



Life
Saving
Commodities
Improving access,
saving lives

**Demand Generation for Reproductive, Maternal,
Newborn and Child Health Commodities**

DEMAND GENERATION FOR 13 LIFE-SAVING COMMODITIES: A SYNTHESIS OF THE EVIDENCE

JULY 2014



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Acronyms

ACS	Antenatal Corticosteroids
AMTSL	Active management of third stage of labor
ANC	Antenatal care
CBRHA	Community-based reproductive health agent
CCM	Community case management
CHW	Community health worker
c-IMCI	Community integrated management of childhood illnesses
DT	Dispersible tablet
EC	Emergency contraception
ECP	Emergency contraceptive pill
ENC	Essential newborn care
EWEC	Every Woman Every Child
FCHV	Female community health volunteer
FP	Family planning
HC3	Health Communication Capacity Collaborative
HCI	Health Care Improvement Project
HEW	Health extension worker
ICT	Information Communication Technology
IMCI	Integrated management of childhood illness
IPC	Interpersonal Communication
IU	International units
JHU-CCP	Johns Hopkins Bloomberg School of Public Health Center for Communication Programs
LARC	Long-acting reversible contraception
LHW	Lady health workers
MCH	Maternal and child health
MCHIP	Maternal, Newborn and Child Health Integrated Program
MDGs	Millennium Development Goals
MgSO₄	Magnesium sulfate
MoH	Ministry of Health
NGO	Non-Governmental Organization
ORS	Oral Rehydration Salts
PE/E	Pre-eclampsia/eclampsia
PMV	Private patent medicine vendor
POUZN	Point-of-use Water Disinfection and Zinc Treatment
PPH	Postpartum hemorrhage
QAP	Quality Assurance Project
RDS	Respiratory distress syndrome
RMNCH	Reproductive, Maternal, Newborn, and Child Health
SBCC	Social and Behavior Change Communication
SM	Social Marketing
SRH	Sexual and reproductive health
STI	Sexually transmitted infection
SUZY	Scaling Up Zinc for Young Children
SW	Sex worker
TBA	Traditional birth attendant
TTI	Time temperature indicator
UN	United Nations
UNFPA	United Nations Population Fund
UNICEF	United Nations Children's Fund
USAID	United States Agency for International Development
VHT	Village health teams
VHW	Village health worker
WHO	World Health Organization



Executive Summary

The global community has the power to save six million¹ lives by 2015 by increasing access to and appropriate use of 13 underutilized life-saving commodities during pregnancy, childbirth and early childhood identified by the UN Commission on Life-Saving Commodities for Women's and Children's Health (the Commission) (UNCoLSC, 2012). Demand generation—or the process of creating a need or belief in the need for a health product or service among a particular target audience—is a persistent weakness across all priority commodities.

This report reviews, assesses and synthesizes the current evidence of social and behavioral drivers of demand generation for the 13 commodities, as well as effective practices in implementing demand generation programs. This review aims to provide a foundation for future evidence-based demand generation programming and activities, with a focus on helping others to better understand the facilitating factors and barriers to utilization and generating demand for these underutilized life-saving commodities.

Using the social ecological framework to guide the evidence synthesis, the review identifies facilitating factors and barriers at the individual, community and society levels that influence the demand and uptake of life-saving commodities. The literature review also examines a wide range of evidence for successful strategies to overcome barriers and generate demand for each commodity.

For some commodities—such as ORS, zinc and the female condom—there were a large number of studies available. However, the evidence base for demand generation for other commodities, especially the newborn health commodities, is extremely limited. It is clear that additional research is needed in these areas.

Cross-cutting Conclusions and Recommendations

Based on the available evidence, summary conclusions and recommendations for individual, community and society levels are presented below to guide further research and implementation of demand generation programs.

Individual Level

Analysis of current literature reveals that it is essential to **increase knowledge** among health care consumers and providers about the essential commodities in order to increase use. Although many of the commodities

are primarily provider driven, research shows that both formal and informal health care providers lack knowledge about all essential commodities. As formal and informal providers are key sources of health information for consumers, it is critical to increase knowledge of the commodities among all health care providers. Including even minimally trained birth attendants, pharmacists, community health workers and others in demand generation programs may help increase the use of some of the commodities. Communication messages aimed at health care consumers should be tailored to different audiences (including fathers and caregivers other than mothers) and should be disseminated via all available channels to reach caregivers everywhere, especially those living in remote areas.

Unfortunately, individual demand for inappropriate and ineffective treatments often persists among both consumers and providers. The literature review revealed the need for additional research to **better understand and address existing local practices and demand for such treatments**.

Much of the research indicated that perceived or actual provider bias often prevents consumers from seeking appropriate care and treatment. Trainings should **address provider biases** and provide concrete examples of how to withhold their personal biases when treating patients.

Research shows that many providers are not familiar with treatment options and guidelines for specific commodities, like oxytocin, misoprostol and magnesium sulfate. At the administrative level, it will be important to **strengthen guidance and protocols on and communication about certain commodities** and include health care workers in the development and dissemination of new clinical guidelines in order to help with their adoption.

Community Level

Moving forward it will be important to **conduct additional research on barriers to demand generation at the community level**. To date, research has revealed very little in this area, especially for magnesium sulfate, injectable antibiotics and emergency contraception. Evidence is needed on the best strategies to educate caregivers and community health workers to support community-level provision of commodities. Additionally, more research is needed to understand why some families refuse or fail to comply with referrals to local facilities for treatment, such as for newborn sepsis. Rigorous evaluation is needed of social marketing approaches and other non-medical

¹For assumptions used to estimate lives saved, see UNCoLSC *Commissioner's report* (annex), 2012.

channels for provision of commodities such as emergency contraception, the female condom, ORS and zinc, especially through the private sector.

Research revealed an overall shortage of quality health education for all caregivers at the community level about certain illnesses and appropriate prevention or treatment. Moving forward, it will be important to **provide health education for all caregivers in the community.**

Many health care consumers face considerable barriers to gaining access to health care and are unable to obtain life-saving commodities, even when knowledgeable about them. It is critical to **increase community-based access to health care** for all consumers by improving community-based provision of care and increasing outreach to rural and other underserved communities.

Supply-side issues—like stock-outs and breakdowns in the cold chain—appeared often in the literature, especially those related to oxytocin and injectable antibiotics. It is critical to **ensure an adequate, consistent, affordable supply of life-saving commodities** in appropriate facilities when implementing demand generation activities.

Society Level

At the society level, several factors were identified as important facilitators for successful demand generation, including a supportive national and international political environment, in-country manufacturing and respected project leadership.

As evidence shows that political support is crucial to the effective introduction of a new commodity, it is therefore critical to **increase supportive national and international policies for these commodities.** Favorable policies—such as allowing trained community health workers to treat certain illnesses like newborn sepsis, childhood pneumonia and diarrhea—can facilitate the uptake of the commodities used to treat these illnesses.

Individual countries, as well as regional and international organizations, **should support the development and adoption of new products that may increase uptake of essential commodities.** New products, like the Uniject™ device for oxytocin administration, have the power to expand the use of certain commodities. Without the support of and regulation by national, regional and international organizations, innovative developments, such as the Uniject™ device, will not be approved and disseminated.

The evidence also showed that social, cultural and religious barriers exist that may deter individuals from asking for and/or using any of the 13 commodities. Gender norms impact a broad array of health issues through social norms and expectations of how men and women should behave in terms of prevention, care seeking and treatment. Although gender norms are difficult to change—because they are so deeply rooted in society—it is critical to **address gender-related barriers** to the use of these essential commodities, if scale up is to be successful.



Introduction














In 2010, the United Nations (UN) Secretary-General's Global Strategy for Women's and Children's Health (the Global Strategy) highlighted the impact that a lack of access to life-saving commodities has had on the health of women and children around the world. The Global Strategy called on the global community to save 16 million lives by 2015 by increasing access to and appropriate use of essential medicines, medical devices and health supplies that effectively address leading avoidable causes of death during pregnancy, childbirth and childhood.

Under the Every Woman Every Child (EWEC) movement, and in support of the Global Strategy and the Millennium Development Goals (MDGs) 4 and 5, the UN Commission

on Life-Saving Commodities for Women's and Children's Health (the Commission) was formed in 2012 to catalyze and accelerate reduction in mortality rates of both women and children (UNCoLSC, 2012). The Commission identified 13 overlooked life-saving commodities across the RMNCH "Continuum of Care" (Figure 1) that, if more widely accessed and properly used, could save the lives of more than six million² women and children. Eight countries in sub-Saharan Africa were the first to join the Commission's initiative as "pathfinder" countries: Democratic Republic of Congo, Ethiopia, Malawi, Nigeria, Senegal, Sierra Leone, Uganda and the United Republic of Tanzania. For more information on the Commission please refer to <http://www.everywomaneverychild.org/resources/un-commission-on-life-saving-commodities>.

²For assumptions used to estimate lives saved see UNCoLSC Commissioner's Report Annex (http://www.everywomaneverychild.org/images/UN_Commission_Report_September_2012_Final.pdf)

Figure 1: 13 Lifesaving Commodities

Reproductive Health			
			
Female Condom	Contraceptive Implants	Emergency Contraception	
Prevent HIV and unintended pregnancy: A female condom is a plastic pouch made of polyurethane that covers the cervix, the vagina, and part of the external genitals. Female condoms provide dual protection by preventing STI infection, including HIV, and unintended pregnancies.	Prevent unintended pregnancy: Contraceptive implants are small, thin, flexible plastic rods that are inserted into a woman's arm and release a progestin hormone into the body. These safe, highly effective, and quickly reversible contraceptives prevent pregnancy for 3-5 years.	Prevent unintended pregnancy: The emergency contraceptive pill (ECP) is the most widely available emergency contraceptive in developing countries. It is optimally taken in one dose of 1.5 mg as soon as possible after sexual activity. An alternative product of 0.75mg is also widely available.	
Maternal Health			
			
Oxytocin	Misoprostol	Magnesium Sulfate	
Post-partum hemorrhage: WHO recommends oxytocin as the uterotonic of choice for prevention and management of postpartum hemorrhage.	Post-partum hemorrhage: In settings where skilled birth attendants are not present and oxytocin is unavailable, misoprostol (600 micrograms orally) is recommended.	Eclampsia and severe pre-eclampsia: WHO recommends MgSO ₄ as the most effective treatment for women with eclampsia and severe pre-eclampsia.	
Child Health			
			
Amoxicillin	Oral Rehydration Salts	Zinc	
Pneumonia: Amoxicillin is an antibiotic that is used to treat pneumonia in children under five. Amoxicillin is prepared in 250mg scored, dispersible tablet (DT) in a blister pack of 10 DTs.	Diarrhea: Oral rehydration salts (ORS) is a glucose-electrolyte solution given orally to prevent dehydration from diarrhea. ORS is packaged in sachets of powder to be diluted in 200 ml, 500 ml or 1 liter of fluid, prepared to an appropriate flavor.	Diarrhea: Replenishment with zinc can reduce the duration and severity of diarrheal episodes. Zinc is prepared either in 20 mg scored, taste masked, dispersible tablets or oral solutions at concentration of 10 mg/5ml.	
Newborn Health			
			
Injectable Antibiotics	Antenatal Corticosteroids	Chlorhexidine	Resuscitation
Prevent newborn sepsis: WHO recommends benzylpenicillin and gentamicin, in separate injections, as first-line therapy for presumptive treatment in newborns at risk of bacterial infection.	Prevent Pre-term RDS: ANC are given to pregnant women who are at risk of preterm delivery to prevent respiratory distress syndrome in babies born in preterm labor.	Prevent umbilical cord infection: Chlorhexidine digluconate is a low cost antiseptic for care of the umbilical cord stump that is effective against neonatal infections.	Treat asphyxia: Birth asphyxia, or the failure of a newborn to start breathing after birth can be treated with resuscitation devices.

An Overview of Demand Generation

Demand generation increases awareness of and demand for health products or services among an intended audience through social and behavior change communication (SBCC) and social marketing (SM) techniques. Demand generation can occur in three ways:

- **Creating new users**—convincing members of the intended audience to adopt new behaviors, products and/or services;
- **Increasing demand among existing users**—convincing current users to increase or sustain the practice of the promoted behavior and/or to increase or sustain the use of promoted products and services; and
- **Taking market share from competing behaviors** (e.g., convincing caregivers to seek health care immediately, instead of not seeking care until their health situation has severely deteriorated or has been compromised) and products or services (e.g., convincing caregivers to use oral rehydration salts (ORS) and zinc instead of other anti-diarrheal medicines).

When well designed and implemented, demand generation programs can help countries reach the goal of increased utilization of the commodities by:

- Creating informed and voluntary demand for health commodities and services;
- Helping health care providers and clients interact with each other in an effective manner;
- Shifting social and cultural norms that can influence

individual and collective behavior related to commodity uptake; and

- Encouraging correct and appropriate use of commodities by individuals and service providers alike.

In order to be most effective, demand generation efforts should be matched with efforts to improve logistics and expand services, increase access to commodities and train and equip providers, in order to meet increased demand for products and/or services. Without these simultaneous improvements, the intended audience may become discouraged and demand could then decrease. Therefore, it is highly advisable to coordinate and collaborate with appropriate partners when forming demand generation communication strategies and programs.

Who Are the Audiences of Demand Generation

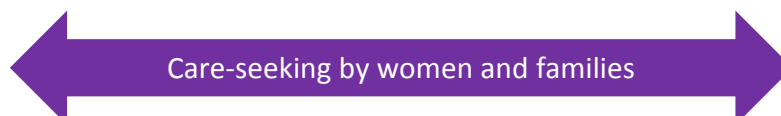
Programs for the 13 Life-Saving Commodities?

Reducing maternal and child morbidity and mortality through increased demand for and use of reproductive, maternal, newborn and child health (RMNCH) commodities depends on the collaboration of households, communities and societies, including mothers, fathers and other family members, community and facility-based health workers, leaders and policy makers.

Some of the commodities are more provider focused in terms of demand and utilization, but all depend on the care-seeking behaviors of women and families (Figure 2).

Figure 2: Audiences of Demand Generation

Provider-focused	Provider and End-user
<input type="checkbox"/> Oxytocin	<input type="checkbox"/> Female condoms
<input type="checkbox"/> Magnesium sulfate	<input type="checkbox"/> Implants
<input type="checkbox"/> Injectable antibiotics	<input type="checkbox"/> Emergency contraception
<input type="checkbox"/> Antenatal corticosteroids	<input type="checkbox"/> Misoprostol
<input type="checkbox"/> Resuscitation equipment	<input type="checkbox"/> Chlorhexidine
<input type="checkbox"/> Amoxicillin	<input type="checkbox"/> ORS
	<input type="checkbox"/> Zinc



Key Concepts and Definitions in Demand Generation

Social and Behavior Change Communication (SBCC)

SBCC promotes and facilitates behavior change and supports broader social change for the purpose of improving health outcomes. SBCC is guided by a comprehensive ecological theory that incorporates both individual-level change and change at the family, community, environmental and structural levels. A strategic SBCC approach follows a systematic process to analyze a problem in order to define key barriers and motivators to change, and then design and implement a comprehensive set of interventions to support and encourage positive behaviors. A communication strategy provides the guiding design for SBCC campaigns and interventions, ensuring communication objectives are set, intended audiences are identified and consistent messages are determined for all materials and activities.

Social Marketing (SM)

SM seeks to develop and integrate marketing concepts (product, price, place and promotion) with other approaches to influence behaviors that benefit individuals and communities for the greater social good. (http://socialmarketing.blogs.com/r_craig_lefebvres_social/2013/10/a-consensus-definition-of-social-marketing.html)

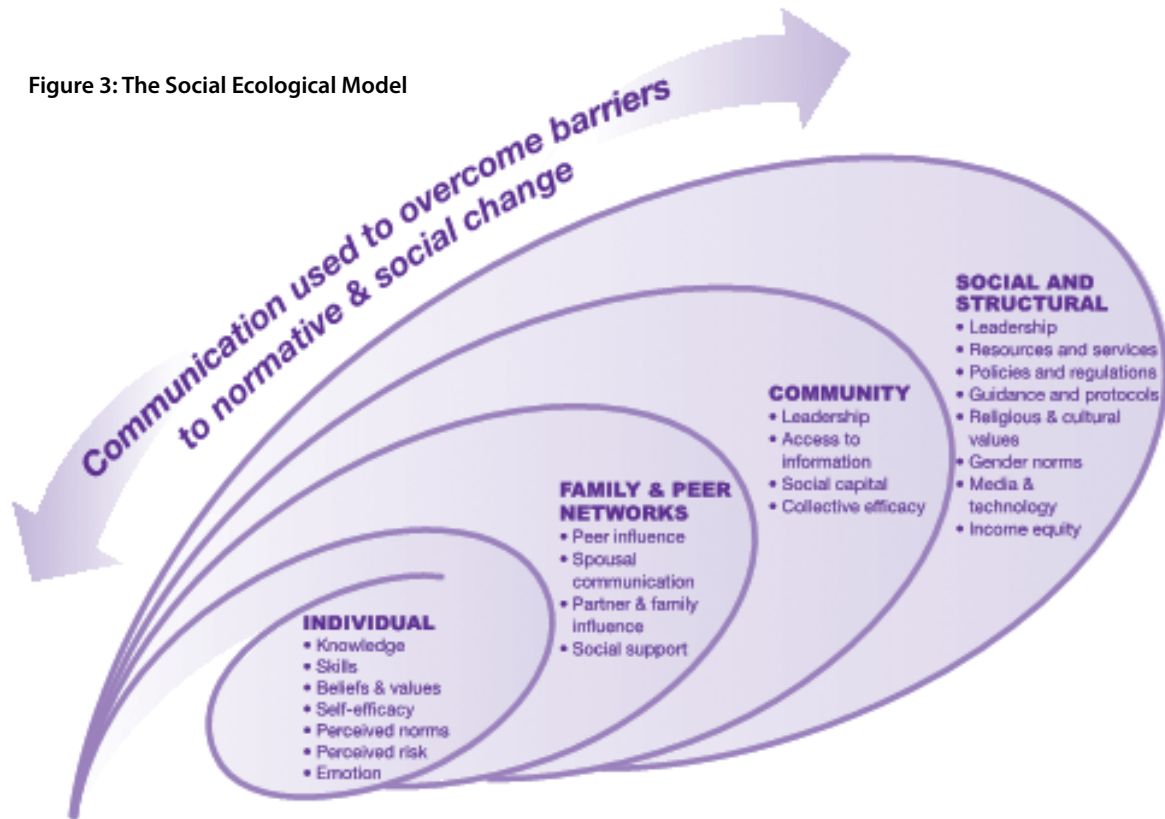
Channels and Approaches

- **Advocacy.** Advocacy processes operate at the political, social and individual levels and work to mobilize resources and political and social commitment for social and/or policy change. Advocacy aims to create an enabling environment to encourage equitable resource allocation and to remove barriers to policy implementation.
- **Community Mobilization.** Community mobilization is a capacity-building process through which individuals, groups or organizations design, conduct and evaluate activities on a participatory and sustained basis. Successful community mobilization works to solve problems at the community level by increasing the ability of communities to successfully identify and address its needs.

- **Entertainment Education.** Entertainment education is a research-based communication approach where entertaining educational programs are deliberately designed and implemented to capture audience attention to increase knowledge about a social issue, create favorable attitudes, shift social norms and change behavior.
- **Information and Communication Technologies (ICTs).** ICTs refer to electronic and digital technologies that enable communication and promote the interactive exchange of information. ICTs are a type of media, which include mobile and smart phones, short message service (SMS) and social media such as Facebook and Twitter.
- **Interpersonal Communication (IPC).** IPC is based on one-to-one communication, including, for example, parent-child communication, peer-to-peer communication, counselor-client communication or communication with a community or religious leader.
- **Mass and Traditional Media.** Mass media reaches audiences through radio, television and newspaper formats. Traditional media is usually implemented within community settings and includes drama, puppet shows, music and dance. Media campaigns that follow the principles of effective campaign design and are well executed can have a significant effect on health knowledge, beliefs, attitudes and behaviors.

Behaviors related to demand for care and treatment take place within a complex web of social and cultural influences and the social ecological framework is a useful model to understand the multi-faceted aspects of demand for life-saving commodities (see Figure 3). This perspective views individuals as nested within a system of socio-cultural relationships—families, social networks, communities, nations—that are influenced by and have influence on their physical environments (Bronfenbrenner, 1979; Kincaid, Figueroa, Storey, & Underwood, 2007). Within this framework, individuals' decisions and behaviors are theorized to depend on their own characteristics as well as family and peer networks and the communities and society within which they live, including structural and policy environmental contexts.

Figure 3: The Social Ecological Model



In order to effectively address demand generation for live-saving commodities, interventions are essential at each level of the social ecological framework. A variety of approaches may be utilized, including individual health promotion, community mobilization and engagement, and supporting structural and policy environments. Behavior change communication is a central element across these demand generation approaches.

Aim

In order to provide a foundation for future activities, this review was conducted to assess and synthesize the current evidence of social and behavior drivers for demand of the 13 commodities as well as effective practices in program implementation. The review also aims to highlight gaps that could be addressed through further research.



Methodology

Computerized bibliographic databases (PubMed, POPLINE, Scopus, Web of Science, PsycINFO, Google Scholar, 3ie impact assessment database and LILACS) were searched to identify relevant literature. A snowball approach was then used to identify references from literature retrieved from initial searches. All articles in English, from both peer-reviewed and gray literature, between 2003 and 2013 were included to capture evidence from the last 10 years. Additionally, websites of key donors and implementing organizations were reviewed. Manuscripts and reports were also requested from UNCoLSC commodity Technical Resource Teams, which include leading technical experts and active organizations working on each commodity.

The search was limited to research conducted in developing countries and included only those that referred to at least one of the 13 life-saving commodities. Although general issues and approaches—such as care-seeking behavior or service quality—certainly influence demand in general, it was beyond the scope of this review to examine that body of literature because it is not related to demand for a specific commodity. The search also excluded studies focused on product efficacy; instead, it focused solely on those that addressed either the social and behavioral determinants of product utilization or those that described implementation or impact of demand generation programs.

The following search terms were used alone or in combination:

- Oxytocin
- Misoprostol
- Magnesium sulfate (MgSO₄)
- Newborn resuscitation
- Helping babies breathe
- Chlorhexidine
- Injectable antibiotics
- Antenatal corticosteroids (ACS)
- Oral rehydration salts (ORS)
- Zinc
- Amoxicillin

- Female condom
- Contraceptive implants
- Emergency contraception (EC)
- Postpartum hemorrhage (PPH)
- Pre-eclampsia/eclampsia (PE/E)
- Birth asphyxia
- Cord care
- Preterm respiratory distress syndrome (RDS)
- Newborn sepsis
- Diarrhea
- Pneumonia
- Developing country/sub-Saharan Africa/Asia/Latin America
- Demand
- Marketing
- Promotion
- Behavior change
- Acceptability
- Communication
- Education
- Community
- Counseling
- Outreach
- Mass media
- Advocacy
- Health worker
- Traditional birth attendant (TBA)
- Midwives

A framework summarizing the literature reviewed for each commodity was developed. The draft frameworks and draft report were shared with the commodity Technical Resource Teams for review and comment at various stages of development, which in some instances, led to referrals to additional literature not captured in the initial search.

Analysis of the literature used the social ecological perspective as a guiding model, particularly when examining the social and behavioral drivers and facilitators of demand and utilization of the 13 commodities.

Search Results

Commodity by Life Stage	Documents that Met Inclusion Criteria	Geographic Focus of Literature
Maternal Health Commodities		
Oxytocin	17 (11 peer-reviewed)	Latin America (7), Africa (4), Asia (5) and 1 literature review spanning low-income countries
Misoprostol	21 (10 peer-reviewed)	Africa (9), Asia (9), 1 literature review spanning low-resource countries and 2 crosscutting technical reports
Magnesium sulfate	15 (13 peer-reviewed)	Latin America (2), Africa (8), Asia (3) and 4 documents with a global focus
Newborn Health Commodities		
Injectable antibiotics	7 (6 peer-reviewed)	Asia (5) and 2 reviews spanning multiple low-income countries
Antenatal corticosteroids (ACS)	6 (5 peer-reviewed)	Latin America (1 multi-country), Africa (2), US (1), UK (1) and 1 conference proceedings document
Chlorhexidine	16 (14 peer-reviewed)	Africa (9) and Asia (7)
Resuscitation devices	4 (4 peer-reviewed)	Africa (3) and Asia (1)
Child Health Commodities		
Oral rehydration salts (ORS) and zinc ³	108 (42 peer-reviewed)	Africa (66) – with many from Kenya (12) and Nigeria (17); Asia (38) – with many from India (18) and Bangladesh (10); Latin America and the Caribbean (2), Middle East (1) and Regional/global studies (3)
Amoxicillin	37 (27 peer-reviewed)	Africa (28), Asia (5) and reviews of multiple countries (3)
Reproductive Health Commodities		
Female condoms	27 (19 peer-reviewed)	Africa (18), Asia (5) and Latin America (4)
Contraceptive implants	15 (7 peer-reviewed)	Africa (12) and Asia (2)
Emergency contraception	22 (12 peer-reviewed) and 1 book	Africa (12), Asia (5) and Latin America (3)

Results

The results of the literature review are presented by health area, under which the appropriate individual commodities are then presented. Findings for each individual commodity are presented in the same format including commodity overview, key social and behavioral drivers, implemented strategies and impact and conclusions. The latter may also include lessons learned, knowledge gaps and recommendations, if applicable.

