

The Nonpneumatic Anti-Shock Garment in Nigeria: The Tension Between Research and Implementation

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Location: Nigeria, Africa

Name of Project: The Nonpneumatic Anti-Shock Garment (NASG) for Obstetric Hemorrhage

Sponsoring Organization (and Funders): Safe Motherhood Program, Bixby Center for Global Reproductive Health at the University of California, San Francisco in collaboration with the Centre for Population and Reproductive Health, College of Medicine/University

College Hospital, University of Ibadan, Nigeria. Funding provided by the John D. and Catherine T. MacArthur Foundation.

Target Population: Nigerian women suffering from obstetric hemorrhage

Project Goal: Reduction of maternal mortality in Nigeria through research and dissemination on the use of the NASG for obstetric hemorrhage

Project Objectives: Test the effectiveness of the NASG for obstetric hemorrhage in Nigeria using a pre-post design. Scale up from the initial pilot study by expanding to several facilities in northern Nigeria.

BACKGROUND

With the inception of the Safe Motherhood movement, ignited by an international meeting in Nairobi in 1987, global leaders have been working toward the elimination of maternal mortality. These efforts were reaffirmed by the establishment of the Millennium Development Goals (MDGs), wherein goal 5 calls for a reduction of maternal mortality by 75% by the year 2015 (United Nations, 2000).

Nigeria, with 2% of the global population, accounts for 10% of maternal deaths (World Health Organization, 2007). This most populous African country has one of the highest maternal mortality ratios (MMR) in the world, with national figures officially at 1,100 maternal deaths per 100,000 live births (World Health Organization, 2007). The leading causes of maternal death in Nigeria, as in many other developing countries, include hemorrhage, eclampsia, sepsis, and incomplete abortion (Ujah et al., 2005). Hemorrhage alone accounts for at least 34% of deaths (Khan, Wojdyla, Say, Gülmezoglu, & Van Look, 2006; Ujah et al., 2005).

In 2004, researchers from the University of California, San Francisco (UCSF) teamed up with researchers from the University of Ibadan, University College Hospital (UCH) in Ibadan, Nigeria, to investigate a new technology to decrease deaths from hemorrhage. The approach involved using an old device in a new way. The Nonpneumatic Anti-Shock Garment (NASG) is a simple neoprene and Velcro lower body compression device that is used to stabilize patients experiencing obstetric hemorrhage, consequently affording more time for patients to



Figure 16-1 A woman in a nonpneumatic anti-shock garment.

Source: Courtesy of Safe Motherhood Program, UCSF.

access definitive treatment and care. The NASG can very quickly and effectively arrest the shock that arises from heavy blood loss, restoring consciousness and normalizing vital signs (Hensleigh, 2002; Miller, Hamza, et al., 2006).

As is often the case in low-resource settings, most maternal deaths from obstetric complications are related to delays. The woman or her family delay making the decision to seek care at a facility; after the decision is made, transportation is often difficult to obtain; and upon her arrival at the facility, there may be a delay before adequate care is given (Society of Gynaecology and Obstetrics of Nigeria, 2004; Thaddeus & Maine, 1994). These delays are particularly pernicious in the case of obstetric hemorrhage—due to the physiology involved, a woman can easily bleed to death in just 2 hours (Li, Fortney, Kotelchuck, & Glover, 1996). When it is wrapped tightly around a woman's body, the NASG reduces blood loss and shunts pooled blood from the lower to the upper body, restoring oxygen and blood to the core organs. Through this stabilization process, a woman suffering hemorrhage and shock can survive the delays.

Though the NASG is not a definitive treatment for obstetric hemorrhage, it offers strong advantages for use in Nigeria and other low-resource countries. It is simple to use, and with a few hours of training, anyone can competently apply it (although removal should be done only under medical supervision after treatment is complete). The NASG is low-tech, inexpensive (approximately US\$4.25 per use), and reusable (up to 40 applications).

