



# **Expanded Retrospective:** Non-Pneumatic Anti-Shock Garment

This retrospective was developed to inform Discerning Demand: A Guide to Scale-Driven Product Development and Introduction, a publication developed by the Center for Innovation and Impact, USAID that explores how global health practitioners (including funders, investors, innovators, implementing partners, etc) can better account for actual demand of new products. This retrospective is an in-depth historical analysis of how demand for this product was understood by different stakeholders suppoting its development and introduction. The insights generated from this retrospective informed the recommendations in the full report.





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### Expanded Retrospective: Non-Pneumatic Anti-Shock Garment (NASG)

#### **1. Introduction**

#### 1.1. Product Summary

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Each year, post-partum hemorrhage (PPH) is the leading cause of maternal mortality worldwide, impacting 14 million during childbirth and resulting in about 70,000 maternal deaths globally.<sup>1</sup> Current PPH interventions often include antenatal misoprostol distribution for prevention of PPH and use of uterotonics in the third stage of labor, among others.<sup>2</sup> While these interventions are successful at controlling the majority of PPH events, in the case of severe PPH, further steps may need to be taken to treat hypovolemic shock and stop severe bleeding. The non-pneumatic anti-shock garment (NASG) is a lightweight medical device designed to stabilize women during these instances of severe PPH until appropriate care is available (usually in the form of a blood transfusion or surgery).<sup>3</sup> It works by reducing blood flow to the uterus and can prolong life up to 48 hours, providing the woman with significantly more time to get to a facility that can provide comprehensive care. The garment is washable and reusable up to approximately 150 times and does not require extensive training to use.<sup>4</sup> NASG can be purchased for between \$40 and \$75 per unit, depending on order quantity.

#### 1.2. Fast Facts

Fast Fac (Note: s	ts sources noted in retrospectives)	Non-pneumatic anti-shock garment (NASG)
Ş	Health Area	Post-partum hemorrhage (PPH)
C	Market Archetype	Niche product, crowded PPH market
5]3	CII Global Health Innovation Index	Incremental
5	Expected Buyers/Procurers	Limited gov't procurement (e.g., Ethiopia): some private sector procurement
٨	Funders	Major donors: CHAI, UNICEF, UNFPA; studies funded by USAID PRH, MacArthur Fdm, BMGF, Laerdal Fdm.
$\langle \rangle$	Countries	Scale-up strongest in Africa; 4-5 countries with significant procurement; small quantities procured in 90+ countries
P	Manufacturers	LifeWrap International in China (~80-85% of market), VISSCO in India
$\succ$	Intended Delivery Setting	Primarily found in public & private-sector hospitals, some health centers & remote maternal care sites; distributed through local/regional networks
0	Cost	Product cost is ~\$40-75 incl. shipping (varies, can be high for small shipments)
	Uptake	Low, in peak years can be ~10-15K units per year; historically has been lower

Fast fact sources: Innovation Index,<sup>5</sup> Expected Payer,<sup>6</sup> Countries,<sup>7</sup> Cost,<sup>8</sup> Uptake.<sup>9</sup>

<sup>1</sup> WHO Post-Partum Hemorrhage (PPH) Summit (2022). Current Project Brief.

<sup>2</sup> World Health Organization (2018). WHO Recommendations: Uterotonics for the Prevention of Post-Partum Haemorrhage.

<sup>3</sup> UNICEF (2020). Non-pneumatic Anti-Shock Garment: Product Profile.

<sup>4</sup> Clinton Health Access Initiative Annual Report (2015).

<sup>5</sup> USAID Center for Innovation & Impact. Global Health Innovation Index – A tool for identifying the most promising Global Health Innovations,

<sup>6</sup> UNICEF (2020). Non-pneumatic Anti-Shock Garment: Product Profile.

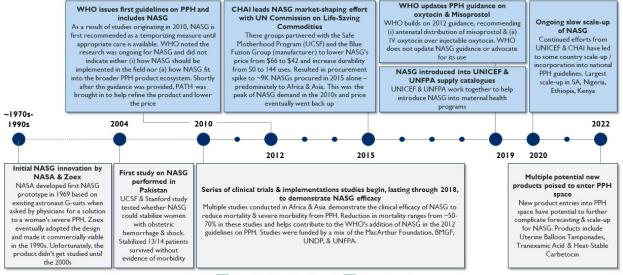
<sup>7</sup> Ibid; Based on conversation with VIA Global Health (NASG Distributor).

