Non-pneumatic Anti-shock Garment: Product Profile

UNICEF Supply Division

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1. Summary

- The non-pneumatic anti-shock garment (NASG) is an innovative life-saving medical device used to stabilize women during obstetric haemorrhage. Designated by the World Health Organization (WHO) for use as a temporizing measure, it can stabilize a patient sufficiently for transport to an appropriate health care facility, as part of a “continuum of care”.
- In many resource-limited settings, a large number of births still occur at home, often in locations at some distance from any appropriate medical facility. In instances of postpartum haemorrhage (PPH), a NASG can effectively contribute to reducing maternal mortality in situations where patients experience delays in reaching appropriately resourced referral hospitals, or where they experience delays in receiving the necessary treatment and care after arriving at a referral hospital.
- WHO included the NASG in its global recommendations for the prevention and treatment of PPH. However, despite the product’s adoption, its uptake has been very limited, and it is not always available in countries with high maternal mortality rates from PPH.
- Some of the main challenges faced by countries in scaling up the use of NASGs is product information and awareness, in addition to its relatively high cost-price. Although some projects and studies document best practices and lessons in NASG implementation, there has not yet been any comprehensive programmatic or technical guidance issued that includes recommended criteria or conditions to guide countries in introducing the NASG, and in which settings.
- UNICEF introduced the NASG into its supply catalogue in 2019 and will issue a technical bulletin in 2020. UNICEF has been working jointly with United Nations Population Fund (UNFPA) to support countries to introduce the NASG into their maternal health programmes targeting PPH. UNICEF will also support health teams to document the findings of any trials and to translate them into product guidance that can be used to support scaling up activities.

2. General Brief and Background

Postpartum haemorrhage is heavy bleeding after birth. WHO defines PPH as the loss of 500 ml of blood, or more, within 24 hours after birth.¹ It affects about five per cent of all women giving birth around the world, and severe PPH is one of the leading causes of maternal mortality. The severe loss of blood from PPH, postnatal infections, high blood pressure (pre-eclampsia and eclampsia), complications from delivery, and unsafe abortions account for approximately 75 per cent of all maternal deaths globally.² Most maternal deaths occur in resource-limited settings in rural and urban poor communities,³ and more than half of these deaths take place in fragile and humanitarian contexts located in sub-Saharan Africa (SSA) and South Asia. Most of the maternal deaths can be prevented with well-known health-care interventions and access to available antenatal, intrapartum, and postnatal health care, as well as with the attendance of skilled care during childbirth. Still, approximately 830 women die a day from preventable causes related to pregnancy and childbirth, representing 303,000 a year, of which 99 per cent occur in low- and middle-income countries (ICCs and ICs). Most PPH related deaths could be prevented through proper healthcare management to prevent complications.⁴ The timely diagnosis and treatment of anaemia and pre-eclampsia/eclampsia (seizures in pregnant women related to high blood pressure) and the administration of a uterotonic (agents used to induce contraction or greater tonicity of the uterus) immediately after the birth help to prevent PPH.⁵ PPH affects approximately seven million women annually, and is especially life-threatening in settings where women may be hours away from comprehensive emergency obstetric care. Consequently,

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² Ibid.
PPH continues to place a disproportionally large burden on the world’s most disadvantaged mothers, newborns, and children.\textsuperscript{6} In addition to the suffering and loss of their mother, infants whose mothers die in childbirth have a 46-times higher chance of dying within their first 42 days of life compared to those whose mothers survive (Figure 1).\textsuperscript{7}

**Figure 1 Probability of Child’s Survival with Mother Alive and Mother Deceased**

Efforts to improve maternal mortality by improving PPH prevention and care are necessary to help achieve the third Sustainable Development Goal (SDG 3), and specifically its target 3.1 “to reduce the global maternal mortality ratio to less than 70 per 100,000 live births by 2030”.\textsuperscript{8}

