

UN COMMISSION ON LIFE-SAVING COMMODITIES FOR WOMEN AND CHILDREN

Commissioners' Report September 2012



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Executive summary

In 2010, the UN Secretary-General's *Global Strategy for Women's and Children's Health* highlighted the suffering of women and children around the world caused by lack of access to life-saving commodities. The Strategy called on the global community to work together to save 16 million lives by 2015 through 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.

This challenge was taken up by the UN Commission on Life-Saving Commodities for Women and Children (the Commission), which is a part of the Every Woman, Every Child (EWEC) movement and has the overall goal to increase access to these life-saving commodities in 50 of the world's poorest countries. With a strong focus on the reproductive, maternal, newborn and child health (RMNCH) 'Continuum of Care', the Commission identified and endorsed an initial list of 13 overlooked life-saving commodities that, if more widely accessed and properly used, could save the lives of more than 6 million women and children.

The Commission also identified key, interrelated barriers that prevent access to and use of the 13 commodities. These include severely under-resourced regulatory agencies in low-income countries, leading to delayed registration of commodities; lack of oversight of product quality and general inefficiencies; market failures, where return on investment is too low to encourage manufacturers to enter the market or produce sufficient quantities; and user supply and demand challenges such as limited demand for the product by end-users, local delivery problems and incorrect prescription and use.

To address these challenges and deliver on the promise of saving the lives of millions of women and children, the Commission recommended 10 time-bound actions. These focus on the need for improved global and local markets for life-saving commodities, innovative financing, quality strengthening, regulatory efficiency, improved national delivery of commodities and better integration of private sector and consumer needs.

The Commission estimated that an ambitious scaling up of these 13 commodities over five years would cost less than US\$2.6 billion and would cumulatively save over 6 million lives including 230,000 maternal deaths averted through increased access to family planning. This would catalyse an accelerating reduction in deaths for women and children. Achieving these goals would save an extra 1.8 million child deaths a year, reducing the estimated 7.1 million deaths in 2010 to 5.3 million. Likewise, the estimated 287,000 maternal deaths in 2010 would be reduced to 213,000 by increased access to maternal health and family planning commodities. The estimated costs per lives saved are low and represent excellent global development investments. Thus, the scaling up of these commodities is not solely a moral obligation but one of the most effective ways of getting more health for the money invested. It would make a significant contribution to putting maternal and child health on a trajectory to end these preventable and tragic deaths.

A detailed plan for implementation has been developed with cross-cutting and commodity-specific actions and clearly stated national, regional and global activities and associated costs. In addition, national plans aimed at country-level implementation at scale will be developed and shaped during in-country stakeholder meetings, building on and linked to existing planning and costing processes and timelines.

Recognizing that many commodity-related obstacles are linked to financial and social barriers and rooted in broader health system challenges – such as poor governance, inadequate human resources, ineffective local supply chains and insufficient information systems – the Commission calls for further links between the identified solutions and priority actions and other global and national initiatives for strengthening health systems.

The Commission's 10 recommendations

Improved markets for life-saving commodities

- 1. **Shaping global markets:** By 2013, effective global mechanisms such as pooled procurement and aggregated demand are in place to increase the availability of quality, life-saving commodities at an optimal price and volume.
- 2. **Shaping local delivery markets:** By 2014, local health providers and private sector actors in all EWEC countries are incentivized to increase production, distribution and appropriate promotion of the 13 commodities.
- 3. **Innovative financing:** By the end of 2013, innovative, results-based financing is in place to rapidly increase access to the 13 commodities by those most in need and foster innovations.
- 4. **Quality strengthening:** By 2015, at least three manufacturers per commodity are manufacturing and marketing quality-certified and affordable products.
- 5. **Regulatory efficiency:** By 2015, all EWEC countries have standardized and streamlined their registration requirements and assessment processes for the 13 live-saving commodities with support from stringent regulatory authorities, the World Health Organization and regional collaboration.

Improved national delivery of life-saving commodities

- 6. **Supply and awareness:** By 2015, all EWEC countries have improved the supply of life-saving commodities and build on information and communication technology (ICT) best practices for making these improvements.
- 7. **Demand and utilization:** By 2014, all EWEC countries in conjunction with the private sector and civil society have developed plans to implement at scale appropriate interventions to increase demand for and utilization of health services and products, particularly among under-served populations.
- 8. **Reaching women and children:** By 2014, all EWEC countries are addressing financial barriers to ensure the poorest members of society have access to the life-saving commodities.
- 9. **Performance and accountability:** By end 2013, all EWEC countries have proven mechanisms such as checklists in place to ensure that health-care providers are knowledgeable about the latest national guidelines.

Improved integration of private sector and consumer needs

10. **Product innovation:** By 2014, research and development for improved life-saving commodities has been prioritized, funded and commenced.

I. Introduction: the need for increased access to and appropriate use of essential life-saving commodities

The United Nations Secretary-General's *Global Strategy for Women's and Children's Health* highlights the inequitable access to life-saving medicines and health supplies suffered by women and children around the world and calls on the global community to work together to save 16 million lives by 2015.¹ Recognizing that many millions die each year from preventable causes (see panel), the Strategy identifies the need for increased access to and the appropriate use of essential medicines, medical devices and other commodities.

Evidence from developing countries suggests that, in addition to overarching health system and financial impediments for both governments and end-users, three main types of barriers prevent women and children from accessing and using appropriate commodities: (1) the insufficient supply of high quality health commodities; (2) the inability to effectively regulate these quality commodities; and (3) the lack of access and awareness of how, why and when to use them, resulting in limited demand.

Understanding the current stark reality

Imagine the despair of a skilled birth attendant who cannot stop the excessive bleeding of a mother who has just delivered a baby because the health centre is stocked-out of the medicine that the attendant needs to do her job and save this mother's life. Imagine the frustration of a health worker who is unable to effectively treat a child who has a simple case of pneumonia because a child-friendly form and dose of the needed antibiotic has not yet been registered for use. Imagine the fear of a 45-year-old woman who finds out she is pregnant for the seventh time, after almost dying the last time she gave birth, and who was not aware of and did not have access to modern methods of family planning. Unfortunately, these scenarios depict everyday realities. In the case of reproductive health, for example, if unmet need for modern contraceptive methods were fully satisfied, an estimated 53 million unintended pregnancies would be avoided, about 90,000 women's lives would be saved and an estimated 590,000 newborn deaths would be averted.² And many of the over 800,000 deaths of children each year from diarrhoea could be prevented with oral rehydration solution and zinc that cost less than US\$0.50 per treatment.