³Literature on demand for ORS and zinc was collected and evaluated using a combined approach given the overlap of many studies for these two commodities.

**Maternal Health Commodities:
Oxytocin, Misoprostol, Magnesium Sulfate**

Globally, more than eight million of the 136 million women giving birth each year suffer from excessive bleeding after childbirth. This condition—medically referred to as postpartum hemorrhage (PPH)—causes one out of every four maternal deaths that occur annually, and accounts for more maternal deaths than any other individual cause (UNCoLSC, 2012). Deaths due to PPH disproportionately affect women in low-resource countries.

The World Health Organization (WHO) recommends using uterotonics during the third stage of labor to prevent PPH. Although the most effective uterotonics are oxytocin and ergometrine, which ergometrine is sensitive to heat and light and has more side effects than oxytocin, oxytocin is the recommended drug. Despite having more side effects than oxytocin, misoprostol is also recommended because it can be administered by community health workers (CHWs) when skilled birth attendants are not present and oxytocin is unavailable (WHO, 2012).

The second leading cause of maternal death is pre-eclampsia and eclampsia (PE/E)—most often detected through the elevation of blood pressure and evidence of edema during pregnancy—which, if untreated, can lead to seizures, kidney and liver damage, and death. These conditions claim the lives of an estimated 63,000 women each year, as well as the lives of many of their babies. The risk that a woman in a developing country will die of PE/E is approximately 300 times higher than that for a woman in a developed country. Several studies have identified magnesium sulfate as the most effective medicine for preventing and treating deadly seizures caused by PE/E (WHO, 2011).

The majority of the commodities described here—to prevent and treat PPH and PE/E—are recommended to be administered by a skilled birth attendant, such as a midwife, doctor or nurse. These skilled birth attendants are educated and trained to identify and manage complications during pregnancy, childbirth and the immediate postnatal period, and, if necessary, refer women and newborns to a higher level of care. However, approximately 30 percent of births throughout the world are attended by unskilled attendants (KFF, 2012). Although all regions have shown improvement in the proportion of assisted births, great disparities still exist both between and within countries (UNFPA, n.d.). In sub-Saharan Africa, where nearly half of the world's maternal deaths occur, only 46 percent of deliveries are assisted by skilled attendants. Poor women and women living in rural areas are far less likely than their wealthier or urban counterparts to receive skilled care during childbirth (UNFPA, n.d.).

Because the largest threat of maternal mortality occurs during labor, birth and the 24 hours following birth, there is a serious need to increase women's access to skilled birth attendants. Without this, the adoption and use of the maternal health commodities described here will be limited. Increasing access to and use of skilled birth attendants, as well as the uptake of oxytocin, misoprostol and magnesium sulfate, will help countries to achieve Millennium Development Goal 5 of reducing the maternal mortality ratio by three quarters by 2015.

Oxytocin



Commodity Overview

The WHO recommends the use of uterotonics for the prevention of PPH during the third stage of labor for all births and recommends oxytocin as the uterotonic of choice for prevention and management of PPH.

Oxytocin has three major benefits: 1) in moderate doses, synthetic oxytocin produces slow, generalized contractions of the muscles in the uterus with full relaxation in between; 2) when used for PPH, oxytocin takes effect sooner than most other uterotonic drugs, including misoprostol; and 3) oxytocin also has fewer side effects than some other uterotonics.

Oxytocin is most often available in 1 ml glass vials, containing either 5 international units (IU) or 10 IU, and is administered by injection into the woman's vein or muscle. Doses range between 10 IU for prevention and up to 40 IU for treatment of PPH. The medicine costs approximately US \$0.18 for 10 IU (supplier median price) and is produced by more than 100 manufacturers globally.

Because oxytocin is temperature sensitive and loses effectiveness after three months of being stored at temperatures higher than 30 degrees Celsius (86 degrees Fahrenheit), WHO recommends that health personnel pay attention to the cold chain and not stockpile oxytocin for more than three months.

[Sources: UNCoLSC, 2012; WHO, 2012]

The evidence review found 17 documents related to demand generation for oxytocin that met the inclusion criteria, of which 11 were published in the peer-reviewed literature. The evidence was documented from Latin America (7 studies), Africa (4 studies) and Asia (5 studies), as well as one literature review spanning low-income countries. The review did not identify any studies from pathfinder countries.

Key social and behavioral drivers

In addition to the supply-side and product issues, such as stock-outs and the need for cold-chain storage described

previously, a number of social and behavioral barriers may also hinder the uptake of oxytocin by health care providers—the primary audience for demand generation of this commodity. At the administrative level, the lack of leadership commitment and explicit guidelines on PPH prevention and treatment—and oxytocin use specifically—leaves health workers without clear guidance on standard protocols.

Health workers may also lack knowledge, access to information and/or have poor self-efficacy with regard to the use of uterotonics (Hermida et al., 2012). For example, one study in Ghana found that midwives lacked

knowledge of the risks associated with uterotonics (oxytocin and ergometrine) and the appropriate dosages for each (Koski, Mirzabagi, & Cofie, n.d.). Inadequate training in the management of PPH is a contributing factor to the lack of knowledge and self-efficacy. A study in Honduras found that active management of the third stage of labor (AMTSL) was not included in nurse trainings (Low et al., 2012) even though such trainings have shown to be easy to implement and very effective in other settings (Althabe et al., 2011; Tsu et al., 2003). In addition, health care providers were resistant to change (Althabe et al., 2011; Belizan et al., 2007), particularly when new guidelines or protocols were imposed from the top down.

Formative research in Argentina and Uruguay identified a variety of barriers to changing provider practices in hospitals related to AMTSL, including the use of oxytocin (Belizan et al., 2007). At the individual level, barriers included lack of access to and evaluation of up-to-date information, negative attitudes toward change, perceived irrelevance of information to the hospital and individual competencies and skills. Providers identified peer-level factors as extremely influential when considering the adoption of new practices—as many expressed fear of negative judgments by colleagues.

The study concluded that neither scientific evidence nor written guidelines were sufficient enough on their own to change provider behavior. The evidence and associated guidelines need to be recognized and accepted as valuable by the hospital staff through dissemination of new knowledge by physicians recognized by staff and peers as well informed. Changes in behavior were seen to occur most effectively when physicians, identified as leaders, model new practices and “later adopters” are able to assess those efforts.

The traditional packaging of oxytocin in ampoules also creates difficulties for some birth attendants and limits their willingness and ability to use the commodity. This is especially true in instances where no assistance is available to attend to multiple demanding needs in the moments after birth (PATH, 2010; Tsu et al., 2009; Viet Nam MoH & PATH, 2005).

Implementation strategies and impact

Health care workers, in general, were the primary target audience for interventions reported in the evidence. This group includes physicians, midwives, nurses and community health officers. In the research analyzed, the primary intervention approach used was the training of health care workers, in order to improve front-line services. Many of the interventions provided training on AMTSL, in general, with specific sessions on the use of

oxytocin. Three studies used a participatory approach to intervention design by actively involving health professionals, not only in the training, but also in the development of clinical guidelines. Two of these studies focused on the development of facility-specific guidelines by the facility’s own practitioners of obstetric care.

One such study, conducted in Argentina and Uruguay, used behavior change theories (stages of change and diffusion of innovations) to develop a strategic program that identified peer opinion leaders and trained them to develop and disseminate their own evidence-based guidelines on AMTSL (Althabe et al., 2008). The study showed dramatic increases in prophylactic use of oxytocin in intervention hospitals (2.1 percent to 83.6 percent), and found that rates of oxytocin use remained high during the one-year post-intervention follow-up period. Similar gains were found in the GIRMMHP Initiative, a multi-country observational study in Latin America promoting active participation of obstetrics health personnel in the development of hospital-specific evidence-based clinical guidelines for PPH (Figuera et al., 2008). The pre-post evaluation showed that the use of oxytocin, administered during the third stage of labor, increased from 71 percent at baseline to 83.9 percent 12 months after the education intervention.

Some of the training interventions noted the inclusion and use of supporting communication materials—primarily posters placed in labor and delivery wards and emergency rooms—as well as surgical packages and clinical records to remind health workers to practice AMTSL and/or use oxytocin (Althabe et al., 2008; Figueras et al., 2008). In Ecuador, a more comprehensive implementation package—including advocacy, health education and knowledge management, in addition to training—was used in the USAID’s Quality Assurance Project (QAP) and its follow-on Health Care Improvement Project (HCI) (Hermida et al., 2012). The project assisted the Ministry of Health (MoH) with the national-level implementation of AMTSL in three phases over a six-year period using a “collaborative improvement” approach, which relies on the “adaptation, discussion and dissemination of evidence-based best practices by teams of healthcare providers.” The implementation process included facilitation of high-level advocacy with MoH authorities to establish AMTSL as a national policy; development of new AMTSL guidelines, which were incorporated as an addendum into national obstetric care standards; identification and dissemination of lessons on how to overcome operational barriers; promotion of AMTSL in all hospitals; distribution of health education materials; as well as the provision of oxytocin. The rate of oxytocin administration increased from 29 percent of women delivering vaginally during the first

three months of phase one (2003) to 38 percent in phase two (2006) and 75 percent in phase 3 (2009).

The overuse and misuse of oxytocin was identified as an unexpected outcome in one Honduran study that examined increasing AMTSL in a low-resource birth center staffed by auxiliary midwives (Low, Bailey, Sacks, Robles, & Medina, 2012). Although oxytocin use immediately after birth increased from 64 to 97 percent, the use of oxytocin at the intrapartum stage also increased—from six to 22 percent of cases—and significantly correlated with a higher estimated blood loss. The overuse of oxytocin for labor induction and augmentation by auxiliary midwives at home births had also been reported in India (Jeffery, Das, Dasgupta, & Jeffery, 2007). In a review of the literature on uterotonics used for home births, qualitative evidence suggested that both laboring women and birth attendants perceived intrapartum uterotonics positively, even though uterotonics had been shown to cause harm to the woman and fetus when used prior to delivery (Flandermeier, Stanton, & Armbruster, 2010). The findings suggest that programs that aim to increase use of oxytocin for PPH should also consider increasing risk awareness among women and birth attendants on the appropriate use of uterotonics.

A new technology to deliver oxytocin—the Uniject™ device developed by PATH—was the focus of eight studies conducted in Latin America, Asia and Africa (Althabe et al., 2011; PATH, 2010, 2011; POPPHI, 2008; Stanton et al., 2012; Tsu et al., 2003, 2009; Viet Nam MoH & PATH, 2005). The prefilled syringe addresses common challenges faced by skilled health care workers administering oxytocin, by ensuring that an accurate dose of medicine is delivered to a patient with minimal preparation.

In Argentina, the use of prophylactic oxytocin among birth attendants in hospitals increased from 14.6 percent at baseline to 85.6 percent during the intervention period, and most of the birth attendants (96 percent) reported that the Uniject™ device facilitated oxytocin administration (Althabe et al., 2011). In Indonesia, Tsu et al (2003) interviewed 140 village midwives and 2220 mothers—whose deliveries the midwives attended during the intervention period—about their experiences and views of oxytocin delivered by the Uniject™ device. The assessment was done in three rural districts and one municipality in Lombok. Midwives had little difficulty using the Uniject™ device properly and stated an overwhelming preference for it over standard needles and syringes. Postpartum hemorrhage rates did not change

substantially. Similar results were found in three districts of northern Viet Nam in (Tsu et al., 2009). Using baseline and post-intervention questionnaires, 52 midwives from a district where AMTSL was already practiced and 35 midwives from a district where AMTSL was introduced as part of the study, reported that the Uniject™ device was easier to use than and preferable to ampoules and standard syringes.

The Uniject™ device also makes it easier for non-skilled attendants to administer oxytocin, because it is prefilled with the correct dosage. Studies that have examined its use among non-skilled attendants have also found positive results. In Mali, auxiliary midwives (non-skilled birth attendants) were trained in AMTSL and the use of oxytocin in a Uniject™ device. The majority of study participants found the Uniject™ device to be highly acceptable and easier to use than standard syringes and considered the trainings to be effective in training health workers on AMTSL and the Uniject™ device.

Because oxytocin is temperature sensitive and loses effectiveness after three months of being stored at temperatures higher than 30 degrees Celsius (86 degrees Fahrenheit), the use of a time temperature indicator (TTI) affixed to the oxytocin packaging is a potentially valuable tool to decrease the administration of ineffective oxytocin and improve quality of care. Where tested, the TTI has been well received and found to be easy to interpret (PATH, 2010, 2011). Among private midwives in Indonesia, the TTI was the “most preferred market differentiator and a priority innovation for oxytocin” (PATH, 2011). Only two of the studies reviewed included client perceptions of the device; however, those views were communicated through provider reports.

In Mali, the majority of providers felt that there were no negative reactions from clients. Only nine providers (6.4 percent) responded that women had refused to be injected with the Uniject™ device and cited lack of knowledge about the product and fear as reasons for the women’s decisions (POPPHI, 2008). In Indonesia, midwives reported that clients were satisfied with the device. Of those that provided specific client comments, less bleeding and pain at the injection site were reported, though a few perceived the Uniject™ needle as being too big (Tsu et al., 2003).

Conclusions and recommendations for oxytocin are included with the misoprostol section on the next page.

Misoprostol



Commodity Overview

The WHO recommends the use of uterotonics for the prevention of PPH during the third stage of labor for all births and recommends oxytocin as the uterotonic of choice for prevention and management of PPH. In settings where skilled birth attendants are not present and oxytocin is unavailable, the administration of misoprostol (600 mcg orally) is recommended for the prevention of PPH. WHO recommends 800 mcg sublingually as third line treatment for PPH.

Misoprostol is a prostaglandin—a synthetic hormone-like substance available in an oral tablet form containing 25, 100 or 200 mcg per tablet. Because the tablets can be affected by moisture and heat, they can be stored at room temperature if appropriately packaged in double-aluminum blister packs. The cost per tablet from manufacturers is approximately US \$0.15. It is available from more than 50 manufacturers globally (at least 35 of which are in developing countries).

Misoprostol can also be used for other indications, including to treat gastric ulcers, induce labor or missed miscarriages, and as an abortifacient. The latter use explains some of the controversy surrounding the drug and some countries' reluctance to recommend its use.

[Sources: UNCoLSC, 2012; WHO, 2012]

The evidence review found 21 documents related to demand generation for misoprostol that met the inclusion criteria, of which 10 were published in peer-reviewed literature. The evidence was documented from Africa (9 studies) and Asia (9 studies), as well as one literature review spanning low-resource countries and two crosscutting technical reports. The review identified five studies from four pathfinder countries – Senegal, Tanzania, Nigeria and Ethiopia.

Key social and behavioral drivers

Five articles evaluating interventions to promote and educate on the use of misoprostol for PPH in the evidence review specified key social and behavioral drivers. All

studies showed that birth attendants and community health workers with knowledge of misoprostol and the significance of PPH, play a strong role in use of misoprostol.

In all three studies from Bangladesh (EngenderHealth/The RESPOND Project, 2010; Mobeen et al., 2011; Prata et al., 2012b), community distribution of misoprostol helped increase use of misoprostol after delivery. Misperceptions, especially concerning when to take the drug (either before or after delivery), were one of the main reasons for nonuse of the drug in one study (EngenderHealth/The RESPOND Project, 2010). In another study, the following factors were cited as reasons that women did not take the drug after delivery: lack of knowledge about misoprostol (66 percent), belief that it is not necessary (14.4 percent), community

health workers (CHWs) were not present or drug was not available (17.6 percent) and husbands' objection to use of the drug (1.6 percent) (Mobeen et al., 2011).

Results from a community mobilization effort in 2009 to increase access to misoprostol for PPH prevention in five communities around Zaira, in northwestern Nigeria, highlighted the importance of birth attendants in use of misoprostol (Prata et al., 2012a). Community mobilization efforts reached most women with information about PPH and misoprostol (88 percent), resulting in high comprehension of intervention messages. During postpartum interviews with the 1875 women enrolled in the study, women said that TBAs, midwives and health facilities (in that order) were the main sources of information about bleeding after childbirth. These women also said that TBAs, community-oriented resource persons and midwives (in that order) were the primary sources of information about misoprostol. The small proportion (18 percent) of women who did not take misoprostol to prevent PPH primarily reported that they either were not offered misoprostol (60 percent), took an injection (12 percent), forgot to take misoprostol (7 percent) or, in a few cases (4-5 percent) could not find the drug, did not think they would need it or their husband/family would not allow them to take it (Prata et al., 2012a).

Although results of an evaluation of a pilot study in Ethiopia confirmed the ability of CHWs to deliver misoprostol safely, the evaluation highlighted the importance of training others to distribute misoprostol as well (Ethiopia FMOH, 2008). In 2007, 128 health extension workers (HEWs), representing 120 health posts in Amhara, Oromiya, SNNP and Tigray regions, were trained on the administration of misoprostol. The introduction of misoprostol into these communities by HEWs increased the community's willingness to seek delivery care from HEWs, increased collaboration between HEWs and TBAs, and increased demand for misoprostol from community members (Ethiopia FMOH, 2008).

Implementation strategies and impact

In articles evaluating PPH interventions using misoprostol, the target populations were health workers (15 articles), pregnant women (12 articles) and TBAs (7 articles). Most implementation strategies focused on front-line services and delivery, particularly health worker training both for skilled and unskilled birth attendants. In India, rural primary health center paramedical workers and medical officers received training on AMTSL, including the administration of oral misoprostol; 99 percent of the intervention group workers experienced a significant reduction in the duration of third stage labor and median

blood loss after delivery (Chandhiok, Dhillon, Datey, Mathur, & Saxena, 2006).

In Bangladesh, a program targeting TBAs' knowledge, attitudes and practices related to PPH management in home births trained community-based providers on aspects of misoprostol, absorbent delivery mats, identifying high risk pregnancies and danger signs, referral procedures, stages of labor, general use of clean delivery kits and other safe delivery practices (Prata et al., 2012a). Knowledge of misoprostol as a way to prevent excessive bleeding increased significantly immediately after training ($p < 0.0001$) and increased further at six and 18 months—of which the increase between six and 18 months was statistically significant ($p < 0.0001$).

Knowledge of correct usage also increased following the training, when nearly all TBAs stated that they should not administer misoprostol to a woman while she is still pregnant, with knowledge remaining high at six and 18 months after implementation. In cases where women delivered with a TBA trained in the intervention ($n = 1280$), over 80 percent took misoprostol, which is significantly higher than those who took misoprostol who delivered with a TBA not trained in the intervention ($p < 0.0001$), a relative ($p < 0.0001$), a nurse ($p < 0.0001$), a doctor ($p < 0.0001$) or no one ($p < 0.01$). However, the authors note that the intervention groups participated in a well established and respected maternal health program, which may limit the generalizability of program results. The potential for incorrect timing of misoprostol administration among unskilled birth attendants is often cited as a concern for scaling up community-based misoprostol programs. In Bangladesh, Prata et al (2012b) found that incorrect timing was very low overall, it was reported in 0.1 percent of women who had TBAs assist them and 0.3 percent across all other groups.

Direct distribution of misoprostol to pregnant women through antenatal care and community outreach has also been tested. In Mozambique, awareness generating activities included education sessions at antenatal care (ANC), community meetings and one-on-one sessions with women on birth preparedness and PPH prevention. The outreach messages focused on four key points: delivering in a health facility, planning for a safe delivery, PPH identification using traditional pieces of cotton cloth and misoprostol for prevention of PPH (Ikafara Health Institute, VSI, Bixby Center for Population, Health and Sustainability, & PSI Tanzania, 2011). The majority of women enrolled used misoprostol they received at ANC and over 99 percent took the correct dose. Acceptability was very high, with over 96 percent willing to recommend misoprostol to a friend or use in a subsequent delivery.

Women who used misoprostol were significantly more likely to say they would purchase the tablets, compared to those who had not used it. The authors concluded that all ANC providers should be trained to distribute misoprostol during routine ANC services. Community awareness and education were integral to community acceptance and utilization of services (Ikafara Health Institute et al., 2011).

In Bangladesh, a pilot project to distribute misoprostol in the community to prevent PPH started with advocacy efforts targeted at health policy makers and program managers to build support for the approach (EngenderHealth/The RESPOND Project, 2010). Partners drafted a misoprostol policy and implementation plan, and developed training curricula, educational materials and monitoring tools prior to implementation. During the implementation period, field workers were trained on how to educate women about misoprostol and safe motherhood. Community outreach included community meetings, home visits, registration of pregnant women and placing stickers in women's homes to remind them to take the tablets immediately after birth. 12,961 women received the medicine at 32 weeks gestation, 92 percent of whom took the medicine after delivery.

Most women were satisfied and noticed decreased bleeding after pregnancy, compared to previous deliveries. Non-usage of misoprostol in the intervention group was associated with misperceptions of the medicine, but the authors argue that increased inclusion of TBAs and other influential community members can increase coverage in areas where home births are the norm (EngenderHealth/The RESPOND Project, 2010).

In northwest Kaduna state, Nigeria (Prata et al., 2012a), a program aimed at increasing community mobilization around PPH prevention trained community-oriented resource persons and TBAs on counseling pregnant women through individual and group education sessions. The program also recruited community members and trained them to serve as "drug keepers" to properly store and dispense misoprostol. Community outreach was used to educate participants on birth preparedness and the prevention of PPH through community dialogues and drama, as well as print materials.

Based on feedback, the program distributed hijabs for Muslim women, head ties for Christian women and butas for Muslim men and inscribed them with the simple message, "Take three tablets of misoprostol immediately after birth to prevent post-partum hemorrhage." The materials were often cited as helping to disseminate information on PPH prevention and misoprostol within the target area. Most women (88 percent) who used

misoprostol for PPH prevention reported using it at the correct time and 98 percent reported using the correct dose. The authors concluded that the use of community-recommended methods for message delivery proved effective in increasing the relevance of the messages, as well as tailoring dissemination, which in turn contributed to intervention uptake. They also noted that regardless of the distribution of the medicine, the TBA or person assisting the delivery is essential in helping to spread educational messages and ensure proper drug usage (Prata et al., 2012a).

In Zambia, a program included community awareness activities on birth preparedness and PPH prevention in five rural districts (Zambia MoH, 2010). The awareness campaign used radio, posters, pamphlets and counseling sessions with ANC providers, and community safe motherhood action groups. Acceptability of the medicine was extremely high; 80 percent of women who took the medicine home reported using it and 88 percent properly recalled the appropriate timing of usage. Most women reported they would use the medicine again—even purchase it themselves—or recommend it to others. The authors concluded that multiple strategies and channels were key to reaching communities with information. ANC was an important point of contact to reach pregnant women with the misoprostol tablets, and community-level sensitization agents successfully reinforced messages about proper usage of the drug. Common materials used in community outreach efforts included flipcharts for use in counseling sessions with pregnant women, leaflets, posters, clean birth kits, pictorial instructions on safe delivery and PPH prevention, including misoprostol usage (Zambia MoH, 2010).

Conclusions, knowledge gaps and recommendations

Interventions to increase the use of oxytocin and misoprostol for the treatment of PPH were primarily focused on front-line services and delivery, particularly skilled health worker training. Yet, approximately 30 percent of births throughout the world are attended by unskilled attendants (KFF, 2012). Although it was beyond the scope of this review to assess literature related to skilled birth attendance, it is clear that increasing the proportion of births delivered with a skilled birth attendant is a foundational intervention to ensure uptake and utilization of oxytocin and misoprostol to reduce PPH.

Low awareness of PPH among communities and providers, inadequate knowledge of uterotonic among providers and lack of guidelines on PPH prevention and treatment are key barriers that need to be overcome in order to accelerate the uptake of oxytocin and misoprostol.

