

New Dialogue for the Way Forward in Maternal Health: Addressing Market Inefficiencies

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Abstract Despite notable progress in Millennium Development Goal (MDG) five, to reduce maternal deaths three-quarters by 2015, deaths due to treatable conditions during pregnancy and childbirth continue to concentrate in the developing world. Expanding access to three effective and low-cost maternal health drugs can reduce preventable maternal deaths, if available to all women. However, current failures in markets for maternal health drugs limit access to lifesaving medicines among those most in need. In effort to stimulate renewed action planning in the post-MDG era, we present three case examples from other global health initiatives to illustrate how market shaping strategies can scale-up access to essential maternal health drugs. Such strategies include: sharing intelligence among suppliers and users to better approximate and address unmet need for maternal health drugs, introducing innovative financial strategies to catalyze otherwise unattractive markets for drug manufacturers, and employing market segmentation to create a viable and sustainable market. By building on lessons learned from other market shaping interventions and capitalizing on opportunities for renewed action planning and partnership, the maternal health field can utilize market dynamics to better ensure sustainable and equitable distribution of essential maternal health drugs to all women, including the most marginalized.

Keywords Maternal health · Market shaping · Total market approach · Lifesaving medicines · Barriers to access · Market segmenting

Introduction

Every year, an estimated 275,000 women die from complications related to childbirth [1], with 99 % of deaths occurring in the developing world [1]. The two primary causes of maternal deaths, accounting for over half of deaths, are post-partum hemorrhage and pre-eclampsia/eclampsia. Three effective medicines to treat these conditions, oxytocin and misoprostol for postpartum hemorrhage and magnesium sulfate for pre-eclampsia and eclampsia, are available and low-cost [2]. Yet these drugs remain largely inaccessible to those who most need them [3]. A delivery package containing these medicines, estimated to cost <US\$1.50 per person, is predicted to save 1.4 million lives over 10 years, if available to all women [3]. These data make clear the challenge lies of today lies in moving drugs we know can work to the women who need them.

Top Barriers in Scaling-Up Use of Essential Maternal Health Medicines

In 2012 the UN Commission on Life Saving Commodities for Women and Children (UNCoLSC) identified three top barriers to women accessing essential maternal health drugs. These are: (1) insufficient supply of quality drugs due to market failures, (2) regulatory issues leading to variability in drug formulation and quality, and (3) lack of provider and consumer awareness of drugs and/or their appropriate use (see Table 1) [2].

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Table 1 Top barriers to women accessing essential maternal health drugs [2, 3]

	(1) Market failures	(2) Regulatory/quality issues	(3) User knowledge gaps (awareness/training)
Oxytocin (PPH)	Lack of reliable needs estimations lead to stock-outs and lack of availability in rural areas; not included in vaccine cold supply chain	Many unregistered products on the market of unknown quality; Storage requirements vary between manufacturers; many products unstable if not refrigerated; Use by midwives not allowed in some countries	Poor knowledge of appropriate use of drug and proper storage at provider and community level
Misoprostol (PPH)	Little economic interest in costly bioequivalence studies needed for regulatory approval	Large numbers of unstable and ineffective products on market, partly due to black-market potential; Generic misoprostol receives WHO pre-qualification	Can be used with multiple indications, with different dosing regimens depending on medical indication; Concern over correct dosing leads to under-use
Magnesium sulfate (PreE/E)	Little commercial interest to manufacture due to low price and small market volumes in most countries; Need to package product for emergency use with needle, syringe and calcium gluconate	Multiple formulations available that require complicated dilutions, provider fear of error; No WHO support yet for community use; Use by midwives not allowed in many countries	Inefficient use by health workers due to inadequate awareness of correct dosage and concerns related to toxicity

Inherent in the challenge of addressing these barriers is their dynamic interplay [2]. For example, the development of quality-assured drugs is conditional on an attractive market to incentivize manufacturers to produce sufficient quantities of medicines and obtain regulatory approval. A robust market in turn relies on sufficient product demand, driven by community awareness of the drug's life-saving potential and provider training on appropriate use. A strong regulatory environment, in which drugs are packaged and registered for their indicated purpose, also influences demand. To address the interrelated nature of identified barriers, a coordinated approach is required. As evidenced from other reproductive health commodity markets, market shaping strategies which employ a "total market approach" (TMA), may offset inefficiencies in the maternal health market by capitalizing on the respective competencies of the public and private sectors. Coupled with programmatic investments necessary to address service delivery challenges and augment demand, utilization of market opportunities has the potential to facilitate access for all women [4, 5].