The good news is that recent experiences have shown it is possible to overcome these seemingly entrenched barriers if partners work together towards the common goal of improving access to quality commodities. For example, the success in substantially reducing the price and improving the distribution of antiretroviral drugs for HIV is testimony to the effect of such partnerships, with 6.6 million people in low-and middle-income countries receiving these drugs at the end of 2010.³ In the fight against malaria, aggregating orders, better forecasting, sustained financing and extending manufacturing capacity into Africa for insecticide-treated nets (ITNs) increased capacity to supply ITNs in sub-Saharan Africa from 5.6 million in 2004 to 145 million in 2010 and contributed to substantial reductions in deaths due to malaria.⁴ Collaboration between the GAVI Alliance and suppliers reduced the price of rotavirus vaccines by two thirds, "signalling [a] potential market impact of US\$650 million" saved.⁵ Moreover, there is now near universal use of auto-disable (AD) syringes for immunization. Introduced in 1992 to prevent the re-use that is common in developing countries and that spreads infection, AD syringes initially cost over six times as much as normal syringes, which limited their use. But increased demand through GAVI Alliance support and the use of AD syringes in measles campaigns has meant that the price difference is now trivial.⁶

In addition, Mobile Health (mHealth) solutions have led to improved forecasting and stock-out reporting (e.g., cStock, SMS for Life and ILSGateway), as well as increased demand and care-seeking associated with texting of health information and appointment reminders (e.g., Mobile Alliance for Maternal Action, MAMA).⁷

Experiences such as these show that, where there is the necessary commitment and action, it is possible to expand access and use even in the most deprived communities.

II. The UN Commission on Life-Saving Commodities for Women and Children

The UN Commission on Life-Saving Commodities for Women and Children (the Commission) takes on the challenge outlined in the UN Secretary-General's *Global Strategy for Women's and Children's Health* of saving lives through improving equitable access to life-saving commodities. The Commission is a part of the Every Woman, Every Child (EWEC) movement and has the overall goal to increase access to simple life-saving commodities in 50 of the poorest countries that account for more than 80 per cent of all maternal and child deaths.⁸ It is estimated that an ambitious scale up over five years in these countries of the 13 commodities identified by the Commission would cost US\$2.6 billion: US\$579 million for the direct costs of purchasing the commodities and a further US\$2.05 billion to cover distribution and health systems service delivery. These estimated costs are based on the assumptions for the estimates presented at the Family Planning Summit in London in July 2012⁹ (see Annex for further details).

The potential benefits from investing in these 13 commodities over a five-year period are extraordinary. It would save an estimated 6 million lives, including approximately 230,000 maternal deaths averted because of increased use of family planning commodities. Achieving these goals would also save an extra 1.8 million child deaths a year, reducing the estimated 7.1 million deaths in 2010 to 5.3 million. Likewise, the estimated 287,000 maternal deaths in 2010 would be reduced to 213,000 by the increased access to maternal and family planning commodities. This is among the 'best buys' in global health. The assumptions and methods used for calculating these estimates are set out in the Annex.

The Child Survival Summit in Washington¹⁰ adopted a new trajectory to end preventable child deaths by 2035. The scale up of the 13 commodities would make a major contribution to transforming current trends into that trajectory.

To take this forward the Commission brought together high-level experts and advocates who, with the support of a Technical Working Group, worked rapidly to identify bold recommendations to support improved and equitable access to selected life-saving commodities.

The key steps the Commission undertook were:

- ≠ Defining a list of overlooked life-saving commodities for women and children (see section III);
- ✓ Identifying key barriers preventing access to and use of these commodities (see section IV);
- ≠ Recommending innovative action to rapidly increase both access and use (see section V).

Recognizing that many commodity-related obstacles are linked to financial barriers and rooted in broader health system challenges – such as poor governance, inadequate human resources, ineffective local supply chains and insufficient information systems – the Commission worked to foster links between the identified solutions and priority actions presented in section V and other global and national initiatives for strengthening health systems.

III. Defining overlooked life-saving commodities

As defined initially during a high-level global stakeholders' meeting in September 2011 and further refined and adopted by this Commission, life-saving commodities are those medicines, medical devices and health supplies that effectively address leading avoidable causes of death during pregnancy, childbirth and childhood and that, if more widely accessed and properly used, could significantly reduce preventable deaths among women and children.

inherent in this definition is an acknowledgment and strong focus on the reproductive, maternal, newborn

and child health (RMNCH) 'Continuum of Care', which considers the health services needed by women and children from pre-pregnancy to delivery, the immediate postdelivery period and childhood (see Figure 1).¹¹ Essential interventions and commodities are required at



Household	0	Com	nmunity & Outreach \circ Facility
Adolescence and before Pregnancy pregnancy	\geq	Birth	Postnatal (mother) Motherhood
		Birth	Postnatal (newborn) Infancy Childhood

each of these stages, whether health care is provided by families and communities or through health facilities. A recent Partnership for Maternal, Newborn and Child Health publication, *Essential Interventions, Commodities and Guidelines,* comprehensively describes these essential interventions and commodities.¹²

Building on the above listing, the World Health Organization (WHO) also provides a list of 'Priority lifesaving medicines for women and children', which are chosen according to the global burden of disease and the evidence of their efficacy and safety for addressing the RMNCH Continuum of Care.¹³

Additional recent publications and key documents¹⁴ were consulted and, as a result, two further criteria were established for identifying overlooked, life-saving commodities:

- Inadequate funding: The commodity lacks the monetary support that would allow a rapid increase in its distribution and use. Selected commodities are, for example, not funded by mechanisms such as The Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM) or the GAVI Alliance.
- Untapped potential: The affordability, availability and use of the commodity could be enhanced by innovative improvements in product development (such as better formulations), price reductions, stability of supply and market guarantees.

The Reproductive Health Supplies Coalition also identified three contraceptive methods that are particularly overlooked, and often unavailable when requested, but that show promise for public health benefits.

Based on these criteria, an initial list of 13 effective but overlooked life-saving commodities was identified and endorsed by the Commission. The list is not meant to be comprehensive but rather a preliminary sample of life-saving commodities that represent common challenges and require a priority response. It is anticipated that the Commission's recommended actions will also increase access to other commodities through cross-cutting improvements such as regulatory efficiencies and support tools for health-care workers. The 13 commodities are presented in Table 1.

Table 1: Snapshot per commodity of barriers, recommendations and impact

The table provides estimates of how many lives could be saved if common barriers were overcome and equitable access achieved for 13 life-saving commodities. The Commission's recommendations are in section V.

Commodity by life stage	Examples of key barriers	Recommendations	Potential 5-year impact			
Maternal health commodities						
1. Oxytocin – post-partum haemorrhage (PPH)	Often poor quality	1, 4, 5	15,000 maternal lives saved			
2. Misoprostol – post- partum haemorrhage	Not included in national essential medicine lists	5				
3. Magnesium sulfate – eclampsia and severe pre- eclampsia	Lack of demand by health workers	1, 9, 10	55,000 maternal lives saved			
Newborn health commodities			_			
4. Injectable antibiotics – newborn sepsis	Poor compliance by health workers	1, 9, 10	1.22 million neonatal lives saved			
5. Antenatal corticosteroids (ANCs) – preterm respiratory distress syndrome	Low awareness of product and impact	9	466,000 neonatal lives saved			
6. Chlorhexidine – newborn cord care	Limited awareness and demand	2, 5	422,000 neonatal lives saved			
7. Resuscitation devices – newborn asphyxia	Requires trained health workers	1, 9, 10	336,000 neonatal lives saved			
Child health commodities	•					
8. Amoxicillin – pneumonia	Limited availability of child-friendly product	2, 7, 9, 10	1.56 million lives saved			
9. Oral rehydration salts (ORS) – diarrhoea	Poor understanding of products by mothers/	2, 5, 7, 9, 10	1.89 million lives saved			
10. Zinc – diarrhoea	caregivers					
Reproductive health commodities						
11. Female condoms	Low awareness among women and health workers	1, 7				
12. Contraceptive implants – family planning/ contraception	High cost	1, 7	Almost 230,000 maternal deaths averted			
13. Emergency contraception – family planning/ contraception	Low awareness among women	2, 7				

DISCLAIMER: the numbers presented here are draft estimates meant to give a general overview of the barriers certain commodities face and the potential impact if these barriers were surmounted. These draft estimates are based on a systematic analysis approach explained in the Annex.