Recommendations to overcome such barriers include:

1. **Raise awareness of PPH in communities.** Increasing awareness of PPH—and the use of oxytocin to prevent it—among community members may be useful, especially if the use of the Uniject™ device by community-based health workers at home births is found to be an effective strategy. Careful sensitization of local communities may be important in certain contexts, such as where women are fearful of being given contraceptive injections against their will (POPPHI, 2008). Little evidence was found that examined client perspectives related to the use of oxytocin—such research could inform communication messaging targeted at pregnant women and their communities. A combination of mass media and traditional communication channels could be used to reach pregnant women and their families with messages framing oxytocin as a safe, highly effective replacement for traditional substances that may be used by women and TBAs for PPH.
2. **Increase knowledge among all healthcare providers.** Evidence shows that skilled birth attendants at health facilities are often trained in AMTSL as a way to increase use of oxytocin for PPH prevention and treatment. However, this training is not often provided to untrained or minimally trained birth attendants. Targeting PPH prevention in home births through AMTSL, including oxytocin and misoprostol, would fill a significant gap in coverage and care for populations without access to health facilities.
3. **Develop explicit guidelines on PPH prevention and treatment.** At the administrative level, lack of leadership commitment and explicit guidelines on PPH prevention and treatment—and oxytocin use specifically—leaves health workers without clear guidance on standard protocols. The active participation of health care providers in the development of such protocols was found to be an effective way to overcome resistance to change when new guidelines or protocols are imposed from the top down (Althabe et al., 2011). Use of peer opinion leaders as innovators or early adopters and continued reinforcement and retraining of providers are other potential strategies that could be more widely implemented.
4. **Consider product packaging.** The traditional packaging of oxytocin in ampoules creates difficulties for some birth attendants, especially when no assistance is available to attend to multiple demanding needs in the moments after birth (PATH, 2010; Tsu et al., 2009; Viet Nam MoH, 2005). The potential contribution of the Uniject™ device may help expand the use of oxytocin to a wider variety of users, including minimally trained birth attendants, by reducing the complexity of administration.

Magnesium Sulfate



Commodity Overview

MgSO₄ is the most effective medication for the prevention and treatment of eclampsia and is recommended by the WHO for the treatment of women with severe pre-eclampsia or eclampsia, in preference to other anticonvulsants.

Magnesium sulfate is the standard treatment for eclampsia in the majority of developed countries, but less effective and riskier medications, such as diazepam and phenytoin, are still widely used in developing countries.

Magnesium sulfate is administered by injection into the woman's vein or muscle. The full intravenous or intramuscular magnesium sulfate regimens are recommended for the prevention and treatment of eclampsia. Calcium gluconate—a mineral supplement—is an antidote available in the rare event of magnesium toxicity.

The number of vials required to treat depends upon the strength of the preparation (ideally 50 percent) and volume of each vial (2 ml upwards). Recommended dose is 14 g loading and 5 g every four hours, which would result in 44 g. Magnesium sulfate costs approximately US \$0.10 per ml (supplier median price) and is produced by one global manufacturer and many local manufacturers worldwide.

[Sources: UNCoLSC, 2012; WHO, 2011]

The evidence review found 14 documents related to demand generation for MgSO₄ that met the inclusion criteria. The evidence was documented from Latin America (2 articles), Africa (7 articles) and Asia (2 articles), as well as three documents with a global focus.

Key social and behavioral drivers

The documents reviewed suggest lack of knowledge as a key barrier to use and highlighted the need to promote education among providers and community members on the benefits of MgSO₄ to prevent and treat pre-eclampsia and eclampsia (PE/E). Incorrect knowledge regarding potential side effects to mother and unborn child can also lead to reluctance in timely administration of MgSO₄.

For example, a study in India (Barua, Mundle, Bracken, Easterling, & Winikoff, 2011) found that some providers do not use MgSO₄ out of concern for side effects, safety, and utility. Providers were not familiar with the treatment options and guidelines for PE/E using MgSO₄ and did not feel knowledgeable enough in its administration. Although the providers in this study were generally familiar with the severity of PE/E, practice differed across different levels in the health system—the primary fear was the effect on the fetus or mother when MgSO₄ was used in combination with other medical procedures. The study suggests that interventions need to address service provider knowledge and attitudes about treatment of PE/E (Barua et al., 2011).

In addition to provider lack of knowledge, an observational study of obstetric services in Lusaka, Zambia (Ridge, Bero, & Hill, 2010), found that poor procurement, market demand and poor training also contributed to low MgSO₄ administration. The study suggests that lack of knowledge, plus poor access and other structural barriers, impede prioritization of MgSO₄. To address these barriers, job incentives, professional development opportunities and refresher classes could help increase uptake and improve the health of women. Similarly, a global report on PE/E by O'Hanley et al (2007) states that even when health care providers understand the severity of PE/E they fail to treat due to the absence of clinical guidelines and standards, inadequate knowledge and lack of skills to administer correctly.

Implementation strategies and impact

Although most countries include MgSO₄ on their essential medicines lists, the studies reviewed show a gap between policy and practice concerning the use of MgSO₄. The interventions examined focused on policy and service delivery changes to increase use of MgSO₄, with an emphasis on building health care provider knowledge and capacity to administer the medication. In Tanzania, one study evaluated quality of care for PE/E women in a tertiary hospital setting using a criterion-based audit approach (Kidanto, Mogren, Massawe, Lindmark, & Nystrom, 2009). A total of 389 eclamptic patients were admitted into the hospital within a seven-month period. The study found that quality of care was seriously compromised and MgSO₄ was not part of a broader quality of care package for pregnant women. The authors identified specific management improvement mechanisms for emergency care of PE/E, including standardizing management guidelines, involving the appropriate health care cadres, and providing educational and training opportunities for junior staff. The study shows how the introduction of quality improvement approaches can lead to actionable items to improve care (Kidanto et al., 2009).

A retrospective study, conducted in both Mexico and Thailand, assessed uptake of MgSO₄ for the treatment of PE/E following a randomized controlled trial that introduced an educational strategy to improve overall clinical obstetric practice (Lumbiganon, Gülmezoglu, Piaggio, Longer, & Grimshaw, 2007). The clinical trial randomized hospitals to receive three interactive trainings on evidence-based medicine; however, the trainings did not specifically focus on MgSO₄. The study found that the provision of MgSO₄ remained low in both settings. The authors speculated that providers might be reluctant to introduce a practice for a condition that is relatively rare and requires demanding monitoring. They concluded that despite the compelling evidence for a drug like MgSO₄,

measures should be taken to ensure that clinical practices are audited and quality care is provided. The findings show that general training without explicit guidance on MgSO₄ was ineffective and highlighted the importance of targeting the specific barriers associated with MgSO₄ in the local context.

Other studies demonstrate the effectiveness of a comprehensive, multi-level approach by integrating advocacy, collaborative protocol development and health care provider training. In Nigeria, a series of advocacy and training workshops to increase demand and acceptability of MgSO₄ for the treatment of PE/E took place in Kano, where eclampsia is the most common cause of maternal death (Tukur et al., 2011, 2012). The intervention began with a series of advocacy meetings with government officials, which included demonstrating the strong evidence that MgSO₄ could reduce maternal deaths. The next step was a training workshop for doctors and midwives on the administration of the medication and the training of peers who were unable to attend the workshop. During this workshop, they also developed a locally relevant treatment protocol. Results were evaluated through medical records over a 12-month period and suggest that maternal deaths attributable to PE/E had reduced. The authors also concluded that patient-provider relations improved, stock outs were minimized and the state government began procuring MgSO₄ because of the perceived success of the drug and social pressures (Tukur et al., 2011, 2012).

Low-cost, participatory, upstream efforts can also engage policy makers and researchers to create a window of opportunity where priorities for maternal health and MgSO₄ overlap. Using a qualitative case study methodology that included key informant interviews with stakeholders and a document review, a multi-country study conducted in Malawi, South Africa and Zimbabwe, assessed how effective various policy approaches were in the introduction of MgSO₄ for PE/E (Woelk et al., 2009). Results suggest that the process of putting evidence into practice was more successful when key stakeholders were involved in generating and evaluating the evidence (e.g., health care providers that participated in clinical trials). Additionally, the creation of regional research networks helped build a culture of evidence-based medicine and created spaces for researchers, obstetricians and policy makers to come together to prioritize maternal health and MgSO₄ (Woelk et al., 2009). Another case study (Daniels & Lewin, 2008) explored how findings from randomized control trials and systematic reviews informed the prioritization of MgSO₄ in South Africa. The study focused on understanding the policy process in the development of clinical guidelines for

the treatment of PE/E through key informant interviews and a document review and analysis. Similar to Woelk and colleagues (2009), this study provides experience of successful policy interventions to improve maternal health that are focused on bringing key stakeholders together, allowing for knowledge translation and evidence-based planning. Findings suggest that creating networks of researchers was especially important for building interest around improved maternal health and seizing a window of opportunity to translate evidence and political will into action—bringing together researchers and policy makers and creating the space needed for both groups to find common ground. The result was the development of new maternity guidelines informed by internationally recognized randomized trials recommending MgSO₄ for the treatment of PE/E (Daniels & Lewin, 2008).

Although the majority of research focused on provider-level administration, MgSO₄ can be administered at the community level; however, little evidence has been published. Results of a quasi-experimental intervention in rural Bangladesh showed remarkable achievements in using MgSO₄ at the community level for eclampsia and severe eclampsia cases; among 256 women participating in the study, only three maternal deaths were reported in the study group (2.3 percent) compared to 14 (10.4 percent) in the non-intervention group (Shamsuddin et al., 2005). It is clear that more research is needed in the area of community-based provision of MgSO₄.

Conclusion, knowledge gaps and recommendations

The barriers to uptake of MgSO₄ were similar across the studies reviewed and included lack of political will, lack of country-specific clinical guidelines for administration, poor availability of the medication, lack of incentives for health care providers, poor understanding of the symptoms of PE/E, resistance to change and lack of or inaccurate provider and community knowledge about MgSO₄—

specifically faulty knowledge about side effects of the drug on mother and fetus. Specific recommendations to increase the use of MgSO₄ follow.

1. Increase provider knowledge about treatment options and guidelines for PE/E. Research showed that providers did not feel sufficiently knowledgeable in the administration of MgSO₄; incorrect knowledge regarding potential side effects to mother and unborn child can lead to provider reluctance in timely administration of MgSO₄ to treat PE/E. Providers were also not familiar with established treatment guidelines for PE/E using MgSO₄. The implementation strategies reviewed suggest the importance of partnership and collaboration among researchers, health care providers and local leaders, and provide practical examples of successful efforts.
2. Increase political support for MgSO₄. Although the effectiveness of MgSO₄ has long been established and many countries have MgSO₄ in their essential medicines lists, increased political will is necessary to ensure that MgSO₄ is available and that international clinical guidelines are translated into local clinical practice. In areas of high population density and high maternal mortality, demonstration projects can show communities, providers and politicians how MgSO₄ can reduce mortality and morbidity.
3. Conduct more research on community-level barriers to MgSO₄ uptake. The review resulted in very little information about specific MgSO₄ efforts at the community level, indicating a significant research gap. More evidence is needed to understand community-level barriers to MgSO₄ uptake, such as addressing lack of knowledge of the medication and late recognition of pregnancy-related complications, especially those related to PE/E.



Newborn Health Commodities: Injectable Antibiotics, Antenatal Corticosteroids, Chlorhexidine, Resuscitation Devices

Approximately 3.1 million newborns die every year before their first birthday. These deaths account for 41 percent of the total under-five mortality rate (Rajaratnam et al., 2010). The highest risk of death is on the first day of life, and three-quarters of neonatal deaths happen within the first week (Bryce, Boschi-Pinto, Shibuya, & Black, 2005; Kinney et al., 2010; Lawn, Cousens, & Zupan, 2005; Lawn, Ruban, & Rubens, 2008; Seale, Mwaniki, Newton, & Berkeley, 2009). Approximately 99 percent of neonatal

deaths occur in developing countries (Black et al., 2010). However, treatments and medicines are available, yet not widely used, that could prevent many of these deaths. Four underutilized commodities—specifically aimed at improving newborn health—identified by the Commission are injectable antibiotics for newborn sepsis, antenatal corticosteroids for fetal lung maturation, chlorhexidine for newborn cord care and resuscitation devices for newborn asphyxia (UNCoLSC, 2012).

Injectable Antibiotics



The risk of death is great for newborns with serious infections—whether hospitalized or at home—in part due to late or inadequate administration of necessary antibiotics. Mortality rates of early-onset sepsis (< 7 days) is between 3 percent and 40 percent, and for late-onset sepsis (> 5 days) is between 2 percent and 20 percent. Low birth weight, HIV or other co-morbidities can hasten early demise (UNCoLSC, 2012).

Sick newborns often present with non-specific signs and symptoms, which makes diagnosing neonatal sepsis difficult, and, as a result, treatment—if sought at all—is often received too late. Because newborn infection has such a rapid onset, urgent diagnosis and treatment is needed.

Commodity Overview

The WHO lists four injectable antibiotics for the treatment of neonatal sepsis on the Essential Medicines List for Children: ampicillin or benzylpenicillin, gentamicin and ceftriaxone. WHO recommends antibiotic treatment with benzylpenicillin and gentamicin as first-line therapy for presumptive treatment in newborns at risk of bacterial infection. The recommendation is a standard therapy of intramuscular injections of 50 mg/kg body weight of ampicillin (or a comparable penicillin such as benzylpenicillin) every six to eight hours—depending on age—plus 7.5 mg/kg body weight of gentamicin (or another comparable aminoglycoside), divided twice daily for at least ten days. It is important to note that gentamicin and benzylpenicillin cannot be mixed in the same syringe, separate injections must be administered.

WHO also recommends ceftriaxone delivered alone for the treatment of neonatal sepsis as a second-line therapy. In a randomized clinical trial in Pakistan, ceftriaxone was shown to be as effective as once daily administration of procaine benzylpenicillin and gentamicin. The recommended dose of ceftriaxone is 50 mg/kg once daily for all newborns, except those older than one week and who weight more than 2 kg. In slightly older and heavier newborns, the dose is increased to 75 mg/kg once daily for ten days.

The average cost, depending on weight and length of treatment, is approximately US \$0.13–0.16 per treatment for benzylpenicillin, US \$0.17–2.03 per treatment for gentamicin and US \$0.50–0.90 per treatment for ceftriaxone.

WHO does not recommend procaine benzylpenicillin as first-line treatment for neonatal sepsis except in settings with high neonatal mortality—when given by trained health workers in cases where hospital care is not achievable.

[Source: UNCoLSC, 2012; WHO, 2012]

The evidence review found seven studies related to demand generation specifically for injectable antibiotics that met the inclusion criteria, six which were published in the peer-reviewed literature. The evidence was documented from India (1 article), Bangladesh (1 article) and Nepal (3 articles). Also, the review found two articles related to demand generation for neonatal care, including injectable antibiotics, which spanned multiple countries.

Key social and behavioral drivers

Current guidelines recommend that injectable antibiotics for treatment of neonatal sepsis be delivered by skilled health providers (WHO, 2012). However, a number of social and behavioral barriers hinder the uptake of this commodity by skilled providers. Even in the most sophisticated settings, diagnosing neonatal sepsis is difficult (Qazi & Stoll, 2009; WHO, 2012). As a result, treatment—if sought at all—is often received too late (Every Woman Every Child, 2012). On the supply-side, drugs needed to treat the illness are often not readily available and stock outs are common. Additionally, some health facilities lack pediatric syringes, making the proper dosing of antibiotics for infants challenging (Every Woman Every Child, 2012).

Barriers also exist at the community level that limit the use of injectable antibiotics to treat neonatal sepsis. In countries such as Ethiopia, general low demand for neonatal health care limits the use of available services (Knippenburg et al., 2005). Limited access to media, few relevant or appropriate messages, use of traditional practices and belief in fatalism can contribute to lack of demand for neonatal care (Knippenburg et al., 2005). For example, in Nepal, strong cultural taboos forbid taking newborn infants out of the home. Additionally, caregivers are often opposed to the concept of giving newborns injections (Shrestha, et al., 2011). Underrecognition of illness, caregiver delay in seeking treatment, cost of treatment and lack of access to workers appropriately trained to manage sepsis limit the uptake of injectable antibiotics (Qazi & Stoll, 2008).

Implementation strategies and impact

The level of attention to the topic of neonatal sepsis, including approaches to treatment, differs by country. Many countries do not include the antibiotics used to treat neonatal sepsis on their essential medicines lists and have unclear or nonexistent policies regarding the availability and use of these drugs at the various levels of the health system. Similarly, few countries have strategies that address community-based treatment and management of neonatal sepsis by lay health workers, and there is often no clear agreement by policy makers on the optimal

antibiotic treatment at the community level (Coffey et al., 2012a; Every Woman Every Child, 2012).

Current guidelines recommend treatment of neonatal sepsis by a trained health worker; however, this is often difficult to achieve in rural and/or low-resource areas. Interventions in India, Bangladesh and Nepal, have tested the treatment of newborn sepsis by community health workers (CHWs). In these studies, CHWs were trained to diagnose and treat sepsis during visits to households with newborns. In India, village health workers (VHWs) used injection gentamicin and oral co-trimoxazole to treat suspected cases of sepsis (Bang et al., 2005). In Bangladesh, CHWs treated neonates from families who were unable to comply with referrals, but consented to home treatment with injectable procaine penicillin and gentamicin for 10 days (Baqui et al., 2009).

In Nepal, female community health volunteers (FCHVs) treated infants with possible severe bacterial infections with gentamicin in Uniject™ (Coffey et al., 2012b). The majority of lay health workers were able to correctly diagnose sepsis cases—in one Indian study, 89 percent were reported (Bang et al., 2005); and, in a Bangladesh study, 33 percent of very severe disease cases were identified by the second day of life and 67 percent by day eight (Baqui et al., 2009). Case-fatality rates were lower for those infants who were treated—6.9 percent from 16.6 percent reported (Bang et al., 2005) and 4.4 percent from 28.5 percent (Baqui et al., 2009). Although these few studies demonstrated that community-based management of neonatal sepsis is feasible and effective, WHO recommends additional research and evaluation in this area.

The main strategies for demand creation were presented only within the author recommendations of the two studies. Bang et al (2005) found that reducing sepsis-related neonatal mortality in the community setting in rural India with limited resources was possible because national opinion leaders and decision makers actively supported the approach. Although the community was initially skeptical of the ability of VHWs to treat sick infants with injectable antibiotics in the home, they became great supporters once the success of the intervention was established. In rural Bangladesh, Baqui et al (2009) concluded that home-based management of neonatal infections required at minimum: strong monitoring and evaluation, supportive supervision, an enabling policy environment and policy decisions to implement home-based management. The study also found that community education and mobilization was required to create awareness and increase demand for services.

Knippenberg and colleagues (2005) reviewed literature on the scale up of neonatal care—which included many interventions to both treat newborn sepsis and improve neonatal care. The authors found that the most highly recommended strategies to overcome demand barriers to scaling up neonatal care included: conduct research to understand practices, beliefs, community roles and networks; strengthen skills of existing CHWs; partner with community opinion leaders, especially women's groups; develop specific messages and use appropriate channels; promote collaboration and involvement of non-governmental organizations (NGOs); strengthen supply chain logistics; implement community-based distribution; and develop social marketing to educate and engage communities.

In rural Nepal, a study on a participatory intervention with women's groups on birth outcomes promoted demand for care through nine female-facilitated groups that met monthly and learned about prenatal issues through picture card games, health funds, stretcher schemes, production and distribution of clean home delivery kits and home visits (Manandhar et al., 2004). The women's groups brought about changes in home-care practices and health-care seeking behavior for both neonatal and maternal morbidity. The only barrier to using women's groups to help scale up use of injectable antibiotics was that CHWs would not be able to deliver injectable antibiotics beyond the intervention without the involvement and support of policy makers.

Conclusion, knowledge gaps and recommendations

Newborn infection has a rapid onset, and urgent diagnosis and presumptive treatment is needed. However, a number of social and behavioral barriers hinder the uptake of injectable antibiotics by health care providers. Recommendations to overcome each major barrier are presented in the next column.

1. Educate communities about danger signs in newborns and the important of seeking care, including treatment for neonatal sepsis. Poverty, cultural factors and limited access to media—which sometimes communicate inappropriate or inaccurate

messages—contribute to an overall lack of demand for neonatal care. More research is needed to determine the best strategies for educating mothers and other caregivers about neonatal sepsis. In some countries where CHWs are allowed to treat newborn sepsis, research has shown that families often refuse treatment. Although the research is limited, community education and mobilization through women's groups are potential approaches to educate communities and scale up the use of injectable antibiotics. However, these approaches need to be carried out in an enabling environment that includes support from policy makers.

2. Support additional research in various countries on community management of neonatal sepsis by lay health workers. Few countries allow village or community health workers to treat newborn sepsis. However, in a few studies, lay health workers have been shown to be successful in treating suspected cases of newborn sepsis with injectable antibiotics. In rural areas and areas with limited trained health providers, allowing CHWs to deliver this treatment could significantly increase uptake of this commodity and decrease neonatal mortality.
3. Support policy makers to reach consensus on the optimal antibiotic treatment for community scenarios. Agreement on optimal treatment would improve the assessment and development of a community strategy.
4. Ensure consistent, adequate, affordable supply. Increasing use of injectable antibiotics for neonatal sepsis depends upon the availability of appropriate-sized needles and antibiotic doses for neonates. Research revealed supply-side issues—such as health facilities only carrying adult-sized needles, making the proper dosing of antibiotics for infants impossible—can greatly impede the scale up of this commodity. Research also highlighted that many families refuse or fail to comply with referral to a health clinic because of the cost of and their inability to pay for treatment. Adequate, affordable supplies are critical for scaling up injectable antibiotics for neonatal sepsis.]

Antenatal Corticosteroids



Preterm birth is one of the highest burden conditions highlighted in the Global Burden of Disease report—nearly one in ten babies are born preterm (WHO, 2012). Over one million babies die each year due to preterm complications, most commonly from Respiratory Distress Syndrome (RDS) resulting from lung immaturity, which is second only to child deaths due to pneumonia (Black et al., 2010). Coupled with this high mortality, severe morbidity in surviving babies leaves millions with long-term disabilities and adult chronic diseases that result in financial and emotional strain on families, communities and society, which, in turn, potentially affects global economic growth (WHO, 2012).

An ACS injection can be given to women expected to deliver prematurely to help the lungs of the fetus develop. The availability and systematic utilization of ACS injection interventions could save more than 400,000 lives each year, if implemented in the highest burden countries (March of Dimes, PMNCH, Save the Children, & WHO, 2012). Studies have found that ACS injection for women at risk of preterm delivery is the most effective intervention to reduce the risk of RDS for preterm babies. It is the standard-of-care in most high-income countries, reducing neonatal mortality by 31 percent and moderate/severe RDS by 45 percent. Unfortunately, in middle and low income, high burden countries, ACS coverage is only 10 percent (Lawn et al., 2008).

Commodity Overview

Betamethasone and dexamethasone are two corticosteroids that are used to help premature babies' lungs develop. Both betamethasone and dexamethasone are administered as intramuscular injections. The positive effect on babies' lungs is higher if the first dose is injected at least 24 hours prior to time of birth.

Both drugs have a long history of wide use, strong efficacy and safe administration. In order to make definitive recommendations on choice of steroid and confidently measure risk of rarer outcomes, a very large trial or series of trials would be required, both of which are fairly cost prohibitive. However, it is clear that current evidence supports the use of either product to save lives safely. An advantage to using betamethasone is that it requires only two injections, compared to four injections of dexamethasone, which may be an important consideration at lower levels of the health system. However, injectable betamethasone is less commonly available and more costly. The average wholesale price for a full course in developed countries is approximately US \$40. Injectable dexamethasone is widely available at low cost from many producers of generic drugs. The average price across more than ten Indian suppliers is US \$0.51 per course of treatment.

Despite the extensive, high quality evidence of ACS for the indication of fetal lung maturation, only Argentina, Australia and New Zealand, have registration of ACS for the indication of fetal lung maturation. In other countries, the use of ACS for fetal lung maturation is technically off-label, although considered as a standard of care by ministries of health and obstetric societies.

[Source: Every Woman Every Child, 2012]

The evidence review found six documents related to demand generation for antenatal corticosteroids, five of which were published in the peer-reviewed literature. Given the paucity of literature, two studies from developed countries were retained in the review. The evidence was documented from Latin America (1 multi-country study), Africa (2 studies from Cameroon), the United States (1 study), the United Kingdom (1 study) and one conference proceedings document. The review did not identify any studies from pathfinder countries.

Key social and behavioral drivers

In addition to well-known non-behavioral barriers, such as lack of supplies, lack of or inadequate financing and lack of governmental promotion of interventions, studies show that awareness and knowledge of ACS were key factors determining use among providers. In Cameroon, a study of health workers found that only 29 percent (95/328) knew about ACS and only 10.2 percent (33/328) had ever used ACS. Barriers to awareness cited by these providers included: lack of continuing education; lack of adequate formal training (e.g., curricula do not emphasize use of evidence-based care); lack of access to educational resources (e.g., journals, newsletters, databases); lack of habit of self-learning, which includes lack of reading culture and updating knowledge; lack of exposure to evidence-based interventions; and slow dissemination of new interventions (Tita et al., 2005).