Prior to the beginning of this project, the NASG had only been used for obstetric hemorrhage cases in Pakistan by Drs. Paul Hensleigh and Carol Brees, who published a small case series on their work (Brees, Hensleigh, Miller, & Pelligrini, 2004; Hensleigh, 2002). Dr. Suellen Miller of UCSF met Dr. Hensleigh, and they collaborated with Dr. Oladosu Ojengbade, University College Hospital, Ibadan, Nigeria for this project.

THE PROJECT

Stakeholders

The project, a pilot study and scale-up, had multiple stakeholders involved. The principal investigator, Dr. Suellen Miller, is the director of the Safe Motherhood Program, Bixby Center for Global Reproductive Health at UCSF. Dr. Miller is a certified nurse-midwife with many years of experience in international research and a long-standing frustration with the lack of tools to decrease maternal mortality. The John D. and Catherine T. MacArthur Foundation funded the study with the hope of lowering maternal mortality in Nigeria through projects that result in concrete and replicable outcomes.

The primary in-country partner was Dr. Oladosu Ojengbade from the Centre for Population and Reproductive Health at the UCH, College of Medicine, University of Ibadan and is an obstetrician-gynecologist and national trainer of Life Saving Skills (Basic Emergency Obstetric Care) for midwives. The study was reviewed and supported by the Federal Ministry of Health, whose drive to lower maternal mortality is further fueled by Millennium Development Goal number 5 and the lack of progress being made toward reducing maternal mortality. The study was carried out in hospitals across Nigeria where providers witness women dying from hemorrhage and eclampsia on a daily basis. Ministries of Health for each of the four states in which the project was set were also stakeholders, as were members of professional obstetrical (Society of Gynaecology and Obstetrics of Nigeria) and midwifery organizations. Hospital directors and heads of departments of obstetrics were involved in the expansion.

Design

The project was designed to improve on the evidence provided by Dr. Hensleigh's original case series. However, since reports of NASG use indicated that it could have a dramatic and obvious effect on resuscitation, it was clear that a randomized design was neither practical nor ethical. Thus, it was agreed to do a period of observation of cases in the hospitals without using the NASG (preintervention phase) followed by a period of observation of cases with the NASG (intervention, or NASG phase). Work began first in four hospitals in southern Nigeria, but it was eventually expanded to include 12 hospitals covering four states in the north and south of the country. Nigeria is a diverse country with important differences between north and south, so there was a strong commitment by stakeholders to address both regions.

Staff Training

Obstetric hemorrhage is, by definition, an emergency that can occur at any time to patients in various wards within a hospital. Hiring and retaining a round-the-clock research staff was not feasible, so it was necessary to train existing staff members to identify patients for the study and enroll them. Before initiation of preintervention data collection, staff trainings were held at each study facility to sensitize the staff to the issue of maternal mortality, review standard management of obstetric hemorrhage, and orient the staff to study data collection forms. The staff was also trained in the use of a blood collection drape for measurement of blood loss for patients enrolled in the study. These trainings occurred at the different study sites and were facilitated by lead staff from UCH and UCSF for both the preintervention and intervention phases. After 3 to 6 months of collecting preintervention data, the staff at the different facilities were trained in the use of the NASG and its integration into the standardized treatment protocol for obstetric hemorrhage. Thereafter, the staff collected data on each case of obstetric hemorrhage in which the NASG was applied. Research team members conducted regular follow-up visits and retrainings at hospitals for new staff members as needed.

Data Collection

Data collection forms included the following information:

- Basic obstetric history
- Details of the labor and delivery

- The cause(s) and initiation of hemorrhage
- Hemorrhage treatment and outcomes, including regular monitoring of vital signs, all blood, fluid, and uterotonics administered, and procedures and surgeries performed to treat the cause of hemorrhage
- NASG side effects
- Maternal and child outcomes

Expansion

Our research team was the first to use the NASG for obstetric hemorrhage in low-resource settings. In addition to collecting data, our research partners gained firsthand experience in treating women with the NASG. Providers had become accustomed to the difficulties of trying to treat women in shock who were slipping away. With the NASG, women in dire condition now became stable and treatable, and the providers and researchers became advocates of the NASG. As the project progressed, emerging results confirmed the physicians' experience. These results were duplicated in a similar study that our team carried out in Egypt with local partners (Miller, Hamza, et al., 2006).