IV. Cross-cutting barriers to access and use of life-saving commodities

The Commission acknowledges the broader health systems challenges countries face when accelerating access to and use of life-saving commodities. Nevertheless, the production, distribution, availability and demand generation for medicines and commodities is a persistent weakness that requires specific attention and interventions. The Commission underscores the need for synergies and linkages between commodities-focused actions and broader systems interventions and efforts.

The Commission paid particular attention to the fact that the technical working papers on the 13 lifesaving commodities confirmed three main barriers to access and use: (1) regulatory issues, (2) market failures and (3) supply and demand challenges. It tasked its Technical Working Group to further assess these three barriers and propose corrective actions, detailed in section V.

1. Regulatory issues: The regulatory environment ensures that only effective and trusted commodities are available. Regulatory authorities are set up to assess the efficacy, quality and safety of health commodities, provide approval for their distribution and support authorization for their purchase. However, many low-income countries' regulatory agencies are severely under-resourced, causing delayed registration of life-saving commodities, a lack of oversight of the quality of products and general inefficiencies that discourage manufacturers from engaging in the market. For example, zinc is recognized as a safe mineral supplement in industrialized countries and generally available in shops and pharmacies without a prescription. However, in many low-income countries it is registered as a prescription medicine, creating an unnecessary obstacle that inhibits access to an essential diarrhoea treatment. As in this example, inefficient regulatory processes can impede access to other much-needed life-saving commodities.

2. Market failures: Another barrier affecting many life-saving commodities is market failures, where return on investment is not sufficiently high to create incentives for manufacturers to enter the market or sustain sufficient levels of production. For example, several studies have identified magnesium sulfate (MgSO4) as the most effective medicine for preventing and treating the deadly seizures caused by high blood pressure during pregnancy (pre-eclampsia and eclampsia); yet, according to a brief by the Caucus on New and Underused Reproductive Health Technologies, "magnesium sulfate is rarely globally manufactured because its low cost leaves little profit-based incentive for pharmaceutical companies to produce it".¹⁵ Furthermore, while magnesium sulfate is eligible for the WHO Prequalification of Medicines Programme, which pre-qualifies products from specific manufacturers for bulk purchase by procurement agencies, no MgSO4 medicine has qualified under this programme to date.¹⁶ The lack of global supply limits distribution and availability. As this example illustrates, market dynamics can play an important role in achieving equitable access to life-saving commodities and ensuring that women and children can obtain the health care they need.

3. User supply and demand challenges: The third main barrier affecting many of the commodities is user supply and demand challenges such as low demand for the product by end-users, local delivery and distribution breakdowns and incorrect prescription and use. There has been an insufficient focus on optimizing innovative approaches to product formulation, packaging and delivery devices. Attempts to harness social media and mobile technology to promote demand and proper use and respond to supply chain management bottlenecks have been limited. The only major product change to the female condom since its introduction on the market in 1992, for example, has been to the material it is made from. Compared to the male condom, it suffers from limited choice and variety and from design challenges that require users to be trained in its proper use.¹⁷ Both supply and demand challenges can have a negative

impact on access to this effective commodity, while an increased focus on product innovation and marketing could help overcome these barriers and give women more control over their reproductive health.

While the barriers above are discussed separately, they are interrelated and interdependent. Quality products will only be developed and wide uptake will only be achieved if there is a guaranteed, strong market that gives manufacturers the incentive to invest in product development and regulatory approval. Products that do not respond to user preference and that are either misunderstood or unknown by providers and patients suffer from low sales, leading to low returns on manufacturer investments and thus limited manufacturing, research and development. Interplay between regulation, market dynamics and innovation is needed to ensure that women and children receive the treatments and interventions they need. As stated at the outset of this section, to fully optimize access this interplay needs to be linked to broader health systems strengthening interventions and efforts.

V. The Commission's recommendations

Drawing on the latest technical data, and with the support of the Technical Working Group, the Commission has proposed the following 10 recommended actions to deliver on the promise of saving the lives of millions of women and children.

Improved markets for life-saving commodities

1. Shaping global markets: By 2013, effective global mechanisms such as pooled procurement and aggregated demand are in place to increase the availability of quality, life-saving commodities at an optimal price and volume.

While all selected life-saving commodities would benefit from market-shaping activities, some of the 13 life-saving commodities face more specific global market challenges such as limited competition and fragmented procurement. Contraceptive implants are a good example. Priced from US\$8–18 per device,¹⁸ they are considered expensive and out-of-reach by many governments and women. This relatively high price is in part due to lack of competition, given that there are a limited number of manufacturers (the cost is front-loaded into a product that is used only every few years, compared to shorter-acting contraception that is used monthly or daily). The product is caught in a trap: the high price discourages greater uptake by governments and end-users, while the resulting lower demand maintains the high price. Effective global mechanisms, working in tandem with recommendations 3 (innovative financing) and 7 (demand and awareness), are necessary to overcome this trap. If a commodity suffers from weak global market dynamics, there are a number of potential solutions such as pooled procurement and demand and minimum volume guarantees. The specific global market-shaping tools per commodity are detailed in the implementation plan.

2. Shaping local delivery markets: By 2014, local health providers and private sector actors in all EWEC countries¹⁹ are incentivized to increase production, distribution and appropriate promotion of the 13 commodities.

Just as weak global market dynamics signal the need for global market-shaping interventions, weak local delivery markets signal the need for local market-shaping interventions. Weak local delivery may be due to many factors including patient and provider lack of awareness and demand for the commodity, breakdowns in the local supply chain and distribution system and limited local production due to expectation of low sales and profit. Local delivery can be strengthened by utilizing many of the global mechanisms identified for recommendation 1 at a national level. For example, chlorhexidine is a product that is widely available and used for a variety of purposes (such as a surgical antiseptic, mouthwash, etc.). However, the formulation recommended to prevent babies' umbilical cord stumps from infection is not widely available because the use is not known. Government action is required to alert manufacturers to this opportunity and potentially de-risk the new product formulation costs for a period of time. Examples of more specific mechanisms for effective local market shaping are detailed in Figure 2 (see next page). The specific local market-shaping tools per commodity are listed in the implementation plan.

Given the importance of increasing demand, the demand aspects highlighted in Figure 2 are covered in recommendations 7 and 10.

