

# Affordable, High-Quality, Non-Pneumatic Antishock Garments

## Demand Modeling and Commercialization Report

February 2011



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## Introduction

Severe postpartum hemorrhage occurs in approximately 1 percent of pregnancies yet is responsible for 24 percent of maternal mortalities.<sup>1</sup> These numbers are higher in developing countries where lack of adequate neonatal and nutritional care and an increased likelihood of anemia in the mother increase the probability that complications will arise during childbirth. Postpartum hemorrhage (PPH) can occur as a result of many complications in the third stage of labor such as uterine atony, laceration, retained placenta, or uterine rupture. A large proportion of these conditions can successfully be treated with the correct procedures or medical interventions. However, these interventions are oftentimes not feasible in low-resource settings where delivery occurs far from local health facilities or where those facilities do not have the resources (staff, equipment, drugs, blood supplies, or dependable utilities) to adequately care for a woman suffering from PPH. Depending on the extent of blood loss and prior condition of the patient, moderate to severe bleeding can lead to the onset of hypovolemic shock and can ultimately prove fatal.

In rural locations or low-resource settings, especially where delivery takes place at home, it is time that proves to be the most valuable commodity. If a woman can be stabilized for transport to an adequately equipped and staffed facility, this greatly increases her chances for survival. While there are many barriers to decisive and swift decision-making that would result in a birth attendant or family member seeking adequate care,<sup>2</sup> in some locations it is purely the distances that must be traveled and means of transport available that decide the fate of women experiencing PPH.

### **The Non-Pneumatic Antishock Garment**

The non-pneumatic antishock garment (NASG) is a device constructed primarily from neoprene and velcro that applies external circumferential counter pressure to the lower body. This pressure maintains blood supply to the major organs and reverses the onset of hypovolemic shock, thus stabilizing the patient for up to 36 hours. Proper application of the NASG provides an extended window of opportunity to arrange management of necessary resources by (1) stabilizing a patient during transport to an adequate facility where treatment can be administered or (2) providing essential time for triage or arrangement of needed resources such as obtaining essential supplies, skilled personnel, or finding and processing blood transfusions.

A detailed market assessment was conducted in Nigeria and India to inform the creation of demand models as a tool for manufacturers to estimate the market potential. This assessment included comprehensive background research detailing the clinical needs for supporting PPH care and an assessment of the critical support infrastructure and policies of the Nigerian health system and Indian health system as documented by the United Nations Population Fund and the National Rural Health Mission of India. Additionally, with the gracious support of Pathfinder, we were able to gain invaluable on-the-ground insights into demand drivers by conducting site visits to review operational program details and meet key stakeholders of the Continuum of Care program which is introducing the garment in Nigeria and India. Pathfinder was instrumental in arranging site visits to facilities using the garment, allowing us to document and understand how the garment is being used and if it is meeting the specific local needs.

A major contributor to the background and understanding of real world applications and use of the device was provided by Pathfinder International's US and field teams. We greatly appreciate their time and contribution and were able to rapidly accelerate our commercialization objectives based on information provided from the Continuum of Care programs in Nigeria and India funded by the MacArthur Foundation. This program focuses on three elements to address postpartum hemorrhage and improved maternal care (1) advocacy to promote government support, (2) community engagement, and (3) clinical interventions. This program has clearly demonstrated the need for a multiple-front introduction strategy—engaging policymakers, procurement decision-makers, end-users, and manufacturers.

Site visits in Nigeria included interviews with the local Pathfinder office; seven facilities spanning rural, peri-urban, and urban settings; and primary through tertiary centers in Lagos, Abuja, and Nasarawa. In India interviews were conducted in eight facilities in Delhi, Udaipur, and Chennai, also representing rural, peri-urban, and urban settings ranging from primary health care clinics to tertiary facilities. Additional findings were informed through information interviews with the local Pathfinder office, MacArthur Foundation, and with Indian-based nongovernmental organizations Action, Research, Training in Health, and Seva Mandir.

## **Nigeria—Customer Profile**

Nigeria is a country of extremes. It is the most populous country on the African continent with just under 160 million people, the third largest economy in Africa, and one of the fastest growing economies in the world according to the International Monetary Fund. In addition, Nigeria is the largest oil producer in Africa and seventh globally. However, there is also great disparity in health and socioeconomic status. Seventy percent of the population lives below the poverty line; the country has the third highest number of newborn deaths globally, second highest maternal deaths, and a life expectancy of 47 years. The Nigerian public health system is tiered into three distinct levels: primary health care facilities, secondary hospitals and tertiary hospitals, though gradations within each tier are significant and are highly variable based on geographic region and proximity to an urban center.

