



# Stronger markets, increased access to essential maternal health supplies



Advocacy recommendations for Nigeria

*A companion to Increasing Access to Essential Maternal Health Supplies: A scoping of market-based activities, gaps and opportunities (2016)*



RESULTS FOR  
DEVELOPMENT



Reproductive Health  
SUPPLIES COALITION



# Summary of advocacy recommendations



## Quality

- Increase resources committed to the regulation of health products.
  - Government should increase budgets to improve regulation.
  - Advocates should encourage the government to prioritize health product regulation by highlighting persistent concerns about product quality and communicating a sense of urgency.
- Align registration and procurement requirements with international standards.
  - Public-sector procurement entities should include and prioritize international quality standards when procuring health products.
  - Advocates should urge national and subnational procurement entities to prioritize international quality standards by demonstrating demand for quality assured products.
- Strengthen implementation of guidelines on the proper storage and distribution of maternal health products.
  - Regulatory and health officials should ensure that storage and distribution guidelines are widely disseminated and adapted for local use.
  - Advocates should raise awareness of research related to storage and distribution and push for actionable guidelines.



## Availability

- Align state guidelines with national guidelines and global recommendations and support appropriate dissemination and training.
  - State ministries of health should align guidelines on postpartum hemorrhage (PPH) and pre-eclampsia/ eclampsia (PE/E) with national policies and global normative guidance and ensure updates and/or changes are disseminated and reflected in operational practices.
  - Advocates should urge state ministry officials to align guidelines with national policy and global recommendations.
- Improve communication and coordination between agencies responsible for health product forecasting, budgeting, procurement, and supply planning.
  - Federal and state agencies should create or support multi-stakeholder forecasting “task teams” to review and ensure accountability for forecasts and supply plans.
  - Advocates should highlight changes to policies that may impact demand for maternal health products and use costed forecasts to urge the government to allocate sufficient resources to meet demand.
- Address procurement inefficiencies to improve availability of maternal health products.
  - Procurement and budget officials should explore mechanisms to coordinate and potentially pool public-sector procurement at the subnational level.
  - Advocates should raise visibility of stockouts in their communities and promote the value of coordinating and consolidating orders with local procurement units.

# Introduction

In the last 15 years, global efforts have nearly halved maternal mortality worldwide.<sup>1</sup> However, Nigeria still faces a staggering burden of maternal mortality, leading the world in total number of maternal deaths per year.<sup>2,3</sup> In 2015 alone, 58,000 Nigerian women lost their lives to pregnancy and childbirth-related causes.<sup>4</sup> This burden is not borne equally across the country. For example, Kaduna State, the third most populous state in the country and focus geography of this paper, has a maternal mortality rate that is nearly 50 percent higher than the national average.<sup>3</sup> Additional efforts are urgently needed. **This advocacy paper outlines actions that advocates and decision-makers in Nigeria can take to increase access to lifesaving maternal health products to save mothers' lives.**

## Maternal mortality in Nigeria

In 2015, there were an estimated 814 maternal deaths per 100,000 live births in Nigeria.<sup>2</sup> About half of these deaths result from two causes: uncontrolled bleeding after childbirth, or postpartum hemorrhage (PPH), and a condition which causes high blood pressure and seizures during pregnancy, or pre-eclampsia/ eclampsia (PE/E).<sup>5</sup> Both conditions can be addressed with effective, low-cost maternal health products: oxytocin and misoprostol, to prevent and treat PPH, and magnesium sulfate, to treat PE/E. In 2012, the United Nations Commission on Life-Saving Commodities for Women and Children (UN Commission) identified these three maternal health products as lifesaving and issued a global call to action to improve access.<sup>6</sup>

Despite this momentum, women in countries worldwide, including Nigeria, still lack reliable access to essential maternal health products. Further, products that are available are sometimes of poor or unverified quality.<sup>7</sup>

## Addressing market shortcomings

Advocates and decision-makers likely recognize the visible symptoms of **market shortcomings** for health products:

## About this advocacy paper series

This advocacy paper is part of a series of four—each with a different geographic focus—all informed by an analysis published by the Reproductive Health Supplies Coalition (RHSC), in partnership with the Results for Development Institute (R4D) and PATH. The report, [\*Increasing Access to Essential Maternal Health Supplies: A scoping of market-based activities, gaps and opportunities\*](#), maps current market strengthening efforts and identifies additional opportunities to improve the availability and quality of oxytocin, misoprostol, and magnesium sulfate for women in low-resource settings.