Figure 2: Example from the local delivery market-shaping toolkit²⁰

4	Marketplace issue	Possible solutions / interventions
Demand	Limited consumer & caregiver demand Consumers seeks inappropriate treatment or no treatment Low caregiver awareness/training Caregivers not aware of product as appropriate treatment or lack skills	Increase patient and caregiver demand for optimal products Initial government action to increase demand, e.g. mass marketing and free product trial Funding for high-impact marketing/promotion Umbrella logo for optimal products/ presentations Training curriculums for resource -limited situations Simplified products to leverage community health workers & nurses
Supply	Limited supplier engagement Manufacturers deprioritize low volume, low margin products Low product availability Regulatory barriers & poor in country supply chain management limit access	 Incentivize supplier investment Incentives to manufacturers, wholesalers, and retailers for availability in remote areas Incentives to suppliers for marketing and promotion "De-risk" investment through common quality standards Prioritize development of improved product presentations Look for opportunities to engage suppliers across a multiple-product bundle Improve regulatory & operating environment Ensure product registration & OTC status Enhanced government attention on in-country supply chain management Creation of PPPs to sustain broad participation

3. Innovative financing: By the end of 2013, innovative, results-based financing is in place to rapidly increase access to the 13 commodities by those most in need and foster innovations.

Financing is necessary to fund the implementation of the Commission's recommendations, for procurement of the commodities (even though many commodities are low-cost) and for associated costs such as marketing, results-based incentives, research and development.

Results-based financing rewards outcomes and can be tailored to improve equitable access to life-saving commodities. In order for the financing to be sustainable, it must include both domestic and external funding and be aligned with existing financing mechanisms. The funds need to be allocated and managed through highly efficient and effective channels. The incentives must be flexible, consist of both financial and non-financial rewards (e.g., recognition) at both national and sub-national levels and be accessible to private and public actors alike.

4. Quality strengthening: By 2015, at least three manufacturers per commodity²¹ are manufacturing and marketing quality-certified and affordable products.

The WHO, the United Nations Children's Fund (UNICEF), UNFPA, national and international regulators, private sector actors and other partners will jointly review the quality of the most commonly used lifesaving commodities to make a rapid analysis of global market quality, determine the most common safety and quality risks and identify the most promising manufacturers. As part of this joint review, these partners will establish and/or update clear guidelines for all of the 13 commodities in terms of use, manufacturing, quality, dosage, etc. to guide procurement decisions.

At least three promising manufacturers per commodity will then be supported in order to assist them in developing and marketing a product of assured quality with a focus on good manufacturing practices, quality production, bioequivalence, stability and competitive pricing so that low- and middle-income countries can afford these commodities. Existing product assessment systems such as the WHO Expert Review Panel (ERP)²² and WHO Prequalification will be used with a guaranteed and predicable fast-track assessment, endorsement and registration of these products for procurement. For products such as chlorhexidine, a risk-based approach will be applied to ensure quality production while avoiding a level of stringency that would prevent manufacturers from entering this market. Tendering mechanisms will also be based on price and quality.

The Commission recommends that the WHO, UNICEF, UNFPA, private sector actors and other partners actively support manufacturers in low- and middle-income countries to improve good manufacturing practices (GMP), strengthen regional trade and promote growth and development.

5. Regulatory efficiency: By 2015, all EWEC countries have standardized and streamlined their registration requirements and assessment processes for the 13 live-saving commodities with support from stringent regulatory authorities, the WHO and regional collaboration.

In many EWEC countries, new formulations or dosages of the 13 life-saving medicines have not been registered because National Medicine Regulatory Agencies (NMRAs) maintain their autonomous assessment processes (not accepting assessments or market approvals made by other NMRAS), which can be time-consuming and inefficient. Some NMRAs, for example, request additional clinical studies done in their own country as a condition of registration, causing delays in the supply of the commodity. Most manufacturers do not want to invest in preparing separate registration dossiers for different countries because the fragmented market volumes are too small for a sufficient return on investment. Regulatory barriers may also prevent the use of some life-saving commodities (e.g., amoxicillin, oxytocin and zinc) by lower-level health workers. Standardizing and streamlining regulation processes would make them more efficient and would help to provide incentives to both manufacturers to invest in product development and registration and regulators to prioritize and facilitate registration of life-saving commodities. Work toward fulfilling this recommendation needs to be conducted in synergy and alignment with current international and regional medicines regulatory harmonization programmes in order to avoid duplication and promote efficiencies. Potential solutions are:

- NMRAs will standardize their registration requirements following the format of the internationally
 agreed Common Technical Document, including the abridged applications for generic medicines. This
 format will also be used as the standard for regional harmonization programmes. International
 guidelines on bundling commodities that can be distributed together for maximum impact will be
 added to NMRAs' standard registration requirements. NMRAs will not request that additional clinical
 studies be conducted in their own country as a condition of registration.
- The WHO and stringent regulatory authorities (SRAs) will support joint dossier reviews of new and innovative priority commodities with regional groups of national regulators, following models such as the WHO Prequalification Programme and risk-based approaches, in order to facilitate predictable fast-track approval. These joint reviews will also assess products for over-the-counter use and self-administration.
- The WHO and SRAs will support NMRAs in target countries in standardizing their registration requirements, in streamlining their assessment procedures to make maximum use of existing information from UN agencies, SRAs and other NMRAs and in supporting regional harmonization initiatives.
- The WHO and partners will support joint regulatory reviews to assess the safety of administration of life-saving commodities by lower-level health workers.

Improved national delivery of life-saving commodities

6. Supply and awareness: By 2015, all EWEC countries have improved the supply of life-saving commodities and build on information and communication technology (ICT) best practices for making these improvements.

Supply chain management bottlenecks exist in all areas of procurement, distribution, storage, information systems and inventory management. Common challenges include (a) a lack of standard commodity specifications for procurement, leasing and donations; (b) a lack of predictable and sustained funding to procure commodities at critical times of the year; (c) poor commodity forecasting; (d) poor data for supply chain decision-making, including the quantification of commodities; (e) poor distribution channels and storage, which expose drugs and commodities to conditions causing degradation; and (f) poor stock inventory management, leading to rationing of commodities and stock-outs. These bottlenecks impact all

the other recommendations. Without a predictable supply chain, increased supply through market shaping (recommendation 1) and improved quality (recommendations 4 and 5), for example, are pointless. Improved demand and awareness (recommendation 7) is also detrimentally affected by poor supply chains.

While ICT cannot overcome all supply chain challenges, recommendation 6 builds on best practices and innovations from around the world showing that, if adjusted and adapted to the local context, ICT can play an important role in providing solutions. Examples include the use of ICT to identify where stock-outs are occurring, gather demand data and improve forecasts, integrate separate national supply chains and remove costly redundancies.

7. Demand and utilization: By 2014, all EWEC countries in conjunction with the private sector and civil society have developed plans to implement at scale appropriate interventions to increase demand for and utilization of health services and products, particularly among under-served populations.