Currently, Pathfinder International has deployed garments and training in 4 states at 52 facilities representing all 3 levels of care as a major focus of their Continuum of Care program funded through the MacArthur Foundation. To accommodate distribution needs for each facility Pathfinder provides two garments for the first one hundred deliveries per month, and one additional garment for every additional hundred monthly deliveries. Of the Pathfinder deployment and pilot countries, Nigeria has seen the greatest number of NASG uses—with 963 uses since 2008 and 220 garments distributed. Of note, our survey of facilities found an unmet need and desire for these garments at all levels as a means of stabilizing patients not only for transport but also triage once they enter a facility. This greatly differs from our findings in India where often blood for transfusion was available at district and tertiary facilities, so the garment was primarily seen as a tool for stabilization during transport.

### **Primary Health Care Facilities**

Primary health care facilities include dispensaries, health care clinics, primary health care centers (PHCs), and comprehensive health care centers (CHCs). The primary two facilities in regard to the NASG are PHCs and CHCs as they provide comprehensive obstetric care (antenatal, labor and delivery, and postnatal) and in the case of CHCs can also provide minor surgical services.

There are approximately 6,000 PHCs that see an average of 15 to 50 births per month. Their monthly budget is approximately US\$200 for consumables and are primarily staffed with community health extension workers managed by midwives with the more comprehensive centers also having an attending physician on call. These facilities see approximately one case of severe PPH per every three months, and Pathfinder estimates a need of two NASGs per facility.

### **Secondary Hospitals**

There are approximately 861 secondary hospitals. They see anywhere between 15 to 200 deliveries a month with a monthly budget for consumables of approximate US\$500 for a rural hospital. These hospitals are primarily staffed by midwives with multiple family health care physicians attending and several specialists (OB/Gyns) on call. These facilities see approximately 1 to 4 severe cases of PPH per month and also have received two NASGs per facility based on the Pathfinder supply algorithm.

### **Tertiary Hospitals**

Nigeria has 45 tertiary hospitals—centers that provide comprehensive care across the spectrum of health care services. These centers see approximately 200 to 300 births a month, though some see as many as 600. In attendance, these facilities have a significant number of midwives and physicians as well as a number of specialists on hand. They see approximately 5 to 10 severe cases of PPH per month and have between 5 to 10 NASGs on hand. Most of the deliveries are either scheduled caesarean sections or are referrals from surrounding public and private clinics and hospitals.

### **Demand Indicators**

Nigeria has three main drivers and a more evenly distributed unmet need, thus providing a clearer map of demand and value proposition.

#### **1. Location of delivery**

The NASG is not considered by medical professionals in the field to be appropriate for use in domestic settings due to logistical challenges around getting the garment to traditional birth attendants. As a result, demand is primarily facility based where treatment or transport options are available. Demand in Nigeria is consistent among primary through tertiary facilities as well as urban and rural settings.

#### **2. Blood banking**

Presence of reliable blood banking requires consistent power and donor supplies to be able to provide emergency transfusions to hemorrhaging mothers. Without the availability of blood, the NASG is a critical tool for filling this important intervention gap by stabilizing the patient, controlling shock, and minimizing blood loss until donors can be found and a direct is transfusion administered. Blood banks are found only at select tertiary centers, requiring the transport of the supplies or patients which can result in significant delay.

### **3. Number of births**

Number of births and referrals drive demand within each facility. The basic Pathfinder algorithm of two garments for the first hundred births and one for every additional hundred seemed generally sufficient to meet demand for each facility.

## **India—Customer Profile**

India has a highly decentralized public health system where the national government provides guidance, but decision-making power for policy and procurement is concentrated at the individual state level. The public sector represents the largest and most important customer for the NASG in India in that it interfaces most directly with those at greatest risk of obstetric complications. While India as a country has the highest absolute numbers of maternal deaths, it ranks 45<sup>th</sup> in terms of maternal deaths per 100,000 live births. As a result PPH, though a major contributor to maternal mortality, is still a relatively rare occurrence.