In another study in Cameroon, Tita and colleagues (2006) sought to identify the factors associated with the variation in awareness and practice of evidence-based obstetric interventions. They found that awareness of ACS was associated with 15-fold increase in practice. Other factors associated with increased awareness, but not practice, were obstetric/ gynecologic training and 5–15 years of work experience. Access to information through the Internet was associated with increased practice only. In the crude analysis, attending reproductive health educational events, access to the WHO Reproductive Health Library and working at an autonomous military or national insurance funds unit, were all associated with increased awareness of evidence-based obstetric care. Though these factors did not meet the criteria for statistical significance, the authors indicate that they are indicative of potentially important variations in awareness or practice of at least 50 percent.

In Latin America, ACS is used more frequently, although great variation exists between countries. In a multi-country regional study, Aleman and colleagues (2013) found that the proportion of providers administering ACS to women with threatened preterm labor varied

from 70 percent in Mexico to 97 percent in Ecuador. In Mexico, providers were less likely to administer ACS if the pregnant woman presented with complications (e.g., diabetes, hypertension, and any infection). In Ecuador, ACS are mentioned to be frequently provided in multiple pregnancies, in preterm premature rupture of membranes, and in hemorrhage in the second half of pregnancy. Previous preterm birth and pre-eclampsia without threatened preterm labor were cited as indications of ACS by more than 50 percent of the professionals in all the countries.

However, more than 25 percent in El Salvador and Ecuador, and more than 50 percent in Mexico, would not give ACS to a healthy woman with a gestational age of 27 weeks who was hospitalized due to threatened preterm labor. In contrast, almost all of the Uruguayan providers would give ACS in the same situation. Around two-thirds of providers in El Salvador, Ecuador, and Uruguay, would not give additional ACS to a woman in this clinical situation after discharge. However, in the case of a woman being hospitalized again with threatened preterm labor, approximately 40 percent of providers in all three countries would give an additional ACS dose.

The barriers to uptake and use of ACS found in the Latin American study included: the availability of ACS commodities (7.5 percent to 32 percent); and provider fear or doubt of the side effects (9 percent to 33 percent) (Aleman et al., 2013). Similar results were found in relation to questions about misinformation about the correct use of ACS. Other barriers cited included economic barriers and women's misinformation about the correct use of ACS. Many providers limited the use of ACS under certain obstetric conditions, without providing support from the literature to justify their decision.

Chan, Kean and Marlow (2006) found that neonatal doctors and nurses, in one hospital in the United Kingdom, were significantly more likely to recommend treatment at gestations earlier than 26 weeks, compared to obstetricians or midwives:

- at 21 weeks–32 percent vs. 0 percent ($p = 0.003$);
- at 22 weeks–32 percent vs. 0 percent ($p = 0.003$);
- at 23 weeks–80 percent vs. 17 percent ($p = 0.00$);
- at 24 weeks–100 percent vs. 82 percent ($p = 0.01$); and
- at 25 weeks–100 percent versus 85 percent ($p = 0.01$).

Despite the recommendation that every effort should be made to initiate ACS therapy in women between 24 and 36 weeks gestation, there was a lack of universal agreement amongst practitioners, especially midwives, on the administration of corticosteroids from 24 weeks gestation. The neonatal staff was much more likely

to request that corticosteroids be given at very early gestations, compared to the obstetric staff. Obstetricians who were pessimistic about neonatal survival were less likely to administer corticosteroids. The study concluded that decision making by healthcare professionals regarding the interventions was greatly influenced by their knowledge and attitudes.

Implementation strategies and impact

One study in the United States evaluated dissemination strategies aimed at increasing appropriate use of ACS for fetal maturation (Leviton et al., 1999). Researchers randomly assigned 27 tertiary care institutions to either usual dissemination of practice recommendations or usual dissemination combined with an active, focused dissemination effort, which consisted of a year-long educational effort led by influential physicians and nurses at each facility (coupled with grand rounds, chart reminders, group discussions of case scenarios, monitoring and feedback). The focused dissemination effort significantly increased odds of ACS use (OR 1.63) and increased the use of corticosteroids by 108 percent with active dissemination, compared to 75 percent in institutions with usual dissemination. However, this increase varied greatly across hospitals and was not explained by the treatment effect. Patient characteristics including gestational age and presence of premature rupture of membranes were both associated with baseline and increased ACS use.

McClure and colleagues (2011) reported from the 2011 Maternal, Newborn and Child Health Integrated Program (MCHIP) conference that, from the health system perspective, hiring and/or training skilled birth attendants who can identify women at risk of preterm births, who have knowledge regarding appropriate timing and use of ACS, and who can refer mothers to higher levels of care, is required for effective scale-up of ACS use. They recommend that ACS use can be increased through the training of providers and maintenance of the supply chain. The research presented at the conference also identified a number of crucial issues in communities where the majority of births and related care occur in home settings—e.g., how to engage mothers who intend to deliver at home and their caregivers to identify early signs of preterm labor; how to encourage families to seek care at hospitals that provide ACS and newborn care. The authors concluded that including the community is important for the success of most strategies aimed at addressing preterm birth.

Conclusions, knowledge gaps and recommendations

As with injectable antibiotics, the scope of research on demand generation for ACS is extremely limited. However, using the available literature, tentative recommendations to overcome the barriers identified are presented below.

1. Increase provider knowledge of ACS. Available studies show that awareness and knowledge of ACS were key factors determining use among providers. Barriers to awareness cited by these providers included: lack of continuing education, lack of adequate formal training, lack of access to educational resources, lack of habit of self-learning, lack of exposure to evidence-based interventions and slow dissemination of new interventions (Tita et al., 2005). Researchers found that awareness of ACS was associated with a 15-fold increase in practice (Tita et al., 2006).

One study suggested the use of daily physician-led ward rounds and weekly lectures, in addition to seminars and refresher courses at the hospitals to increase ACS use (Tita et al., 2005). Another study also showed increased ACS use following an active, focused dissemination effort led by influential peers, including grand rounds, chart reminders, group discussions of case scenarios, monitoring and feedback (Leviton et al., 1999).

2. Train skilled birth attendants and engage communities to identify early signs of preterm labor and refer to hospitals. From the health system perspective, hiring and/or training skilled birth attendants who can identify women at risk of preterm births, who have knowledge regarding appropriate timing and use of ACS and who can refer mothers to higher levels of care is required for effective scale-up of ACS use.

The 2011 MCHIP conference identified a number of crucial issues in communities where the majority of births and related care occur in home settings, and noted that including the community will be important for the success of most strategies aimed at addressing preterm birth (McClure et al., 2011). However, more research is needed to provide a better understanding of how to effectively engage communities to identify early signs of preterm labor and seek care at hospitals that can provide ACS to aid in fetal lung development.

Chlorhexidine



Severe infection is one of the top three causes of newborn deaths worldwide, claiming approximately 13 percent of all neonatal deaths each year. In low-resource, high-mortality settings, infections can account for over half of the neonatal deaths (Chlorhexidine TRT, n.d.). A baby's newly cut umbilical cord can be an entry point for bacteria, which can lead to cord infection and potentially life-threatening sepsis. Unsafe cord care techniques can lead to unnecessary illness and neonatal death by tetanus and other infections. In addition, provider preference for dry cord care does not sufficiently address newborn sepsis (Chlorhexidine TRT, n.d.).

The evidence review found 16 documents related to demand generation for chlorhexidine and/or newborn cord care that met the inclusion criteria. The evidence was documented from Asia and Africa.

Key social and behavioral drivers

At the individual level, traditional cord care practices and lack of access to knowledge about new interventions such as chlorhexidine are two key barriers to neonatal health and the scale up and use of the commodity. Research in Bangladesh and Nepal reveal several unhygienic traditional cord care practices. In Bangladesh, more than half of families surveyed applied substances to the stump after cord cutting of which turmeric and boric powder were the most common (83 percent and 53 percent respectively). Other common substances applied were mustard oil, ash, Dettol, coconut oil, Nebanol ointment, ginger and chewed rice (Alam et al., 2008). This research also showed that approximately 40 percent of newborns were bathed on the day of birth and umbilical stump care included bathing, skin massage with mustard oil and heat

massage on the umbilical stump (Alam et al., 2008). Similar traditional cord care practices were found in Nepal. The application of heated mustard oil mixed with different other substances over the cord stump, immediately after cutting the cord and during the first week of birth, was a very common practice in all the study castes (Nepal Family Health Program, 2007).

In the African studies reviewed, mothers also provided most newborn skin and cord care, and dry cord care was rare. In Nigeria, the mother's education level was the main predictor of beneficial cord care (Abullimhen-Iyoha & Ibadin, 2012; Opara et al., 2012). In a study where most respondents gave birth in a facility, received antenatal care (ANC) and were advised about cord care, 95.3 percent of respondents cleaned the stump with methylated spirit, but 32.4 percent applied additional substances to the stump (Opara et al., 2012).

The types of substances applied to cord stumps in Africa include antiseptics, liquids, oils, powders, ashes and herbal preparations. Other practices have potential impact on the use of chlorhexidine, particularly with regard to the timing of the release of the cord stump. In Tanzania, mothers and babies stay at home until the cord falls off in order to protect the newborn from witchcraft (Mrisho et al., 2008). In Uganda, dry cord care was found to conflict with spiritual beliefs attached to the use of local herbs (Byaruhanga et al., 2011). In Zambia and elsewhere, the length of time to cord detachment was of near-universal concern (Herlihy et al., 2013). Similarly in Bangladesh, caregivers were concerned about the timing of separation of the umbilical cord, and became worried if it did not fall off after seven days.

Commodity Overview

Chlorhexidine digluconate—used to make a variety of chlorhexidine-finished products—is readily available on every continent at low cost. The finished product for care of the umbilical cord stump (4 percent free chlorhexidine or 7.1 percent chlorhexidine digluconate) costs about US \$0.23 in raw materials per baby. Chlorhexidine has no toxicity risks, potential for misuse, and no special storage requirements.

Chlorhexidine digluconate is a widely used, low-cost antiseptic effective against major agents of neonatal infection. Since its introduction in the 1950s, it has been used regularly as a surgical and detail antiseptic, and carefully studied for safety and efficacy. The WHO recommendations for the care of the umbilical cord (1998) state that research from developed countries has shown that, compared to no treatment, application of a topical antimicrobial on the cord stump reduces colonization by harmful bacteria in hospital nurseries, but the effect on reducing infections is less clear. The recommendations also state that there is not enough evidence to recommend the widespread use of topical antimicrobials on the cord stump and that the decision to use them will depend very much on local circumstances.

The recommendations differ depending on place of birth and environmental context. For hospital settings, a topical antimicrobial is recommended if newborns are kept in nurseries or in intensive care units, but not if a 24-hour rooming-in system is in place and the mother is the main caregiver. For home deliveries, clean cord care is sufficient and the application of an antiseptic is not required. However, in areas at high risk of neonatal tetanus or where harmful practices, such as putting cow dung on the stump, are prevalent, an antimicrobial can be recommended to replace the harmful substance. The chosen antimicrobial should have a broad spectrum of activity against bacteria and should be affordable, culturally acceptable (a colored antiseptic is usually preferred), and available. If other harmful practices are prevalent, they should be discouraged or replaced with safer alternatives—e.g., if it is the custom to put bandages on the cord stump, a more sanitary alternative such as a clean piece of gauze can be recommended.

Since 2007, members of the Chlorhexidine Working Group have advocated for revision of the cord care guidelines to be more inclusive of effective topical antiseptics such as chlorhexidine. In September 2012, WHO convened an expert consultation to review evidence for postnatal care. The consultative meeting participants reviewed the evidence for chlorhexidine cord care and made the following recommendation to WHO: Daily application of 7.1 percent chlorhexidine digluconate to the umbilical cord stump immediately and during the first week of life is recommended for newborns who are born at home in settings with high neonatal mortality rate (greater than 30 per 1000 live births). Although WHO included 7.1 percent chlorhexidine digluconate (delivering 4 percent chlorhexidine) for umbilical cord care on the WHO Model List of Essential Medicines for Children in July 2013, the 1998 recommendations on cord care have not yet been updated. It is expected that WHO will issue updated guidance on umbilical cord care in the near future.

Recent community-level randomized controlled trials in Nepal, Pakistan and Bangladesh have shown that applying a 7.1 percent chlorhexidine digluconate (delivering 4 percent free chlorhexidine) product to the umbilical cord saves lives (ICDDR, 2012; Mullany et al., 2006; Soofi et al., 2012). Across the three countries, data from over 54,000 newborns showed an aggregate 23 percent reduction in neonatal mortality (not including deaths in the first few hours of life) and a 68 percent reduction in severe infections for the chlorhexidine intervention groups. These are some of the largest effect sizes seen in any neonatal intervention (UNCoLSC, 2012). It is estimated that chlorhexidine has the potential to reduce overall newborn mortality risk by up to 18 percent, resulting in over half a million newborn lives saved (Hodgins, Pradhan, Khanal, Upreti, & KC, 2013; UNCoLSC, 2012).

In the literature reviewed, mothers were the principal providers for skin and cord care during the neonatal period. However, factors at the family/peer and community levels influence cord care practices, including lack of social support for use of chlorhexidine. A study from Nigeria found that nurses were most influential regarding cord care (51.3 percent), followed by the maternal grandmother (32 percent) and paternal grandmother (5.8 percent) (Abullimhen-Iyoha & Ibadin, 2012). In Uganda, grandmothers play a key role in determining cord care practices, especially with young mothers. Other family and community members are also involved in newborn care, these include sisters, older children and neighbors. Family networks are a key source of information about cord care (Ayiasi et al., 2013). Two studies in Bangladesh found that mothers, grandmothers and other female caregivers felt that traditional practices—like the application of mustard oil to the cord—are essential to protect the neonate from cold and associated health problems (Alam et al., 2008; Winch et al., 2005).

At the society level, key barriers include gender power dynamics within families and lack of access to the commodity. Mothers are often not able to make decisions related to care seeking and treatment, which was a potentially important determining factor to consider. In Bangladesh, India and Nepal, a majority of births take place at home, often with the help of untrained or minimally trained birth attendants who are not knowledgeable about or equipped with chlorhexidine. In these countries, Chlorhexidine is not usually included in the supplies used in home births like clean delivery kits.

Barriers—such as high cost, lack of access to the drug, clear guidance, and need for physician buy in—are also present at the health system level. A study conducted in rural Bangladesh highlighted the willingness of 1717 couples to pay for three types of topical antiseptic products (single-dose liquid, multi-dose liquid and gel preparation) containing 4 percent chlorhexidine that could prevent umbilical cord infections in newborns (RTM International, 2009). The majority of respondents were not willing to pay the preset prices asked for any of the products, but all respondents were willing to pay some amount of money for the product they preferred. Most respondents were also willing to borrow money to cope with higher prices in order to prevent neonatal infection, which indicates a high level of motivation among these potential users.

The study found that a unit price of multi-dose 4 percent chlorhexidine liquid between Taka 15–25 (US \$0.21–0.35)

would be affordable to the primary target population in rural Bangladesh (ICDDRDB, 2012). Sold at this price, this product would be expected to generate a large market. Pre-market research in Bangladesh showed that pharmacists were interested in distributing chlorhexidine provided that it was recommended by physicians (RTM International, 2009).

Since chlorhexidine is a new intervention, sources of distribution are not yet established and the intervention must prove itself in the market before outlets will stock it on a regular basis. In rural Bangladesh, the effectiveness of chlorhexidine and the willingness of couples to pay for this intervention indicates that this may be a good product for pharmaceutical companies to produce and distribute throughout the country. This is particularly important in countries like Bangladesh, India and Nepal where a majority of births occur in the home and are often accompanied by untrained or minimally trained birth attendants. In these cases, mothers, family members and birth attendants would need the ability to purchase chlorhexidine without requiring physician's approval/prescription.

In general, ANC and skilled providers were found to play a limited role in teaching about cord care or newborn care overall. The quality of ANC—including health education and especially newborn care education—were major impediments to beneficial cord care (Ayiasi et al., 2013). In Egypt, only half of mothers received newborn care advice during ANC visits, and only half of these received advice on cord care (Darmstadt et al., 2008). Given the large proportion of home births, especially in rural areas, health systems may need to be willing and able to work with TBAs to improve cord care and other essential newborn care (ENC) practices. A disconnect found between health providers and communities indicates a need for providers and communities to work together to develop strategies to improve care and outcomes (Moyer et al., 2012). In Uganda, communities and providers found recommended newborn care practices acceptable, but barriers such as pregnant women not understanding the value of early and frequent ANC visits when they did not feel sick, the cost of drugs and supplies, the lack of postnatal care and the rejection of dry cord care by both health providers and parents, often prevented the uptake of recommended newborn care practices (Waiswa et al., 2008).

There is an overall lack of guidance and training on how to use chlorhexidine. In fact, the most recent WHO recommendations, published in 1998, focus on dry cord care, except in unhygienic conditions where antiseptics such as chlorhexidine can be used. Given this recommendation, it would not be expected that health

care workers would consistently use chlorhexidine, an assumption supported by pre-market research in Bangladesh (RTM International, 2009). Although updated global and national guidelines are needed, global guidance is in itself insufficient to effect practices at the provider and caregiver level. The research in Bangladesh highlighted little knowledge of the WHO recommendations among health care providers in Bangladesh.

The formulation of the chlorhexidine product should also be considered before large-scale distribution. Results of two studies in Nepal indicate that chlorhexidine in the form of a gel, liquid or lotion was most acceptable to users (ICDDR, 2012; Nepal Family Health Program, 2007). Results from a hospital-based randomized trial of chlorhexidine gel and solution suggest that satisfaction and compliance were high for both products and that the gel formulation was not inferior to the liquid (ICDDR, 2012). In Nepal, researchers found that lotion was the preferred type of chlorhexidine formulation for application on the freshly cut cord stump of the neonate as it is considered easy to use, spreads easily on the skin and is easily absorbed, and is considered to be warm in temperature, which respondents viewed as valuable to the neonate (Nepal Family Health Program, 2007).

Implementation strategies and impact

Mothers, family members and TBAs were the primary target audiences for the interventions reported in the evidence. One operational research study explored how to develop a low-cost, scalable approach to delivery of chlorhexidine for newborn care in rural Bangladesh by addressing questions related to chlorhexidine distribution and use, behavior change and community perception (ICDDR, 2012). In the first phase of this intervention, community health workers (CHWs) visited households or community meetings and chlorhexidine was distributed for free at antenatal care visits. In the second phase, chlorhexidine was manufactured in Bangladesh and promoted through various channels of communication such as community meetings, posters, leaflets, stickers and folk songs, and was included in home delivery kits that were provided free of charge. Data was collected on acceptability and coverage of chlorhexidine through surveys, observations and interviews. During the intervention, coverage went from 0 percent to 60 percent in five months and was achieved largely through TBAs. To overcome identified barriers to uptake, the authors recommend promoting chlorhexidine and making it available at both the community and health facility levels. Promotional efforts should target both those who will apply the chlorhexidine and those who might remind

them to apply it. Monitoring and maintaining the supply of chlorhexidine to distributors is also necessary (ICDDR, 2012).

In Nepal, a cluster-randomized trial was conducted in 413 communities in Sarlahi (Mullany et al., 2006). Infants were assigned to one of three cord-care regimens—application of 4 percent chlorhexidine, cleansing with soap and water, and dry cord care. This cord cleansing trial was nested within a study of the effect of full-body skin cleansing with antiseptic on neonatal mortality. In that trial, the local health workers wiped newborns' bodies with either 0.25 percent chlorhexidine or placebo solution immediately after birth. In both groups, newborns were randomized to one of the three cord-care regimens. In intervention clusters, the newborn cord was cleansed in the home on days 1–4, 6, 8 and 10 by a non-medical project worker. The primary outcomes for the cord cleansing intervention study were incidence of neonatal omphalitis and neonatal mortality (Mullany et al., 2006).

Frequency of omphalitis was reduced significantly in the chlorhexidine group. Severe omphalitis in chlorhexidine clusters was reduced by 75 percent compared with dry cord-care clusters. Neonatal mortality was 24 percent lower in the chlorhexidine group than in the dry cord care group. In infants enrolled within the first 24 hours, mortality was significantly reduced by 34 percent in the chlorhexidine group (Mullany et al., 2006). The authors postulate that these results may be applicable to other areas of Nepal as well as northern India, Pakistan and northwestern Bangladesh, given the similarity in cultural, social and economic characteristics among these areas (Mullany et al., 2006). The authors state that the strong safety record, low cost and ease of implementation make cord cleansing with 4.0 percent chlorhexidine an ideal intervention. Mothers, TBAs or other people with little training who might assist with deliveries in low-resource settings, could all implement this intervention. The authors offer ideas for increasing use of chlorhexidine by including topical antiseptics in clean delivery kits for use by skilled birth attendants or caretakers in low-resource settings, and by implementing this intervention within comprehensive community outreach efforts to improve newborn care (Mullany et al., 2006).

Similar results were found in Pakistan in a two-by-two factorial, cluster-randomized trial in Dadu, a rural area of Sindh province (Soofi et al., 2012). In this study, live born infants were randomized into four different groups. In group A, TBAs provided families with a clean birth kit, which included 4 percent chlorhexidine solution and a bar of soap. TBAs applied chlorhexidine after tying the cord and demonstrated this method to mothers and caregivers.

The TBA advised caregivers to apply the solution once a day for 14 days and encouraged caregivers to wash their hands with soap and water before handling the newborn. In group B, families were provided a birth kit containing a bar of soap but no chlorhexidine. Caregivers were advised to practice standard dry cord care and were encouraged to wash their hands in the same manner as group A. In group C, families received birth kits with 4 percent chlorhexidine solution but no soap. The TBA applied chlorhexidine first and then advised caregivers to apply chlorhexidine daily for 14 days; hand washing was not promoted in this group. Families in group D (control cluster) received standard birth kits, without any chlorhexidine solution or soap and were advised to conduct dry cord care. No hand washing techniques were discussed with this group (Soofi et al., 2012).

Results showed that application of chlorhexidine to the umbilical cord was effective in reducing the risk of omphalitis and neonatal mortality in rural Pakistan. Of 9741 newborn babies delivered by participating TBAs, there was strong evidence of a reduction in neonatal mortality in neonates who received chlorhexidine cleansing (RR = 0.62 [95 percent CI 0.45–0.85]; $p = 0.003$), but no evidence of an effect of hand washing promotion on neonatal mortality (RR = 1.08 [95 percent CI 0.79–1.48]; $p = 0.62$) (Soofi et al., 2012).

The authors believe that these findings have implications in South Asia, where many areas share similar cultural, social and economic characteristics (Soofi et al., 2012). To scale up use of chlorhexidine, the authors suggest including chlorhexidine in birth kits for deliveries in community settings and public sector facilities. They also recommend assessing the effectiveness of this approach in large-scale programs and considering making this intervention available to Lady Health Workers (LHW) in Pakistan (Soofi et al., 2012).

Conclusions, knowledge gaps and recommendations

The decision to use topical antimicrobials on the cord stump depends on local circumstances (WHO, 1998). However, studies related to community-based use of chlorhexidine for newborn cord care have only been conducted in four countries—Nepal, Bangladesh, Pakistan and India—and as such, the findings are not generalizable to other countries and contexts. It is important to highlight that the most successful behavior change strategies are those that are culturally relevant, so what has been shown to work in Bangladesh, Nepal or India, may not work in another setting. Individual countries will have to find the most culturally relevant strategies to increase chlorhexidine use according to internationally recognized guidelines. To do so, the following is suggested:

1. Study local cord care beliefs and practices at the community level, especially in countries at high risk of neonatal tetanus. Information about the potential lack of risk-perception of harmful practices would be useful when planning demand generation activities for chlorhexidine. In settings where caregivers are concerned if cord separation does not happen quickly—as the application of topical antiseptics like chlorhexidine generally increase the average time to cord separation—it will be important to educate caregivers about this possibility when promoting chlorhexidine use (Alam et al., 2008).
2. Design and implement pilot tests on demand generation programs in different settings, especially in countries at high risk of neonatal tetanus. Conduct information, education and communication activities for families and traditional birth attendants based on research findings. Beneficial cord care practices should be promoted, neutral ones left as is, and harmful ones replaced with safer alternatives acceptable to the community. For example, in communities where harmful practices such as putting cow dung on the stump are prevalent, an antimicrobial can be recommended to replace the harmful substance. Mothers, family members, TBAs and all potential caregivers should be considered target audiences for demand generation programs to increase the use of chlorhexidine.
3. Consider integration into existing intrapartum/neonatal programs and services. For example, including chlorhexidine in birth kits might be a useful strategy for the prevention of neonatal mortality in high-mortality settings (Soofi et al., 2012).
4. Provide appropriate persons with a consistent supply of an acceptable form of chlorhexidine. Based on research findings, ensure that the people who will be encouraged to apply chlorhexidine—e.g., mothers, TBAs or other caregivers—have a steady supply of the commodity to be used in all required situations. Also, consideration of the formulation is essential to increasing uptake in appropriate settings. Limited research shows that mothers and other caretakers prefer gel or lotion. At the same time, market research is needed among public and private providers to identify barriers to and potential solutions that encourage adequate supply at a reasonable price. In order to avoid financial burden for households, the range of unit prices should be carefully considered by all supply-side stakeholders.