A Total Market Approach for the Way Forward

Adopting a total market framework for maternal health medicines engages stakeholders across the public (e.g., government), private commercial (e.g., manufacturers and distributors), and private non-profit sectors [6]. TMA seeks to harness the mission and reach of the public sector with

the innovation and adaptability of the private sector, drawing on governmental regulatory support and coordination. A core element of developing the total market is market segmentation, or the targeted distribution of resources to intended user groups (e.g., clinics, providers and women) based on ability to pay, accessibility, and need. The strategy maximizes donor subsidies for those unable to pay, while encouraging those with greater resources to use the private sector. In this way limited public resources to deliver services to the poor are offset by private sector participation to create a sustainable market where all population groups have access to health options.

Recent successes in reproductive commodity markets demonstrate the potential of such market shaping strategies [7–11]. Historically, however, developing country markets for maternal health medicines have lacked a total market approach. Current failures in markets for maternal health drugs deter manufactures from producing sufficient amounts of quality-assured products, limiting global supply and availability (Table 1) [2, 12]. The prevalence of drugs that are poor quality or in formulations not specific for maternal health indications leads to provider concern over use, limiting demand and discouraging manufacturer production [3]. It is hence also critical to consider demand side inefficiencies and their influence on overall market health. Broader programmatic initiatives that address gaps in provider training, supply chain capacity, and consumer awareness could be employed to encourage sufficient demand and in turn supply [4, 5].

A Strategic Time for Change

It is increasingly evident that the majority of developing countries will not meet MDG5 by 2015 [1]. New priorities in maternal health should consider the market principles that drive current barriers to lifesaving maternal health medicines. By developing the “total market” we can shift away from unsustainable donor dependency for subsidized products and develop long-term healthy drug markets to meet the needs of women.

The largest cohort of reproductive-aged women, 1.8 billion, is projected for 2015 [13] signaling a likely increase in demand for maternal health drugs. The greatest population growth is estimated for Sub-Saharan Africa, [14] where resource constraints underscore the need for more efficient use of subsidized products. Given the region’s burgeoning middle class, with a 30 % increase in real income per person over the past decade, [15] there is indication that more users will be able to pay for health services in the coming years. In combination with growing momentum for universal health coverage in low and middle-income countries [16, 17], this emerging context highlights the potential for growing private sector involvement in developing country markets. Following the recent launch of the UNCoLSC, a global consortium is in place to move this agenda forward.

We provide three examples from the family planning, HIV and maternal health services fields to illustrate how market interventions can enhance access to essential drugs. While we focus our commentary on market shaping methods employing TMA, we recognize the success of such strategies is reliant on complementary programmatic action to enhance the regulatory environment, institutional and provider capacity, and address broader issues such as community prioritization of maternal health. To foster cohesive action, we discuss programmatic components secondarily within the context of broader market dynamics.

3 Case Studies: Illustrative of Market Dynamics to Scale-Up Production and Access to Sufficient, Quality-Assured Quantities of Essential Maternal Health Medicines

Case Study 1: Building Cross-Sector Partnerships to Shape Global Markets

In 2012, global leaders in reproductive health pledged to expand contraceptive access to 120 million women residing in developing countries by year 2020 [18]. In support, the Jadelle Access Program was launched as a public–private partnership including Bayer HealthCare AG, the

