with unreliable electricity. The device costs $400. They have formed an organization, Salud del Sol, to manufacture and test this device in rural Nicaragua. Their “Solarclave” was selected as a World Health Organization “Innovative Technology that addresses global health concerns.”

While the solar autoclave is an improvement over existing technologies, the AGP device would be even smaller and much less expensive.

Conclusion:
The AGP device could be used for many of the hygienic needs of child birth. For vaginal delivery, the current hygienic methods have a higher per-use cost than the AGP device would, but the AGP device has a much higher up-front cost. The AGP device has the added advantage of not requiring large amounts of clean water for its use. It can be used thousands of times without needing a new battery, while alcohol-based antiseptics must be replenished. For surgical instrument sterilization for cesarean sections, the AGP device would be both the lowest-cost and most reliable option.
CASE STUDIES

Following are two case studies of successful maternal and child health interventions: the Solar Suitcase and the Clean Delivery Kit. The AGP team can look at these examples to find strategies for creating a scalable, sustainable, and socially responsible organization.

The Solar Suitcase:

When Laura Stachel visited Northern Nigeria on a research project, she saw that one of the most important factors leading to maternal deaths was the lack of electricity in healthcare facilities. Healthcare workers were doing cesarean sections in the dark, it was difficult to contact a doctor, and medical devices that required electricity were going unused. She collaborated with her husband, Hal Aronson, to create the “Solar Suitcase,” a product that provides solar electricity to power overhead lighting and charge mobile communication devices and batteries for head lamps. The solar suitcase was engineered to be cost-effective and durable.\(^{xxxv}\)

They created a non-profit organization, WE CARE Solar, to produce and distribute the Solar Suitcase. The organization will keep the cost of their device down by making bulk sales to large purchasers, raising philanthropic funds for early research and development, and subsidizing sales to the poorest health facilities. They are aiming to raise 90% of their funds from sales and 10% from donations and grants.\(^{xxxvi}\)

There are now about 50 Solar Suitcases in use in eleven countries.\(^{xxxvii}\) As WE CARE Solar has scaled up, the organization has had to make decisions about which business functions to keep in-house and which to outsource. WE CARE solar will keep product development, marketing & brand management, monitoring & evaluation and fundraising in-house. The organization will choose a company in Asia to manufacture to suitcases. They will partner with in-country electronics vendors to sell, distribute and maintain the product for health facilities. These intermediaries will receive a percentage of revenue from each Solar Suitcase they sell. WE CARE Solar will train these in-country intermediaries.

WE CARE Solar’s first contract is to provide the government of Nigeria with Solar Suitcases for 700 health facilities. After learning lessons from this pilot, the organization will move into other countries in sub-Saharan Africa. Later on, they will expand by acquiring or creating medical devices that are compatible with the Solar Suitcase. The AGP device could potentially be one of those devices. Laura Stachel once noted that sterilizing surgical instruments is a major challenge in the field. If the AGP
device was powered by the solar energy provided by the solar suitcase, it would not need a battery, and the cost of producing it would be much lower.

At the first hospital in Nigeria to use a Solar Suitcase, maternal deaths went from 7-8 per month to 0-1. \(^{xxxviii}\) WE CARE Solar is partnering with the WHO to conduct a randomized controlled trial to compare the maternal health outcomes of facilities with solar suitcases to other facilities.

Many factors, including women’s health behaviors, lack of access to health facilities, and healthcare provider shortages, contribute to maternal mortality in developing countries. Facing these multiple challenges seems insurmountable, but Laura Stachel’s work shows that an affordable medical device can make an impact.

**The Clean Delivery Kit:**

A disposable clean delivery kit contains the essential supplies for a hygienic vaginal delivery. The basic components are a razor blade, umbilical cord tie, small bar of soap, plastic delivery sheet, and pictorial instructions. The kits can be either be sold at retail outlets or provided to birth attendants, women, or health facilities by an NGO or government. The kit can be used for either a home or institutional delivery, but are mostly used in home deliveries. \(^{xxxix}\)

Clean delivery kits were first developed by the Program for Appropriate Technology in Health (PATH) in the early 1990’s for use in Egypt. Now, the clean birth kit is commonly used in at least 51 low-resource countries. In Pakistan, for example, clean birth kits are used in about 30% of all home births. \(^{xli}\)