Neonatal Resuscitation Devices



Globally, about one quarter of all neonatal deaths are caused by birth asphyxia (WHO, 2012). Effective resuscitation at birth could prevent a large proportion of these deaths. With a neonatal bag and mask, suction device and a resuscitation training mannequin, successful newborn resuscitation can be accomplished in about 30 percent of cases that would otherwise end in death among full-term babies, and 5 to 10 percent among preterm births (Every Woman Every Child, 2012).

However, this basic equipment is not available in many low-resource settings. Ensuring universal access to newborn resuscitation is essential in the effort to reduce neonatal mortality, but considerable challenges remain. In 2012, WHO published guidelines on basic newborn resuscitation, in order to provide clinical guidance suitable for low-resource settings. The guidelines classify each recommendation as weak or strong depending on availability and implications of existing evidence.

The evidence review identified four documents related to provider attitudes, knowledge, skills and practice regarding neonatal resuscitation, all of which of which were published in the peer-reviewed literature. The evidence was documented from four countries (including two pathfinder countries): Senegal, Pakistan, Kenya and Malawi.

Unfortunately, it was difficult to identify articles that reported demand generation, either with the public or

with health providers. Skilled birth attendants at health facilities—including doctors, nurses and midwives—and skilled health workers in operating rooms, emergency wards, postpartum wards, nurseries and neonatal special care units, are the primary target audiences for demand creation of neonatal resuscitation devices. At the community level, linked facility-community committees that may exist in some countries, such as Senegal, can be an important target audience for demand creation. These committees can be particularly important for ensuring support to the peripheral facilities, as governments are promoting births at health facilities. Additional audiences may include skilled health workers at the community level, such as community midwives and assistant nurse midwives.

Social and Behavioral Drivers

In Malawi, a qualitative study was conducted to explore the barriers and facilitators present for obstetric nurse providers in a central urban hospital regarding the training and provision of neonatal resuscitation (Bream, Gennaro, Kafulafula, Mbweza, & Hehir, 2005). The researchers found four dominant themes: (1) nurse-midwives were very experienced and confident in their ability to deal with the serious issue of neonatal asphyxia; (2) there was significant frustration with lack of resources, especially lack of protocols; (3) there was a clear belief that nurse-midwives could successfully institute and sustain a basic newborn resuscitation program; and (4) there was confidence that long- and short-term solutions could be implemented.

Commodity Overview

Three key commodities described in the WHO guidelines for low-resources settings include the following neonatal resuscitation devices:

- **Mask and Bag.** Neonatal masks for resuscitators generally come in two sizes—to fit both low- and normal-birth-weight babies. An important safety feature is the pressure-relief valve that is designed to limit the pressure that the resuscitator can deliver to prevent lung damage to the newborn. Additional features augment ease of use such as ridged surfaces on parts that facilitate assembly and disassembly with wet hands and color-coded parts that distinguish different components. A resuscitator bag (usually 240 ml or 500 ml size volume) specifically designed for providing appropriate tidal volumes (volume of air between normal inspiration and expiration) for neonates can help reduce errors during use and simplify training. Prices range from US \$8 to over US \$100.
- **Neonatal suction devices** are used to clear the airway of the newborn to help facilitate breathing. WHO guidelines recommend use of a mechanical source of negative pressure (such as an electric or foot-operated vacuum pump) or, in the absence of such a device, use of bulb suction. Vacuum suction pumps are composed of disposable single-use sterile suction tubes attached to a low-pressure suction machine. No industry reference standards are available for newborn bulb suction devices. Manual bulb suction device requirements include the following design parameters: (a) for use on neonates for mucus and amniotic fluid, (b) able to suction mouth and nose, (c) easy to use, (d) durable and reusable, (e) affordable and (f) easily cleaned and disinfected. Product prices range from US \$2 to US \$10 each.
- A **training mannequin** is a model of the baby that enables visualization of selected features of effective ventilation, such as chest rise. Although the mannequin is not required for resuscitation of babies, it is a critical component for programs as it allows competency-based training of health care workers before practicing on babies. It also is useful for subsequent follow-up practice and during supervisory visits to improve quality of care, especially in centers with fewer births where lack of exposure to adequate cases of resuscitation results in loss of skills. Prices range from US \$50 to US \$1500.

Although the UN Commissioner's report (UNCoLSC, 2012) includes only three commodities—resuscitator, suction devices and training mannequins—additional elements are also recommended in countries where they can be procured including infant stethoscopes and non-mercury clinical thermometers. Further discussion has also included the value of maintaining neonatal temperature, which has been stressed in all essential newborn care and basic resuscitation training programs. In that case, then the presence of a warming device or table where resuscitation takes place is necessary. Construction of such a device may vary from locally made tables with lights or heating rods to manufactured overhead warmers. It may not be practical to add these additional elements to the list of the three UN life-saving commodities because of additional cost. However, the additional items should be promoted as a part of essential newborn care at birth.

[Source: WHO, 2012]

Although the results are from one hospital, they reflect the global lack of protocols and training and ethical dilemmas regarding “futile care” and identifying newborns that should not be resuscitated. Providers indicated that they did not feel comfortable initiating the procedure on babies who might not respond or might require more than five minutes of resuscitation. Nurse-midwives were also concerned the length of time required for resuscitation—when to stop resuscitation and the fear of being accused of stopping too soon. Nurses-midwives were often in a position where they were asked to decide

between caring for the baby, caring for the mother or caring for another mother or baby, often resulting in prioritization of the mother. Midwives expressed frustration in prioritizing these needs and stated that the development of community ethical norms and protocols would be helpful. This lack of clear protocols is seen as a major barrier to performing consistent resuscitation. Despite the use of posted guidelines for newborn resuscitation by anesthesia personnel in the hospital's operating theater, the same had not been adopted for use or implemented in the labor ward.

The development of guidance and protocols for newborn resuscitation was also identified as a priority in Kenya (Opiyo et al., 2008). The study noted that such guidance should be developed by an interdisciplinary group and should not be specific to the labor ward, given that newborn resuscitations also occur in the nursery, the emergency department and the operating rooms, and should include guidance around transfer to the pediatric service. Confusion about who had the responsibility for instituting newborn resuscitation sometimes resulted in unnecessary barriers.

Implementation strategies and impact

In Kenya, Opiyo and colleagues (2008) aimed to determine if a simple one-day newborn resuscitation training would alter health worker resuscitation practices in a public hospital setting in Kenya. The one-day course taught the A (Airway), B (Breathing) and C (Circulation) approach to resuscitation, laying down a clear step-by-step strategy for the first minutes of resuscitation at birth. The curriculum included focused lectures aimed at understanding the modern approach to resuscitation and practical scenario sessions using infant mannequins to develop skills in airway opening, use of a bag-valve-mask device and chest compressions.

Two weeks before the training, candidates were provided with a simple instruction manual for self-learning. At the end of the training day, trainees were assessed, using a multiple-choice written examination and a formal scenario—evaluating actual practical skills and their integration into a clinical context. Trained providers demonstrated a higher proportion of adequate initial resuscitation steps compared to the control group (trained 66 percent vs. control 27 percent; RR 2.45, [95 percent CI 1.75–3.42], $p = 0.001$, adjusted for clustering). In addition, there was a statistically significant reduction in the frequency of inappropriate and potentially harmful practices for resuscitation in the trained group (trained 0.53 vs. control 0.92; mean difference 0.40, [95 percent CI 0.13–0.66], $p = 0.004$). Participants expressed need for a policy on continual training and renewal of skills.

In Pakistan, doctors and nurses were invited to attend modular training programs through local health authorities (Zaeem-ul-Haq et al., 2009). During the training, participants learned the skills necessary to save lives during the “golden hours” of emergency situations. The training content included using a structured (ABC) approach, to maintain the airway, breathing and circulation and save lives with the help of both manual and pharmacological interventions in a step-wise and structured manner. Ninety percent of respondents (n

= 100: 81 doctors and 19 nurses) reported the use of acquired skills and the structured ABC approach in handling emergencies. Lack of equipment and lack of support from higher levels were the common barriers and 81 percent of respondents reported that these training courses had resulted in better availability or use of supplies at their facilities. After the training, 88 percent of participants made efforts to institutionalize the trainings and discussions. Hand washing was the most commonly used skill, followed by the use of bag valve and mask resuscitation, with the newborn at birth. Following the training, those catering for neonates expressed their confidence to carry out obstetric procedures and obstetricians described themselves as being self-assured in neonatal resuscitation. The findings suggest that “hands-on skills-based” training should be a regular component of all pre- and in-service continuing medical education.

A study from three regions in Senegal—Ziguinchor, Louga and Thies—was carried out in 69 health facilities (regional hospitals and health centers) (Sylla et al., 2012). The purpose of the study was to assess the state and conditions of use of basic equipment intended for taking care of newborns at birth, three years after distribution and training of key personnel. The study found that the healthcare facilities were generally equipped with ventilator bags and masks (60/69).

However, in more than half of the healthcare centers (20/38), the equipment was not used, often because there had been worker turnover and the new providers were not trained in their use. Eighty-five percent (59/69) of healthcare facilities had at least one aspirator, generally adapted to newborns (negative pressure, 100 mmHg). The maintenance of the material was globally satisfactory because the aspirator bottles were most often clean. As for the aspirator tubes, they were always available, but a few instances of supply rupture were observed in some healthcare centers. Warming tables were available in only 52 percent (36/69) of healthcare facilities, fifteen of which did not comply with initial specifications.

Conclusions, knowledge gaps and recommendations

The results presented here are limited in their generalizability due to the dearth of studies regarding provider attitudes, knowledge and behaviors regarding the use of neonatal resuscitation equipment. No articles were identified that explored individual or community knowledge about the availability of neonatal resuscitation. There was no information on the knowledge and skills of skilled or traditional birth attendants related to resuscitation of newborns. However, the four

studies included in this review highlight some barriers that hinder the uptake of use of neonatal resuscitation. Recommendations to overcome those barriers are listed below.

1. Adopt a standard, multidisciplinary, continually re-certified approach to newborn resuscitation. This approach would be useful in resource-poor environments. Studies indicate that even after initial training, refresher training and continual renewal of skills for experienced providers, and training of new providers is crucial to increase uptake and maintain continued use of newborn resuscitation equipment.
2. Increase knowledge of technical specifications at various levels. Ministry-level personnel and administrators responsible for procurement of equipment; determining policies, standards and guidelines; and setting quality standards and regulations related to these commodities, would benefit greatly from increased knowledge in this area, as would those who deal with the country implementation of neonatal resuscitation within essential newborn care and maternal health. Additional target audiences should include distributors who procure and sell commodities, staff in health facilities—including those in administration responsible for procurement, repairs and replacement equipment—and skilled attendants caring for newborn babies at all sites. The latter should also be competent in the daily maintenance of these devices including disassembly, disinfection, cleaning, sterilization and reassembly, where required.
3. Develop local protocols and guidelines. Protocols are necessary to assist providers in making crucial decisions regarding the care of women and babies. All departments that might need to resuscitate newborns, including labor and delivery, the operating theatre, pediatric care and emergency room, should be included in the development of these protocols and guidelines. In addition, transforming the protocols and guidelines into clear, easy-to-use job aides, such as laminated cards or posters, SMS messages, short videos, etc., can serve as reminders and reference materials for providers.



**Child Health Commodities:
ORS, Zinc and Amoxicillin**

Pneumonia claimed the lives of approximately 1.24 million children under five in 2011—18 percent of all child deaths worldwide. Although deaths due to diarrhea among children under five dropped to 760,000 in 2011, di-arrheal diseases still cause approximately 11 percent of child deaths worldwide (UN-IGME, 2012).

The WHO-recommended treatment for diarrhea is oral rehydration salts (ORS) and zinc, products that are highly effective and affordable. Low osmolarity ORS and zinc prevent a majority of diarrhea deaths and cost less than US \$0.50 per treatment course. Antibiotics, such as amoxicillin, can prevent the majority of pneumonia deaths and cost about US \$0.23–0.63 per treatment course (UNICEF, n.d.). Despite the existence of these simple, life-saving treatments, many children with diarrhea and pneumonia in developing countries are not receiving these products: only 38 percent of children receive ORS, less than 5 percent receive zinc and only 30 percent of children with suspected pneumonia receive an antibiotic (Black et al., 2010; UNICEF, 2011).

Research and pilot programs have demonstrated effective approaches to scaling-up treatments, such as amoxicillin, and a growing number of countries are scaling up integrated community case-management programs;

however, these programs require significant systems support in order to reach the majority of children in need. Additional attention and investment in comprehensive and ambitious programs can significantly improve access to these simple, low-risk products. Increasing access to and use of ORS, zinc and amoxicillin will help to achieve Millennium Development Goal 4 of reducing child mortality by two-thirds by 2015 (Fisher Walker, Fontaine, Young, & Black, 2009).

The determinants of pneumonia and diarrhea are often the same and effective interventions for prevention and treatment of these illnesses exist. However, preventive strategies and delivery platforms through health care facilities, families, communities and schools are not always integrated to provide maximum benefit. The integrated Global Action Plan for the Prevention and Control of Pneumonia and Diarrhoea (GAPPD) provides an integrated framework of key interventions proven to effectively prevent and treat childhood pneumonia and diarrhea (WHO & UNICEF, 2013). The GAPPD brings together critical services and interventions to create healthy environments, promotes practices known to protect children from disease and ensures that every child has access to proven and appropriate preventive and treatment measures (WHO & UNICEF, 2013).

ORS and Zinc



Commodity Overview

ORS is a glucose-electrolyte solution given orally to prevent dehydration from diarrhea. ORS is packaged in sachets of flavored powder to be diluted in 200 ml, 500 ml or 1 liter of fluid. Airtight packets made of aluminum laminate are the preferable packaging. ORS is inexpensive—each sachet costs approximately US \$0.15–0.25.

The recommended dose of ORS follows:

- At no signs of dehydration– 50–100 ml for children under 2 years;
- Until diarrhea stops– 100–200 ml for children aged 2–10 years; and
- At some dehydration– dosing scheme as indicated in WHO diarrhea treatment guidelines should be followed or the amount of fluid that is equal to the child's weight (in kg) multiplied by 75 ml.

Zinc becomes depleted in the body during diarrhea, but replenishment with zinc can reduce the duration and severity of diarrheal episodes. Zinc is prepared either in 20 mg scored, taste-masked, dispersible tablets or oral solutions at concentration of 10 mg/5ml. Zinc is inexpensive—the average cost for ten tablets is approximately US \$0.50 for zinc.

The recommended dose is 20 mg daily for 10 days (or 10 mg daily for 10 days for children > 6 months).

[Sources: Every Woman Every Child, 2013; USAID, UNICEF, & WHO, 2005]

The evidence review found 108 documents that met the inclusion criteria, of which 42 were peer-reviewed. Sixty-six documents focused on Africa (12 from Kenya and 17 from Nigeria); 38 documents focused on Asia (18 from India and 10 from Bangladesh); two documents focused on Latin America and the Caribbean; one document focused on the Middle East; and three documents were regional or global studies. All of the pathfinder countries were included in the literature: DRC (1), Ethiopia (2), Malawi (4), Nigeria (17), Senegal (1), Sierra Leone (3), Tanzania (5) and Uganda (5).

Key social and behavioral drivers

At the individual level, knowledge gaps—on the pathology of childhood diarrhea and the most effective treatments, especially zinc and ORS—among healthcare providers in the public and private sectors were found in many countries. In Nigeria, knowledge of the causes, signs and effects of diarrhea was good among private patent medicine vendors (PMVs), but their knowledge of diarrhea prevention among children was poor (Aguwa, Aniebue, & Obi, 2010; CHAI, 2011). This is a major gap, given that caregivers in Nigeria often seek care from drug

vendors and private clinics for diarrhea treatment. In most countries, knowledge among caregivers about ORS is higher than for zinc (CHAI, 2012; Morris, Gilbert, & Wilson, 2012; Mosites et al., 2012a–f; Shah et al., 2012; Wilson, Morris, & Gilbert, 2012a–e).

Low perceived threat of diarrhea is also a factor in limited uptake of appropriate treatments. In Nigeria, Mali, Uganda and Kenya, studies have found that diarrhea may be perceived as a common, non-threatening condition, and caregivers lack knowledge about the potential dangers (CHAI, 2011; Ellis, Winch, Daou, Gilroy, & Swedberg, 2006; Ipsos, 2012; Taffa & Chepngeno, 2005). Consequently, care seeking for diarrhea is delayed until the presentation of severe or life-threatening symptoms.

Perceived effectiveness of ORS and zinc is also a factor in demand for the products, even when awareness is high. In Nigeria, ORS may be perceived as weak or ineffective, possibly because of misperceptions about the purpose of ORS to avert dehydration, rather than to stop diarrhea (CHAI, 2011). Studies from Mali and Nigeria, found that even when caregivers do understand that ORS replaces fluid, caregivers may also feel the need to give “medicine” for diarrhea and thus seek and use additional treatments that they believe will have a curative effect, such as antidiarrheals or antibiotics (Ellis et al., 2006; Uchendu, Ikefuna, & Emodi, 2009). Findings from India, Cambodia and Benin, also note that poor perceptions of ORS and/or zinc effectiveness may also lead providers to co-prescribe ORS and/or zinc with ineffective treatments (Borapich & Warsh, 2010; FHI Solutions, 2011; Sanders & SHOPS Project, 2012; Shah et al., 2012).

When knowledge and perceived efficacy of the product are in place, caregivers have demonstrated self-efficacy to request specific treatments. For example, observation of customer and provider behaviors in one Nigerian study showed that 79 percent of customers of PMVs requested specific medicines. In response, PMVs usually sold the medicine requested by the customer (Brieger, Osamor, Salami, Oladepo, & Otusanya, 2004). Similar behaviors were documented among healthcare providers in both the public and private sectors in Uganda (Sanders & SHOPS Project, 2012). In Kenya, research showed that providers sometimes also perceive that caregivers want “real” or “western” medicines—typically antibiotics (Blum, 2011; Kenya MOPHS, 2010). These providers are often under pressure to prescribe cost-effective treatments that caregivers believe address immediate symptoms of diarrhea, in order to maintain client loyalty in a competitive environment (CHAI, 2012).

The literature contained limited examination of the

influence of family and peer networks on demand for ORS and zinc. Although women may be socially identified as the care providers, in some contexts, their ability to treat diarrhea is dependent on their husband’s approval to seek care or spend money on treatment. For example, in Nigeria, mothers expressed that male household members had little understanding of childhood illnesses, preventing effective and timely care seeking as the mothers’ ability to seek care independently was seriously restricted (Bedford, 2012c).

At the society level, a range of factors has been identified as key facilitating factors in successful demand generation for ORS and zinc. These include a supportive national and international political environment, in-country manufacturing and respected project leadership (Morris et al., 2012; Mosites et al., 2012a–f; Wilson et al., 2012a–e). However, in some contexts, social level factors played a limiting role. For example in Niger, religious beliefs were identified as a barrier to care seeking, emphasizing the need for education and sensitization of religious leaders to promote utilization of health services and overcome negative rumors (Bedford, 2012b).

Problems with equitable access to commodities and services are also factors in demand and utilization of ORS and zinc. In Malawi, Kenya, Mali and Uganda, studies identified a range of access barriers including high costs, long distances to health facilities and perceived attitudes of health workers—highlighting the importance of harmonized supply and demand activities (Mbonye, 2003; Morris et al., 2012; Opwora, Laving, Nyabola, & Olenja, 2011; PSI Mali, 2009). In Nepal, product availability was found to be one of the most reliable and valid determinants of zinc usage (PSI Nepal, 2008).

In Bangladesh, many caregivers who do seek care for diarrhea, do so through health care providers in the private sector (Larson, Koehlmoos, & Sack, 2011). Similarly, in Nepal, the Point-of-use Water Disinfection and Zinc Treatment (POUZN) project found that the majority of caregivers purchased zinc at cost through private sector outlets, even though it was available free of charge in public clinics. This highlights the value of private sector channels in zinc distribution in Nepal (Wang & MacDonald, 2009). In Nigeria, however, the low demand for ORS and zinc by customers of health care providers in the private sector, combined with low profitability, means that providers may view ORS and zinc as low priority products (CHAI, 2011).

The features of the product and packaging are also important for demand generation and utilization. Formative research in Ethiopia and Malawi showed

that community health workers found packaging and pictorial instructions important product considerations for uptake of zinc and/or ORS (SC4CCM, 2013). The research also showed that ease of use is important and caregivers preferred syrups or dispersible tablets and sachets; splitting tablets introduces risk for product contamination and inappropriate dosing. In Bangladesh, dispersible zinc tablets were found to be an acceptable formulation among caregivers and were used correctly in 98 percent of cases (Nasrin, Larson, Sultana, & Khan, 2005).

Implementation strategies and impact

Social marketing

Social marketing (SM) has been used in a variety of country contexts to promote ORS and zinc. Programs have combined mass media, interpersonal and health provider training, along with branding, pricing and other SM strategies. For example, in Benin, a pre-packaged branded diarrhea treatment kit containing ORS and zinc was marketed through mass media and other communication channels (MacDonald, Bank, & Rakotonirina, 2010). The proportion of caregivers with children under five with diarrhea in the past two weeks treating with ORS or a recommended home fluid, increased from 30 percent to 53 percent. Those treated with zinc increased to 31 percent, even though zinc was virtually unknown in Benin when this program was designed. Of the caregivers who used zinc, 88 percent said that it was an effective treatment and 94 percent said that they would use it again (MacDonald et al., 2010; PSI Benin, 2011).

In Cambodia, in 2006, only 21 percent of Cambodian children received treatment with ORS; zinc was not available. During implementation of a pilot project to promote and distribute a diarrhea treatment kit, branded OraselKIT®, including both ORS and zinc, 39,867 diarrhea treatment kits were sold, which was double the projected sales figures, and caused a stock out. An independent evaluation of the project found that people in 10 intervention villages fared better on a number of indicators compared to those in 17 non-intervention villages, including product recognition (68 percent vs. 26 percent), knowledge of zinc (33 percent vs. 13 percent), and provision of ORS (72 percent vs. 56 percent) (Borapich & Warsh, 2010).

In Malawi, a SM campaign successfully increased perceived availability of a commercial ORS brand. Caregivers of children under five who believed that ORS was available were more likely to administer ORS to their children than those who believed ORS had limited or no availability. Administration of ORS among children who had diarrhea increased from 58.1 percent in 2005 to 64.3 percent in 2008.

Although exposure to the program was not associated with ORS use, perceived availability as well as positive brand attributes were, suggesting that messages on product attributes and where a product can be obtained are important components of a communication campaign (PSI Malawi, 2005, 2008).

Few studies explored the use or impact of social networks in diffusion of knowledge, attitudes, or practices related to care seeking or use of ORS and zinc. However, in Burundi, mothers identified interpersonal discussion as an important channel of message diffusion following a social marketing campaign targeted at women of reproductive age that showed increase in ORS usage from 20 percent in 2006 to 30 percent in 2007 (PSI Burundi, 2007).

Mass media

Mass media was a key element in several initiatives to increase demand for ORS and zinc. For example, in Bangladesh, the first country to initiate a nationwide scale up of zinc use in childhood diarrhea treatment, mass media was the primary communication channel used in the Scaling Up Zinc for Young Children (SUZY) project. The national campaign used television, radio, press, articles, billboards, posters, wall paintings, branded buses and other promotional materials (Mosites et al., 2012a).

Messages disseminated via mass media varied in their focus. In Burundi, messaging centered on communicating the effectiveness of the product as well as availability (where to get it) and affordability (price) (PSI Burundi, 2007, 2010). In Nepal, messaging focused on ensuring that caregivers understand that zinc is an appropriate treatment for diarrhea, know where it is available, understand that inappropriate diarrhea treatments may be harmful and administer correct treatment of both zinc and ORS for the recommended period of time (Wang & MacDonald, 2009).

The effect of mass media on outcomes was assessed in some studies. In Benin, a study found that mass media was particularly effective for raising awareness, especially about zinc, which is often a less known diarrheal treatment (MacDonald et al., 2010). The SUZY project in Bangladesh, which focused on increasing knowledge of the brand Baby Zinc among caregivers of children under five, demonstrated increased product awareness—almost 95 percent of Bangladeshi mothers of children under five in urban and semi-urban locations and 50 percent in rural areas were familiar with Baby Zinc and the use of zinc as a treatment for diarrhea. Following the zinc scale-up campaign, ecological surveys found that caregivers' zinc awareness as a treatment for childhood diarrhea greatly increased—from 5 percent to 50 percent in rural areas and

90 percent in urban non-slum areas (Larson, Saha, & Nazrul, 2009).

In other settings, impact on behaviors was measured. In Madagascar, the initiation of a television campaign was associated with a spike in sales of zinc (MacDonald & Banke, 2010). In Benin, a mass media campaign promoting a combined ORS-zinc product—OraselZinc®—found that mothers who were exposed to the campaign were significantly more likely to treat diarrhea with a ORS-zinc product (59.2 percent) compared to those who were unexposed (11.7 percent) (PSI Benin, 2011).