Patients, caregivers and health-care providers often lack awareness of a commodity and its ability to improve health outcomes. Women are often unaware of their rights to health care and products. For instance, emergency contraception is usually available through private sector pharmacies but requires patient awareness to seek it out. In some settings, financial and socio-cultural issues may also limit uptake of commodities. Understanding these issues and patient, family and community perspectives is critically important not only for shaping social and behavioural change communication but equally for developing and refining commodities that are acceptable to those who need them. Potential solutions include:

- Providing the private sector (e.g., pharmacies, shops and private clinics) with incentives to standardize and control the quality of their services in order to improve quality of care and increase demand.
- Assessing the acceptability of commodities in different settings to understand patient requirements for improving commodity design and packaging.
- Tailoring communication activities around the use of these commodities, including through different communication techniques (mass, medium-level, interpersonal, community mobilization and empowerment):
 - Malaria No More's experience with the *Surround Sound: Senegal* campaign "activates key sectors of Senegalese society – including entertainment, sport, faith, local business and government – to encourage people to use mosquito nets, to recognize malaria symptoms and to seek treatment".²³
- Utilizing women's support groups and social marketing to increase local demand.

Countries are encouraged to analyse and adapt these and other best practices and/or develop other innovative solutions in line with their unique social, political and economic contexts.

8. Reaching women and children: By 2014, all EWEC countries are addressing financial barriers to ensure the poorest members of society have access to the life-saving commodities.

Even though almost all of the commodities cost only pennies, this cost may still be prohibitive for poorer and other deprived sections of society, who largely pay out-of-pocket for health-related expenditures. Young people also often lack the means to access services. Despite the fact that the removal of fees at the point of care has shown increased demand and uptake of services,²⁴ the UNFPA *State of the World's Midwifery Report* (2011) found that many countries were not implementing incentive schemes, conditional cash transfers or insurance schemes to support increased access to services and commodities.²⁵ Slightly less than half of the countries surveyed provided free access to institutional births and only a third had cost-recovery models in place. The following are two evidence-based examples of mechanisms to remove financial barriers that could be built on in fulfilling recommendation 8:

- Rashtriya Swasthya Bima Yojana in India is providing prepaid health smart cards that can be swiped at health facilities for free medicines, hospitalization and treatment.²⁶
- Uganda has implemented a technology-based cash transfer system for facility delivery and neonatal home health checks.²⁷

These strategies require built-in accountability mechanisms to ensure that the desired outcomes – increased access to and use of life-saving commodities – are obtained.

9. Performance and accountability: By end 2013, all EWEC countries have proven mechanisms such as checklists in place to ensure that health-care providers are knowledgeable about the latest national guidelines.

The ability of health systems to deliver live-saving commodities depends on many factors, one of which is the performance of its health-care providers. Barriers to increased demand among health workers include lack of training in and knowledge about the efficacy and use of a particular commodity, use of outdated standards of practice, and policies restricting certain levels of health workers – including community health workers and pharmacists – from prescribing and administering live-saving commodities. Potential solutions include:

- Using checklists to help ensure that all critical steps associated with a specific health event (e.g., birth) are completed. Checklists not only work as a memory aid, particularly in time-sensitive situations, but also help to ensure that health-care workers are using the latest procedures. The EWEC Innovation Working Group on Checklists has come up with a number of recommendations, including how to effectively combine checklists with mobile technology.
- Evaluating the use of performance-based incentives for health-care personnel to reinforce national guidelines.

Accountability for improved access and use of live-saving commodities needs to be anchored in the context of broader accountability efforts, such as those defined by the UN Commission on Information and Accountability.²⁸

Improved integration of private sector and consumer needs

10. Product innovation: By 2014, research and development for improved life-saving commodities has been prioritized, funded and commenced.

To facilitate demand for maternal and child health commodities, product improvements are required, specifically new formulations, packaging and/or delivery devices. Such improvements require investment in consumer market research to understand consumer preferences, in product innovation research and development and in analysing lessons from existing experiences. Research and development that builds the evidence base for a proposed innovation or develops innovations based on solid evidence will be promoted. The most pressing product innovations are listed in Table 2 below. Given the low cost of many of these commodities, manufacturers are often reluctant to invest in innovations that may potentially increase costs. The WHO's Consultative Expert Working Group on Research and Development: Financing and Coordination has recommended a number of mechanisms to de-link the cost of research and development from the price of the commodity, such as awarding prizes, offering incentives to lower the cost of development, placing publicly funded research in the public domain and using equitable licenses (that allow generic competition for specific geographic regions).²⁹

Financing defined under recommendation 1 needs to be effectively utilized to fund these prioritized research and development needs.

Table 2: Potential product innovations by commodity

This table describes examples of potential product innovations that need to be confirmed through further research.

Commodity	Examples of potential product innovations		
Oxytocin	Thermo-stable oxytocin formulation		
	Temperature monitoring devices for oxytocin packaging		
	• Promotion of oxytocin in pre-loaded, single-use injection devices for		
	use by lower cadres of health workers		
	 Non-parenteral inhalation/ intranasal spray-dried (dry powder) 		
Misoprostol	Address issues with the manufacturing processes and packaging		
	Innovative marketing		
Magnesium sulfate	Simplified dosing regimen and single dose packaging		
	Spring-driven infuser pump or other devices		
Injectable antibiotics	• Fixed-dose presentations for basic needles and syringes and pre-		
	filled delivery devices for administering gentamicin		
	Auto-disable syringes for administering gentamicin		
	Micro-needle patch technology for administering gentamicin		
Antenatal corticosteroid	• Clear protocols for use of injectable dex and beta for this indication		
(ANCS)	(and user education especially for physicians and midwives)		
	 Job aids to recognize preterm labour, get dosing right, etc. 		
	Clearly labelled, pre-packaged products/ pre-filled delivery systems		
Chlorhexidine (CHX)	 Increase demand and manufacturing capacity for the 4 per cent CHX 		
	gel or liquid formulation		
Resuscitation devices	• Need for simplification of device design and parts so that infrequent		
	users at peripheral health centres will be better able to use the		
	technology		
Amoxicillin	 Child-friendly packaging that clearly directs caregivers how to use it 		
	Dispersible tablet		
	Packaging that can protect from degradation		
Oral rehydration salts	• Improve ORS presentation and formulation, as well as marketing and		
(ORS)	'positioning' in order to increase consumer appeal		
	• Investigate alternative rehydrating products in food/beverage		
	categories		
Zinc	• Co-packaged or co-dispensed ORS and zinc (and, in some contexts,		
- <u>-</u>	water purification tablets)		
Female condoms	Market/programme development to support sustainable supply		
	Innovative financing mechanisms		
Contraceptive implants	Innovative marketing		
Emergency contraception	 Improved packaging with clear instructions and marketing 		

VI. Implementation and next steps

The Commission's work was highlighted at important RMNCH-related events over the summer of 2012, including the ones listed below. The outcomes of these and other future events will greatly facilitate and enhance the implementation of the Commission's recommendations.