Clean birth kits are designed, developed, produced, and distributed by organizations located in the countries the kits will be used in. This helps ensure that the kits are culturally appropriate. In Nepal, women’s groups create clean delivery kits to earn income. \(^{xlii}\) Birth kits vary in price – most cost between US $0.20 and US $1.00. Women are highly sensitive to the price of a birth kit, so local producers face tradeoffs between including more items in the kit and keeping costs down. \(^{xliii}\) PATH has released non-proprietary instructional manuals to support organizations that would like to promote or produce clean birth kits. This strategy of decentralized growth has allowed the birth kit innovation to diffuse organically. \(^{xliii}\)

There are no randomized controlled trials measuring the effects of the clean delivery kit; some studies had the clean delivery kit as only one component their interventions. \(^{xliv}\) Preliminary evidence shows that the clean birth kits can affect infection rates. A cross-sectional study done by PATH in Tanzania showed
that mothers who used clean birth kits were three times less likely to develop sepsis and their infants were thirteen times less likely to develop umbilical cord infections.\textsuperscript{xlv}

\section*{POTENTIAL USERS}

There are two potential uses for the AGP device related to childbirth. The device could be used by traditional birth attendants (TBAs) in the field. Each TBA would be given a device they could use during home births. Or, the AGP device could be used in healthcare facilities for institutional births. There are several advantages of using the AGP device in healthcare facilities rather than for home births:

\begin{itemize}
  \item Low-cost solutions for hygienic home births, like the clean delivery kit, already exist.
  \item The AGP device would be the lowest cost method (both up-front and per-use) for sterilizing surgical instruments for cesarean sections.
  \item Healthcare facilities provide emergency obstetric care, and it is during these invasive deliveries that women are most likely to die or contract infections.
  \item When TBAs are using the device in different homes and carrying it between locations it is more likely to get lost or damaged than if it were being used in one healthcare facility.
  \item If the AGP device is brought into the home, family members will have more influence over whether and how it is used. Husbands will have to be engaged and educated about the advantages of the device and how it can be used to prevent infections.\textsuperscript{xlv}\textsuperscript{i}
  \item TBAs are less educated than healthcare professionals. The devices will be engineered for simplicity, but it is expected that healthcare professionals will make fewer errors in using the devices.
  \item The consensus is that strengthening health systems is the best approach for reducing maternal mortality.\textsuperscript{xlvii} As healthcare systems in low-resource countries improve with time, there will be fewer home births and more institutional births and caesarean sections.
\end{itemize}

Use of the AGP device in healthcare facilities has many advantages, but in many South Asian and sub-Saharan African countries, more than 50% of women deliver in the home\textsuperscript{xlviii} and are at risk for infections. It is worth exploring whether there is a promising model for using the device in homes. If the devices were given to rural health extension workers, they could use it during home deliveries, and also for other purposes, such as sanitizing their own hands when they see patients, and disinfecting wounds.
CHOOSING A PILOT LOCATION

The pilot location for this device should be selected carefully to maximize chances of success and impact. There are several criteria.

Need:
The prevalence of child-birth related infections in the pilot location is important factor, since this is the health condition we are trying to prevent. Infection is major cause of maternal death in both sub-Saharan Africa and Asia, causing 9.7% of maternal deaths in Africa and 11.6% of deaths in Asia.\textsuperscript{xiix}

The overall lifetime risk of maternal mortality in sub-Saharan Africa is 1 in 31, much higher than the lifetime risk in South Asia, 1 in 110.\textsuperscript{1} The highest rates of neonatal mortality are also in sub-Saharan Africa. But, this device could have a great impact in South Asia as well. Because of India's large population. 27% of all global neonatal deaths are in India alone.\textsuperscript{ii} (See Appendix C)

Cesarean Section rate:
If we are focusing on using this device for cesarean sections, we must look at cesarean section rates when choosing a pilot location. The percentage of deliveries with a skilled attendant are similar in South Asia and sub-Saharan Africa (between 40 and 50%), but the cesarean section rate is much higher in South Asia. In 2005, the cesarean section rate in rural India was about 6%, while in rural Ethiopia, Malawi, and Tanzania, it was 3% or less. Cesarean section rates below 5% indicate a severe lack of emergency obstetric care.\textsuperscript{iii}

But, the availability of emergency obstetric care in sub-Saharan Africa may have increased since these statistics were collected, and will continue to increase. To remedy acute provider shortages, five countries in Africa (Ethiopia, Ghana, Malawi, Mozambique, and Tanzania) have started allowing non-physician clinicians to do cesarean sections. The outcomes of cesarean sections done by these clinical officers have been shown to be as good as those done by physicians.\textsuperscript{iii}

Ability to pay:
If the business model for the AGP device is primarily commercial, rather than donation and grants based, it is important to look at the ability of the target market to pay for the device. Some countries,
including Ethiopia and the Democratic Republic of Congo, have a very low per capita healthcare expenditure. Others, including India and Nigeria, have higher healthcare expenditures. (See Appendix C)

Feasibility:
Political stability and absence of violence are important factors in successful implementation. Several of the countries on the list of highest number of neonatal deaths (See Appendix C) are very politically unstable, including Afghanistan, Pakistan, and the Democratic Republic of Congo. Others, like Tanzania and India, are more stable.