The report applies a global lens to current challenges and opportunities and then focuses in on three countries: Nigeria, Bangladesh, and Ethiopia.

The three focus countries were selected because they contribute to a significant proportion of global maternal deaths, accounting for 25 percent of all maternal deaths worldwide. There are also key variations in their health systems structures (i.e., centralized versus decentralized public-sector health systems) and in the presence and strength of local manufacturing capacity, resulting in diverse lessons across contexts that can be applied to improve access to maternal health products.

**The advocacy papers aim to draw out the findings from the full report and translate them into actionable advocacy recommendations for advocates and decision-makers in Nigeria.**

- Inconsistent or limited product availability.
- Products of poor or unverified quality.
- Unusable products due to locally inappropriate design.
- Lack of affordable products.
- And often, a combination of several of the above issues.

To improve access, the global health community must work together to strengthen markets—the systems, structures, and institutions that facilitate the buying and selling of lifesaving health products. When markets function well, products that are appropriately designed, quality assured, and affordable are

## What is market strengthening?

Market strengthening activities focus on influencing the practices of manufacturers, buyers, suppliers, governments, donors, health care providers, and/or consumers to improve how products are produced, procured, distributed, and delivered. Such interventions, when implemented by technical specialists with a strong understanding of markets and in coordination with all market actors, respond thoughtfully to the dynamics and failings of a specific market and seek to alter them to improve product access and, ultimately, public health outcomes.<sup>8</sup>

In global health, market strengthening interventions focus on improving the **appropriateness, quality, affordability, and availability of health products.**

consistently available to the women who need them. Advocates have a key role to play in strengthening the policy environment in which markets function.

This advocacy paper provides **specific and actionable recommendations that advocates and decision-makers can use to raise awareness of the urgent actions needed and push for positive policy change to improve the quality and availability of essential maternal health products.**

## Market shortcomings and advocacy recommendations



### Quality: Context and challenges

#### General quality issues and safeguards

Access to quality assured maternal health products can mean the difference between life and death for women in pregnancy and childbirth. Poor quality medicines can be ineffective or even harmful, potentially resulting in the death of mothers and their babies. Safeguarding the quality of maternal health products throughout the supply chain is therefore paramount, but it is not easy. Success requires efforts at every step of the supply chain—

from manufacturer to user—to assure that women receive a safe and efficacious product.

### Quality of maternal health products in Nigeria

Nigeria has made strides in improving the quality of maternal health products in circulation. Yet there are still gaps, particularly with regards to health product registration and regulation, procurement, and appropriate storage and distribution.

#### *Product Registration and regulation*

Registration of quality assured health products is critical in Nigeria, because only products registered by the country's national medicines regulatory agency (NMRA), the National Agency for Food and Drug Administration and Control (NAFDAC), can legally be purchased for distribution in the public sector or sold in the private sector. As of March 2016, 2 oxytocin products, 1 magnesium sulfate product, and 1 misoprostol product verified to meet international quality standards were registered in Nigeria, a

## Safeguarding quality

Many different actors have a role to play in safeguarding quality:

- Manufacturers should produce products in accordance with current good manufacturing practice (cGMP). GMPs are the minimum requirements a manufacturer must meet to ensure product quality at the point of manufacture and to comply with internationally accepted quality standards.
- National medicines regulatory agencies (NMRAs) can choose to only register products verified to meet specified quality standards and can perform routine quality checks to ensure compliance.
- Donors and governments can choose to purchase products that have been verified to meet international quality standards and are registered in country by the NMRA.
- Suppliers, distributors, and providers can ensure they transport and store products in accordance with delineated storage conditions.

positive step towards expanding access to quality assured products. However, NAFDAC has registered a greater number of products that have not been verified to meet international quality standards. As of March 2016, there were 13 oxytocin products and 4 magnesium sulfate products registered in Nigeria that had not yet been judged to meet international quality standards.<sup>9</sup> This increases the risk that maternal health products of poor or unknown quality are being provided to Nigerian women.