The World in Transition: Charting a New Path in Global Health, Oslo, Norway, 1 June 2012

- US Secretary of State Hillary Clinton and Norwegian Foreign Minister Jonas Gahr Støre launched the Saving Mothers, Giving Life (Saving Mothers) partnership, coordinated by the US Global Health Initiative (GHI), together with Merck for Mothers and other partners.
- The founding partners pledged more than US\$200 million and additional in-kind resources to save mothers from dying in childbirth.
- For more information, see: <u>www.savingmothersgivinglife.org/</u>
- The Child Survival Forum, Washington, DC, USA, 14–15 June 2012
- The Child Survival Call to Action kicked off the Commitment to Child Survival: A Promise Renewed, which mobilizes the world toward the goal of ending preventable child deaths.
- Governments and partners signed A Promise Renewed, a pledge to work toward greater child survival.
- For more information, see: <u>5thbday.usaid.gov/pages/ResponseSub/Event.aspx</u> and <u>www.apromiserenewed.org/</u>

The 19th African Union Summit, Addis Ababa, Ethiopia, 9–16 July 2012

- Nigeria, as co-chair of the UN Commission on Life-Saving Commodities for Women and Children, called on African countries to join the Promise Renewed and highlighted the importance of scaling up access to life-saving commodities.
- For more information, see: <u>au.int/en/summit/19thsummit</u>
- The Family Planning Summit, London, UK, 12 July 2012
- Global leaders mobilized commitments to extend access to family planning for 120 million women by 2020.
- This milestone will help stop 200,000 women and girls from dying in pregnancy and save the lives of 3 million babies across the world's poorest countries.
- Donors and the private sector pledged more than US\$2.6 billion to reach the goal.
- For more information, see: <u>www.londonfamilyplanningsummit.co.uk/</u>

The recommendations in section V will be accompanied by a detailed implementation plan as well as a monitoring and evaluation plan. The implementation plan will unpack the recommendations for the 13 commodities and the EWEC countries. It will therefore have cross-cutting and commodity-specific actions, with clear articulation of national, regional and global activities and associated costs. The actions and activities will be prioritized based on country priorities, emerging commitments from stakeholders, 'quick wins' in the early phase of implementation and the potential for cost-effective impact.

The activities will be incorporated into national plans aiming at implementation at scale at country level. These national plans will be developed and shaped during in-country stakeholder meetings, building on existing and on-going planning exercises such as those emanating from the events listed above and linked to existing planning and costing processes and timelines.

In order to ensure that countries and partners are working to deliver on the actions recommended by this Commission, the already existing independent Expert Review Group formed under the Commission on Information and Accountability for Women's and Children's Health will regularly report to the UN Secretary-General between 2012 and 2015 on progress in implementing the recommended actions.

The UN Secretary-General, Ban Ki-Moon, succinctly defines the work of the Commission: "Together we want to help the world see and believe in a better future. Mothers and children are at the heart of this future, and the recommendations ... provide the tools needed to get there. Let us pledge to the women and children of the world that this time we will deliver on the promise so that our shared future is brighter."

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- \neq the UNFPA and UNICEF technical teams; and
- ≠ the Secretariat staff, hosted by UNICEF.

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Annex: Lives saved and cost estimate analysis process

This annex describes the key assumptions used to estimate lives saved and costs of scale-up for 10 of the 13 life-saving commodities identified by the UN Commission on Life-Saving Commodities for Women and Children. Family planning commodities were excluded as these were very recently and comprehensively addressed in a paper by Guttmacher Institute and UNFPA.³⁰

Summary of approach to estimating impact

The Lives Saved Tool (LiST version 4.48) module of Spectrum was used to project neonatal, under-five and maternal lives saved through increasing coverage of child and maternal health interventions in the 50 poorest countries (i.e., 49 EWEC countries, plus India).³¹ Baseline projections were supplied by the Department of International Health, John Hopkins Bloomberg School of Public Health.³²

Scenarios for scaling up life-saving commodities

The complex interaction between the direct effect on fertility rates caused by the scaling up of family planning interventions and the impact of further life-saving commodities on fertility rates and demographic composition necessitated the development of two scenarios.

One scenario was created for a five-year scale-up period for interventions using 10 non-family planning life-saving commodities. Intervention coverage rates were scaled up to 90 per cent over a five-year implementation period, except in the case of India where coverage rates were raised to 70 per cent. Births in facilities offering basic emergency obstetric and newborn care were scaled up 2 per cent a year. For FP, modern contraceptive prevalence rate is held constant in order to isolate the impact of increasing availability of these 10 commodities. Further, use of a constant birth rate makes the relative impact of each individual intervention, and the associated commodity, more straightforward to assess.

The three maternal interventions used coverage rates for active management of 3rd stage of labour (proxy for oxytocin and misoprostol) and for magnesium sulfate (MgSo4) for both eclampsia and preeclampsia. For neonates, neonatal resuscitation (proxy to calculate the number of neonatal manual resuscitation bags and face-masks, suction equipment and training manikins needed), injectable antibiotics for neonatal sepsis (proxy for use of first-line procine penicillin and gentamicin, with ceftriaxone added as a second-line therapy),³³ antenatal steroids for pre-term labour, clean post-natal care (proxy for chlorhexidine use), and oral rehydration salts (ORS) for diarrhoea were used. For children under five years of age, ORS and zinc for diarrhoea plus pneumonia case management (proxy for amoxicillin) were modelled.

The other scenario focused on the impact of the family planning commodities; it kept the coverage of the 10 life-saving commodities for women and children constant and increased the coverage of family planning commodities. For the rate of scale-up of family planning commodities we used the assumptions used by the FPS (London Summit on Family Planning) Metrics Group. In personal communications with these researchers, it was felt that a conservative modelling of a 2 per cent per annum increase in contraceptive prevalence rate (CPR) over five years would most closely approximate the scale-up presented at the London Summit: to have an additional 34 million women access modern methods. This 2 per cent increase per annum in CPR was applied to all 50 countries using the LiST software, resulting in 230,000 deaths averted for women who otherwise would have died from complications surrounding pregnancy and childbirth.

Costing the scaling up of life-saving commodities for women and children

The modelling for costing the purchase of commodities applied the same set of assumptions on linking interventions to specific commodities as was used for the estimate of lives saved. Neonatal coverage was based on total birth estimates for each country generated by the FamPlan module (Spectrum); these birth estimates also were used as a proxy for assessing the number of women requiring oxytocin, misoprostol

and MgSO4 coverage. Under-five cohorts were based on projections from the DemProj module of Spectrum.

A conservative approach to costing was used. For each commodity, the coverage gap was calculated as the difference between the baseline coverage and the target of 90 per cent coverage (70 per cent for India) after five years of implementation for the 10 non-family planning commodities and 2 per cent increase per year for the family planning commodities. The high treatment cost estimate for each commodity was used – as provided by the technical working papers available on the Commission's website, with the exception of India where the cost of commodities is at the low end of the spectrum.³⁴

Two further major cost categories were added: (1) the cost of maintaining buffer stocks was calculated at 25 per cent of the total direct commodity costs – a commonly used figure for assessing vaccine buffer stock expenses – excluding for neonatal resuscitation equipment and family planning commodities; (2) an approximation of the health system costs to support this scale-up was made employing the approach used by the London Summit working group, working off the costing framework from the 2009 Adding it Up report³⁵ updated with current data. The non-commodity costs included supply costs, labour costs and systems and programme costs, with the latter encompassing indirect demand and supply costs.