Another factor is whether the country has made progress in recent years. If a country’s MMR and NMR statistics are improving, this shows that maternal and child health is a priority and/or the country’s health care system is improving. These are success factors for the implementation of the AGP device. One example is Tanzania, where the MMR dropped from 714 to 449 between 2000 and 2008.iv While we may eventually choose to expand into a country where little progress has been made, this may not be an ideal scenario for first efforts.

We may also look at where other innovative MCH programs and technologies have been implemented. People from those organizations could provide valuable advice and local connections. For example, the Solar Suitcase team conducted an analysis of which markets to target first (based on ability to pay, market infrastructure, government receptivity, and level of need) and decided to start in eight countries: Botswana, Ethiopia, Kenya, Nigeria, Senegal, Uganda, Zambia and Zimbabwe.iv

Conclusion:
Based on need, cesarean section rate, ability to pay, and feasibility, India and Tanzania are potential pilot locations. Conditions vary greatly at the local level, so once a decision is made about which country to target, more fieldwork is needed to choose a pilot location.

ANALYTIC LENSES

INNOVATION FEASIBILITY ANALYSIS
Several factors impact how quickly a healthcare innovation will diffuse. The following innovation feasibility framework was adapted from articles by Mary Cain and Robert Mittman, and Abdallah Daar.\textsuperscript{li, lvii}

Relative Advantage:

*How much benefit is anticipated from this technology relative to current practice?*

A low-cost method for sterilizing surgical instruments would receive much interest in developing countries. Lack of equipment to sanitize surgical instruments is a serious problem in the field. For providers who travel to faraway hospitals to sanitize surgical instruments, this would save much time. For those who must choose between re-using surgical instruments without sanitizing them or turning patients away, this technology would result in better health outcomes.

Lack of hygiene puts healthcare workers at risk. When a mother or child dies suffers from an infection, healthcare workers are often blamed and retaliated against. Healthcare workers may also see this technology as away to protect themselves from infection, especially in HIV-endemic areas.\textsuperscript{lviii}

Observability:

*To what extent can potential adopters witness the adoption of this technology by others?*

Since this device is a novel technology, it is likely to attract attention. Laura Stachel commented in an interview that when she left a solar suitcase in a clinic in Nigeria and returned six months later, news of it had spread to neighboring clinics.\textsuperscript{lix}

Once the AGP device is in use in one clinic, healthcare providers and administrators from other clinics would be able to visit and watch the device while it is being used, talk to people about their experience using it, and make a decision about whether it would be suitable for their own clinic. The possibility of being able to observe the technology before adopting it will help it to diffuse.

Infrastructure:

*Is there a sufficient infrastructure in place for this technology?*
The AGP device is being designed for settings with minimal infrastructure. The AGP device will require no supplies for its use except a little bit of electricity and water. The electricity could be generated through solar energy or through a foot pump. As much as possible, the device will consist of off-the-shelf parts that are used in the country (for example, a scooter engine) in order to make local repair possible.

**Appropriateness:**

*Will the technology be affordable in developing countries, and will it be socially, culturally and politically acceptable?*

Even though the AGP device is relatively low-cost, 100 US dollars/device is a high cost for a developing country’s economy. These are countries where the total yearly per-capita healthcare expenditures are under $50. Financing mechanisms may help facilities to bear this cost.

Though infection prevention is generally socially, culturally, and politically acceptable, the device is a novel technology, so provider education will be important. The AGP team could look at the literature on “Behavioral Change Communication” to create strategies for communicating to healthcare workers about the device. Field testing will uncover specific aspects of the device that will present cultural challenges.

Training providers to use the device is another challenge, and should not be underestimated. Even though instructions in the clean delivery kits are simple and mostly pictorial, people have trouble using them. Some birth attendants do not look at the instructions because they are illiterate, do not have time, or believe that the kits are self-explanatory. WE CARE Solar is taking the approach of training their in-country intermediaries/sales teams to train local healthcare providers on how to use their technology.