The study showed that access to media campaigns was correlated with the mother's age and education level, and noted the need to address gaps in access to messaging among mothers with children under five to help change perceptions of the availability of OraselZinc® and increase knowledge about ORS as an effective diarrhea prevention and treatment method. Evidence from the SUZY project in Bangladesh, showed that zinc usage rose from a negligible level before the start of the project, to 10 percent in rural areas and 25 percent in urban non-slum areas (Larson et al., 2009). However, the study found that actual usage of zinc and ORS often lagged behind increases in knowledge and awareness (Akhter & Larson, 2010; Larson et al., 2009, 2011).

Community-based

In a number of countries, community case management of diarrhea among children under five was provided by CHWs, which led to significant increases in knowledge and uptake of ORS and zinc, especially in rural areas with limited access to public health services. The programs found that zinc was easily incorporated into CHW management of diarrhea; village-based workers with minimal education were able to effectively deliver messages. However, success was dependent on strong supervision and CHW retention (Gupta, Rajendran, Mondal, Ghosh, & Bhattacharya, 2007; Littrell, Moukam, Libite, Youmba, & Baugh, 2012; PSI, n.d.; Winch et al., 2008). The use of non-cash incentives could be used to acknowledge and reward CHW efforts (Littrell et al., 2012; PSI, n.d.).

A pilot project in a rural area of southern Mali found that CHWs easily incorporated zinc supplementation into their management of childhood diarrhea and had few difficulties in prescribing (Winch et al., 2008). Reaction to zinc was largely positive and community members appreciated the packaging, taste of the tablets and outcomes seen in their children post-administration. Although only 28 percent of caretakers in the two study zones had knowledge of zinc post-intervention, 59 percent of those who lived in villages with a CHW had knowledge of zinc. Use of zinc was 66 percent in villages with a CHW, but only 5 percent in villages

without a CHW. The proportion of children receiving ORS for diarrhea at four months post-intervention went from 11 percent to 18.3 percent and children receiving antibiotics dropped from 65 percent to 47 percent (Winch et al., 2008).

Also in Mali, zinc was promoted at the community level at marriages, baptisms and other events and meetings. Community members also suggested additional channels that could be utilized to promote zinc, including plays, drumming and dancing, school-based teaching and student-performed skits (Winch et al., 2008). Community demonstration events were found to be an effective strategy in increasing ORS use in Burundi (Kassegne, Kays, & Nzohabonayo, 2011; PSI Burundi, 2007), as was street theatre in Indian urban slums (Abt Associates, 2008).

In Kenya and Niger, caregivers expressed the desire for more group health education in their community. This is often lacking, or not conducted in an effective way—with messages failing to resonate in simple, memorable ways with the intended audience (Bedford, 2012a, 2012b). In some contexts, group health education may need to be conducted separately for men and for women to ensure participation, respect cultural practices and deliver tailored messaging. Alternatively, house-to-house education for women may be more appropriate, especially in Muslim communities that practice purdah.

Front-line services and delivery

Health care provider promotion and education was carried out in a number of countries, either as a stand-alone intervention or as one component of integrated campaigns. In Bangladesh and Nepal, provider education has been targeted at a range of clinicians (physicians, nurses, CHWs) as well as non-clinical health care providers working in the private sector, such as pharmaceutical representatives (salesmen, chemists, etc.). Training was conducted through outreach visits, face-to-face trainings and the development and distribution of educational and promotional materials (Khanal et al., 2009; Larson et al., 2011). Messages in these materials focused on the biological attributes of ORS and zinc, correct use, products available from local manufacturers, government policies and programs, advantages of ORS and zinc, product safety and potential side effects. However, more attention is needed to reinforce messages that zinc is a quality and essential treatment for diarrhea rather than a supplement, and that unnecessary anti-diarrheals should be discouraged.

Several interventions showed increased prescribing of ORS and zinc and reduced use of antibiotics among healthcare providers. For example, in Nepal, prior to the intervention in which visits were made to prescribers over a two-month period promoting use of ORS and zinc and discouraging

use of antibiotics, only five providers prescribed ORS, two prescribed zinc and all prescribed some form of antibiotic for the treatment of diarrhea. After the intervention, eight prescribed ORS and zinc and only two prescribed antibiotics (Khanal et al., 2009). However, in Madagascar, despite training and detailing, both public and private providers continued to overprescribe antibiotics (MacDonald & Banke, 2010). In India, an intervention that compared co-prescribing of ORS and zinc to just ORS alone, showed that the combined prescription of ORS and zinc was found to be more satisfactory and in line with caregivers' expectations for diarrhea treatment (Bhandari et al., 2008).

Public/private partnerships

In Uganda, social franchising has been used to create a recognizable, common brand among private sector healthcare providers in order to increase access, quality and demand for services through the Five & Alive social franchise. The network connects private clinics and drug shops that agree to adhere to a set of operational standards on quality of care and pricing of products and services. Franchise providers purchase pre-packaged therapies from PACE for about US \$0.04-0.16 and receive initial training on the use of a standard algorithm to diagnose children, supported by job aids to guide identification of common childhood illnesses. Following initial training, network provider quality of care is monitored and continuously improved through monthly supportive supervision visits. Furthermore, community-based village health team volunteers strengthen linkages between target caregivers and network providers through health education, franchise network promotion, case identification and referral to franchise outlets (PACE Uganda & PSI, 2011). No evaluation results from this project were found in the literature review.

Partnerships with the pharmaceutical industry to manufacture, distribute and promote zinc were also found to be winning strategies in other countries. For example, the SUZY project in Bangladesh identified private sector partnerships as a key strategy, thanks to formative research that found more than 90 percent of all health care visits for child diarrhea were in the private sector (Larson et al., 2011). In India, partnerships have leveraged private-sector resources and existing marketing channels for product promotion, which has been shown to be a sustainable way to ensure long term, competitively priced zinc (USAID & AED, 2010). However, in Tanzania, local producers of ORS did little to stimulate demand (Wilson et al., 2012d).

Other partnerships have focused on engagement, rather than the leveraging of resources. For example, a zinc

promotion project in Nepal co-sponsored continuing medical education programs that focused on introducing zinc through new treatment protocols to doctors and other medical professionals, or through technical assistance and training on correct messaging for product detailing and correct dispensing practices. However, only partial effectiveness was found, as undesirable practices such as prescribing antidiarrheals were still prevalent (Wang & MacDonald, 2009).

Conclusion, knowledge gaps and recommendations

Some countries have made huge advances in scaling up programs to the national level. For example, in Bangladesh, multi-channel marketing campaigns by BRAC, Population Services International (PSI) and others, have reached large numbers of caregivers, resulting in impressive and sustained gains in ORS use. The success of the campaigns have been attributed to a range of factors, including a supportive national and international political environment, in-country manufacturing, over-the-counter availability, continuity in project leadership, leadership by a highly respected local institutional champion and the use of social marketing campaigns that work with the private sector, as well as intensive interpersonal communication to target end users (Morris et al., 2012; Mosites et al., 2012a–f; Wilson et al., 2012a–e).

Yet, this literature review highlighted several gaps in knowledge, especially with regard to understanding the shift from awareness to action, and finally to sustained behavior change among caregivers and providers in relation to zinc and ORS for treatment of childhood diarrhea. More research is also needed to identify the best communication strategies and messages for promoting this shift among caregivers and providers.

The role of social networks, peer influence and social support has not been well explored or incorporated into demand generation programs for ORS and zinc, neither for caregivers nor providers. The value of such networks is articulated in the Diffusion of Innovations theory (Rogers, 2003), which highlights the role of opinion leaders who convey their own interpretations of messages received through mass media to others in their social networks. By identifying and tapping into these opinion leaders, behavior change programs can understand the flow of information that caregivers and providers receive, process and use to act.

The review also revealed topics that are important to consider when planning future demand generation activities. Following is a list of specific recommendations to increase the use of ORS and zinc for childhood diarrhea:

1. Utilize all available channels for demand generation and consider complementary activities.

Social marketing, mass media and provider training were the most common channels for increasing demand for ORS and zinc. Mass media is a channel that can be used to raise awareness of ORS and zinc and encourage trial and use, but may not be as effective in sustained behavior change (MacDonald & Banke, 2011). Such efforts need to be accompanied by more intensive interpersonal approaches, as well as provider recommendation, in order to achieve changes in behavior (Larson et al., 2011; Panisset et al., 2012).

A number of other potential channels for demand generation were not utilized, including information, communication, technology (ICT) and social media, which has been used successfully in low-resource settings to increase knowledge of other health areas such as HIV, reproductive health and family planning. Peer-to-peer approaches to increase provider knowledge and improve attitudes toward ORS and zinc are also underutilized. For example, in Nigeria, health care workers cited colleagues as their primary source of information on zinc supplementation, followed by formal training (Omuemu, Ofuani, & Kubeyinje, 2012). The role of influential community leaders was acknowledged in Nigeria as a means to lead by example (Bedford, 2012c), but few studies explored the use or impact of social networks in diffusion of knowledge, attitudes, or practices related to care seeking or use of ORS and zinc.

2. Evaluate demand generation interventions and programs. The review highlighted the lack of concrete evidence of what actually works in driving uptake of ORS and zinc. It is essential that current and future demand generation activities are appropriately evaluated to measure the impact of such activities.

3. Use a two-stage knowledge and behavior approach where appropriate. Depending on the country context, a two-stage approach may be necessary to increase knowledge and bring about behavior change. The first stage focuses on increasing awareness and knowledge about treatment with ORS and zinc, and then quickly shifts to the second phase which targets actual behavior change.

4. Tailor messages to different audiences. As in all strategic communication for behavior change, audience segmentation and the development of tailored messaging is essential for increasing demand for ORS and zinc. However, key barriers among caregivers and providers need to be well understood

before developing key messages for each group.

Health communication targeted at fathers and other male community members—as well as extended family such as grandparents—is lacking, despite demand from these audiences for more direct, tailored messaging (Bedford, 2012a, 2012b; Ellis et al., 2006). More research is needed to understand the perspectives of fathers and other male community members in order to develop tailored messages that take into account the influential role of these actors. Male outreach may be useful in order to provide positive role modeling and facilitate engagement with male community members.

5. For caregivers, ensure that messages aimed to increase awareness and knowledge of symptoms and appropriate care-seeking and treatment practices address key barriers or behavioral challenges. For example, a key behavioral challenge identified in the literature was caregivers' failure to adhere to a 10-day course of treatment (Larson et al., 2009; MacDonald & Banke, 2010; MacDonald et al., 2010). Targeted messaging is needed through mass media and accurate provider counseling to increase knowledge of, belief in and adherence to the 10-day regimen of zinc.

Messages that clearly articulate the purpose and benefits of ORS and zinc can reduce disappointment through misaligned expectations. In Pakistan, formative research identified mothers' distressed feelings when dealing with diarrhea as a potential hook for emotional messaging by emphasizing the relief that mothers can find through using zinc (POUZN Project, 2010).

6. For providers, increase education about ORS and zinc and utilize peer-to-peer approaches. In areas where doctors are the most common or most trusted source of information, provider education is critical. Tailored training is needed that acknowledges that non-clinical private-sector providers contribute significantly to the continuum of care for diarrhea, including consideration of business mindset and specific customer needs in private settings. More efforts are also needed to improve public and private provider behaviors, e.g., through refresher training, and to address pharmacy stockage issues, e.g., through financial incentives (Blum, 2011; Borapich & Warsh, 2010; MacDonald et al., 2010). Future research should investigate provider motivations and barriers to ensure that messaging and demand generation programs frame the messages in a way that connects with the intended audience. Despite research that

shows that health care workers cite colleagues as a primary source of information, peer-to-peer education approaches are underutilized (Omuemu et al., 2012). This approach may be an effective method to increase provider knowledge and improve attitudes toward ORS and zinc.

7. Reposition ORS and zinc as legitimate “medicines” and combined medical treatment for diarrhea among both caregivers and providers. Messaging could use creative and meaningful ways to make comparisons of cost and effectiveness between ORS and zinc, antibiotics, and antidiarrheals. Messages could also focus on changing perceptions of zinc from a “supplement” to an “essential medicine,” thereby leveraging the perceived need among providers and caregivers to administer “medicine” for diarrhea. In the literature, messages about zinc’s effectiveness in preventing future bouts of diarrhea appear to be less emphasized, but could be a useful positioning approach.

8. Consider the product and packaging. Pre-prepared combination packages of ORS and zinc was found to be an effective way to increase use of both commodities. However, in settings where ORS use is already high, co-packaging may be an unnecessary expense; instead, zinc could be marketed as a stand-alone, but complementary, product to be used with ORS. Encouragingly, many of the zinc studies found no adverse effects on ORS use.

Product packaging in forms deemed acceptable by CHWs and caregivers is important to consider—such as whether caregivers prefer syrups rather than tablets. There was little evidence in the literature that explored caregiver preference. Attention should also be given to developing and pretesting low-literacy packaging and instructions for health commodities to ensure comprehension and correct use.

Amoxicillin



Commodity Overview

Amoxicillin is an antibiotic that can be used to treat pneumonia. Amoxicillin is prepared in 250 mg scored, dispersible tablet (DT) in a blister pack of 10 DTs. The average cost per treatment course is approximately USD \$0.23–0.44 for children aged 2–11 months to US \$0.46–0.63 for children aged 12–59 months.

[Source: Every Woman Every Child, 2013]

The evidence review found 37 documents related to demand generation for amoxicillin that met the inclusion criteria, 27 of which were published in the peer-reviewed literature. Most of the evidence was from Africa (28 documents); five documents were from Asia, and three documents were reviews of multiple countries. Documents from six pathfinder countries were identified: DRC (1), Ethiopia (3), Malawi (1), Nigeria (7), Sierra Leone (1) and Uganda (7).

Key social and behavioral drivers

A number of social and behavioral barriers hinder the uptake of amoxicillin. Lack of caregiver knowledge is a common barrier to prompt care seeking for pneumonia, including knowledge about signs and symptoms—especially the differences from malaria—and the benefits of antibiotics. Misperceptions about the severity of symptoms are also common (Amuyunzu-Nyamongo & Nyamongo, 2006; Awasthi, Srivastava, & Pant, 2008; Bedford, 2012a–c; Hildenwall, et al., 2009; Mathew, et al., 2011; Mulholland, Smith, Carneiro, Becher, & Lehmann, 2008; Ogunlesi, Runsewe-Abiodun, & Olanrewaju, 2010; Taffa & Chepngeno, 2005). Cultural beliefs play a large role in caregivers' decisions in many contexts. For example, several studies both in Kenya and India showed that caregivers may believe that pneumonia is caused by supernatural forces or other non-medical causes, and is therefore not treatable by modern medicines (Awasthi et al., 2008; Bedford 2012a–c; Irimu, Nduati, Wafula, & Lenja, 2008; Mathew et al., 2011; Opwara, Laving, Myabola, & Olenja, 2011; Simiyu, Wafula, & Nduati, 2003).

The influence of relatives was identified in Viet Nam, where 60 percent of the survey respondents thought older relatives were an important source of health information (Kaljee et al., 2010). Lack of male knowledge or involvement in childcare was identified as a barrier to care seeking for children with diarrhea, pneumonia and malaria in Niger, Nigeria and Uganda (Bedford, 2012b, 2012c; Mbonye, 2003). However, in Nigeria and Kenya, caregivers other than mothers, including fathers and older relatives, felt that health education was directed only at women (Bedford, 2012a; Ebuehi & Adebajo, 2010). In Kenya, caregivers felt that there was a general shortage of health education at the community level about pneumonia, home management, when to seek treatment and the cost of treatment. When such education was available, key messages were not conveyed in simple, memorable ways (Bedford, 2012a). A review by Mulholland et al (2008) found that inequitable access to child health messages also is a barrier, with messages not reaching mothers in the most remote areas.

Another key social barrier is the lack of access to care, including distance, cost and availability of amoxicillin. Studies from Kenya and India, found that distance to health facilities and inability to afford treatment prevented caregivers from seeking care, and higher household income was significantly correlated with care-seeking behavior (Mbagaya et al., 2005; Taffa & Chepngeno, 2005; Mulholland et al., 2008; Mathew et al., 2011; Burton et al., 2010). In Sierra Leone and Uganda, perceptions of poor quality of service in health facilities also hindered caregivers from seeking appropriate treatment (Concern Worldwide, 2010; Hildenwall et al., 2009; Kallander et al., 2008; Mbonye, 2003).

For many of these reasons, caregivers in Kenya, Nigeria, Sierra Leone and Uganda, often visit private health facilities (Amuyunzu-Nyamongo & Nyamongo, 2006; Concern Worldwide, 2010; Kallander et al., 2005; Mbagaya et al., 2005; Ogunlesi et al., 2010). In Nigeria, observation of caregiver and provider behaviors showed that 79 percent of customers of private patent medicine vendors (PMVs) requested specific medicines. In response, PMVs usually sold the medicine requested by the customer (Brieger et al., 2004).

Implementation strategies and impact

Community case management (CCM) by trained CHWs, often as part of a broader integrated management of childhood illness (IMCI), has been a key strategy used to increase access and acceptability of amoxicillin for pneumonia treatment. Community integrated management of childhood illnesses (c-IMCI) takes an integrated approach to child health and focuses on the total well being of the child and aims to reduce death, illness, and disability, and to promote improved growth and development among children under five years of age. The c-IMCI strategy aims to improve case management skills of health care staff, improve the overall health system, and improve family and community health practices.

In Ethiopia, a phased c-IMCI intervention that first aimed to mobilize communities to access facility-based care for pneumonia then added CCM, found that the availability, quality, and demand for CCM was high (Degefe et al., 2009). This program included training CCM workers in rural areas to educate caregivers about the signs and symptoms of pneumonia, and the urgency to seek treatment upon the first sign of symptoms. Household surveys about demand for CCM for pneumonia—e.g., knowledge and care seeking—indicated that caregivers' knowledge of rapid breathing as a sign of pneumonia increased from 39 percent at project start (1997) to 92

percent at project end (2006), when nearly all mothers knew at least two childhood danger signs of pneumonia. Additionally, appropriate care seeking for pneumonia increased from 30 percent to 54 percent in Phase I of the project when communities were trained to recognize danger signs and seek care at health facilities. The level increased to 84 percent in phase II when CCM workers were deployed in communities. However, the project found that tailored strategies are needed for the most inaccessible communities where supervision is not feasible (Degefe et al., 2009).

In Nepal, one effective intervention trained FCHVs in rural areas to diagnose pneumonia and treat children with antibiotics (Dawson et al., 2008). Behavior change communication materials were developed, including pictorial training manuals, educational materials and reporting booklets. FCHV training included role-play and practical skills development. To demonstrate that FCHVs were capable of correctly diagnosing and treating pneumonia, two intervention arms—treatment and referral—were tested. In both arms, FCHVs were trained to assess children according to the WHO algorithm for danger signs requiring referral. In the treatment arm, FCHVs assessed children aged 2–59 months and treated them if necessary, reassessing them on the third day. Children whose condition deteriorated or did not improve were then referred. In the referral arm, FCHVs assessed children and referred those with fast breathing to the nearest health facility. In both arms, all sick infants under two months of age were referred to the nearest health facility. Home care advice was given in both arms. The study showed an increase in treated cases from 18 percent to 35 percent.

A later evaluation of the program by WHO showed an overall agreement for 81 percent of cases between the FCHVs and the surveyors (this figure represents total agreement, i.e. “total number of cases where surveyor and FCHV classification agreed/total number of cases assessed”). There was 95 percent agreement for “no pneumonia” cases (196/206). When classification was correct, the FCHVs' choice of treatment was always correct and there was minimal evidence of misuse of antibiotics. Only three percent (3/116) of children were given antibiotics when not indicated (Dawson et al., 2008).

Since the intervention in Nepal, improved access to care and CCM in remote villages has remained strong and more than half of all treated childhood pneumonia cases receive treatment from the FCHVs. An analysis of the success of the scale-up of this intervention identified a few key contributors. First, the effectiveness of CCM of pneumonia was documented, which influenced high-level

decision makers to support a pilot program. Establishing a permissive policy of community-based care combined with improved treatment rates provided a supportive environment for expansion. The established FCHV cadre and the functioning supply chain, which maintained an adequate supply of antibiotics, were also critical. Quality of care was maintained by providing supportive supervision and review meetings (Dawson et al., 2008).

Soofi and colleagues (2012) also found that local health workers in rural Pakistan successfully identified and treated cases of severe pneumonia in children. Researchers conducted a cluster-randomized controlled trial in which public-sector lady health workers (LHWs) were trained on CCM of severe pneumonia in children. Over 4000 children participated in the study and findings showed that LHWs satisfactorily diagnosed and treated severe pneumonia at homes in rural areas, with no increased risk of treatment failure or other adverse events.

In the Democratic Republic of Congo, studies have shown that quality of CHW services was better when CHWs continued working with their communities for an extended length of time (ASF & PSI, 2011). The importance of retention of CHWs to ensure quality and sustainability of programs was also identified in South Sudan (PSI, IRC, Malaria Consortium, & Save the Children, n.d.). A multi-country systematic review found that the basic requirements for effective CCM of pneumonia by CHWs are proper training, support and consistent availability of antibiotics (Graham, English, Hazir, Enarson, & Duke, 2008).

PACE Uganda combined one-on-one outreach through volunteer CHWs providing free diagnosis and treatment of pneumonia with education sessions led by village health teams (VHT), which was shown to be an effective way to promote awareness about the importance of case management and treatment-seeking behavior among caregivers. In this program, PACE Uganda implemented the Five & Alive social franchise network in the rural Mubende District. The network connected private clinics and drug shops that agreed to adhere to a set of operational standards around quality of care and pricing of products and services. Franchise providers purchased pre-packaged therapies from PACE for about US \$0.04–0.16 and received initial training on the use of a standard algorithm to diagnose children, supported by job aids to guide them in identifying common childhood illnesses.

Following initial training, network provider quality of care was monitored and continuously improved through monthly supportive supervision visits. Community-based VHT volunteers strengthened linkages between target caregivers and network providers through

health education, franchise network promotion, case identification and referral to franchise outlets (PACE Uganda & PSI, 2011). No evaluation results from this project were found in the literature review.

Conclusions, knowledge gaps and recommendations

This literature review highlighted the need to focus on increasing demand for child survival practices and life-saving commodities—like amoxicillin—among caregivers and providers. Creating and increasing demand depends on training CHWs to encourage caregivers to demand more and ensuring that healthcare providers are adequately equipped to meet that demand. For example, CHWs and other providers should encourage and support mothers and other caregivers to seek care and treatment at the first sign of illness and be informed about amoxicillin as an appropriate treatment. This increase in demand must be supported by trained healthcare providers who have adequate supplies.

Based on the behavioral drivers and program findings identified in the review, following is a list of specific recommendations to increase the demand and use of amoxicillin for childhood pneumonia:

- 1. Increase use of mass media and other channels to educate caregivers about amoxicillin for childhood pneumonia.** As reflected in the literature, efforts thus far primarily focus on educating caregivers at the interpersonal and community levels. CHWs and other health care workers educate caregivers—primarily mothers—to recognize the signs, symptoms and severity of pneumonia and seek appropriate treatment when necessary. The use of mass media and other channels was not documented but has proved a successful channel to increase knowledge and awareness of ORS and zinc, among other commodities and services, and could be used effectively to increase demand for care and treatment with amoxicillin.
- 2. Expand education efforts to increase knowledge and care-seeking behavior among all caregivers, including fathers and grandparents, in all locations.** Research found that educating caregivers resulted in better care-seeking behavior, but not all target populations were reached. Diversifying education messages to separately target mothers, fathers and grandparents has not been tested in the literature reviewed. The use of mass media offers the potential to reach wider audiences, especially those in rural areas, and increase awareness and demand when complemented by one-on-one efforts by CHWs and other health care workers at the community level.

Address caregivers and providers preference for home remedies to treat pneumonia. The literature reviewed showed that many caregivers and providers believe that pneumonia is the result of underlying non-medical causes that modern medicines cannot treat. Although many authors noted that education and communication strategies must address these entrenched cultural beliefs, the best methods or strategies are not clear. For example, simply trying to “replace” traditional beliefs with science is unlikely to resonate with target audiences.

- 3. Target health education programs to providers—both formal and informal—working in the private sector.** These providers often provide first-line treatment, but often lack accurate knowledge to diagnose or properly treat pneumonia; many often inappropriately prescribe anti-malarials for cases of pneumonia. Education and treatment interventions among this group of providers should be sensitive to their reality and, where appropriate, interventions must be framed within the business framework within which private providers operate.
- 4. Institute a permissive policy to allow CHWs to deliver amoxicillin in the community or home setting.** Without this, efforts to increase demand and use will be largely ineffective in places where barriers to facility-based care are prevalent. Since

barriers to access, such as distance to a health facility and financial constraints, were identified in many countries, expanding CCM of pneumonia and offering free treatment would likely increase antibiotic use for pneumonia. Documentation of the effectiveness and acceptability of community-based pneumonia care has been shown to strengthen political and decision-maker support, which allows for greater scale-up of intervention programs. Yet, evidence on the best strategies for fostering political support, which was found to be critical for scaling up interventions and increasing demand, was also limited.