In addition to the above mentioned critical interventions in PPH prevention, a key determinant of achieving this target, as well as target 3.2, which is the prevention of newborn mortality, is to ensure that an increased proportion of births are delivered by skilled birth attendants, as well as a reduction in the number of homes births.\textsuperscript{9}

The NASG is a life-saving device used to stabilize women with severe PPH during delays in receiving definitive care. The NASG is a lightweight, washable, and reusable neoprene compression device that looks like part of a wetsuit cut into segments (Figure 2). It can reduce the blood flow to the uterus and treat shock (hypovolemia) resulting from the sudden and significant loss of blood before, during, or after childbirth, until a woman can obtain definitive treatment, such as a blood transfusion or surgery.\textsuperscript{10}

**Figure 2 Non-pneumatic Anti-shock Garment - Closed on a model (left) and an open graphic representation (right)**


Evidence from rigorously conducted clinical trials suggests that a NASG can reduce maternal mortality and severe morbidity from haemorrhage by an average of 63 per cent across a number of different populations, countries, and levels of rural and urban health care (Table 1). The sooner a NASG is applied, the more likely a woman can survive delays in receiving appropriate, qualified care. 

Table 1 Reported Maternal Mortality Reduction Rates for Obstetric Haemorrhage from NASG Clinical Trials and Implementation Studies

<table>
<thead>
<tr>
<th>Country</th>
<th>% reduction in mortality</th>
</tr>
</thead>
<tbody>
<tr>
<td>Egypt</td>
<td>69 %</td>
</tr>
<tr>
<td>India</td>
<td>53 %</td>
</tr>
<tr>
<td>Nigeria</td>
<td>68 %</td>
</tr>
<tr>
<td>Tanzania</td>
<td>67 %</td>
</tr>
<tr>
<td>Zambia and Zimbabwe</td>
<td>54 %</td>
</tr>
</tbody>
</table>

Source: Several studies

3. Innovation

A company called ZOEX developed the first commercially available NASG in the early 1990’s. It was based on the United States (US) National Aeronautics and Space Administration’s (NASA) anti-gravity suit, or “G-suit”, technology developed by their Ames Research Center. The G-suit was an inflatable compression garment designed to counter the gravity’s pull on blood during moments of extreme acceleration during lift off, or when the body is subject to the Earth’s gravitational pull, which pushes blood to the lower half of the body causing astronauts to experience dizziness and fainting. The G-suit pushes blood back towards the upper body. Ames Research Center first modified the G-suit and adapted it to treat a patient suffering severe PPH in California in 1969. The treated woman gained a full recovery. This led NASA to conduct further research into the suit to understand the physiological effects it had on the lower body.

In 1989, NASA published a technical memorandum detailing the suits application of positive pressure to the lower body. ZOEX adapted the garment by applying lower but sufficient amounts of pressure using a non-inflatable elastic pressure garment. Compared to the earlier versions of the garment, the ZOEX garment was simpler in its design, and could be applied more quickly and easily, in addition to being less expensive, lighter, and far more flexible, making it easier for a person to use for a longer period of time. However, the NASG never gained traction in any pre-hospital emergency care settings, and fell into disuse. In 2004, the first series of casestudies in using the NASG as a primary PPH intervention in developing settings published encouraging results. In one facility in Pakistan, it showed that out of the 14 obstetric haemorrhage cases

17 National Aeronautics and Space Administration, Pressure Garments Save New Mothers’ Lives, NASA Spinoff, 2016, p. 34.
18 Ibid.
that were clinically managed using the NASG, 13 mothers survived with no morbidities. These encouraging findings led to a series of pilot and clinical trials on the NASG’s application for women experiencing obstetric haemorrhage in low-resource settings (see 2. General Brief and Background), in order to gather definitive evidence for WHO to include the NASG in its guidelines.

4. Current Market Situation

Despite WHO including the NASG in its global PPH recommendations and 2012 guidelines, its adoption and uptake has been limited. Some of the main challenges for LICs and MICs in scaling up their use of this product is not being aware that the product exists, its relatively high cost (see 4.3 Pricing), in addition to it not being supported by any donor funding initiatives to promote its adoption.