### **Rural Public Health Facilities**

These facilities are at the frontline of emergency obstetric care and perceive the NASG as a lifesaving first aid device in that it stabilizes patients while they can be transported to a facility capable of treating the root cause of PPH with a range of nonmedical, medical, and surgical interventions. Facilities considered in this segment are CHCs, PHCs and sub centers (SCs) that have been designated as birthing centers (those without the designation are primarily used for immunization, antenatal, natal and postnatal care, prevention of malnutrition and common childhood diseases, family planning services and counseling).<sup>3</sup> The designation as a birthing center is based on the higher number of deliveries taking place at a SC (approximately 40 per month) and constitutes approximately 1 percent of SCs. These facilities will typically require a quantity of garments based on the number of births occurring per month following the Pathfinder algorithm of two garments for the first hundred births.

### **District Hospitals**

These facilities are commonly urban and will typically have access to the full range of treatment options. The value proposition of the NASG in these facilities is primarily as a patient management device, allowing the facility to manage multiple patients with limited resources (blood, operating theater tables, etc.). In some cases these facilities may need to refer cases to tertiary facilities and in this instance the NASG allows for patient stabilization and transfer. These facilities will typically require a quantity of garments based on the number of births occurring per month, as well as additional capacity to support a garment exchange process with referring facilities.

### **Tertiary Facilities**

It is unlikely that a tertiary facility will require the NASG for patient stabilization or transport as these are full-service facilities; however, the garment does have a role to play in both patient management and as a means of resuscitating women who may be referred to the facility in an extremely critical condition. These facilities will typically require a quantity of garments based on the number of referrals occurring per month, as well as additional capacity to support a

garment exchange process with referring facilities and training of birth attendants from referring facilities.

## **Demand Indicators**

While there are a large number of maternal deaths in India on an annual basis due to PPH (approx 21,000 as per India Ministry of Health and Family Welfare statistics), this still represents a small percentage of all pregnancies in the country. Therefore, rather than the NASG being needed at each delivery, the indicators of demand are those factors that more accurately predict the probability of the NASG being a necessary and appropriate intervention.

### **1. Location of delivery**

The NASG is not considered by medical professionals in the field to be appropriate for use in domestic settings and so demand is primarily facility based.

### **2. Type of facility**

Core need for the NASG is at the PHC and CHC level where treatment options are minimal and the need for stabilization and transport are critical. Some SCs have sufficient numbers of deliveries to have special designation as a delivery center. This constitutes approximately 1 percent of all SCs. Need still exists at district hospital and tertiary facilities for training, exchange, and occasional use for triage or referral cases.

### **3. Number of births**

Some SCs and PHCs with up to 40 deliveries per month have a need for a NASG for transport to a referral center. District and tertiary facilities handling up to 1,500 births per month have need for the NASG as a patient management device, for training, and for exchange with referring facilities.

### **4. Percentage of referrals**

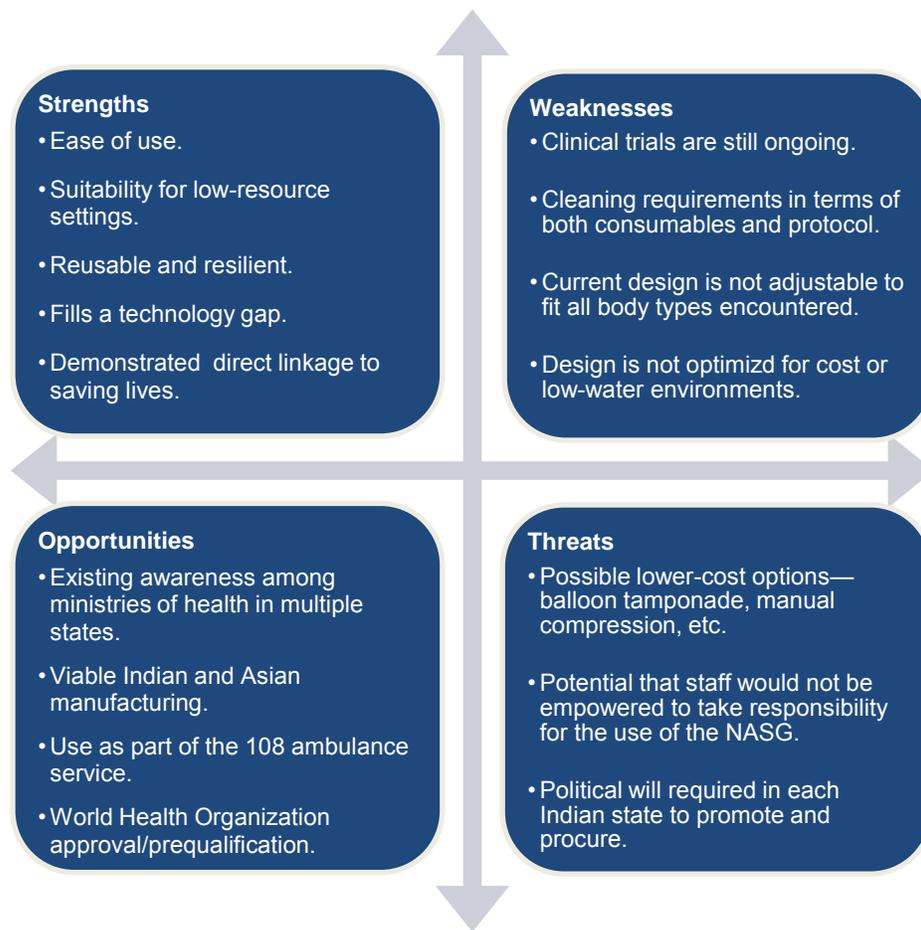
A high percentage of referrals implies a higher rate of complications and a potential need for exchange garments.