The London Summit Family Planning working group³⁶ estimated average scale-up costs would be US\$8.3 per person per year. The working group has not published their cost breakdowns, but in personal communications with members of the working group the consensus was that a figure of about US\$1.9 per user per year would approximate the direct costs of procuring FP commodities, leaving US\$6.4 per user per year to cover the system costs of scaling up. As there are many common delivery systems for all these commodities, we assumed that there would be a 20 per cent savings through synergies in health systems costs. These assumptions are consistent with another study on the system costs of scaling up commodities: a report forecasting the costs of a fully immunized child estimated that vaccines take up about 24 per cent of the costs, with systems strengthening (e.g., training, management, equipment, etc.) making up 76 per cent.³⁷

In this scenario looking at the scale-up of only the 10 non-family planning commodities, the total direct cost for commodities (including buffer stocks) is US\$270 million. Using a similar ratio of health system to total costs used by the FP working group and the immunization study, we estimate that US\$953.6 million is required to cover the health systems costs. This translates into an average of US\$203 per life saved. Similarly the total direct costs of scaling up access to modern family planning methods is US\$309 million, and the health system costs would be approximately an additional US\$1.1 billion dollars for family planning commodities.

Limitations of the methodology

These costs are merely for illustrative purposes and do not represent a rigorous and country-specific estimate of actual costs. Unit costs were estimated from the background documents written for the Commission. Coverage estimates have varying confidence intervals according to the underlying quality of the MICS/DHS data sets. Also, while the LiST projections use the latest available data sets for modelling, these data sets come from a range of years, introducing another source of variance. Health systems costs are notoriously difficult to estimate, given the great differences in the cost structure of health systems across these 50 countries. For instance, these approximations do not estimate costs of preservice training, refurbishing facilities or any cash transfer or other social protection schemes that would be needed to remove financial barriers to access faced by poor and marginalized groups. It is important to note that *these illustrative health system costs should be used very cautiously*.

General assumptions for costing

Sub- population	Tracer intervention for determining coverage	Linked commodities			
Neonates	1. Neonatal sepsis (injectable antibiotics)	 Gentamicin, procaine benzylpenicillin (PBP); ceftriaxone (2nd line) 			
	2. Premature births	2. Antenatal steroids ⁱⁱ			
	3. Neonatal resuscitation	3. Bag and mask, suction devices, manikin ⁱⁱⁱ			
	4. Clean post-natal care	4. Chlorhexidine ^{iv}			
	5. Diarrhoea	5. ORS + $zinc^{v}$			
Under-5s	1. Diarrhoea	1. ORS + zinc ^v			
	2. Pneumonia case management	2. Amoxicillin ^{vi}			
Women	1. Active management 3 rd stage	1. Oxytocin and misoprostol ^{viii}			
aged 15-49	labour [™] to prevent PPH [™]	vii			
	2. Active management 3 th stage labour to treat PPH	2. Oxytocin and misoprostol ^{**}			
	3. Pre-eclampsia	3. MgSO4 ^{ix}			
	4. Eclampsia	4. MgSO4			
	5. Family planning commodities ^{xi}	5. Injectable, oral and other modern contraceptive methods ^x			
Health	Above the direct commodity purchasing costs of US\$579 million, around US\$2.05 billion				
System	will be needed to ensure health systems have sufficient capacity to deliver these				
costs	commodities. This amount include (a) costs of buffer stocks (i.e., enough spare supplies				
	to cope with fluctuations in demand) and (b) system building such as storage/distribution				
	(e.g. outreach services and creating demand for services). Not included are any costs				
	associated with building or refurbishing facilities; given the great variance in country				
	contexts, there are no feasible ways to estimate capital investment requirements with currently available data.				

Notes to the table:

i) Gentamicin + PBP given for all sepsis; a very conservative treatment failure of 10 per cent was assumed for which costs of additional ceftriaxone treatment are added. Treatment failure rates vary widely in reported literature, ranging from 11 per cent <<u>www.springerlink.com/content/u7q543561m772878/fulltext.pdf</u>> to 14 per cent <<u>http://tinyurl.com/c4ph4rw</u>>.

ii) Antenatal steroids given to all women with premature births, calculated as 12.5 per cent of total births for least developed countries (LDCs); see www.who.int/bulletin/volumes/88/1/08-062554-table-T3>. Dexamethasone is the only antenatal steroid recommended for LDCs due to its low cost and is thus the only one included in the costing analysis.

iii) For resuscitation equipment, modelling assumes a five-year life cycle for bag-masks and manikins, thus costing is only for their initial purchase and excludes any replacement costs. Suction bulbs require replacement each year. Costs are based on the minimum requirement for every facility – any hospital, primary health or other facility offering maternal delivery services – to have at least one functioning bag and mask, one functioning suction device and one training manikin. Manikin training costs used low and mid-point estimates of costs provided on the EWEC website as it was felt that the high end would not apply to procurement for these countries. Additionally, India as well as China are low-cost producers of manikins in the range of US\$50-100.

iv) Assumes clean post-natal care is given to every child at birth with one application of chlorhexidine. Generic 4 per cent chlorhexidine is available at US\$0.003/ml. If 10 cc is needed for one application, the cost is roughly US\$0.03/treatment. *Lancet* notes research showing even one application is very beneficial; see www.thelancet.com/journals/lancet/article/PIIS0140-6736(11)61848-5/fulltext.

v) Assumes ORS average treatment costs are the same for neonates and children under five (use one 500 ml packet/day, packet cost US\$0.042 X 7 = US\$0.29/treatment). See International Drug Price Indicator Guide website at <erc.msh.org/mainpage.cfm?file=1.0.htm&module=DMP&language=English>.

vii) Dispersible amoxicillin costs US\$0.21–0.42 per treatment course. See

<www.everywomaneverychild.org/component/content/article/1-about/305-amoxicillin--product-profile->.

vii) Assumes 100 per cent of women should receive uterotonics for all births attended by skilled birth attendants (SBAs), i.e., all women should receive oxytocin or misoprostol to prevent post-partum haemorrhage (PPH). Global figure of 74 per cent oxytocin

and 25 per cent misoprostol used for all countries to cost achieving a combined 90 per cent coverage for preventing and treating PPH. [NB, increased coverage to target of 90 per cent was only applied to SBA-attended births and did not include either unattended home deliveries or deliveries attended by a traditional birth attendant (TBA). In the case of India, coverage was to 70 per cent.]

viii) Assumes for all SBA-attended births, 20 per cent of women will need oxytocin or misoprostol to treat PPH. [Again, this was only costed for SBA-attended births and did not include either unattended home deliveries or deliveries attended by a TBA.]

ix) WHO guidelines call for using the same treatment for eclampsia and moderate to severe pre-eclampsia: an initial dose of 4 g, followed immediately with 10 g, followed by a maintenance dose of 1 g of 20 per cent MgSO4 for at least 24 hours. [See World Health Organization, *Managing Complications in Pregnancy and Childbirth: A guide for midwives and doctors*, WHO, Geneva, 2007.] Cost is based on 14 g + 24 g = 38 g. The dose is supplied as 500 mg/ml at a cost of US\$0.1049, so 38 X 2 X 0.1049 = \$7.97 per treatment (two highest costs for Caribbean islands were discarded as not relevant to LDCs). See International Drug Price Indicator Guide website at <erc.msh.org/mainpage.cfm?file=1.0.htm&module=DMP&language=English>.

x) For FP, a fixed unit cost for commodities was employed based on the Technical Annex prepared for the London Summit on Family Planning, as well as personal correspondence with John Stover. See: FPS Metrics Group, 'Technical Note: Data sources and methodology for developing the 2012 baseline, 2020 objective, impacts and costings', Working Draft_— 15 June 2012, prepared for the London Summit on Family Planning, July 2012.

xi) Assuming a 2 per cent increase in coverage per year throughout the five year period.