<sup>8</sup> Based on conversations with Clinton Health Access Initiative, VIA Global Health, and Blue Fuzion Group (LifeWrap International).

<sup>9</sup> UNICEF (2020). Non-pneumatic Anti-Shock Garment: Product Profile; Based on conversations with Blue Fuzion Group (LifeWrap International).

#### 2. Demand Story

#### 2.1. Product Development Timeline



Key: Regulatory/Payer/Supplier events Research events

#### 2.2. Development

For women experiencing severe PPH in rural LMIC contexts, mortality and severe morbidity is a matter of how soon they can reach appropriate care. The NASG was invented as a first aid device to treat hypovolemic shock and stabilize a woman experiencing PPH until she can be transported to a higher level of appropriate care. NASG works by moving blood away from the uterus and can extend life for up to 48 hours.<sup>10</sup> The design originated from a NASA G-suit and was picked up commercially by ZOEX in response to physician requests in the 1990s.<sup>11</sup> The garment eventually caught the eye of Dr. Suellen Miller, a midwife and professor at the University of California San Francisco (UCSF) School of Medicine and the founder of the UCSF Safe Motherhood Program. Over a decade after the product's initial patent in 1992,<sup>12</sup> Dr. Miller helped organize the first study on the NASG in 2004 in Pakistan.<sup>13</sup>

#### 2.3. Research

The Pakistan study showed promise and helped generate support for NASG in the global health community. Thirteen of fourteen women in that study survived PPH without any evidence of prolonged morbidity.<sup>14</sup> This inspired confidence in the NASG's ability to be a life-saving medical device in LMICs. Further studies ensued, conducted mostly by Dr. Miller and her colleagues at the UCSF Safe Motherhood Program. A pre/post analysis on the first of these studies in referral facilities in Nigeria and Egypt showed a reduction in mortality and severe morbidity from 20% to 6% in women with more than 60 minutes between the start of hemorrhage and study admission.<sup>15</sup> In 2012, the WHO included NASG in its guidelines on PPH treatment.<sup>16</sup> The WHO's recommendation listed NASG as a temporizing measure until substantive care is available, noting the recommendation as weak but that further studies were ongoing. This catalyzed additional studies, which demonstrated a reduction of severe PPH-related mortality ranging from 53% to 69% across multiple sites.<sup>17</sup> Each study noted that NASG was not, by itself, a life-saving product. It needed to be paired with further treatment (typically a blood transfusion or surgery) in a referral facility. Despite these additional studies, the WHO has not updated its PPH guidelines for NASG.

<sup>10</sup> UNICEF (2020). Non-pneumatic Anti-Shock Garment: Product Profile.

<sup>11</sup> Health & Medicine (2016). Pressure Garments Save New Mothers' Lives.

<sup>12</sup> NASA (1996). Anti-Shock Garment.

<sup>13</sup> Brees, et al (2004). <u>A non-inflatable anti-shock garment for obstetric hemorrhage</u>.

<sup>14</sup> Ibid.

<sup>15</sup> Turan, et al (2011). Positive Effects of the Non-pneumatic Anti-shock Garment on Delays in Accessing Care for Postpartum and Postabortion Hemorrhage in Egypt and Nigeria.

<sup>16</sup> World Health Organization (2012). WHO Guidelines for the prevention and treatment of postpartum hemorrhage.

<sup>17</sup> UNICEF (2020). Non-pneumatic Anti-Shock Garment: Product Profile.