Thus, as the project progressed, the stakeholders' commitment to expansion grew. The second funding cycle included an expansion into northern Nigeria. The maternal mortality rates in northern Nigeria are higher than those in the south, and the conditions are considered more challenging. Some of the facilities that were added later were deemed to have inadequate staffing for rigorous data collection and were not required to do the observational preintervention phase. In the last year of the project, interest by stakeholders in seeing the NASG reach as many patients as possible led the team to pilot the inclusion of several Primary Health Centers (PHCs) in the same catchment areas as the hospitals using the NASG. These PHCs are often the first stop for patients coming from the community. The PHC cases were not included in the study data, but the experience of working with and training them was valuable.

RESULTS AND REACTIONS

Acceptance of the NASG by providers was overwhelming. Doctors and midwives describe the device as a "life saver" (Oshinowo et al., 2007). One nurse described it this way: "It is very, very effective. Especially when there was low blood pressure—blood pressure which could not be recorded. When you apply it, you start to pick [up] the blood pressure" (Liu, 2009). Patients who were

given up for dead by their relatives, regained consciousness and walked away from the hospital a few days later. One woman who gave birth at home arrived at the emergency room bleeding heavily. She had no pulse, no blood pressure, and was pale and cold. Her relatives left her bedside to go outside and grieve her death. The doctors in the hospital had just received the NASG, and they placed it on the woman. Within 2 minutes, her eyelids began to flutter and she began murmuring. The doctors called to her relatives to tell them that she was alive. The relatives returned, elated, and said to her, "You need a new name. From now on you are Ayorunbo—she who has been to heaven and returned."

Another woman who was treated with the NASG had this to say: "I beg the government, both state and federal hospitals, the [NASG] garment should be available. This thing is really saving life. The way women here give birth these days it takes women's lives . . . if this is available many women will not die" (Liu, 2009).

The results of the trial showed enormous promise. Statistically significant reductions were found in blood loss and extreme adverse outcomes, and these results emerged in peer-reviewed publications, where they have been presented in greater detail (Miller, Hamza, et al., 2006; Miller, Ojengbede, et al., 2009; Miller, Turan, et al., 2007).

As a result of this study, the Federal Ministry of Health in Nigeria has approved the NASG for use within Nigeria and is actively seeking funds to get it distributed nationally. The United Nations Population Fund (UNFPA), Pathfinder, and other nongovernmental organizations (NGOs) have expressed interest in using the NASG in national programs. Pathfinder included the NASG as one of the interventions in a large implementation project, Continuum of Care for Postpartum Hemorrhage, to address postpartum hemorrhage in Nigeria and India. Other NGOs have expressed interest in using the device, and local investigators are working with other states that want to implement the NASG.

The study has also been an important catalyst for building local capacity. It has reinforced the proper management of hemorrhage and shock and has given providers a new tool in the face of daunting maternal mortality rates. As one Nigerian doctor said, "the NASG to me is emergency preparedness. Because if you don't have it, you can't use it and you can't salvage life. That's the truth. To me, it should be made available" (Liu, 2009).

The NASG has generated a lot of positive publicity, and media response has been strong. Local and international investigators have been interviewed by

local television and newspapers, and the potential of the NASG has gained a lot of exposure within the region (Ejiogu & Adejokun, 2008; Nigerian Television Association, 2006; Oguntola, 2005; Orji, 2006). However, as important as these research findings and reactions are, of equal importance have been the challenges identified during this project that will need to be addressed when larger scale implementation in Nigeria or another low-resource setting is undertaken.