Indeed, like many low- and middle-income countries, Nigeria faces challenges with substandard and counterfeit drugs.\* Although the efforts of NAFDAC have dramatically reduced the prevalence of counterfeit products on the market, there remain concerns that the significant proportion of health products imported primarily from Asian countries such as India and China, coupled with insufficient human and financial resources for regulation, make Nigeria's pharmaceutical system vulnerable to counterfeit products.<sup>10</sup> To illustrate, according to a March 2016 report by *The Guardian* in Nigeria, NAFDAC destroyed 1 billion Nigerian naira, or slightly over US\$3 million, worth of fake, substandard, and expired drugs.<sup>11</sup> The prevalence of counterfeit products, moreover, is reported to increase when there are product shortages. According to interviews with key stakeholders in Nigeria, when there are stockouts of popular brands of medicines, some suppliers respond by quickly pushing out counterfeit versions of medicines with similar packaging to capitalize on unmet demand.<sup>7</sup> In addition, as a result of inconsistent availability of products in the public sector, many Nigerians purchase health products from the private sector—of which NAFDAC may not have strong capacity to provide oversight—further underscoring the need to ensure only quality assured products are registered in the country.

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\* WHO defines substandard medicines, also called out-of-specification products, as "genuine medicines produced by manufacturers authorized by the NMRA which do not meet quality specifications set for them by National standards." WHO defines counterfeit medicines as a "medicine which is deliberately and fraudulently mislabeled with respect to identity and/or source." Counterfeiting can apply to both branded and generic products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient or inadequate quantities of ingredient(s), or with fake packaging.

## What are international quality standards?

Mechanisms that are internationally recognized and used to verify the quality of health products include:

- Approval by a Stringent Regulatory Authority (SRA)
- World Health Organization (WHO) Prequalification of Medicines Programme
- A "no objection to procurement" decision for a time-limited period by the WHO Expert Review Panel (ERP)\*

When a product has been judged to meet one of the above quality standards, it is considered quality assured.

\*A WHO ERP "no objection to procurement" decision is time limited, and suppliers are expected to be concurrently pursuing SRA approval or WHO Prequalification.

### Procurement

At the time of analysis, public-sector procurement policies and tenders did not include a preference for suppliers providing products that have achieved international quality standards, removing incentives for suppliers to pursue such standards.<sup>7</sup> Often, seeking such quality approvals requires a sizeable, upfront financial investment, which can be cost-prohibitive for some manufacturers. In addition, investments in approval may require manufacturers to increase the price of their product to recoup costs, which may negatively impact sales if procurers do not recognize the value of procuring quality assured products. Ultimately, the registration of products of poor or unknown quality coupled with the lack of prioritization of products verified to meet international quality standards in public-sector procurement raises concerns regarding the quality of maternal health products provided to Nigerian women. Stakeholders seeking to improve the quality of maternal health products in circulation in Nigeria must work to better align registration and procurement requirements with international quality standards and support regulatory efforts to adequately enforce such standards.





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### *Storage and distribution*

In addition to registering and procuring products of assured quality, it's also critical to safeguard the quality of maternal health products in storage and distribution. For example, in Nigeria, limited access to cold chain equipment and program manager and provider confusion regarding implementation of related guidelines pose a significant challenge in protecting the quality of oxytocin. In 2013, only 47 percent of local government authorities and health facilities in Nigeria had cold chain functionality.<sup>12</sup> Moreover, where cold chain functionality exists, it is often more robust in the vaccine or Expanded Program for Immunization (EPI) cold chain, rather than the broader pharmaceutical cold chain. Recognizing this, in 2015 WHO and the United Nations Children's Fund (UNICEF) issued a [joint statement](#) encouraging integration of oxytocin into the national EPI cold chain, yet lack of clarity on how to operationalize this normative guidance has hindered cold chain integration efforts.<sup>13</sup> Further work—by PATH and Management Sciences for Health