Clinton Health Access Initiative (CHAI) and the Bill and Melinda Gates Foundation, among others [8]. The joint effort worked to expand a sufficient, quality-assured supply of the Jadelle® two-rod implant. At US\$18 per unit, the high cost of Jadelle impeded developing country access. To reduce costs by achieving economies of scale, CHAI, in coordination with partners, triangulated data from USAID’s Procurement Planning and Monitoring Report (PPMR) with historical consumption figures to inform a demand forecast for Jadelle® from 2013 to 2018 [19]. The program gained purchasing power when several donors pledged a US\$230 million volume guarantee for Bayer to produce Jadelle®. In exchange for a more predictable demand forecast, Bayer offered more competitive pricing. The volume guarantee will allow Bayer to achieve economies of scale not previously possible given fragmented developing country markets, and to achieve cost-savings in sourcing raw materials. Under signed contract in early 2013, Bayer agreed to reduce the price of Jadelle® to US \$8.50 per unit in more than 50 countries [8]. A similar initiative by Merck and the Gates Foundation also achieved significant cost savings in the Implanon® single rod implant [11]. While the full impact of such programs has yet to be realized, [20] price reductions are a critical step in reducing unmet need.

Applied Lesson

The low cost of maternal health medicines and resulting limited profit potential discourages manufacturers from entering the market to produce sufficient drug supplies. For example, the low price and small market volumes for magnesium sulfate, deters production and limits supply [21]. While multiple manufacturers produce oxytocin, the market is highly fragmented on both the supply and demand side, limiting the potential for bulk purchasing which could encourage production [3]. Finally, with large upfront costs and an unforeseeable market, little commercial interest exists to conduct costly bioequivalence studies needed for regulatory approval to demonstrate misoprostol is an effective alternative for post-partum hemorrhage when oxytocin is not available [3].

Quantifying the demand for maternal health drugs on a regional or global level is essential. Developing a similar approach as the USAID developed PPMR system could aid in demand planning and stock-out prevention [19]. Bulk purchasing strategies could create a more attractive market for manufactures to produce maternal health drugs, while allowing for prices to remain low.

Global market intelligence gathered through cross-sector partnerships that allows for bulk purchasing

can incentivize manufacturers to produce a sufficient supply of quality-assured products at affordable prices by offering a stable view of the long-term market.

Case Study 2: Shaping Local Markets: Product Innovation to Stimulate Demand

Another strategy to encourage manufacturers to invest in otherwise unattractive commodity markets can be learned from UNITAID, a global health initiative that works to ensure access to quality-assured HIV/AIDS, Malaria, and Tuberculosis products. UNITAID employs an innovative financing mechanism, a micro tax on airline tickets in participating countries, as leverage to scale-up access to resources in developing countries. One success is UNITAID's role in creating a market for pediatric anti-retroviral drugs (ARVs). Prior to UNITAID and CHAI intervention, there was little incentive for manufacturers to produce ARVs for children due to the lack of pediatric HIV in countries that could afford to pay for treatment [9]. Low demand also meant little market competition and correspondingly high drug prices. By investing over US\$300 million from 2006 to 2012, UNITAID encouraged manufacturers to invest in pediatric ARV production [9]. UNITAID partnered with CHAI to utilize demand-side intelligence and pool procurement across 40 countries. The stable UNITAID funding and CHAI informed demand forecast incentivized manufacturers to produce sufficient quantities of quality-assured drugs. This signaled other manufacturers of a viable market, increasing competition, stimulating product innovation and leading to reduced prices. Since UNITAID's intervention, drug formulation has improved to include one-pill "fixed-dose combinations," facilitating procurement logistics and treatment adherence. High-volume drug purchases due to pooled procurement have reduced drug prices by 80 % and 85 % of products are provided by multiple generic manufacturers [9]. The variety of products at different price points offers increased health options for greater segments of the population, as those willing to pay full value for non-generic drugs support the private sector.