The NASG is not under a patent. There are currently globally only three manufacturers: LifeWrap International (China), Vissco (India), and ZOEX (United States). LifeWrap International is currently the main manufacturer of the NASG, supplying an estimated 80-85 per cent of the market. Since 2015, the NASG has been used in 36 countries (Figure 3).23

Figure 3 Countries Using or Having Piloted NASG by 2019

Source: UNICEF Supply Division

Most NASG procurement has been driven by NGOs and professional associations driving comprehensive programmes to address maternal mortality, which include discouraging home births, training birth attendants, and improving access to effective drugs, trained personnel, and equipment in LICs and MICs. In some of these countries, programmes have been able to integrate the NASG into their national health programmes. Ethiopia and Nigeria were some of the first countries to adopt the NASG. In Ethiopia, those health facilities that introduced the NASG experienced a reduction of 80 per cent in maternal deaths from haemorrhagic shock from 2013-2015.24

4.1 Demand

There has to date been no comprehensive assessment of the market volume or revenues from NASG sales. However, UNICEF estimates that to date there have been an estimated 16,500 units sold globally over the three years from 2015 to 2018. United Nations (UN) aid agencies have procured approximately 23 per cent of them, which UNICEF estimates represent 3,800 units (Figure 4, next page). UNFPA has had supply arrangements in place with five NASG suppliers since

24 Clinton Health Access Initiative, Annual Report 2015, CHAI, Boston, 2016, , p. 11.
2015, over which time they procured approximately 3,500 units, representing an estimated 21 per cent of total global NASG sales. UNICEF, which has done some ad-hoc procurement of NASGs since 2017, has procured to date only 300 NASGs representing just two per cent of total NASG sales globally. Based on an estimated price range of USD 70.00 to 75.00 per NASG, UNICEF estimates conservatively revenues from NASG sales could represent between USD 1.1 to 1.2 million over this period.

Figure 4 UN Estimated Share of Global NASG Procurement 2015-2018

Source: UNFPA, UNICEF, Blue Fuzion Group, VISSCO

Figure 5 Global NASG Demand 2015-2018

Source: UNICEF Supply Division

The NASG is included in the UN interagency list of priority medical devices for essential interventions for reproductive, maternal, newborn and child health. Since 2015, UNICEF estimates the total demand for NASGs was on behalf of approximately 30 countries. Eight of them are LICs and 19 are MICs, of which most are lower MICs.

The data from the two main manufacturers shows that approximately 60 per cent of the total demand occurred in 2015 after the Clinton Health Access Initiative (CHAI) and partners had engaged in government advocacy and programme planning in the countries that bought the majority of the NASGs to drive demand, followed by a price reduction (see 4.3 Pricing).

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Over the subsequent three years from 2016-2018, the annual demand for NASG fluctuated between 2,000 and 2,500 units (Figure 5, previous page). Approximately 50 per cent of the total global demand to date has come from countries in Africa (Figure 6, previous page).

UNICEF illustrates the potential number of cases requiring the use of the NASG based on breakdown analysis of global births against WHO’s recommendations for the treatment and prevention of PPH (Figure 7). The World Bank estimates that there are approximately 140 million global births a year. UNICEF assumes a global PPH incidence rate of five per cent, representing an estimated seven million women annually experiencing PPH. Of these women experiencing PPH, an estimated 2.7 million suffer from severe PPH - heavy bleeding that requires further treatment and the referral to a facility with comprehensive emergency obstetric care (CEmOC). Approximately 2.4 million of these women give birth in LICs and MICs. For the purposes of this note, UNICEF assumes that all women with severe PPH in LICs and MICs may be experiencing delays in either reaching care or receiving timely treatment and would thus benefit from the NASG, representing approximately 1.7 per cent of total global births.