(MSH), through the USAID-funded Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program, under the Maternal Health Technical Resource Team of the UN Commission—to identify challenges and solutions with integrating oxytocin into EPI cold chains will yield practical guidance to address obstacles.<sup>14</sup>



### **Quality: Advocacy recommendations**

#### **Increase resources committed to the regulation of health products:**

- **Government:** In Nigeria, inadequate fiscal and human resources committed to health product regulation is a critical driver of the importation, manufacture, sale, and distribution of products of unknown quality. The Ministry of Finance and the NAFDAC must increase and efficiently execute budgets needed to support adequate health product regulation and enforce adherence to quality regulations by all suppliers.

- **Advocates:** Advocates should encourage the Ministry of Finance and the NAFDAC to prioritize and efficiently allocate resources for health product regulation. By highlighting persistent concerns regarding the prevalence of counterfeit or unknown quality health products in both the public and private sectors, along with the staggering number of maternal deaths in Nigeria, advocates can make a strong case: increasing resources for the regulation of health products is a smart and efficient investment that saves lives and resources.

#### Align registration and procurement requirements with international quality standards:

- **Government:** Public-sector procurement entities should include and prioritize international quality standards in health product procurements. Doing so will provide manufacturers with additional incentives to invest in achieving such standards and support the provision of quality assured maternal health products in public-sector health facilities.
- **Advocates:** Advocates should urge national and subnational procurement entities to include and prioritize international quality standards in health product procurements. Because quality assured products are typically more expensive, this goal can only be achieved if procurement and budget officials see value in spending more of their own resources to procure quality assured products. Therefore, advocates should work to demonstrate to decision-makers that there is demand for quality assured products. Advocates should document and share examples from women that spotlight the costs and consequences of poor quality products, with an urgent call to action to increase focus on quality in Nigeria.

#### Strengthen implementation of guidelines on the proper storage and distribution of maternal health products:

- **Government:** Regulatory and health officials in Nigeria should ensure that global normative guidance on the storage and distribution of specific health products, such as oxytocin, is widely disseminated and adapted for local implementation by program and supply chain

managers, staff, and providers, both public and private.

- **Advocates:** While the UNICEF and WHO [joint statement](#) provides decision-makers with additional impetus for integrating oxytocin into the EPI cold chain, program and supply chain managers have questions on how to operationalize the statement. Advocates should raise awareness of additional research conducted under the UN Commission and push for the creation or adaptation of actionable guidelines for implementation of the joint statement.



#### Availability: Context and challenges

To safeguard the lives of mothers and babies, maternal health products must be available when and where they are needed. Consistent availability is crucial, and strong forecasting and procurement practices are key to supporting availability. In Nigeria, however, current public-sector practices are contributing to misalignments between demand and supply of maternal health products, and actually undermining availability.<sup>15</sup>

#### Forecasting and supply planning

Forecasts are a critical tool for informing procurement decisions. They help procurers anticipate future demand and are used to support budgeting and development of effective supply plans, ultimately ensuring that maternal health products are available when and where needed. Although public-sector procurement entities in Nigeria—at the national level and in some states—produce forecasts that include oxytocin, misoprostol, and magnesium sulfate, they face significant challenges regarding accuracy.<sup>16</sup> Causes include a misalignment between policies or guidelines and procurement processes, lack of access to timely data or use of poor quality data, and disconnects between forecasting, budgeting, and procurement.

#### Policy misalignments

In decentralized countries like Nigeria, misalignments between national and subnational guidelines on health product use can negatively affect forecasting and procurement practices. For example, in 2012 WHO released new recommendations for the



prevention and treatment of PPH,<sup>17</sup> which should lead to increases in demand for specific maternal health products like misoprostol due to expanded use of the product. The Nigerian Federal Ministry of Health updated and aligned its PPH guidelines to the WHO recommendations, providing impetus for states to follow suit. State adoption, however, has been uneven. Kaduna State updated its PPH guidelines to reflect the new use of misoprostol for the prevention of PPH, but not for treatment. This creates a misalignment between national and state guidelines, and the Kaduna State PPH guideline may contribute to state-level forecasting that underrepresents demand for products like misoprostol because treatment indications are not incorporated in state policy.