CHALLENGES

Institutional Capacity

The NASG is a remarkable device. It reduces blood loss, stabilizes vital signs, and prevents women on the brink of death from slipping away. However, it is only a first line of defense and *not a definitive treatment*. Full treatment of obstetric hemorrhage may include uterotonics, suturing, Cesarean section, repair of a ruptured uterus, blood transfusion, or any additional indicated treatments for the condition. In addition, though the NASG allows more time for the woman to seek care, it is critical that the facility have adequate, trained staff to monitor and deliver critical interventions, as well as adequate supplies of oxygen and normal saline for resuscitation, and additional medications and materials for definitive treatment. Finally, the timely availability of blood remains crucial for these patients, although fewer transfusions may be required due to the application of the NASG.

Staff Rotation

Training staff members to use the NASG is not particularly difficult or time consuming. However, as with all critical skills, if there is no repetition or continued use of the NASG, retrainings are required at fairly regular intervals. During the study period, we found it was critical to conduct regular retrainings mainly because the NASG was a new and unfamiliar device in these settings, and new staff members who had rotated in after the initial trainings rarely received a thorough orientation to the use and clinical applications of the NASG without retrainings.

Ultimately, in a national program, a significant part of NASG training will be part of preservice training and become the responsibilities of schools of medicine and midwifery to ensure an early and more structured integration of the NASG into the language and curriculum of healthcare providers. Full competency

comes only with experience, so continued hands-on training in facilities will also be imperative.

Need for Supportive Supervision

Until the NASG is incorporated into preservice training, introduction of the device requires a period of intensive supportive supervision. Providers need feedback and a venue to discuss cases as they integrate the NASG into their practice. Because the NASG is most useful and needed during emergency cases—such as when a bleeding woman arrives with no pulse and no blood pressure—it needs to become completely ingrained in the emergency care routine. The NASG needs to be kept easily accessible, and staff members need to be trained to apply it immediately for a patient in shock. The device can ameliorate common problems such as the difficulty in securing a critical IV line in a woman who has already gone into shock. However, for this to occur, the staff must be trained to immediately apply the NASG before securing a line, which means applying the NASG instinctively as part of treating a patient in shock. This can be best achieved through practice and with intense, supportive supervision in all sites where the NASG has been introduced.

Referral Protocols

To date the NASG has mainly been used in tertiary facilities and a few secondary centers. Most of the facilities have been able to provide the definitive treatment that women may need. However, for the NASG to be employed to save the most women possible, its use should be extended to primary care facilities, which may not have the ability to perform emergency Cesarean sections, give blood transfusions, or provide other definitive treatment.

In order to employ the NASG in these situations it is essential that clear referral protocols be put in place, and *all* higher-level facilities to which a patient might be transferred must be trained in managing patients with the NASG. While the NASG is very easy to place, the greatest risk is premature and inappropriate removal. Staff members at a referral center who are not trained in its use might simply remove it as an unknown foreign object, thus causing the woman to rapidly return to a state of shock.

Our limited experience to date in introducing the NASG at the primary care level is a case in point. In spite of a clear emphasis during trainings that all patients must be transferred to specific higher-level facilities already trained in the use of the NASG, two of the first three referrals were made to a private mission hospital,

which had not been trained in the use of the NASG. These referrals were made because the designated project facilities were on strike. Although in these specific cases the primary care facility staff reported accompanying the woman to the referral facility and supervising the removal of the NASG, these cases illustrate the potential risk of introducing the NASG at the community level when tertiary facilities are not prepared for such patients.

Finally, any system that requires the transfer of a woman in an NASG also requires a system for tracking, cleaning, and returning the NASG to the center from which it came. In an environment where even the transport of a critically ill patient can be challenging, setting up such a system is no small feat.