### **5. Availability of alternative interventions**

Facilities with the capability to deploy alternative interventions such as surgical procedures, blood transfusions, ligation. etc. typically have reduced dependence on the NASG for stabilization.

## **Strength, Weakness, Opportunity, Threat Analysis**

Given the market described above for both Nigeria and India, the following strength, weakness, opportunity, threat (SWOT) analysis (Figure 1) describes the strengths and weaknesses of the demand drivers and its market positioning, while identifying potential opportunities and threats that may materialize in the future and have a positive or negative impact on that market positioning.



**Figure 1.** SWOT analysis for India and Nigeria.

### **Strengths**

Key strengths of the garment are perceived to be its ease of use, suitability for low-resource settings, and most importantly its clear ability to save lives. It is believed that the garment can be applied by those with a moderate amount of training and consequently is suitable for the lower levels of the public health system. In addition, a key strength that was commonly identified is the quality of manufacture of the current garment and the fact that it stands up to reuse very well. For both markets the garment also fills a much needed technology gap. For Nigeria the value proposition is around transport to a facility and patient management while blood can be found and administered. The value proposition for India is primarily transport, specifically from a PHC to district or tertiary facility for blood transfusion as well as a triage tool for understaffed hospitals.

### **Weaknesses**

A key weakness of the NASG is the lack of conclusive clinical evidence to prove its effectiveness, and among practitioners it is felt that this is a key barrier to the garment's success

on a global level.\* Furthermore, clinical trials have focused on one size. While through pragmatic deduction we can estimate that the other sizes should be clinically functional—and thus save lives—the current stakeholder mindset is that the proper approach is to establish a scientific basis for each size with bridging studies for small and medium. This approach will enable development of sizing guidelines.

It was observed that views on the sizing of the garment are variable in different regions, which would indicate that variable sizing of the garment is desirable. While the current small size appears to be acceptable in southern Indian states such as Tamil Nadu, states with more impoverished and consequently more undernourished populations may encounter reduced effectiveness of the garment due to lower body mass indexes. Likewise in Nigeria, users noted that while the large size was generally sufficient, even larger sizes were necessary to treat obese women and two deaths already could be attributed to the lack of a solution to address this patient segment.

More locally, the availability of the appropriate materials to clean the garment (water, bleach) may be a hurdle to adoption and proper care. Additionally, when cleaning protocols are not followed some of the benefits associated with the garment's quality of manufacture and resilience may erode resulting in a shorter lifespan and higher cost per treatment.

## Opportunities

An opportunity currently exists in the form of existing unmet demand for the small NASG among a number of states, most visibly Tamil Nadu where they have sought to procure up to 1,500 garments.† Bringing additional manufacturers online will allow for streamlined procurement processes and competitive bids, providing an opportunity to meet this demand and create momentum behind the rollout among early adopters.

In India, the 108 ambulance service operated by the Emergency Management and Research Institute provides the opportunity to place the device within reach of a large number of potential beneficiaries in rural locations using a high-quality and highly respected emergency service.<sup>4</sup> This positions the NASG directly at the point of need for both facility-based and domestic delivery situations and potentially opens the market to other types of trauma resulting in hypovolemic shock such as automobile accidents, work place accidents, etc.