#### 2.4. Challenges Emerged

Although the NASG demonstrated efficacy, it was still often perceived as too expensive relative to other PPH interventions that have existed in the market for decades, notably misoprostol and oxytocin.<sup>18</sup> These products have been widely used in HICs for prevention of PPH, and also treatment in case of oxytocin. They were heavily promoted as part of a package of essential supplies by the UN Commission on Life Saving Commodities (UNCoLSC) in 2012.<sup>19</sup> CHAI, recognizing the unique role of the NASG as a stabilizing tool, leveraged its role supporting the UNCoLSC to spur interest in scaling NASG, chiefly through market shaping interventions. In 2015, CHAI partnered with the UCSF Safe Motherhood Program and the Blue Fuzion Group (NASG manufacturer) to design a volume guarantee. Together, they successfully lowered the price from \$66 to \$42 per unit and increased the product's durability about three ties.<sup>20</sup> The volume guarantee was accompanied by donor support for an integrated maternal health program led by CHAI that included training and mentor ship for traditional and skilled birth attendants, referral system solutions, supply chain support to ensure availability of uterotonics, and community-based data system strengthening.<sup>21</sup> Procurement spiked in 2015 as a result of this market shaping but volumes decreased in the following years. Today's price remains around the \$40 to \$75 range, depending on order volumes. This price does not account for distribution, which can double or triple the landed cost, or the added service costs of NASG, such as cleaning the product after use and returning it to the communities it came from.<sup>22</sup>

NASG has struggled to generate the donor and country buy-in needed for scale-up due to three primary challenges with funding, conveying its relative value proposition, and functioning within the constraints of weak health systems.

- Limited funding has long been an issue for maternal health products, in contrast to other products with global donor support like HIV, TB, and malaria. The NASG story is no different. With what little maternal health funding there is from global donors, the focus for PPH products has often been on commodities for prevention and treatment, not devices. As a result, NASG funding has historically been sporadic and came from a variety of sources including CHAI, UNICEF, UNFPA, country and regional governments, and private sector providers. Without consolidated market monitoring, it has been hard to track NASG market dynamics, stimulate and aggregate demand, and track total procurement to understand market saturation.
- NASG has a more complex value proposition for payers relative to other PPH commodities, driven by cost and perceived utility. Despite being a device designed to complement other PPH interventions, the NASG has commonly been compared to other interventions designed for PPH, including oxytocin, misoprostol, and the uterine balloon tamponade (recommended by the WHO in 2021 to treat PPH from uterine atony).<sup>23</sup> While the NASG has an achievable cost per use of under \$1,<sup>24</sup> the initial investment of \$40 to \$75 per garment has deterred uptake.<sup>25</sup> Perhaps more importantly, the niche use case for NASG is to temporarily stabilize, not treat, PPH until appropriate care is reached. In contrast, other PPH commodities can be used to prevent and treat PPH and are applicable in a wider variety of health settings, for example, self-administration of misoprostol by women when giving birth outside a health facility or without skilled health personnel.<sup>26</sup> The NASG's relatively high initial investment cost and limited use case has made its value proposition harder to convey. This has limited both advocacy and funding to support scaled rollout. This is compounded by the limited available data on PPH needs overall, current use of available products, and NASG usage.
- NASG's success has been perceived as contingent upon multiple health system factors. Assuming NASG can be distributed across maternal health service points in remote areas of the country where it is most useful, the treatment pathway also requires (i) awareness of the correct referral networks, (ii) access to transportation to facilitate that referral, and (iii) capacity to treat severe PPH at the referral center, for example, Comprehensive Emergency Obstetric

<sup>18</sup> For a recent overview of current solutions for PPH please see Table 1 in: <u>Tran NT, Schulte-Hillen C, Bar-Zeev S, et al. How to use heat-stable carbetocin and</u> <u>tranexamic acid for the prevention and treatment of postpartum haemorrhage in low-resource settings. BMJ Global Health 2022;7:e008913. doi:10.1136/ bm-jgh-2022-008913.</u>

<sup>19</sup> UNFPA (2012). UN Commission on Life-Savings Commodities for Women & Children, Commissioner's Report.

<sup>20</sup> Clinton Health Access Initiative Annual Report (2015).

<sup>21</sup> Sloan, N.L., Storey, A., Fasawe, O. et al. Advancing Survival in Nigeria: A Pre-post Evaluation of an Integrated Maternal and Neonatal Health Program. Matern Child Health J 22, 986–997 (2018).

<sup>22</sup> UNICEF (2020). Non-pneumatic Anti-Shock Garment: Product Profile.

<sup>23 &</sup>lt;u>WHO 2021</u>

<sup>24</sup> Lawrie, et al (2019). A systematic review of the cost effectiveness of uterotonic agents for the prevention of postpartum hemorrhage; Pronyk, et al (2016). The UN Commission on Life Saving Commodities 3 years on: global progress update and results. of a multicountry assessment; Sutherland et al. (2013) Use of the Non-Pneumatic Anti-Shock Garment (NASG) for Life-Threatening Obstetric Hemorrhage: A Cost-Effectiveness Analysis in Egypt and Nigeria.