**Figure 7 UNICEF Estimated Total Addressable Use-case Potential for NASG**

<table>
<thead>
<tr>
<th>Description</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Global Births</td>
<td>140,343,910</td>
</tr>
<tr>
<td>...of which births w / PPH</td>
<td>7,017,496 = approx. 5% of total global births</td>
</tr>
<tr>
<td>...of which births w / severe PPH</td>
<td>2,665,649 = approximately 38% of birth w / PPH</td>
</tr>
<tr>
<td>...of which births w / severe PPH in LICs and MICs</td>
<td>2,411,164 = 90% of birth w / severe PPH in need of referral and further care...</td>
</tr>
<tr>
<td>...which may benefit from a NASG</td>
<td>...all of which could potentially benefit from access to a NASG during pregnancy as a lifesaving measure</td>
</tr>
</tbody>
</table>

Source: UNICEF Supply Division

The demand forecast for NASG procurement through UNICEF is difficult to estimate with global procurement numbers being so low. However, UNICEF anticipates that the demand for NASG could increase as countries continue in their efforts to adopt WHO PPH prevention and treatment guidelines as part of their national health systems. However, although projects and studies document best practices and lessons in NASG use, there is not yet any comprehensive programmatic or technical guidance issued with recommended criteria or conditions to guide where and how NASGs should be introduced. UNICEF estimates the potential global demand for NASGs based on the number of cases that could benefit from the device, subject to proper programme design, use, re-use, care, and maintenance guidelines, could provisionally reach 60,000 units a year, but this would be subject to programmatic and technical guidance, approaches, and funding. UNICEF’s estimated potential demand is approximately thirty-times the current annual demand levels, based on potentially treating 2.4 million women suffering from PPH in resource-limited settings in LICs and MICs every year (Figure 5).

### 4.2 Supply

The NASG is produced in two sizes, both of which are adjustable for height. The medium / large garment size accommodates many medium to very large women and is used throughout Africa. The medium / small sized garment provides compression for women <100 pounds (45.5 kg) and shorter than 5’ ft (1.52 m) and is used more in Southeast Asia. This smaller size can also be used on taller up to 5’5” ft (1.67 m), but thin women.

Out of the three manufacturers in the market, only two are presently known to be actively producing NASGs: LifeWrap International, a side unit of the Blue Fuision group located in Hong Kong (China), and VISSCO in India. UNFPA currently holds five long-term arrangements (LTAs) valid through to November 2021 that it awarded to five suppliers that source supply

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from the two active NASG manufacturers (Table 2). UNICEF currently has one LTA, which it awarded to Medical Export Group (Netherlands) for supply valid until 2021. UNICEF’s LTA is a direct order LTA issued on the back of UNFPA’s LTA awarded to Medical Export Group, and as such its validity is contingent and wholly dependent on UNFPA’s LTA with this supplier as well as its terms and conditions.

Table 2 NASG LTAs with UNFPA and UNICEF

<table>
<thead>
<tr>
<th>Supplier</th>
<th>Expiration</th>
<th>Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Supplier A (Germany)</td>
<td>30.11.2021</td>
<td>LifeWrap International (China)</td>
</tr>
<tr>
<td>2 Supplier B (Netherlands)</td>
<td>30.11.2021</td>
<td>VISSCO (India)</td>
</tr>
<tr>
<td>3 Supplier C (Netherlands)</td>
<td>30.11.2021</td>
<td>LifeWrap International (China)</td>
</tr>
<tr>
<td>4 Supplier D (China)</td>
<td>30.11.2021</td>
<td>LifeWrap International (China)</td>
</tr>
<tr>
<td>5 Supplier E (Netherlands)</td>
<td>30.11.2021</td>
<td>LifeWrap International (China)</td>
</tr>
</tbody>
</table>

UNFPA

<table>
<thead>
<tr>
<th>Supplier</th>
<th>Expiration</th>
<th>Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Supplier C (Netherlands)</td>
<td>30.11.2021</td>
<td>LifeWrap International (China)</td>
</tr>
</tbody>
</table>