No clinical results are yet available for consideration by the World Health Organization (WHO) for inclusion in the *WHO guidelines for the management of postpartum haemorrhage and retained placenta*.<sup>5</sup> The inclusion of the NASG and full endorsement by the WHO (or other global regulatory stamp of approval such as inclusion in the Interagency List of Essential Medical Devices for Reproductive Health) will potentially trigger a significant expansion of the market reach to countries outside of the current Continuum of Care program and accelerate worldwide uptake of the product. Since the timing of this is uncertain and dependent upon the outcomes of the clinical trial, both scenarios will be presented in the demand modeling of this document. While approval will not significantly change the overall demand for the product

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\*Ongoing research conducted by Dr. Suellen Miller, University of California, San Francisco, using a cluster-randomized design to examine the effects of applying the NASG at peripheral clinics before transfer to a referral hospital should help to determine the full potential of the NASG for preventing maternal morbidity and mortality in low-resource settings.

(<http://www.clinicaltrials.gov/ct2/show/NCT00488462?term=NCT00488462&rank=1>). Accessed 1/13/11.

† Based on key informant conversation, July 2010.

(demand is assumed to be fixed and a function of need), it will greatly impact the rate of adoption.

### **Threats**

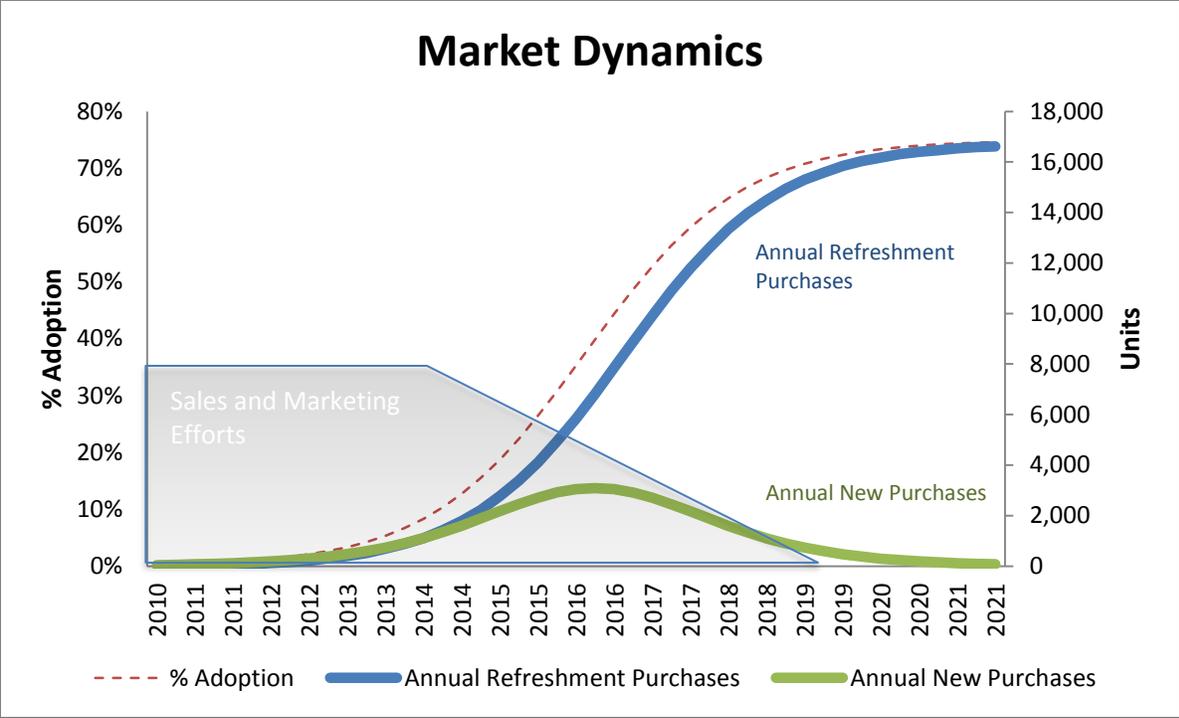
A major threat to the success of NASG adoption is that the garment only fills a technology gap and does not address the wider people and process issues that exist within the public health system in either country. In the case of Nigeria, the garment fills a gap created by inconsistent power and the ability to maintain blood bank temperatures; in India the garment compensates for protocols and under-resourced staff that contribute to delayed care. Given that the garment is typically used in situations where a patient is referred to another facility, there is a dependency on the referral process functioning at a high level and this is, unfortunately, not always the case.

Another threat is the concern among Indian birth attendants of being held responsible for the NASG if it is misplaced during the referral process or damaged during use on a patient when the facility is audited. It is felt that this burden of responsibility is disproportionate to the value of the equipment being handled and is part of the culture of the Indian public health system. As a relatively expensive piece of equipment, users may be intimidated by the prospect of using the garment and potentially having it misplaced or damaged during the course of treating a patient.