For maximum health impact, local cultural practices that raise the risk of infection must change. One common practice is putting substances like ash on the newborn baby’s umbilical cord stump. These practices can be addressed in communities where the AGP device is deployed.

**Feasibility:**

*Can the device realistically be developed and deployed in a time frame of 5–10 years?*
The AGP device is in the first stage of its development. Before the device is ready for launch, there are several steps that must occur, including fundraising, completion of device design, clinical trials, regulatory approval, production, choice of a pilot location, and development of in-country partnerships. 5-10 years is a realistic goal for this to occur, but given the device’s early stage of development, unanticipated challenges may emerge.

**Knowledge gap:**

*Does the technology advance health by creating new knowledge?*

The clinical trials to study the effectiveness of this device present an opportunity to test other public health interventions to prevent, monitor and treat maternal and neonatal sepsis by adding additional intervention arms to the clinical trial.

Knowledge arising from the clinical trials would have a catalytic effect on the development of plasma technologies for low-resource countries. Papers describing the process of developing and implementing the technology would uncover challenges and possibilities for rolling out other AGP devices. If a positive effect on infection rates was found, this would justify funding of other plasma devices.

**Indirect benefits:**

*Does the technology address issues such as environmental improvement and income generation that have indirect, positive effects on health?*

There are several ways to integrate socially conscious elements into the development and deployment of the plasma device. The device could be solar or foot pump powered and use recycled components. Local people could be employed to assemble and sell the device, resulting in income generation and capacity building. The Clean Delivery Kit and Solarclave device are both manufactured by women’s self-help groups.

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**SWOT**

The following table summarizes the strengths, weakness, opportunities and threats of the AGP plasma device, used in developing countries for maternal and child health applications:
<table>
<thead>
<tr>
<th><strong>Helpful</strong></th>
<th><strong>Harmful</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Strengths</strong></td>
<td><strong>Weaknesses</strong></td>
</tr>
<tr>
<td>Works on drug-resistant bacteria, viruses, &amp; fungi</td>
<td>“In vivo” effectiveness and safety not yet proven</td>
</tr>
<tr>
<td>Very cheap per-use</td>
<td>High up-front cost</td>
</tr>
<tr>
<td>Would be the cheapest method for sterilizing surgical instruments</td>
<td>Technology is unfamiliar to people</td>
</tr>
<tr>
<td>Only requires electricity for use - freedom from supply chain</td>
<td>Requires training for appropriate use</td>
</tr>
<tr>
<td>Easy to repair</td>
<td>Device can be broken or stolen</td>
</tr>
<tr>
<td>The device is novel and can be observed, news of it will spread from organically</td>
<td>Organization does not yet have an “on-the-ground” field presence</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Opportunities</strong></th>
<th><strong>Threats</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Increasing number of cesarean section providers in African countries</td>
<td>Competition from other AGP research groups and copy-cat devices created in Asia</td>
</tr>
<tr>
<td>Increasing anti-microbial resistance in developing countries</td>
<td>Regulatory approval needed in the US and in target countries</td>
</tr>
<tr>
<td>Collaboration with Solar Suitcase Team</td>
<td></td>
</tr>
</tbody>
</table>
RECOMMENDATIONS

• The greatest infection prevention need related to childbirth is a low-cost method for sterilizing surgical instruments.

• There are several advantages to using the device in healthcare facilities rather than for home deliveries, including less chance of damage/loss and better targeting of complicated deliveries. Despite this, in areas with a weak healthcare system and high rates of home deliveries, use of the device by a Traditional Birth Attendant or Health Extension Worker may be more appropriate.

• Based on need, cesarean section rate, ability to pay, and feasibility, India and Tanzania are potential pilot locations. Conditions vary greatly at the local level, so once a decision is made about which country to target, more fieldwork is needed to choose a pilot location.

• Making bulk sales and raising funds to subsidize the device for the poorest clinics are two strategies for keeping the cost of the device down.

• Outsourcing some of the organization’s functions and keeping others in-house may be ideal. Alternatively, creating open-source instructional manuals and trainings would make it possible for various organizations around the world to independently produce the device. This decentralized strategy would make the product more diffuse and adapted to local environments.

• The WE CARE Solar team is a natural partner given the organization’s plan to partner with organizations that produce solar-powered medical devices.