<sup>25</sup> UNICEF (2020). Non-pneumatic Anti-Shock Garment: Product Profile

<sup>26</sup> World Health Organization (2020) WHO recommendation on Advance misoprostol distribution to pregnant women for prevention of postpartum haemorrhage.

and Newborn Care Services provision and access to blood for transfusions. The reality is that these elements are not consistently available in many LMICs, and when they are available, women may be able to reach appropriate PPH care before requiring stabilization with a NASG.

#### 2.5. Retrospective

NASG adoption has been slower than anticipated by those who supported its development and introduction. On the one hand, where NASGs have been piloted and adopted such as in Ethiopia and Nigeria, countries have seen significant reductions in mortality from hemorrhagic shock.<sup>27</sup> As of 2022, CHAI, UNICEF, and UNFPA are working together to support countries in adopting NASG into their maternal health programs.<sup>28</sup> On the other hand, wider NASG rollout remains a challenge. Its value proposition seems to be fundamentally misunderstood as it is seen in the context of other changes, including shifts of births from the home to health facilities<sup>29</sup> and access to other PPH commodities like heat-stable carbetocin or tranexamic acid.<sup>30</sup>

#### 3. Learnings

#### Three key learnings from the demand story:

#### 1. Underemphasis on a payer-informed go-to-market strategy

Recall the challenge: NASG innovators invested significant resources and time in demonstrating NASG's efficacy, and likely undervalued the development of a clear commercial strategy that caters to payers, buyers, and local decision-makers. Without support early on for a go-to-market strategy that ensures it is framed and perceived as intended by target audiences, NASG scale-up has been slower than expected and sporadically funded.

Forward-looking learning: Innovators need dedicated support to develop a clear go-to-market strategy centered on specific payers. Products with niche use cases, like NASG, need to clearly articulate their value and target their strategy to payers, buyers, and in-country decision-makers to generate the awareness, advocacy, and funding necessary for adoption.

#### 2. The NASG's value proposition has not been well understood or widely accepted

Recall the challenge: NASG was introduced into a PPH market with multiple other commodities. Compared to oxytocin and misoprostol, which are part of first-line treatment protocols, NASG has a narrower use case as a first aid device used for stabilization. Its relatively high initial investment cost combined with the reliance on and continuous need for other PPH interventions has deterred buyers. Despite its framing as a complementary tool, its value proposition has not been widely accepted. Fundamentally, the NASG should not be compared to uterotonics but rather to the transport options (or lack thereof) women have to get to the care they need sooner. The NASG application makes it more likely that they will survive the time they have either in a remote setting or a facility. By contrast, uterotonics on their own cannot make that difference. Forward-looking learning: NASG illustrates the need for new products to demonstrate a clear value proposition to decision-makers relative to preferred standards of care and in the context of the health system. Ensuring it is appropriately perceived is especially important when products are first aid or interim solutions.

#### 3. Limited funding for health system interventions to accompany product rollout

Recall the challenge: Donors supported both a volume guarantee to lower the price and improve the durability of the NASG as well as health system strengthening interventions to integrate the product (for example, trainings, mentorship, ambulance services, capacity at referral centers). Interest in scale-up has been slower than expected among potential payers.

Forward-looking learning: The inertia associated with limited support for NASG scale-up reflects a wider challenge in markets for maternal health products: Advocacy to-date has produced impact that has not been sustained and uptake of commodities has been sub par. Expanded access for new and existing maternal health commodities

<sup>27 &</sup>lt;u>Clinton Health Access Initiative Annual Report (2015)</u>.

<sup>28</sup> UNICEF (2020). Non-pneumatic Anti-Shock Garment: Product Profile.

<sup>29</sup> The Demographic and Health Surveys Program (2011). Levels and Trends in the Use of Maternal health Services in Developing Countries.

<sup>30</sup> PPH Community of Practice Annual Meeting (2020). Updated WHO PPH Recommendations.

would benefit from a coalition approach that would harness resources and convening power to drive change. For example, a diverse maternal health supplies coalition that includes governments, donors, advocates, and product developers could generate market intelligence for new products, synthesize and provide clarity on the role of different interventions, support resource mobilization for countries, and address market challenges.