Care and Maintenance

The NASG is made of neoprene and Velcro. With proper care, a single NASG can be used for up to 40 women. Washing is straightforward and follows the same procedure as other soiled hospital linens: decontamination with diluted bleach solution followed by scrubbing, washing, and hanging to dry. However, neoprene is an unfamiliar material to most hospital cleaning staff. It is bulky and will float, so it needs to be forcibly submerged in water to allow it to soak. In addition, the folding technique—while simple and easy to learn—is very specific; if it is not followed correctly, the NASG may be found in a tangled ball unable to be used with the speed required in an emergency. The issues around care and maintenance can easily be overcome with training, retraining, and supportive supervision. It is important to keep those who will be responsible for the care and maintenance in mind, especially since this may entail training laundry or cleaning staff, a group that is not usually included in large training sessions for healthcare providers. Separate smaller trainings in the local language are key to success with this group.

Community Acceptance

The NASG, for all its life saving properties, is not yet widely known. Therefore, it is not uncommon to have a woman brought back from unconsciousness only to request that the healthcare provider remove the very device that is keeping her stable! Until the NASG becomes more widely known, it is critical that providers educate patients and family members about its lifesaving properties and work to ensure that someone is always on hand to counsel a woman who has regained consciousness to find herself in an unfamiliar device lest she open the segments and lapse into shock again.

Research Versus Implementation

This project began as a research project to test a device with no previous rigorous testing in an obstetric population. As the project evolved, however, local researchers and other stakeholders became advocates for increased expansion and implementation. Faced with high maternal mortality and few strategies to combat it, after physicians saw the effect of the NASG, their goal was to get it to as many providers as possible. Although the funders were ultimately flexible and supportive of this goal, the researchers were challenged by the resulting data and observations from disparate facilities, with imbalanced comparison groups, and struggled to document enough cases to get statistically significant findings that could measure up in the peer-reviewed press. Publication in widely read journals would lead to broader support for research and dissemination as well as acknowledgement by international institutions, such as the World Health Organization, that have the power to implement the device at the global level. However, implementing this research in resource-poor settings with few other tools to reduce maternal mortality meant that saving lives took precedence over collecting complete and accurate data.

LESSONS LEARNED

The NASG is certainly a useful tool in combating maternal mortality in Nigeria. Any wide-scale implementation of its use, however, will have a number of challenges to overcome. We have presented here a few of the most salient challenges, noted by our team in the stepwise expansion from high-level teaching facilities accustomed to carrying out research to state-run secondary and tertiary facilities in lower-resource settings.

Primary among the important considerations for large-scale implementation is the caution that the NASG, as good as it may be, is no substitute for definitive treatment. Treatment requires facilities with trained personnel and necessary supplies. If a woman is unable to get medications, surgery, or blood after she makes it to a facility, the NASG is limited in how long it can keep her alive. When using an untested device such as this in a research model, it is important to establish clear, rigorous standards for facilities. In low-resource settings, research will often be given a lower priority than the immediate need to save lives. Assessing the capacity of facilities to participate in research, creating clear expectations for participating facilities, and simplifying data collection methods is essential.

Research in emergency settings requires a large staff or extensive training and retraining of facility staff, especially as staff rotate in and out of facilities. Intensive supportive supervision is also critical to assuring protocol compliance as staff members master new skills and integrate new protocols into their standard care.

Maternal mortality is a significant problem in Nigeria and throughout sub-Saharan Africa. Any solution must involve a multifaceted approach, and the NASG is one more important tool to put into the hands of providers.

Discussion Questions

1. List some requirements for the development and use of medical technology for labor and delivery in low-resource settings.
2. Explain the reasons for the rapid uptake of the NASG throughout different health settings and geographical regions of Nigeria.
3. What are the medical limitations of the NASG, and what are the other resources needed for it to be effective? How does this impact its scalability?
4. The use of medical technology is limited by human resources, both with regard to numbers of people and their professional capacity. Outline the human resource requirements for successful implementation of the NASG as presented in this chapter.
5. Discuss the interaction of the empirical demands of scientific research, with the resource needs of poor communities using the NASG as an example. Explore how the needs of both the research community and the client community can be met concurrently.

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