Applied Lesson

Although schemes such as the UNITAID model offer a promising strategy to leverage for manufacturers to meet quality assurance standards, most countries have not employed innovative financing mechanisms in markets for maternal health medicines [22]. Currently, a high prevalence of substandard drugs has been cited in multiple developing countries (Table 1). Variations in recommended drug packaging and labeling in multiple developing

countries for both oxytocin and misoprostol have found high rates of impure or degraded drug content [23]. Multiple health uses and formulations of misoprostol also leads to dosage concerns, thereby limiting effective use [23, 24]. Novel financing schemes could encourage manufacturers to improve product formulations and packaging for effective use [3]. Such innovations include a heat-stable form of oxytocin, dosage and packaging of misoprostol and magnesium sulfate for specific indications, or product bundling into a birthing kit. Improvements that simplify drug delivery (e.g. single use injection vehicle for oxytocin) could also allow for task-shifting to lower level health workers [3]. For product improvements to be successful regulators need capacity strengthening to ensure drug quality, with proper oversight along the supply chain. In some settings, distribution management may be hampered by inadequate logistics or human resources. Providing regional and district distribution centers with protocols that detail maintenance requirements could aid in quality control.

Financial strategies to catalyze markets can stimulate innovations in product development and delivery, leading to improved drug quality and more women treated.

Case Study 3: Growing In-Country Demand: Market Segmenting to Increase Utilization among Target Users

Low community awareness of obstetric complications and the high cost of care often limits access to life-saving maternal health interventions [25]. This includes essential drugs, which are most often available through a skilled provider or facility-based delivery [26, 27]. One strategy to scale-up utilization of maternal health services is demand-side financing (DSF) schemes. In 2006, the Bangladesh Ministry of Health coupled DSF with market segmenting to reduce maternal deaths among marginalized women [28]. The program offered vouchers for transport, care, and conditional cash payment for delivery with a qualified provider (public or private). To concentrate the incentive among the most in-need, women were eligible if identified to have extremely low income and little productive assets, or to live in select high poverty districts. Participating facilities were granted funds to improve services, such as procurement of drugs to manage obstetric complications. Program evaluation showed improved facility-based delivery, skilled-birth attendance, and treatment of obstetric complications among recipients [28, 29]. Voucher facilities also had higher levels of medications recommended for treatment of hemorrhage and eclampsia, relative to control sites [28]. Findings evidence the demand-increasing effects of programmatic interventions to increase access to maternal health interventions, including essential drugs.

Applied Lesson

Demand generation strategies can help underserved women access maternal health drugs. However, increased demand can strain resources and reduce service quality. Supply side improvements to strengthen health systems and provider capacity are also needed. The inclusion of private and public sector facilities in DSF schemes is one mechanism to encourage market competition and improve institutional capacity to deliver needed drugs. Another consideration is the sustainability of DSF programs reliant on donors for user incentives. Market segmenting can develop the total market by shifting paying customers to the private sector. For example, marketing campaigns could encourage private facility utilization among women, developing the total market and aiding in long-term sustainability.

Market segmenting can generate demand among a greater share of the population and guide efficient allocation of resources.

Discussion

Despite notable progress, more needs to be done to end preventable maternal deaths. A total market framework could address market inefficiencies which impede access to lifesaving maternal health drugs. In light of slowing developmental assistance for health and growing calls for sustainable development goals [30, 31], market strategies can maximize the reach of limited public and donor resources for the most underserved women. Engaging those able and willing to pay for commercial products can encourage a healthy private sector, and harness the for-profit sector competency for product innovation to further reduce barriers in procurement and provider usage.

Employing market shaping strategies requires confronting challenges such as quantifying country-level unmet need for maternal health drugs. However, as governments and global consortia begin to plan post-MDG action, [16] now is the time to build partnerships needed to undertake total market strategies. Other programmatic initiatives to address inefficiencies in drug delivery, including provider training and supply chain strengthening, as well as other broader contributors of maternal mortality, such as community recognition and prioritization of maternal health issues, must also be considered. While addressing these varying and context-specific factors is outside the scope of this commentary, an emerging evidence-base for how to scale-up access to essential medicines [2, 3] is accessible through a recently launched online platform which offers the opportunity to share experiences on how to adapt strategies for maternal health drugs across countries (<https://lifesavingcommodities.org>).

Capitalizing on renewed action planning, opportunities for partnership, and evidenced from other global health initiatives, reframing the maternal health dialogue to encompass total market principles can provide timely, applied strategies to better ensure access to life saving drugs for all women.

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