## **Market Size and Demand Forecasts**

### **NASG Market Dynamics**

The dynamics for the NASG market are particularly interesting as the main driver of unit growth is not initial sales but replacement of worn-out or damaged garments. It is assumed that as health providers become familiar with the garment and value its use, they will continue to ensure that the device is stocked at their facility. Because there are no existing substitutes for the specific value proposition the garment provides, the NASG market is seen to perpetuate as long as the underlying infrastructure problems remain. Upfront sales, marketing, and policy efforts (such as the services provided by Pathfinder) will continue to be necessary, with an emphasis on on-the-ground direct interfacing with key stakeholders. This work will be necessary until a tipping point where awareness and acceptability of the product is established. At that point these efforts can taper off without significantly affecting demand. Once NASG market saturation is achieved, the sales, marketing, and policy efforts can essentially end and the system will continue until the replacement saturation rate is achieved (see Figure 2).



**Figure 2.** NASG market dynamics.

**Nigeria**

As Table 1 illustrates, the total addressable public-sector market for Nigeria is estimated at 14,142 units across nearly 7,000 public-sector facilities.

	PRIVATE	PUBLIC			Public Sector Total
		Primary	Secondary	Tertiary	
Estimated number of facilities at the country-level	6,531	6,075	861	45	6,981
Required garments per facility	2	2	2	6	N/A
Total garments	13,062	12,150	1,722	270	14,142

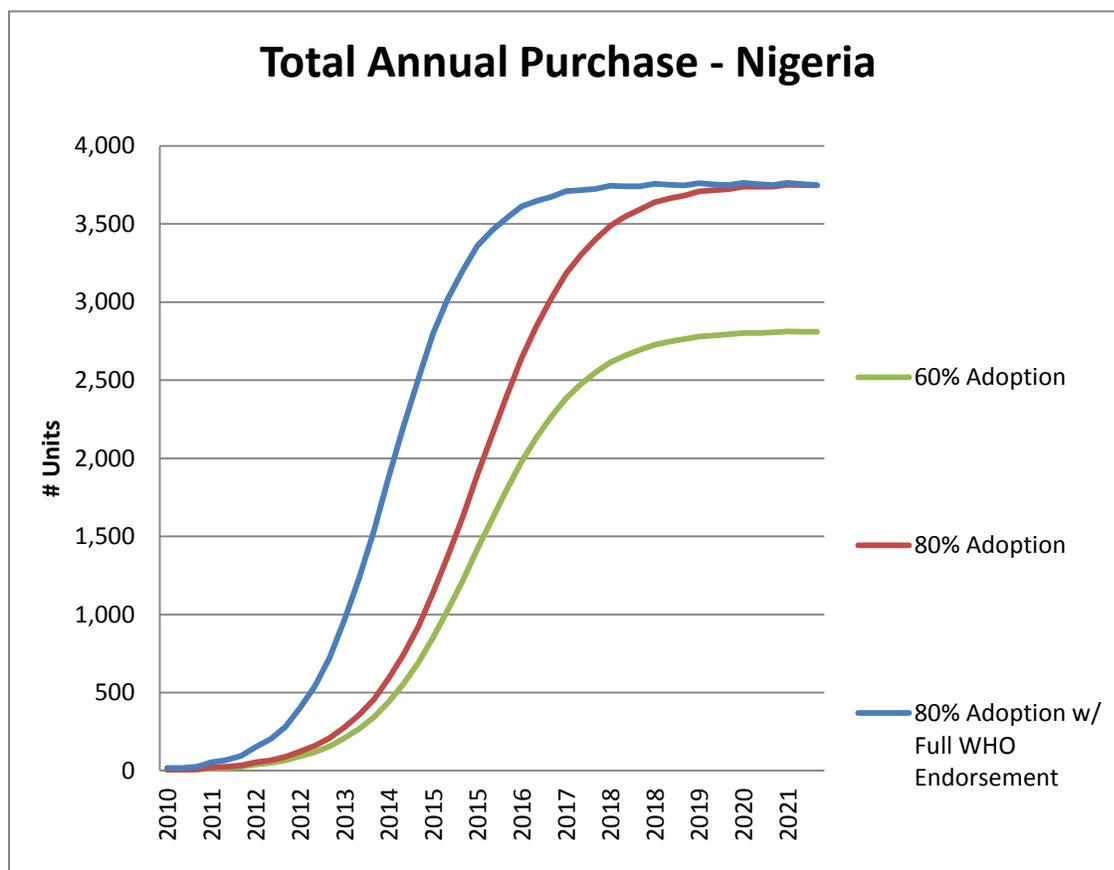
**Table 1.** Private- and public-sector facilities and estimated units required in each market for Nigeria.