Source: UNICEF, UNFPA

4.3 Pricing

UNICEF provides an overview of the spread of spot pricing for NASGs from different suppliers since 2006, which has ranged from as high as USD 365.00 to as low as USD 41.55 (Figure 8). This price of USD 41.55 (rounded to USD 42.00) was achieved with the support of the Norwegian Government and the efforts of CHAI, the Safe Motherhood Program at the University of California, San Francisco (UCSF), the UN Commission on Life-Saving Commodities for Women and Children (the UN Commission), together with the Blue Fuzion Group, a company specialized in supply chain and quality assurance management, and the owner of the LifeWrap™ NASG. It was an initiative to expand access, and to encourage and facilitate LICs and MICs to adopt the NASG. The Blue Fuzion Group agreed to reduce the NASG’s price in 2015 from USD 65.80 to USD 41.55 for public sector procurement in 51 countries. The negotiated pricing was based on a volume guarantee-based price reduction agreement with the supplier in return for a 25,000 unit purchase commitment.

Currently, UN agency supplier agreements have a NASG price range from USD 56.77 per unit to USD 145.00, depending on the supplier, even though most suppliers source their NASGs from the same manufacturer, representing an estimated 80-85 per cent of global supply.

Figure 8 NASG Indicative Price Trend 2007-2018

Source: UNICEF Supply Division

29 The Blue Fusion Group, About Us, BFG, Hong Kong, 2019.
Some of the price differences are due to the different incoterms applied to supplier agreements.\textsuperscript{31} Some prices are based on Ex Works (EXW), in which the seller makes the goods available, suitably packaged, at a specified place, and the buyer undertakes all loading and freight export procedures for its onward shipment and covers all costs. UNICEF’s LTA pricing is based on Free Carrier (FCA) incoterms, whereby the seller arranges pre-carriage to a named place of delivery, and as such, this is reflected in the price depending on the destination, which is often at a higher cost than EXW. However, it does not account for why EXW prices can be 2.5 times the prices of FCA, which is one of the lowest prices listed.

Even though generally the unit cost price of a NASG has gone down over the past seven years, the landed cost of the product still remains high, partly due to the price from the supplier, partly due to the costs of shipping a light weight but bulky device, which can, depending on the destination, exceed the cost of purchasing the device itself. This is particularly true in general of small size of orders. Programme partners, suppliers, and manufacturers have been working on solutions to possibly improve the affordability of small orders in programme countries, with some suggestions of regional stocks to local manufacturing. However, these discussions have yet to conclude into any firm commitments.

Several studies have evaluated the NASG’s cost-efficiency in terms of cost per disability adjusted life year (DALY) averted. WHO considers one DALY to be the equivalent of one lost year of healthy life.\textsuperscript{32} Cost per DALYs can be used to measure and assess cost-effectiveness and the overall burden of disease as a means to compare overall health and life expectancy in different contexts.\textsuperscript{33} In Egypt, the application of the NASG on 1,000 women in severe shock resulted in a decrease in mortality and morbidity averting 357 DALYs and a net savings of USD 9,489.00, primarily due to a reduction in the use of blood transfusions. In Nigeria, the same intervention resulted in avert 2,063 DALYs with a cost of USD 3.13 per DALY.\textsuperscript{34} These results exceeded WHO’s standard for devices being defined as very cost-effective, which WHO’s Commission on Macroeconomics and Health defines as interventions that gain each year of healthy life (DALY averted) at a cost less than gross domestic product (GDP) per capita.\textsuperscript{35} Cost-effective interventions are defined by WHO as those that have a ratio of less than three times GDP.