Notes

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⁵ GAVI Alliance, 'GAVI Alliance Secures Lower Price for Rotavirus Vaccine', 10 April 2012,

<<u>www.gavialliance.org/library/news/press-releases/2012/gavi-secures-lower-price-rotavirus-vaccine/</u>>, accessed 14 May 2012.

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⁷ For more information about (1) cStock, visit: <<u>sc4ccm.jsi.com/Docs/MwSC4CCMcStock_9.12.11_1_1.pdf</u>>; (2) SMS for Life, visit: <malaria.novartis.com/innovation/sms-for-life/index.shtml>; (3) ILS Gateway, visit:

<www.jsi.com/JSIInternet/Features/article/display.cfm?thisSection=Features&thisSectionTitle=Features&thisPage=st ories&ctid=na&tid=20&id=414>; (4) MAMA, visit: <healthunbound.org/mama/>

⁸ The EWEC countries are defined as the 49 countries of the world with the lowest income: Afghanistan, Bangladesh, Benin, Burkina Faso, Burundi, Cambodia, Central African Republic, Chad, Comoros, Democratic Republic of the Congo, Côte d'Ivoire, Eritrea, Ethiopia, The Gambia, Ghana, Guinea, Guinea-Bissau, Haiti, Kenya, Democratic Republic of Korea, Kyrgyz Republic, Lao People's Democratic Republic, Liberia, Madagascar, Malawi, Mali, Mauritania, Mozambique, Myanmar, Nepal, Niger, Nigeria, Pakistan, Papua New Guinea, Rwanda, Sao Tome and Principe, Senegal, Sierra Leone, Solomon Islands, Somalia, Tajikistan, Togo, Uganda, United Republic of Tanzania, Uzbekistan, Viet Nam, Yemen, Zambia and Zimbabwe. The Commission included a 50th: India

⁹ FPS Metrics Group, 'Technical Note: Data sources and methodology for developing the 2012 baseline, 2020 objective, impacts and costings', Working Draft₂ – 15 June 2012, prepared for the London Summit on Family Planning, July 2012.

¹⁰ See <<u>www.apromiserenewed.org/</u>>.

¹¹ The Partnership for Maternal, Newborn & Child Health, 'PMNCH Fact Sheet: RMNCH Continuum of Care', World Health Organization, September 2011, <<u>www.who.int/pmnch/about/continuum_of_care/en/index.html</u>>, accessed 11 June 2012.

¹² The Partnership for Maternal, Newborn & Child Health, A Global Review of the Key Interventions Related to Reproductive, Newborn, Maternal and Child Health (RMNCH), PMNCH, Geneva, 2011,

<a>www.who.int/pmnch/topics/part_publications/essential_interventions_18_01_2012.pdf>, accessed 15 May 2012.

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¹⁶ 'Key Data and Findings: Medicines for maternal health', Working Paper prepared for the United Nations Commission on Life-Saving Commodities for Women and Children, March 2012.

¹⁷ 'Key Data and Findings: Contraceptive commodities for women's health', Working Paper prepared for the United Nations Commission on Life-Saving Commodities for Women and Children, March 2012.

¹⁸ Ibid.

¹⁹ See note 8 for the list of EWEC countries. The language "all EWEC countries" in the recommended actions means all EWEC countries facing such barriers and where action could drive change. During the implementation planning

process, a set of countries will be identified for each recommended action that includes the language "all EWEC countries". The countries will be consulted to ensure their agreement with the classification and their buy-in.

²⁰ UN Commission on Life-Saving Commodities for Women and Children, 'Draft Summary Report: Supporting documents – Compilation of recommendation reports submitted by work streams', 17 May 2012.

²¹ The intention of the recommendation is three manufacturers for each of the 13 commodities overall, not three manufacturers per commodity per country; certain commodities with very small markets may necessitate fewer manufacturers in order to ensure sufficient volume for any one entity.

²² The ERP process is a rapid joint assessment of product dossiers by a global group of national regulators convened by the World Health Organization and managed by very strict procedures. The ERP has not yet started for children's medicines as there is little advance market commitment.

²³ Malaria No More, *Malaria No More Stakeholder Report 2009*, New York, 2009, p. 15.

²⁴ Yeates, Rob, 'Women and Children First: An appropriate first step towards universal coverage', *Bulletin of the World Health Organization*, vol. 88, no. 6, 2010, pp. 401–80.

²⁵ United Nations Population Fund et al., *The State of the World's Midwifery 2011: Delivering health, saving lives*, UNFPA, New York, 2011, www.unfpa.org/sowmy/resources/docs/main_report/en_SOWMR_Full.pdf>, accessed 11 June 2012.

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²⁷ Nabudere, Harriet, Asiimwe, Delius and Amandua, Jacinto, 'Improving Access to Skilled Attendance at Delivery', *SURE Policy Brief*, College of Health Sciences, Makerere University, Kampala, Uganda, 2011, <www.evipnet.org/sure>, accessed 15 August 2012.

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³⁰ Singh, Susheela and Darroch, Jacqueline E., *Adding It Up: Costs and benefits of contraceptive services – Estimates for 2012*, Guttmacher Institute and United Nations Population Fund, New York, June 2012,

³¹ See note 8.

³² <www.jhsph.edu/departments/international-health/IIP/list/projection.html>.

³³ See <<u>http://tinyurl.com/cqvq4pt</u>>.

³⁴ <<u>www.everywomaneverychild.org/resources/un-commission-on-life-saving-commodities/life-saving-commodities</u>>.

³⁵ Singh, Susheela et al., *Adding It Up: The costs and benefits of investing in family planning and maternal and newborn health*, Guttmacher Institute and United Nations Population Fund, New York, 2009.

³⁶ See: <<u>www.londonfamilyplanningsummit.co.uk/</u>>.

³⁷ Hutton, Guy and Tediosi, Fabrizio, 'The Costs of Introducing a Malaria Vaccine through the Expanded Program on Immunization in Tanzania', *The American Journal of Tropical Medicine and Hygiene*, vol. 75, August 2006, pp. 119– 130.

For more information:

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