Demand model forecasts examine three scenarios, each based on the assumption of a 3-year lifespan for the garment (assumes an average of 40 uses per garment, each unit would require replacement every 3 years).

1. 60% countrywide adoption over 10 years.
2. 80% countrywide adoption over 10 years.

- 80% countrywide adoption over 10 years with inclusion in the WHO guidelines for PPH management in 2013.<sup>‡</sup>

Figure 3 compares the total annual purchases for each scenario and illustrates the acceleration aspect factored in with WHO inclusion in the guidelines—thereby increasing awareness beyond early adopters and providing greater credibility to the device’s effectiveness. For Continuum of Care countries (Nigeria and India), endorsement by WHO is seen to accelerate the market but is not expected to have any effect on market expansion as these countries are already purchasing the garment.



**Figure 3: Total annual purchases in Nigeria.**

Scenario 1. Scenario 1 (green line in Figure 3) assumes public-sector growth from near zero to reach a market saturation of 60 percent. Sales accelerate after 2012 and peak around 2015 and 2016, then slow as the market becomes saturated and smaller states and outlying clinics come on board. The refresh rate for garments grows exponentially due to the cumulative nature of the of the refresh cycle—every year the garments purchased three years prior are replaced. However, eventually annual purchases reach a steady state as one-third of all garments in the market are replaced each year.

<sup>‡</sup> NASG clinical trials estimated to be completed by 2012 and reviewed by committee, if deemed safe and effective this will likely result in an update of WHO guidelines.

Scenario 2. Scenario 2 (red line in Figure 3) assumes 80 percent adoption in the public sector (from near zero). As a result of the compounding nature of the replacement rate, initial garment sales are relatively small peaking at an annual volume of 781 units; however, the replacement of garments being cumulative becomes steady state at 3,740 garments per year. Total cumulative sales under this scenario are over 88,000 garments over 10 years.

Scenario 3. Scenario 3 (blue line in Figure 3) demonstrates the effects of full WHO endorsement. For countries already purchasing the device, endorsement is not seen to be a roadblock to entry and is not expected to increase the total market size but will likely accelerate market adoption by increasing awareness and winning over late adopters earlier. In this scenario, market saturation and peak annual sales are assumed to be equal; however, by left shifting the curve and moving more products into the market faster, a greater cumulative number of garments will be sold (area under the curve) as a result of more garments being used and wearing out.<sup>§</sup>

## India

The total addressable market size for India has been estimated to be 67,304 garments.

	<b>Tertiary Hospitals</b>	<b>District Hospital</b>	<b>CHC</b>	<b>PHC</b>	<b>SC*</b>	<b>Total</b>
Number of facilities	908	578	4,276	23,458	1,460	30,680
Required garments per facility	6	6	2	2	2	N/A
Total garments	5,448	3,468	8,552	46,916	2,920	67,304

\*Designated birthing centers.