- 5. Improve quality of care as a means to increase demand for services.** Increasing CHW retention and maintaining an adequate supply of antibiotics in health facilities and drug kits improves quality of care. Inadequate supply of amoxicillin to health facilities and CHWs remains a barrier to use and must be addressed concurrently with education and communication campaigns.
- 6. Evaluate demand generation interventions and programs.** Although this review highlighted many of the barriers to uptake of amoxicillin, there was little evidence of effective strategies to increase use of this commodity. There is a need to evaluate demand generation activities to measure their effectiveness in generating demand.

**Reproductive Health Commodities:
Female Condoms, Contraceptive
Implants, Emergency Contraception**

Women of reproductive age in developing countries are at high risk of unintended pregnancy and sexually transmitted infections (STIs), including HIV. In 2008, of the estimated 185 million pregnancies, almost 90 percent occurred in the developing world. Globally, 86 million pregnancies were unintended; of these, 41 million ended in abortion, 33 million in unplanned birth and 11 million in miscarriage (Singh, Sedgh, & Hussain, 2010). Around the world, about 222 million women have an unmet need for family planning (PRB, 2012).

Although contraceptive use has steadily increased globally during the past three decades, use in some of the poorest areas of the world, such as sub-Saharan Africa, remains low. Sub-Saharan Africa has the highest percentage of women with unmet need; approximately 25 percent of women in the region—some 49 million women—either use traditional methods or no method at all, yet they wish to avoid pregnancy (PRB, 2012). There is global consensus that contraception has direct and indirect influences on a number of health outcomes including maternal, neonatal and infant health, and community health (Glasier, Gülmezoglu, Schmid, Moreno, & Van Look, 2006). Globally,

it is also recognized that expanding method choice leads to higher levels of contraceptive use.

Expanding dual-protection methods that protect from risk of pregnancy and STI/HIV infection could reduce the estimated 2.5 million new cases of HIV per year (UNAIDS, 2007). HIV-related morbidity and mortality can lead to tremendous strain on the lives of individuals, their families and communities. For instance, communities and societies can be affected by lower productivity, higher dependency ratios and increased economic burden.

The vast majority of unintended pregnancies, unsafe abortions and new incident cases of HIV infection occur in less-developed countries with already overstretched health care systems. The staggering figures mentioned previously suggest an urgent need to continue exploring strategies that improve sexual and reproductive health, particularly the prevention of unintended pregnancies and transmission of STI/HIV in developing country contexts and among poor, vulnerable and marginalized populations.

Female Condom



The female condom is the only women-initiated, dual-protection commodity that protects women from both STIs—including HIV—and unintended pregnancy. When first introduced in 1993, the female condom was lauded by the global reproductive health community as a device that could significantly enhance women's power to protect themselves from unintended pregnancy and STIs (Kabira et al., 1997). However, the female condom remains an underutilized, under-prioritized and misunderstood commodity and the Reproductive Health Supplies Coalition recently identified the female condom as one of several underused reproductive health technologies (RH Supplies Coalition, 2012).

However, the female condom must be correctly and consistently used in order to be most effective. When used correctly with every act of sex, about 5 pregnancies per

100 women using female condoms occur over the first year. As commonly used, about 21 pregnancies per 100 women using female condoms occur over the first year (WHO & JHU-CCP, 2011). Mathematical modeling from one study found that perfect use of the female condom for a year by a woman having sexual intercourse twice a week with an HIV-infected partner could reduce her risk of acquiring HIV by 90 percent (Trussell et al., 1994). Although statistically less effective for planning purposes than other methods, the female condom has a number of unique benefits including lack of side effects and the ability to be introduced prior to sexual acts avoiding coital disruption. When correctly fitted, the material and outer ring of the female condom covers part of the vulva, which provide extra coverage for STIs that can be transmitted through skin-to-skin contact (WHO & JHU-CCP, 2011).

Commodity Overview

Since its introduction, several prototypes of the female condom have been developed and tested worldwide. The first female condom approved by USFDA was the FC1[®] developed by the Female Health Company (FHC). In 2009, the FC1[®] ceased manufacture and was replaced by the FC2[®], the FHC second-generation product after it received approval from United Nations Population Fund (UNFPA) and the World Health Organization (WHO), and subsequently by U.S. Federal Food and Drug Administration (FDA) in 2009. The FC2[®] is similar in design and appearance to FC1[®] but is made of synthetic nitrile and considerably less expensive to manufacture. The average cost is US \$0.54.

In 2012, WHO also approved a second female condom design called Cupid[®], from Cupid Ltd. Several other female condom designs are pending technical review and approval by WHO.

[Source: Every Woman Every Child, 2013]

The evidence review found 27 documents related to demand generation for the female condom that met the inclusion criteria, 19 of which were published in the peer-reviewed literature. Most of the evidence was from Africa (12 documents), two documents from Asia (one each from Cambodia and China), two documents from South America (Brazil) and one from Central America (Dominican Republic). Four documents were reviews of multiple countries. Documents from two pathfinder countries were identified: Nigeria and Tanzania.

Key social and behavioral drivers

Studies examining the acceptability of the female condom that were carried out in 2004 and 2005 in both developed and developing countries, found acceptability ranging from 37 percent to 96 percent (Hoffman, Mantell, Exner, & Stein, 2004; FHI, 2005). A male acceptability study found that men reported greater willingness to use the female condom with spouses or long-term sexual partners, than with casual sex partners or sex workers (SWs) with whom the relationship may be less based on trust (Koster, Groot Bruinderink, Kuijper, & Siemerink, 2012). Studies have shown that increasing acceptability in men and women has the potential to increase female condom use (Choi, Gregorich, Anderson, Grinstead, & Gómez, 2003).

Another study looking at patterns and predictors of female condoms among ethnically diverse women also found that female condom use among women was associated with having a steady partner and having a partner who has a favorable attitude toward female condoms (Hoffman et al., 2004). Although both of these studies suggest a long-term, steady partner is positively associated with increased use of the female condom, a study in Zimbabwe, found that use is lower amongst regular sexual partners (Meekers & Richter, 2005). In most studies, female condom use is low when compared to the male condom and generally declines after introduction because of cost and availability (Hoke et al., 2007; Liao et al., 2011; Thomsen et al., 2006).

Looking beyond individual level factors, structural factors as well as community and gender norms and have shaped the success of the female condom introduction and utilization. One of the biggest challenges to increasing the uptake of the female condom has been the disposition of regulatory agencies as well as the negative attitudes of health care providers, both of which have strongly contributed to the lack of information and awareness of the female condom and restricted access to this method of contraceptive (Kabira et al., 1997). Community and gender norms that affect the uptake of female condom use vary by community and have the potential to

significantly affect female condom use. For example, a study in South Africa and Kenya, found that men who adhered to more traditional gender roles were less likely to think of the female condom as a viable form of protection in the future and were less likely to use one if their partner suggested it (Kaler, 2001).

Implementation strategies and impact

National prioritization

In the mid- to late-1990s, Brazil, Ghana, South Africa and Zimbabwe, launched multifaceted female condom campaigns and demonstrated how national governments can increase access to and coverage of the female condom through coordinated national campaigns (Endsley & Maposhere, 2005). Their experience is often cited as a global good practice. In Brazil, the national government played a significant role in promotion, procurement and distribution of the female condom, especially targeting specific vulnerable women due to exposure to sexual or domestic violence or who had limited access to services (Telles Dias, Souto, & Page-Shafer, 2006). In Ghana and Zimbabwe, the approach was driven by grassroots efforts that advocated for greater options for women to protect themselves from HIV infection (Meekers & Richter, 2005; Poole, 2003; Population Council, 2006).

In South Africa, which has one of the largest, well-established, government-funded, public-sector male and female condom programs worldwide, a model of national government leadership was used in combination with an explicit focus on a comprehensive, large-scale provider-focused train-the-trainers initiative for clinic-based programming. The program focused initially on family planning clinics, promoting the female condom for pregnancy and infection prevention. With the program's geographical expansion, the government has complemented the public sector program with donation of free female condoms on request to NGOs. In 2012, South Africa procured one billion male condoms and 11 million female condoms, with an aim to ensure the availability of at least one female condom distribution site in all of the 254 sub-districts in the country.

Warren & Philpott (2003) examined the introduction of the female condom in Brazil, Ghana, South Africa and Zimbabwe, and identified six key elements to expand access and acceptability of the female condom: (1) a clearly identified target audience for promotion messaging; (2) provision of training to ensure that biases do not negatively influence potential users—and ensure they would feel comfortable promoting a product with which they are familiar; (3) face-to-face communication to equip potential users with information and skills; (4)

a broad reproductive health focus that integrates family planning and HIV/AIDS prevention; (5) a mix of public- and private-sector distribution; and (6) a long assessment period to gauge performance of the distribution program. The study suggests that targeted, integrated services and strategies increase knowledge and demand of new contraceptive choices. Each program also took strides to involve a range of partners from the very beginning and take a multi-level approach targeting individuals, communities and service providers while addressing procurement and supply side issues.

Social marketing and mass media

The female condom is an ideal method for social marketing distribution and mass media promotion, and the available gray literature is extensive. However, the actual effect of social marketing on condom use, particularly female condom use, has not been well documented. For example, a recent meta-analysis of social marketing and mass media approaches on condom use only found one study with female condom use as an outcome (Sweat, Denison, Kennedy, Tedrom, & O'Reilly, 2012). The following section will focus on the few more fully documented examples of social marketing and mass media approaches promoting the female condom.

The Zimbabwe national program promoted the female condom through non-medical channels—such as hairdressers and barbers in low-income neighborhoods—extending reach to men, sex workers and people living with HIV/AIDS (UNAIDS & PSI, 2000). As a result of these efforts, Zimbabwe has some of the highest female condom sales in the world—including an 11 percent increase from 2011 to 2012.

In Tanzania, a program was implemented that exposed individuals to a mass media campaign focused on the benefits of the female condom. Additional program components included peer education and health care provider training on female condom counseling. An evaluation of the program aimed to assess how the target population learned about the female condom and their intention to use (Agha & Van Rossem, 2002). Results from the evaluation indicated that about 38 percent of respondents had been exposed to the mass media campaign promoting the female condom in contrast to only 12 percent who learned about the female condom from a peer educator or a health care provider. However, the evaluation showed that intention to use was higher among respondents exposed to peer educators. The study results suggest although mass media approaches are successful at increasing awareness among a large population, peer based strategies are more influential for behavior change.

Interpersonal communication

An important component of the success of several female condom programming projects is building women's interpersonal communication (IPC) skills, especially negotiation. In Zambia and Malawi, efforts to increase female condom use focused on included three components: (1) IPC training for non-medical suppliers, opinion leaders, pharmacists and nurses; (2) community-level activities including female condom promotion at community events and bars, and through raffles; and (3) mass media including radio spots, print ads, call-in shows and billboards (PSI, 2013). In this example, targeted IPC was important for making providers, peers, and opinion leaders comfortable with answering questions and counseling women.

A study in Brazil assessed the impact of a national promotional effort in the long-term adoption of the female condom among both women who used the female condom and their male partners. The intervention program, implemented in six Brazilian sites representing diverse areas and risk groups, included participation in a group or individual standardized training or "educative intervention" sessions, which addressed the following topics and skills-building precepts: condom negotiation, female condom insertion instruction, STIs, genital anatomy and gender-associated vulnerabilities. The study found that adherence to using the female condom requires follow-up sessions and that the first use of the method is a critical moment because it is often met with difficulty and discomfort (Telles et al., 2006).

A report by the Universal Access to Female Condoms Joint Programme (UAFC) stated that having one-on-one IPC is also important because in some contexts, women or men may not feel comfortable asking about insertion or anatomy in a group setting (UAFC, n.d.). An example from the UAFC program in Nigeria, suggests that intensive capacity-building programs are necessary to offer correct information and explain the potential use of the female condom not just for pregnancy protection, but also for STI/HIV protection. Building such capacity to talk and counsel women was important in the internalization of multiple benefits of the female condom (Adeokun et al., 2002). Any promotion strategy should include capacity building on IPC skills—both between women and men, as well as between providers and clients—at the center of efforts to increase use and comfort with the female condom.

Personal demonstration has also been shown to be effective in increasing uptake (Van Devanter, 2002). The female condom requires more practice for correct and consistent use than the male condom, especially for

women who may have limited knowledge about the female anatomy. In the United States, several studies suggest that more comprehensive training protocols that include demonstrations with pelvic models and practice, leads to an increase in uptake (Choi et al., 2008; Exner et al., 2012; Witte et al., 2006). A similar finding emerged from a study in Madagascar targeted at sex workers (Hoke et al., 2007).

Behavioral economics

An innovative study in Zambia, assessed the effectiveness of increasing female condom coverage through the use of four different incentive mechanisms with local hairdressers and barbers (“agents”) who had already been hired by a local organization to sell male condoms and discuss other health issues with their clientele (Ashraf, Bandiera, & Jack, 2012). The evaluation randomized 1222 agents to one of the four groups—three treatment, or incentive, and one control. The incentive groups included one with a small financial reward, one with a larger financial reward and one with a non-financial reward of recognition for their achievements by local leaders of influence. The investigation tracked condom sales on a monthly basis for a year and then evaluated results. The study showed that financial incentives were not the only motivators for increasing coverage. Mechanisms that recognize and reward success can make an impact in extending coverage. The study also showed that financial incentives for pro-social tasks do not ‘crowd out’ motivations to provide this service.

High-risk populations

A number of studies on female condom promotion among high-risk populations showed high acceptability of the female condom among sex workers. In Cambodia, migrant sex workers perceived female condoms to contribute to greater control over negotiation with clients, especially with drunk clients. The introduction of a new method and a space to talk about the methods reinforced sex workers’ intentions to share experiences and support one another (Busza & Baker, 2004). Findings from a study in the Dominican Republic, suggest that the introduction of female-inserted barrier methods could suit the needs of sex workers. They found that younger participants were more likely to use male condoms exclusively and older participants were more likely to use female condoms. One explanation may be that older women felt more comfortable trying new methods and negotiating their use with clients and regular partners—with whom a relationship based on trust may already have been established—than younger ones (Lara et al., 2009).

A randomized-controlled trial in Madagascar, assessed whether individual clinic-based counseling, as a

supplement to peer education for male and female condom promotion, leads to greater use of protection and lower STI prevalence among sex workers already exposed to intensive male condom promotion (Hoke et al., 2007). This study found little evidence for gains from more thorough clinical counseling on male and female condom use, suggesting that less clinically intensive interventions such as peer education could be suitable for male and female condom promotion in populations already exposed to barrier method promotion activities.

Conclusion, knowledge gaps and recommendations

The literature reviewed shows that when contraceptive choices are expanded, coverage and use also increase—but sustained efforts are needed. When the female condom is made available over a long period of time, studies have shown that it fulfills the reproductive and prevention needs of specific populations, which in different contexts ranges from monogamous long-term partners to high-risk groups like sex workers. However, there has been minimal investment in female condom promotion—both in terms of funding and capacity-building for service providers and community-based support, leading to stagnated use and limited outreach to certain vulnerable populations. Limited monitoring and evaluation of promotion strategies have also limited the evidence base and approaches to dealing with challenges.

Issues of power dynamics, gender inequities and social and community norms emerged as significant barriers to method expansion. Recommendations to overcome some of the barriers to use are presented below. However, the high cost of the female condom will continue to hinder availability by discouraging program managers and donors from investing in female condom procurement, impacting female condom availability, which, in turn, influences uptake. At the user level, the higher price and fewer choices of the female condom compared to male condom also limit female condom uptake.

1. Increase information and awareness of the female condom in communities, while addressing social and gender norms.

The literature revealed that lack of information and community and gender norms about the female condom strongly hinder the uptake of female condoms. Marketing the female condom as a family planning option, rather than for STI/HIV protection, may increase acceptability amongst the general population. Using different market positioning in efforts to increase knowledge and awareness of the female condom may also improve willingness to try a new product, in certain contexts, such as the inclusion of messages about pleasure (Warren & Philpott, 2003). Involving men as users and

as female condom promoters is also important to increase male acceptance of the female condom and facilitate couple communication.

- 2. Take a multi-level approach to increasing female condom use.** The literature shows that female condom programs were most successful when they involved a range of partners from the outset and used a multi-level approach targeting individuals, communities and service providers while addressing procurement and supply-side issues. Comprehensive condom promotion programs that promoted the female condom alongside the male condom can increase options for both men and women, and increase the number of protected sex acts by either method (Ray, van De Wiggert, Mason, Ndowa, & Maposphere, 2001).
- 3. Increase social marketing and evaluation of social marketing efforts.** The female condom is an ideal method for social marketing distribution and mass media promotion and the available gray literature on this approach is extensive. However, the actual effect of social marketing on condom use, particularly

female condom use, has not been well documented. In those studies that have evaluated the impact of social marketing approaches, with financial and/or non-financial reward mechanisms, findings have shown that potentially innovative techniques to increase access and coverage can be successful, especially when implemented through peer networks and non-medical channels.

- 4. Increase training on interpersonal communication.** Building women's interpersonal skills, especially negotiation skills around using condoms, comfortably discussing insertion issues and addressing gender associated vulnerabilities may help to increase female condom use.
- 5. Increase female condom promotion among high-risk populations.** A number of studies suggest that female condom promotion among high-risk populations may be an effective strategy in the prevention of pregnancy and STI/HIV in those populations. The studies reviewed show high acceptability of the female condom among sex workers.

Contraceptive Implants



Commodity Overview

Hormonal implants consist of small, thin, flexible plastic rods—each about the size of a matchstick—that release a progestin hormone into the body. They are safe, highly effective and quickly reversible long-acting progestin-only contraceptives that require little attention after insertion. Implants, which are inserted under the skin of a woman's upper arm, prevent pregnancy for an extended period after a single administration and are highly effective. No regular action by the user and no routine clinical follow-up are required.

Implants are available from three main manufacturers, Bayer Pharma AG (Germany), Merck/MSD Inc. (USA) and Shanghai Dahua Pharmaceuticals Co., Ltd (China). The most common types include Jadelle[®], WHO prequalified (two rods each containing 75 mg of levonorgestrel, effective for five years); Sino-implant (II)[®], which is not yet prequalified by WHO and is currently marketed under various trade names including Zarin[®], Femplant[®] and Trust[®] (two rods each containing 75 mg of levonorgestrel, effective for at least four years); and Implanon[®] (WHO prequalified) and Nexplanon[®] (both with one rod containing 68 mg of etonogestrel, effective for three years). Nexplanon[®] is radio-opaque, allowing x-ray detection if the rod is difficult to locate due to deep insertion and also has an improved trocar. Norplant[®] (six rods each containing 36 mg of levonorgestrel, effective for five to seven years) was discontinued in 2008.

In February 2013, an agreement was reached between public and private sector partners and Bayer to reduce the price of its contraceptive implant, Jadelle[®], from US \$18 to US \$8.50 per unit, in more than 50 countries globally. This was followed in May by an agreement with Merck MSD that will see the cost of Implanon[®] and its next generation implant, Implanon NXT[®], drop by approximately 50 percent over the next six years.

The evidence review found 15 documents related to demand generation for contraceptive implants that met the inclusion criteria, of which seven were published in peer-reviewed literature. The evidence was documented from countries in Africa (12 studies) and Asia (2 studies), as well as one article discussing general approaches and potential for contraceptive implant use in African and Asian countries. Eleven articles evaluated program interventions involving contraceptive implant programs and three articles described knowledge, attitudes and behaviors of users and non-users of long-acting reversible contraception (LARC), usually defined as implants and intrauterine device (IUD). Some studies defined LARC to include injectables. The review identified seven studies

from the following pathfinder countries: Ethiopia (4), Nigeria (1), Sierra Leone (1) and Tanzania (1).

Key social and behavioral drivers

Eight articles evaluating family planning interventions—as well as the knowledge, attitudes and behaviors of users and non-users of LARC—specified key social and behavioral drivers.

The literature identified a range of barriers limiting demand for implants, of which fear of side effects was most common. In Ethiopia, married women in urban areas were most likely not to use implants or IUDs because

they were using another method of contraception such as oral contraceptives and condoms or concerned about side effects (Alemayehu, Belachew, & Tilahun, 2012). In Nigeria, sexually active adolescent students did not use LARC (defined in the study as implants, IUDs and injectables) because of belief that the methods could interrupt pregnancy or cause infertility, fear of side effects and religious and cultural barriers (Eke & Alabi-Isama, 2011). Fear of side effects was also found in Bangladesh, especially concerning changes in menstrual patterns (EngenderHealth/The RESPOND Project, 2012), and in Tanzania, where concerns about painful implant insertion and fear it could cause cancer, and weight loss or gain were also prevalent (EngenderHealth/The RESPOND Project, 2010). For women attending public clinics in Zambia, barriers to implant and IUD uptake appeared to be more focused on provider barriers, such as lack of skilled providers, provider bias and commodity supply issues, as well as individual lack of knowledge (Neukom, Chilambwe, Mkandawire, Mbewe, & Hubacher, 2011).

The long duration of implants effectiveness emerged as the most common perceived advantage. Additional benefits identified in Tanzania, Kenya, and Bangladesh, included the ability to use when breastfeeding, comfort and ease of insertion and removal (EngenderHealth/The RESPOND Project, 2010, 2012; Hubacher, Olawo, Manduku, & Kiarie, 2011). Implants were also found to overcome a significant barrier among women in Ethiopia seeking family planning services, but hesitant to expose their bodies, because it does not require pelvic examination (Pathfinder International Ethiopia, 2008). In Zambia, implant acceptors had a lower age and lower parity compared to IUD users (Neukom et al., 2011). Women with HIV in Rwanda and Zambia were likely to use implants when younger in age and current methods of contraception were found to be a significant predictor of LARC uptake. For example, women using injectables were half as likely to adopt LARC compared to condom-only users (Khu et al., 2012). However, a study in Kenya did not find previous use of a modern method to be associated with choosing an implant (Hubacher et al., 2011)

Less evidence was found of social and behavior drivers among providers. In Bangladesh, the Strengthening Health Outcomes through the Private Sector (SHOPS) project conducted formative research to identify key barriers to providing LARC (defined in the study as implants, IUD and injectables) among private providers, including nurses, general doctors and specialized obstetrician/gynecologists (Sanders & SHOPS Project, 2012). The study found a low level of knowledge of method-specific side effects, including beliefs that IUDs and implants have too many or too adverse side effects. Knowledge was also lacking on policy-related issues, such as who is allowed to provide LARC. A high percentage of

those surveyed claimed they felt competent to insert and implant, and many were doing so, but had never received training. The study also found that although women stated their husbands were generally supportive of LARC, the majority of providers believed that husbands were opposed to LARC and that women should not use these methods without their husbands support. This finding suggests that providers may weigh perceived husband approval more heavily than the woman's opinion or desired family size when providing method counseling.

Implementation strategies and impact

Target populations in the demand generation programs identified in the review were potential LARC users (13 articles), as well as providers (5 articles). Potential LARC users were further defined in studies as health clinic clients, young women, married women, women with HIV, poor women and women seeking LARC. Most implementation strategies for LARC uptake were peer counseling/health worker counseling (7 articles), the provision of commodities (5 articles), community-based outreach (5 articles) and mass media (2 articles). Six articles also included strategies that involved health worker training, most of which were to strengthen their LARC counseling and implant insertion skills.

Service integration was a strategy used by several interventions focusing on LARC counseling and provision of commodities to increase uptake of LARC methods. A program carried out in two cities in Rwanda and Zambia, targeting HIV discordant couples found that integrating couples' HIV testing services, family planning counseling and provision of LARC resulted in uptake: providing contraceptive implant counseling and services increased usage by 140 percent in Rwanda and 200 percent in Zambia (Khu et al., 2012).

In Mali, a program targeting unmet need for family planning (FP) among women of reproductive age reached women attending health clinic immunization days for children under one year of age (PSI, 2012). During the event, the midwife, with assistance from clinic personnel, gave a presentation to women waiting for infant immunizations on the importance of family planning for maternal and child health (MCH). The full range of modern contraceptives available in Mali was discussed, with special emphasis on LARC in participatory discussions. Women were also informed that counseling, exams, and implant insertion services were available at the clinic for subsidized prices. In the first wave of 14 immunization event days, 720 women were provided information and over 10 percent chose to receive LARC services. In the second wave of 292 event days, 12,204 women were reached and 18 percent chose to receive LARC services. The authors found clinics did not have enough staff to provide both immunization and LARC

services on the same day and a dedicated LARC midwife would be necessary. Yet, the approach is promising given the significant amount of women who chose LARC when offered.