5. Issues and Challenges

- UNICEF and UNFPA assume that a NASG can be re-used for up to an estimated 40 times. An effort by CHAI, the Safe Motherhood Program of UCSF, the UN Commission, and Blue Fuzion, with the support of the Norwegian Government, undertook product testing and development, and were able to extend the product’s life span and durability from an initially estimated 40 uses to up to 144 uses, representing approximately a 350 per cent increase to this number. To enable health authorities to re-use the NASG, any programme design needs to ensure that it addresses cultural, logistical, managerial, and organizational challenges in accordance to the context and communities in which the NASG is placed. There is currently no established approach, method, or studies that have accurately tracked or evaluated how the NASG is used, or the number of times the NASG is re-used in locations where they have been deployed; or how they are being cleaned and returned to their emplacement. As such, it is difficult to assess the full scope of the device’s use and its degradation in actual field settings in order to identify and offer supply guidance as when to optimally retire and replace the device. This information is critical, as it will inform health care professionals in terms of cost-effectiveness and cost-efficiency, which will vary significantly if it would de facto be treated as a single-use device.\textsuperscript{36}

- An important consideration is to ensure the timely and effective access to a NASG when needed, which depends on having the garment being placed at all levels of the formal and informal health system, and to have them available at all facilities, during transport, and at home and in community settings.

\textsuperscript{31} Incoterms (international commercial terms) are a series of pre-defined commercial terms published by the International Chamber of Commerce (ICC). They are widely used in international commercial transactions and relate to common contractual sales practices intended primarily to communicate the tasks, costs, and risks associated with the international transportation and delivery of goods from the seller to the buyer.


\textsuperscript{33} To work out the cost per DALY saved for a disease, one needs to know the cost in DALYs per infection of disease and the number of infections averted; the cost of treatment.


• Setting up a functioning return and replacement system to ensure that garments make their way back to the communities from the referral hospitals after use will also be a challenge, as NASGs need to be available where they are needed.\textsuperscript{37} Although prior implementation projects and studies have documented best practices in NASG return and exchange,\textsuperscript{38} there has yet to be any comprehensive programmatic or technical guidance on how such systems should be designed and implemented in operational settings.

• Currently, the NASG is not readily available in most resource-limited settings, even after efforts to achieve recent significant cost price reductions. Product awareness, access, and distribution remain some of the main challenges in increasing the use of the NASG.\textsuperscript{39} Most current national health policies and treatment protocols do not include the NASG or consider its application in standard PPH treatment protocols, and many ministries of health and health care workers have limited awareness to the NASG as a product and its use. This, together with a lack of evidence in its local use, cost-effectiveness, and implementation data limit, hinders the scaleup of the NASG in resource-limited settings, especially against competing national health priorities supported by vertical programme support and incentive funding.\textsuperscript{40}

• The average procurement cost of an NASG is relatively high at a minimum cost of USD 41.55 a unit, which excludes the costs of transport and freight costs, which can double or triple the total landed cost of the garment. The high upfront costs will especially have an impact on small orders and the trial programmes that will be necessary to generate local evidence-based data to push changes to national policy treatment guidelines and budget allocations.

6. Steps Forward

• UNICEF will continue to work together with UNFPA and other global maternal health actors to advocate and create access to the NASG and other life-saving health product innovations. This will include creating a comprehensive programmatic and technical guidance on the best practices in NASG implementation as well as recommended criteria or conditions on where NASG should be introduced and prioritized. Access to maternal health innovations, including NASG, is needed to end preventable PPH related deaths. Read more here: \url{https://www.unicef.org/topics/maternal-health}.

• UNICEF will host a package of technical resources to support countries in introducing NASG into maternal health programming. These materials will include UCSF Safe Motherhood Program’s developed job aids, training materials, a UNICEF technical bulletin and several UNICEF NASG webinar recordings, and be available on the UNICEF website.

• UNICEF country offices, including in Bangladesh, Papua New Guinea, and Vanuatu will continue to introduce the NASG into their maternal health programmes targeting PPH. UNICEF will support with the health teams to document local findings of their implementation projects to address the current knowledge gaps in NASG implementation, re-use, maintenance and logistics, and to translate them into product guidance that can be used to support scale up activities globally.

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