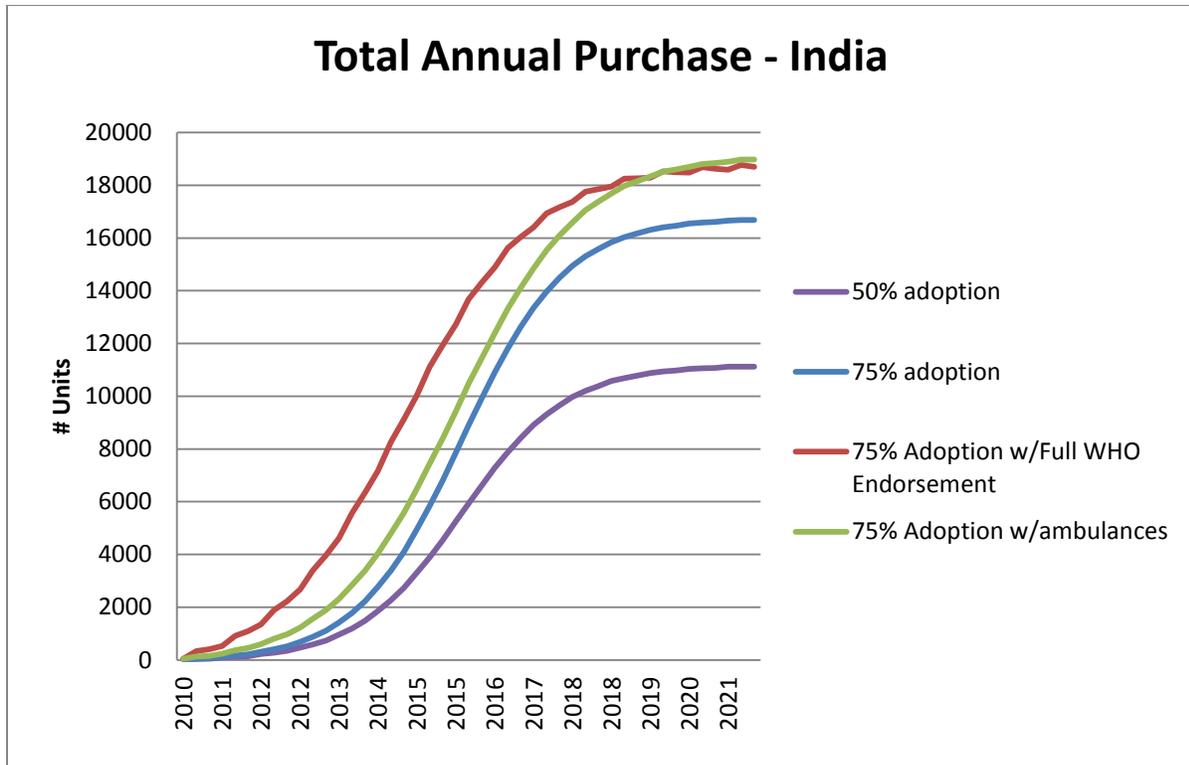
**Table 2.** Facilities and estimated units required in each facility in India.

Demand model forecasts examine four scenarios, each based on a 3-year refresh rate. Total market penetration adoption percentages are lower overall for India than Nigeria due to the fragmented nature of the Indian marketplace:

1. 50% countrywide adoption over 10 years.
2. 75% countrywide adoption over 10 years.
3. 75% countrywide adoption over 10 years with inclusion in the WHO guidelines for PPH management in 2013.
4. 75% countrywide adoption over 10 years with inclusion into the 108 ambulance service program.

Figure 4 illustrates the impact to total units purchased for each scenario.

<sup>§</sup> An additional 13,000 garments could be sold to the private sector in Nigeria to meet the need of an estimated 6,500 facilities serving this market. However, private-sector sales are not included in demand estimates.



**Figure 4.** Cumulative sales in India.

Scenario 1. Scenario 1 (purple line in Figure 4) represents a conservative estimate of 50 percent adoption over 10 years, which could be influenced by a number of factors. These factors include the lack of local manufacturing; the inability of the public sector to have the option of multiple sources, hence slowing the procurement process by not allowing competitive bids; or failure of the clinical trials to demonstrate clear cost-effectiveness.

Scenario 2. In Scenario 2 (blue line in Figure 4) with 75 percent countrywide adoption, new purchase demand for the public sector is estimated at approximately 50,000 garments, averaging about 1,000 per year and peaking at just over 3,000 garments. Replacement rates grow rapidly and stabilize at approximately 16,000 garments per year with a cumulative 10-year volume of 334,541.

Scenario 3. Scenario 3 (red line in Figure 4) introduces the accelerating factor of full WHO endorsement.

Scenario 4. Scenario 4 (green line in Figure 4) recognizes the potential for adoption by the 10,000 ambulances that make up the government-sponsored 108 ambulance service program.

### Disclosure

It is important to note that all demand forecasts were designed based on generic demand growth curve estimates. A clearly defined go-to-market sales and marketing strategy could greatly influence the skew and shape of the curves illustrated above. The accompanying spreadsheets are available from PATH for manufacturers and distributors to build similar forecasts based on specific organizational strategy.

## Funding

Support for this project is made possible by the generous support of the American people through the United States Agency for International Development (USAID) under the terms of the HealthTech Cooperative Agreement # GPH-A-00-01-00005-00. The contents are the responsibility of PATH and do not necessarily reflect the views of USAID or the US Government. Additional funding was provided through private foundations and individual donors to the Health Innovation Portfolio at PATH.

Assistance was also provided through an internship with the University of Michigan, William Davidson Institute, 2010 Global Impact Internship Program.

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