Service integration was also found to be a successful strategy in Zambia, where a program targeted women at clinics and used dedicated midwives trained in LARC services to promote uptake (Neukom et al., 2011). The midwives led talks on LARC with women in clinic waiting rooms who were waiting for a range of MCH health services and informed them that services were available the same day if desired. They used client feedback, summarized on a flip chart, to share user perceptions about LARC. Over 14 months, the program provided LARC services to 33,609 women, who chose either an implant (66 percent) or an IUD (34 percent), and reached new populations—younger and lower parity women. Increased accessibility was also key in a program seeking to address unmet need for LARC among HIV-positive pregnant women in Rwanda (Dhont et al., 2009). Women were invited to family planning counseling sessions by trained nurses before delivery, although no particular contraceptive method was emphasized, a substantial number of women started using contraceptive implants when availability was improved.

Health education through mass media, print and other materials was used in Sierra Leone to increase recognition of implants and raise awareness of implant benefits, alongside health worker training to improve counseling and clinic skills (MSI, 2010). The program distributed posters and other materials through community health workers, aired radio jingles and produced broadcast discussion shows. The program also used a social network approach by working with and through community stakeholders to encourage them to promote method awareness. Evaluation of the program showed increased awareness as clients were able to ask for the product by name at private social franchises.

Task shifting to community-based health workers has shown to be successful in Ethiopia, where a program training HEWs on contraceptive implant counseling and insertion services assessed whether community-based provision could meet unmet need in four rural areas (Pathfinder International Ethiopia, 2012). HEWs recruited women for family planning services during the practicum training period and 96 percent of eligible women chose implants. The authors found the provision of implants at the community level was effective in reaching women with the highest level of unmet need, especially those between the ages of 20 and 35. Providing services in the communities increased accessed to these services by young married women, who often need family approval and escorts to travel.

Another program in Ethiopia (Pathfinder International Ethiopia, 2010), generated demand for contraceptive

implants by working with community-based reproductive health agents (CBRHAs); supporting public and private facilities with equipment, supplies and training; and conducting outreach through marketplace, workplace and youth forums. CBRHAs provided health education at the household level, distributed oral contraceptives and condoms, and referred clients for clinical services. In the program, CBRHAs were the most cited source of information on implants and IUDs. Clients accepting implants increased from fewer than 1000 in 2002–2003 to almost 55,000 in 2005–2006 in the project areas. Most LARC users switched from short-acting contraceptive methods and 30 percent were first time contraceptive users. The authors concluded that to enhance access to and quality of services, programs need further community education to attract new clients, more provider training and supervision, enforced guidelines on the right to method removal on demand and improved logistics and supplies.

Conclusions, knowledge gaps and recommendations

With the recent reduction in cost for Jadelle® and Implanon®, there is a lot of potential for increased demand for implants. However, poor provider counseling skills, lack of information and fear of side effects will likely prove significant barriers to successful uptake. Recommendations to overcome these barriers include:

- 1. Increase knowledge among health consumers.** Although the unmet demand for implants is thought to be high, women and their families still need access to information about the benefits and a clear explanation about potential side effects and ways to deal with them. Health education through mass media, print and other materials is a potential channel and was used successfully in Sierra Leone, to raise awareness of implant benefits. However, myths and misconceptions are best dealt with through interpersonal communication.
- 2. Increase task shifting and dedicated staff for implants.** Research in Ethiopia shows task shifting to community-based health workers can be successful. The use of task shifting and dedicated staff is also influential in increasing uptake within health systems. Service integration with HIV, MCH and other services, with the use of dedicated providers for LARC, offers another facility-based strategy to increase uptake.
- 3. Ensure that provider training on implant insertion includes skills building in counseling for implants and is supported by clear job aides.** Providers at the facility and community levels need skills to counsel women and their families on available contraceptive methods, the benefits of implants and potential side effects and ways to deal with them. Providers should also be able to inform and counsel women on removal of the contraceptive devices.

Emergency Contraception



Commodity Overview

EC offers women a last chance at preventing an unplanned pregnancy after contraceptive failure, sexual assault or other instances of unprotected intercourse. While several products can be used as EC, the levonorgestrel-alone emergency contraceptive pill (ECP) is the only dedicated emergency contraceptive product that is widely available in developing countries. ECPs are optimally taken in one dose of 1.5 mg, as soon as possible after sexual activity, although a product containing two tablets of 0.75 mg each, labeled to be taken 12 hours apart, is more widely available in developing countries.

ECPs are safe and appropriate for dispensing directly, without a prescription, by a pharmacist or drug seller. Currently, it is registered in almost all countries of the world and is registered as a non-prescription product in over 60 countries, including many low-income countries. It is also available directly from pharmacists informally in many developing countries, even where it is registered as a prescription product.

The evidence review found 21 documents related to social and behavioral drivers and demand generation that met the inclusion criteria. Evidence was included from four pathfinder countries: Nigeria (3), Senegal (1), Ethiopia (1) and Uganda (1).

Key social and behavioral drivers

Access to ECPs varies across different country contexts and is influenced by a number of cultural, social, and political contexts. The literature on ECPs is extensive and largely focused on effectiveness studies and barriers to provision due to lack of access or provider-level biases. A low rate of awareness in most developing countries is a significant barrier to ECP access (ICEC, 2011). Data on knowledge levels and use of EC in the pathfinder countries from 2007 to 2011, shows that the proportion of women who have ever heard of EC ranges from 6.2 percent in Sierra Leone to 35.1 percent in Malawi, with seven of the countries at less than 20 percent (ICEC, 2011).

Several studies were identified from pathfinder countries that focused on understanding provider-level barriers and attempts to address them through outreach and training programs (Ahonsi, Salisu, Idowu, & Oginni, 2012; Mané, Brady, RamaRao, & Bintou Mbow, 2012; Williams, 2011). The studies show that even when knowledge about ECPs is high there are significant barriers to address in order to increase provision of ECPs. Two main barriers to provision include lack of correct knowledge about ECPs and negative attitudes about the method held by health care providers, although attitudes were more favorable in Uganda (Byamugisha et al., 2007). Two studies in Nigeria (Ebuehi, Ebuehi, & Inem, 2006; Oriji & Omietimi, 2011) show substantial variability among doctors, nurses and other health care providers in correct administration of ECPs and understanding of the biological mechanism of action. Unique among family planning methods, the mechanism of action of EC is often misconstrued as inducing a medical abortion

and there is widespread belief that repeat use will cause long term health problems, especially related to fertility, despite evidence that suggests no increased risk (Halpern, Raymond, & Lopez, 2011). These knowledge gaps affect provider comfort and ability to properly counsel potential ECP clients. A study from Kenya and Ethiopia (Judge, Peterman, & Keesbury, 2011) also found that although provider knowledge of ECPs as an option to prevent pregnancy after unprotected sex was high, knowledge about the actual biological mechanism was low, which led to confusion on how to administer the ECPs. In all of these studies, there were strong biases among health care providers concerning the administration of ECPs to certain populations, such as adolescents and unmarried women.

Addressing knowledge gaps among health care providers could increase access and coverage of ECPs. In Uganda, for example, government and privately employed health care workers were found to have both high knowledge of the benefits of ECPs and favorable views of ECPs to prevent pregnancy, which were attributed to national education efforts (Byamugisha, Mirembe, Fixelid, & Gemzeli-Danielsson, 2007). The study suggests that training and support to health care providers on ECPs, especially on the latest research and practice, could increase acceptability and coverage of ECPs.

Implementation strategies and impact

Social Marketing

ECPs can safely be provided in pharmacy settings without clinical supervision, making them a good fit for the commercial and SM sectors. This approach has been used in many countries to increase access and utilization. For example, PSI is implementing ECP SM programs in India, Kenya, Nigeria, Paraguay, Myanmar, Zimbabwe and Pakistan. The strategies for scaling up ECPs vary and should be informed by different country contexts, however, they generally include the following steps: 1) generating awareness; 2) building health care provider knowledge and skills; 3) ensuring availability and affordability; and 4) increasing community knowledge and acceptability (PSI, 2013). In 2011, PSI alone sold over 3.7 million doses of ECPs globally. Marie Stopes International (MSI) and affiliates of the International Planned Parenthood Federation (IPPF) have used SM for ECPs as well, although the literature search showed that PSI's and DKT International's approaches were more widely reviewed.

Both PSI and DKT take innovative market segmentation approaches to tailor products to specific populations in order to increase acceptability and ultimately use. They employ a wide range of approaches including branding,

mass media, engaging celebrities and community mobilization. These efforts suggest that many consumers prefer to access ECPs from the commercial and SM sectors and thus there is a need to ensure that information about ECPs is available outside of clinic settings. Overall, SM and other non-medical channels for ECPs are important and effective demand generation strategies. However, a recent assessment shows that at this time, only one third of social marketing programs that offer family planning include ECPs in their range of methods offered (Westley & Shochet, 2013).

Front-line services and delivery

Evaluation of an initiative to mainstream ECPs in both the private and public sectors of Kenya through training of private pharmacists and provision of communication materials found that pharmacies that received the intervention were better positioned and more comfortable providing ECPs to clients, including providing correct knowledge on the mechanism of action and potential side effects, than control sites (Keesbury, Liambila, Obare, & Kuria, 2009a). The study suggests that pharmacies can play an important role in increasing women's knowledge about and access to ECPs when provided with the proper tools, materials and knowledge. Some of the lessons learned from this initiative were used to develop a toolkit for policy makers and service providers to mainstream ECPs in developing countries.

Mass media and interpersonal communication

In Jamaica, which made ECPs a non-prescription behind-the-counter product in 2003, a campaign to promote safer sex focused on three core messages: 1) abstain from casual sex; 2) use a condom consistently; and 3) as a last resort, use ECPs within three days of having unprotected sex. Although the government's priority was adolescent girls, the messages were deliberately designed for all women and positioned ECP within the context of broader sexual and reproductive health. There is no evidence to suggest that ECP use leads to increased risk of pregnancy or contraction of STIs, nor to any increase in sexual or contraceptive risk-taking behavior, including among younger women (ICEC, 2013); however, a key barrier encountered during the study period was the widespread notion that access to ECP will increase casual sex, especially among young people (Chin-Quee, Hinson, L'Engle, Otterness, & Janowitz, 2012).

In Mexico, a ten-year national strategy introducing ECP into the country included awareness raising among the public as part of a four-pronged strategy to increase access to and use of ECPs. Messages about ECPs were disseminated via several methods: humorous postcards placed in strategic locations such as restaurants, bars and

gyms, mouse pads and through a hotline. Findings from two case studies (Ellertson et al., 2002; Schiavon & Westley, 2008) found that awareness jumped from 13 percent to 32 percent, and support for ECP increased from 73 percent to 83 percent.

The case studies also reported nearly a doubling of sales each year over the course of three years. An innovative element to their strategy was a robust media campaign prior to the introduction of ECPs. The campaign planned a media workshop to proactively avoid an inflammatory press response to ECP promotion efforts, especially among the religious community. The writers concluded that “[t]he dominant lesson that emerged from this effort was that partnerships are absolutely critical to achieve the large-scale and multi-sectorial change that is required to introduce EC.”

Counseling hotlines have also been used in other countries to increase knowledge of ECPs among community members and providers. For example, in Sri Lanka, a hotline was developed for community members and service providers with information on how to use ECPs and potential side effects. The hotline was highlighted in newspaper advertisements and other local publications (ICEC, n.d.). In Kenya, ECP information was integrated into a local youth sexuality hotline. A case study documenting the project noted that the integration process entailed a one-day training and follow-up refresher training for hotline counselors that provided basic information on ECPs’ mechanism of action, where ECPs could be found and how to incorporate ECPs into counseling about other sexual and reproductive health (SRH) services (Keesbury et al., 2009).

Improving parent-child communication was a focus of another project in Mexico, which evaluated an intervention geared toward improving adolescent access to SRH services, including ECPs (Campero, Walker, Rouvier, & Atienzo, 2010). The project held workshops on intergenerational dialogue that consisted of group activities and awareness of the benefits of improved communication, information about STIs and adolescent pregnancy, information and access to condoms and ECPs, and skills-development activities including role-play and paired activities. The project also developed a prevention package for parents to provide to their children. The study found that after the workshops there were changes in parent attitudes about communication and SRH—parents felt more comfortable acknowledging the risks that adolescents face and limitations in their knowledge. The study concluded that the prevention package was key to parents’ opening up discussion about sensitive issues and recognizing that their children were in control of their own

sexual lives and decisions.

Peer education and outreach was a strategy used in the Aunties Project in Cameroon (Goergen & Ndonko, 2006), in which adolescent mothers attended a training workshop that included information and counseling on reproductive health, including ECPs. The young mothers then self-selected to be “aunties” in their community to provide SRH education to other girls. The project found that this was a successful, but time-bound context-specific intervention to rapidly increase awareness of ECPs and broader reproductive health, suggesting that short-term interventions could have a ripple effect within a community to increase awareness and acceptability, especially of a new product.

Cross-sectoral

In Zambia, the government started an innovative initiative to involve the country’s police force in the provision of ECPs. Due to high rates of sexual violence, police officers are often the first individuals that survivors face after an attack. By providing ECPs the police officer could put the woman at rest and refer her to seek care. The intervention included a training and orientation on basic counseling skills, male and female SRH issues, risks associated with sexual violence, rights of clients, quality of care, interpersonal skills, role plays and record keeping. A program evaluation found that the police can safely and effectively provide ECPs (Keesbury et al., 2009). It also found that more cases of gender-based violence and rape were being reported because women knew they could get ECPs from the police, and that the police played an important role in referring survivors to other services like post-exposure prophylaxis for HIV.

Conclusions, knowledge gaps and recommendations

Access to ECPs varies across different country contexts and is influenced by a number of cultural, social and political contexts. Recommendations to overcome barriers to ECP uptake are below:

- 1. Increase knowledge and correct misperceptions about ECPs among health consumers.** A low rate of awareness in most developing countries is a significant barrier to ECP use, as the majority of women has never heard of EC, according to DHS data, and therefore do not seek it out. Additional research on the best community-level approaches to increasing awareness of and demand for ECPs is needed.
- 2. Increase social marketing of ECPs.** Because ECPs can safely be provided in pharmacy settings

without clinical supervision, the commercial and SM sectors are ideal for promoting this commodity; this approach has been used in many countries to increase access and utilization. Also, research shows that many consumers prefer to access ECPs from the commercial and social marketing sectors, and thus there is a need to ensure that information about ECPs is available outside of clinic settings. Although the strategies for scaling up ECPs vary and are informed by the local context, there are several key elements to include: 1) generating awareness; 2) building health care provider knowledge and skills; 3) ensuring availability and affordability; and 4) increasing community knowledge and acceptability (PSI, 2013). Overall, SM and other non-medical channels for ECPs are important and effective demand generation strategies. Subsequently, the successes of social marketing approaches and other non-medical channels will need to be rigorously evaluated.

3. **Increase use of mass media and interpersonal communication.** Utilize all available mechanisms to disseminate accurate information about ECP. Robust media campaigns, counseling hotlines and improved parent-to-child communication have all been used to increase utilization of ECPs. However, developing a strategy that combines complementary methods will help to increase knowledge and uptake.
4. **Increase knowledge and reduce bias among health providers.** Two main barriers to provision of ECPs include lack of correct knowledge and negative attitudes about the method among health care providers. Knowledge about the actual biological mechanism is low among providers, leading to confusion on how to administer ECPs. Research shows that these knowledge gaps affect provider comfort

and ability to properly counsel potential ECP clients. Many studies highlighted the strong biases among health care providers concerning the administration of ECP to certain populations, especially adolescents and unmarried women. Training and support to health care providers on ECPs with attention to specific population groups, especially on the latest research and practice, could increase acceptability and coverage of this commodity.

5. **Increase political support for ECPs.** Involvement of national-level decision makers and influencers in politics and the media, and careful consideration of legal and policy environments are essential in the scaling up of ECPs and in advocacy efforts—for example, to change from prescription to non-prescription status. Working in broad coalition will help dispel negative reactions from opposition groups and will ensure that accurate product information is available.
6. **Employ cross-sectoral approaches to increase ECP use.** The previously described government initiative in Zambia, involving the country's police force in the provision of ECPs, highlights an area for future innovation. Opportunities for cross-sectoral approaches, as in the case of Zambia, offer the opportunity to provide increased outreach to key target populations at critical moments. In this way, police and other non-medical public service partners can safely and effectively provide ECPs to survivors of sexual violence, which can lead to an increase in reporting of gender-based violence and rape and referral to other health services. Regulatory barriers such as prescription requirements or rules specifying that only health care workers can dispense ECPs must be addressed.

Conclusion and Recommendations

Using the social ecological framework to guide the evidence synthesis, a range of social and behavioral facilitators and barriers were identified at the individual, community and society levels influencing demand of the RMNCH commodities. For many of the commodities, a supportive policy environment was a key factor for facilitating successful implementation and scale up at all levels. However, the literature revealed mostly a range of barriers that hinder the uptake of essential commodities.

The literature was extremely varied across commodities in terms of evidence of successful strategies to overcome such barriers and approaches for generating demand. For some commodities, such as ORS and zinc and the female condom, there were a large number of studies from which to draw on. However, for others, especially the newborn health commodities, there is a dearth of literature specific to demand generation for the commodities, making the evidence base extremely limited.

Based on the available evidence, the following conclusions and recommendations are presented to guide further research and implementation of demand generation programs:

1 Individual Level – Health Care Consumers

Understand and address existing local practices and demand for ineffective treatments. Cultural and religious barriers exist that deter individuals from asking for and/or using many of the 13 commodities. The literature revealed the need to investigate existing local practices and the potential lack of risk-perception of some of these practices.

Increase knowledge among health care consumers through tailored messaging to different target audiences. The literature revealed that health care consumers lack knowledge about some or all of the 13 commodities. Research showed that messaging regarding the commodities does not always reach key segments of the target audience, such as mothers in the most remote areas, or does not attempt to speak to other important audiences—e.g., fathers, male partners or grandparents. Some studies highlighted that when health education did take place, it was targeted only at mothers, ignoring all other potential caregivers. Given the key role that male partners, mothers/mothers-in-law, and/or others often play in enabling women to seek care, involving husbands, fathers and other family members in health education is critically important. Audience segmentation is important to identify these decision-influencers for care seeking and

uptake of commodities, and to aid in the development of tailored communication messages that address the specific barriers of each population group.

Develop and implement strategies aimed at moving beyond awareness and knowledge to actual behavior change. Although the literature reviewed could not identify specific successful strategies to move health care consumers along the stages of change—from awareness to knowledge to action—some lessons learned were available. For example, while mass media can be an effective channel to increase knowledge, interpersonal communication appeared to be more influential in promoting utilization of the female condom. In general, a multi-level demand generation program is more likely to facilitate behavior change than a single-channel approach.

2 Individual Level – Health Care Providers

Many of the essential commodities, such as oxytocin, misoprostol, magnesium sulfate and neonatal commodities, are provider driven. Yet, research also shows that both formal and informal health care providers lack knowledge about some or all these commodities. Moreover, the literature highlighted the personal biases of providers regarding several of these commodities and the negative affect those have on consumer demand and use.

Increase knowledge among all health care providers. Strategies to promote education and awareness among providers are important components of any effort to improve health. Whether formal or informal, providers are often the most trusted source of health information. It is essential that all providers have current, comprehensive information about the essential commodities. Literature shows that efforts to increase use of some of the provider-driven commodities, focused most commonly on physicians, nurses, midwives and skilled birth attendants. However, including minimally trained birth attendants, pharmacists, CHWs and others may help expand the use of some of the commodities. All appropriate training methods should be considered; peer leaders who are early adopters may help reinforce training messages and can be more influential than formal training.

Educate providers about the danger of personal bias. Much of the research indicated that perceived or actual provider bias prevents consumers from seeking care and treatment. Provider trainings need to address this by providing correct information and sharing concrete examples of how providers can reduce biases to the consumer.

Strengthen guidance and protocols on certain commodities. At the administrative level, stronger leadership is needed to develop and disseminate explicit guidelines on use of certain commodities, like oxytocin, misoprostol and magnesium sulfate. Research shows that many providers are not familiar with the treatment options and guidelines on these commodities and did not feel knowledgeable enough to administer these drugs. Including health workers in the development and dissemination of new clinical guidelines will help with their adoption within the health system and community.



Community Level

Conduct additional research on community-level barriers and demand generation at the community level. Research revealed very little in this area, especially for magnesium sulfate, injectable antibiotics and emergency contraception. More evidence is needed on the best strategies for educating mothers, other household members and community health workers to support community-level provision of commodities. Also, more research is needed to better understand why some families refuse or fail to comply with referral to local facilities for treatment, such as for newborn sepsis.

Ensure that social marketing approaches and other non-medical channels are evaluated. Many SM programs have demonstrated success in commodity uptake, especially for ORS and zinc. However, there is a need for more rigorous evaluation for these approaches and other non-medical channels for provision of other commodities, such as emergency contraception and the female condom, especially through the private sector. Looking more broadly at community-based health interventions could also reveal additional lessons in cost-effective interventions to improve RMNCH demand.

Expand community-based access to health information and services. There is a need to improve community-based provision of care, increase outreach to rural communities and ensure that commodities are accessible to those that are unable to access health facilities. In a range of countries, programs have demonstrated success in increasing community-based access for several of the commodities—such as community-based distribution of misoprostol and community-based IMCI—including partnerships with local-level private providers and shops that sell commodities such as ORS and zinc and the female condom, through both medical and non-medical channels.



Society Level

At the society level, a range of factors were identified as important facilitators for successful demand generation. These include a supportive national and international political environment, in-country manufacturing, and respected project leadership. However, in some contexts, social level factors played a limiting role and strategies are needed to overcome them.

Ensure that demand generation programs integrate or coordinate with supply-side strategies and programs to increase access. Even when demand for a commodity is present, health care consumers often face considerable barriers to accessing health care and are often unable to obtain life-saving commodities. In many locations, individual health care consumers or caregivers live far from a health facility. Those individuals that are able to reach a facility are often faced with stock outs, and breakdowns in the cold-chain were shown to be common, especially for oxytocin and injectable antibiotics. Research also revealed that some health facilities only carried adult-sized needles, making the proper dosing of antibiotics for infants impossible. Furthermore, health care consumers may have to deal with providers with significant knowledge gaps and biases about the commodities. Moreover, individuals may be unable to afford appropriate treatment even when it is available. Consistent, adequate supply of all essential commodities is essential in coordination with implementation of demand generation activities. Negative experiences by consumers, such as being turned away from a clinic without receiving the commodity, or encountering negative attitudes from health care providers, can affect future demand on a wide scale.

Address gender-related barriers. Gender norms impact a broad array of health issues through social norms and expectations of how men and women should behave in terms of prevention, care seeking and treatment. In fact, successful introduction and scale up of commodities often requires a normative change. Although gender norms are difficult to change because they are so deeply rooted in society, changing norms is possible. For example, targeted messaging to both men and women can share information in ways that are sensitive to gender norms, while also encouraging gender transformation through increased spousal communication and joint decision making around reproductive intentions, pregnancy, and neonatal and child health.

Increase supportive national and international policies. Political support is crucial to the effective introduction of a new commodity. Favorable policies such as allowing

CHWs to treat certain illnesses—like newborn sepsis, childhood pneumonia and diarrhea—are critical to the uptake of the commodities that treat these illnesses. Currently, few countries allow CHWs to treat certain illnesses, yet multiple pilot projects in various countries have shown that CHWs can effectively provide treatment and counseling for those same diseases. Documentation of the effectiveness and acceptability of community-based care has been shown to strengthen political and other stakeholder support, allowing for greater scale-up of intervention programs. However, evidence on the best strategies for fostering political support, which was found to be critical for scaling up interventions and increasing demand, was limited in the literature.

Develop and disseminate new products and technologies. Individual countries, as well as regional and international organizations, should support the development and adoption of new products that may increase uptake of essential commodities. For example, the potential contribution of the Uniject™ device may help expand the use of oxytocin to a wider variety of users, including minimally trained birth attendants, by reducing the complexity of administration.

Consider product packaging and instructions. The features of the product and packaging are also important for demand generation and utilization. Ensuring that the essential commodities are provided in packaging that is acceptable and easy for caregivers and providers to understand and use will contribute to increased uptake of these commodities.



Limitations

As noted in the methodology, the evidence review was limited to studies that referred to at least one of the 13 life-saving commodities. Although general issues and approaches—such as care-seeking behavior or service quality—certainly influence demand, it was beyond the scope of this review to examine that body of literature, which is not related to demand for a specific commodity. The search also excluded studies focused on product efficacy, focusing solely on those that addressed either the social and behavioral determinants of product utilization or those that described implementation or impact of demand generation programs. Extensive

efforts were made to reach out to partners and organizations working with the 13 commodities for the purpose of identifying literature, yet some projects and studies were likely missed, especially in the gray literature that was not widely available online.

The review aimed at identifying and documenting demand generation programs and, where available, described evaluation results. The review did not attempt to grade interventions based on study design or other criteria.



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Reproductive Health Commodities

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