### *Data challenges*

Limited and outdated national and subnational data on maternal morbidity and maternal health product consumption also significantly affect the quality of forecasts. A best practice when developing a forecast is to use national- or state-level morbidity and consumption data. Unfortunately, many countries like Nigeria do not adequately track causes of maternal diseases and corresponding mortality rates. In addition, many country logistics management information systems do not accurately track the

consumption rates of specific products. Further, even when data is available, program and supply chain managers do not always use the most recent estimates in forecasts. Fortunately, efforts to improve data collection are being made; in Kaduna State, the governor recently created an initiative to report the incidence and cause of maternal deaths to the State Ministry of Health.<sup>18</sup>

### *Disconnect between forecasting, budgeting, and procurement process*

In order for forecasts to be effective, they must be strongly linked with supply planning, budgeting, and procurement. However, this is not always the case in Nigeria. Analysis undertaken in the [Increasing Access to Essential Maternal Health Supplies](#) report found that Nigeria's national and Kaduna State forecasts did not include critical costs associated with product delivery (freight, clearance, storage, and distribution) when costing forecasts. Comprehensive costing data is vital because it provides public-sector agencies with the information needed to properly budget for procurement sufficient to meet demand.

Furthermore, in Kaduna State, there is a missing link between demand forecasts and the budget needed to procure forecasted volumes. The State Primary Health Care Development Agency (SPHCDA) helps set the budget for the state's procurement of essential health supplies, based on forecasts completed in consultation with local government authorities. The SPHCDA, however, is not involved in the next step of actually procuring these commodities. As it follows, less than half of the forecasted demand for oxytocin, misoprostol, and magnesium sulfate was procured by the public sector in Kaduna State from 2013 to 2015. The most significant procurement gap of the three priority maternal health products was for magnesium sulfate—less than 20 percent of the forecasted need in Kaduna State was actually procured.<sup>20</sup> Improving the operational linkages between the agencies responsible for financing and budgeting, forecasting, and procurement is critical to improving the availability of lifesaving maternal health products.

## **Strengthening forecasting of health products**

Thanks to the efforts of a range of partners, forecast methodologies for the 13 lifesaving health products identified by the UN Commission, including the 3 priority maternal health products, have improved. The [Quantification of Health Commodities: RMNCH Supplement](#) developed by John Snow International and Management Sciences for Health (MSH) under the Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program provides strong guidance on needed data, forecast assumptions, and incorporation of program-specific considerations into forecasts. Additional work is needed to support program and supply chain managers to effectively use the guidance and to standardize forecasting methodologies, particularly in countries like Nigeria with decentralized health systems.<sup>19</sup>

### **Procurement in decentralized settings**

Countries with decentralized health systems, such as Nigeria, encounter unique challenges coordinating procurement, both between national and subnational



procurement units and among various subnational procurement entities. In places where some or all health product procurement has been devolved to subnational levels, procurements are often fragmented, of smaller quantities, and on different schedules. This weakens subnational procurers' ability to negotiate the best prices, because higher volumes typically lead to lower per-unit costs, and increases the risk of products of poor or unknown quality being procured, as quality standards may differ among subnational procurers.

In Nigeria, the majority of health products are procured at the state level. There are a multitude of state-level procurement actors that do not always communicate or coordinate effectively. In Kaduna State, the Drug and Medical Supplies Management Agency (DMSMA) is the only state-level government procurer responsible for the procurement of health products for the public sector. The DMSMA works with a range of additional non-governmental procurers supporting the public sector, such as Marie Stopes International, the Clinton Health Access Initiative, Crown Agents, and the United Nations Population Fund, which may be providing products to one or more Nigerian states. In addition, public-sector health facilities can procure as needed directly from suppliers.<sup>21</sup> This multitude of procurement entities in just one state leads to fragmented, small-volume orders rather than consolidated orders based on coordinated demand forecasting and supply planning. As a result, the availability of maternal health products varies widely within and among states.