• The AGP device has many characteristics that predict successful diffusion, including relative advantage, observability, and minimal need for infrastructure. Because it is a novel technology, communities will need to be educated about it. The social impact of the device can be amplified if socially-responsible production methods are used and the clinical trials for the device test additional public health interventions for reducing deaths from childbirth-related infections.
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APPENDIX A: METHODOLOGY

The information for this paper comes from several conversations with Professor David Graves, Department of Bioengineering, UC Berkeley. I interviewed professors in the School of Public Health, including Art Reingold, Lee Riley, and Ndola Prata. I used several search engines (Google, Google Scholar and PubMed) to look for information from journal articles and websites.
APPENDIX B: COST OF USING AGP DEVICE

August 26, 2010 – Professor David Graves (modified by Santhi Hariprasad)

Estimated Cost of Neonatal Cord Cleaning for AGP Device Compared to Liquid Antiseptics Chlorhexidine-Alcohol and Povidone-Iodine

Assume the following costs:

1. AGP device (5 year lifetime) - $50 ($10/year on straight-line depreciation)
2. 10 NiMH batteries - $30 (@2 A-h), website data.
3. Battery charger (5 year lifetime) - $25 ($5/year)

The device uses 3A, so 2 A-hour battery capacity means 40 minute operation before charging.

If each application is 1 minute, this is 40 applications per charging.

Let’s say this set of 40 applications is one day’s use. For 500-1000 chargings per battery lifetime (as per website specs), this corresponds to about 2 years (365 x 2 = 730 chargings).

Then 730 days x 40 applications/day = 29,200 applications.

For 2 years, the depreciation costs of the device is $20 and for the charger, $10.

The total cost for these 2 years is then: $30 (batteries) + $20 (AGP device) + $10 (charger) = $60.

Since we assume 29,200 applications cost $60, the cost per applications is = $0.0021/operation = 0.21 cents/application.

In Nepal, the chlorhexidine cost for neonatal cord cleaning was 4 cents/application.

4 cents/.21 cents = 19

Conclusion: Chlorhexidine-Alcohol is estimated to cost approximately 19 times as much as the AGP device for neonatal cord cleaning.
APPENDIX C: CHOOSING A PILOT LOCATION

<table>
<thead>
<tr>
<th>Country</th>
<th># of Neonatal Deaths (Thousands) *</th>
<th>% of Global Neonatal Deaths*</th>
<th>Neonatal Mortality Rate (per 1000 live births)*</th>
<th>Maternal Mortality Rate (per 100,000 live births)**</th>
<th>Political Stability &amp; Absence of Violence Index†</th>
<th>Healthcare expenditure per capita (in US$)‡</th>
</tr>
</thead>
<tbody>
<tr>
<td>India</td>
<td>1098</td>
<td>27%</td>
<td>43</td>
<td>254</td>
<td>-1.2</td>
<td>40</td>
</tr>
<tr>
<td>China</td>
<td>416</td>
<td>10%</td>
<td>21</td>
<td>40</td>
<td>-0.4</td>
<td>108</td>
</tr>
<tr>
<td>Pakistan</td>
<td>298</td>
<td>7%</td>
<td>57</td>
<td>376</td>
<td>-2.8</td>
<td>23</td>
</tr>
<tr>
<td>Nigeria</td>
<td>247</td>
<td>4%</td>
<td>53</td>
<td>608</td>
<td>-2.0</td>
<td>74</td>
</tr>
<tr>
<td>Bangladesh</td>
<td>153</td>
<td>4%</td>
<td>36</td>
<td>338</td>
<td>-1.6</td>
<td>15</td>
</tr>
<tr>
<td>Ethiopia</td>
<td>147</td>
<td>4%</td>
<td>51</td>
<td>590</td>
<td>-1.7</td>
<td>9</td>
</tr>
<tr>
<td>Democratic Republic of the Congo</td>
<td>116</td>
<td>3%</td>
<td>47</td>
<td>534</td>
<td>-2.1</td>
<td>9</td>
</tr>
<tr>
<td>Indonesia</td>
<td>82</td>
<td>2%</td>
<td>18</td>
<td>229</td>
<td>-0.6</td>
<td>42</td>
</tr>
<tr>
<td>Afghanistan</td>
<td>63</td>
<td>2%</td>
<td>60</td>
<td>1575</td>
<td>-2.8</td>
<td>42</td>
</tr>
<tr>
<td>Tanzania</td>
<td>62</td>
<td>2%</td>
<td>43</td>
<td>449</td>
<td>0.0</td>
<td>22</td>
</tr>
</tbody>
</table>