### **Availability: Advocacy recommendations**

**Align state guidelines with national guidelines and global recommendations, and ensure updated guidelines affecting the provision and use of health products inform operational practices:**

- **Government:** State ministries of Health, such as the Kaduna State Ministry of Health, should align state guidelines on PPH and PE/E with national policy and global normative guidance. Decision-makers should also ensure that such changes to national or state guidelines—which may affect demand for maternal health products—are appropriately disseminated and reflected in operational practices.
- **Advocates:** Advocates should urge state ministry officials to align guidelines with national policy and global recommendations related to the prevention and treatment of PPH and PE/E and to support appropriate dissemination and provider training. In addition, advocates can assist with flagging future changes to relevant policies and guidelines for agencies and officials responsible for budgeting and financing, forecasting, and procurement, to ensure such changes are represented in operational practices.

### **Improve communication and coordination between agencies responsible for health product forecasting, budgeting, procurement, and supply planning:**

- **Government:** Federal and state agencies should create or support multi-stakeholder forecasting “task teams” to regularly lead reviews and ensure accountability for comprehensive, costed forecasts and supply plans for essential health products, including maternal health products. Teams should include stakeholders responsible for forecasting, budgeting, procurement, supply planning, and program management as well as implementing partners and civil society representatives. Teams should also leverage existing resources on supply coordination mechanisms. For example, under the Supply and Awareness Technical Resource Team of the UN Commission, John Snow International (JSI) developed [guidance](#) for countries regarding the establishment or expansion of existing supply coordination committees to include the full set of reproductive, maternal, neonatal, and child health commodities and stakeholders. The guidance offers best practices for committees—including recommendations for developing terms of references, key membership, structure, and operations of supply coordination committees—and provides a range of resources that can be used to support implementation.<sup>22</sup>
- **Advocates:** Advocates can play a special role in highlighting changes to relevant policies, including updates to essential medicines lists and standard treatment guidelines that may impact the demand for maternal health products. Advocates can also use costed forecasts

as a resource-mobilization tool to urge state governments to allocate sufficient resources to procure maternal health products in accordance with demand forecasts.

### **Address procurement inefficiencies to improve availability of maternal health products:**

- **Government:** Procurement and budget officials should explore mechanisms that coordinate and potentially pool public-sector procurement across subnational procurement units. In decentralized settings like Nigeria, coordinating demand forecasts and budgets and pooling orders across states strengthen buying power, support lower unit prices, reduce transaction costs for suppliers, and often result in better delivery terms. In addition, national and subnational procurement officials should consider strategic contracting mechanisms, such as framework contracts, to reduce lead times and help avert stockouts.
- **Advocates:** Advocates should raise the visibility and awareness of stockouts of lifesaving health products and the impact on the health and survival of mothers and babies in their communities. Advocates should also engage in conversation with local procurement units regarding the value of coordinating orders as a means to both cost savings and improving availability.

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***Sustainable Development Goal 3: Ensure healthy lives and promote well-being for all at all ages.***

***Maternal Health Target: By 2030, reduce the global maternal mortality ratio to less than 70 per 100,000 live births.***

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## **Conclusion**

As the international community builds on the achievements of the Millennium Development Goals and works toward the new Sustainable Development

Goals (SDGs), countries worldwide—including Nigeria—are reaffirming their commitment to the health and well-being of their citizens.

The SDGs continue to elevate maternal health and set ambitious targets to further reduce maternal mortality. To reach these and other targets, it will be critical to ensure that women have reliable access to lifesaving maternal health products. Strengthening the policy environment in which markets function will be fundamental to sustaining well-functioning markets and improving access.

The advocacy recommendations in this brief highlight critical opportunities for advocates working to improve maternal health outcomes in Nigeria. Advocates have a vital role to play in raising the visibility of the costs and consequences of poor quality maternal health products, communicating a sense of urgency, advocating for increased resources to regulate and procure products, ensuring policy coherence and the operationalization of key policies impacting forecasting and supply planning, and calling for increased coordination and collaboration among relevant government agencies.

To learn more, access the full report: [\*Increasing Access to Essential Maternal Health Supplies: A scoping of market-based activities, gaps and opportunities.\*](#)

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