Key Data and Findings

Contraceptive Commodities for Women's Health

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Women and Children
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A. BACKGROUND & RATIONALE

Under the auspices of the United Nations Secretary-General's Every Woman Every Child initiative, the Commission on Life-Saving Commodities for Women and Children will advocate at the highest levels for the increased availability, affordability and accessibility of essential but underutilized commodities for maternal and child health. When the creation of such a Commission was first proposed in 2011, the argument was made that positive health outcomes in reproductive, maternal, newborn and child health were being undermined by poor access to a limited set of life-saving commodities for which there were no global champions or institutionalized sources of financial and technical support. This emphasis on "neglected commodities", while widely applauded, did cause some to question whether contraceptive commodities, which have in the past benefitted from initiatives such as the Reproductive Health Supplies Coalition, could be considered neglected in the same way as other curative drugs and medicines.

The prospect that contraceptive commodities might be excluded from review by the Commission alarmed the broader reproductive health community. Their response was to re-affirm the critical role of family planning in averting maternal and newborn deaths and, perhaps even more importantly, to point out that among the array of family planning methods, certain methods were indeed neglected, underutilized and orphaned.

In October, representatives of the Commission called upon the Reproductive Health Supplies Coalition to identify one contraceptive commodity that most closely fit the criteria of "orphaned" and that held out the greatest promise for improving reproductive health outcomes. The Coalition's Executive Committee responded by identifying three: contraceptive implants, emergency contraception and the female condom.

The Commission's subsequent decision to include family planning in its mandate is an important testament to the need to build on the progress made in meeting the need and desire for contraception over the last four decades. In selecting these three overlooked contraceptive methods—contraceptive implants, emergency contraception and the female condom—the Commission has appropriately focused on ensuring access to methods that are in demand, show promise for increasing public health benefits (including beyond pregnancy prevention), and have received inadequate attention from the public and private sector. Yet, to realize the full public health benefits of increased availability of overlooked contraceptive methods, it is also essential to ensure access for all to a full range of methods and the ability of women to choose a method that fits within their own fertility goals and life circumstances.

Sexually-active women of reproductive age in developing countries experience high rates of unintended pregnancy. Nearly 90 percent of the estimated 208 million pregnancies in 2008 occurred in the developing world, according to the Guttmacher Institute. Globally, 86 million

pregnancies were unintended; of these, 41 million ended in abortions 33 million in unplanned birth and 11 million in miscarriage. Roughly as many women with unintended pregnancies obtain induced abortions as give birth to a child they had not planned for. The majority of these induced abortions take place in non-medical settings under unsafe conditions.

When women and couples can access a wide range of contraceptive methods, they are more likely to find a method they like and can use over a period of time, to switch methods when life circumstances change, and to meet their contraceptive intentions. Even among those who currently use contraception, many who would like to have no more children have no access to long-acting and permanent methods. Similarly those who are at risk of HIV/AIDS or other sexually transmitted infections (STIs) too often do not have access to the means for prevention of both infection and pregnancy. Youth, in particular, must overcome significant barriers to access contraception that meets their needs and vulnerability to unprotected sex.

Among investments in public health, those made to ensure access to contraceptive supplies and services are proven to result in significant improvements in the health of women and children.[1] The 603 million women who currently use modern contraception in developing countries, combined with the 215 million women with an unmet need for modern contraception, attest to the need and desire for contraceptive services and related commodities overall.

The choice of these three specific contraceptive commodities reflected two principal considerations. The first was that all three had long been classified by the Coalition's Caucus on New and Underutilized Methods as being "underutilized". The selected three were among 10 technologies that, to use the caucus' definition, were "not routinely available in the public, private, or social marketing sectors, ... [nor] routinely procured by the major procurers". They also reflected the criteria set forth in the Commission's original concept paper. All three were inadequately funded by existing mechanisms. In the case of implants and the female condom, both of which are currently witnessing price declines, there was evidence of the prospects for "… innovation and rapid scale up in product development and market shaping" (including potential for price reduction and improved stability of supply).

The second reason for their selection was that, as a group, the three serve as a bellwether for identifying opportunities for improving access, use and effectiveness of family planning and

[1] Each year, the current level of modern contraceptive use averts 188 million unintended pregnancies, which in turn results in 112 million fewer abortions, 1.1 million few newborn deaths and 150,000 fewer maternal deaths. If unmet need for modern methods were fully satisfied, an additional 53 million unintended pregnancies would be averted each year, resulting in 22 million fewer unplanned births, 25 million fewer induced abortions and seven million fewer miscarriages. The immediate health benefits of averting these unintended pregnancies would be substantial. Each year, an additional 90,000 women's lives would be saved and 590,000 newborn deaths would be averted. Guttmacher Institute, International Planned Parenthood Federation, *Facts on Satisfying the Need for Contraception in Developing Countries,* November 2010

for meeting Millennium Development Goal 5b—universal access to reproductive health. Many of the access issues that clients and health systems face when seeking to provide safe protection from unwanted pregnancy or infection (e.g. high unit cost, political opposition, poor supply chains, need for ancillary equipment, poor training of providers) are indicative of barriers faced by health systems in providing all contraceptive methods, and particularly those that exist outside mainstream donor and corporate priorities.

In considering improved access to these three and all contraceptive commodities, the Commission is urged to prioritize the following recommendations or interventions:

- Provision of the full range of contraceptive methods needed to meet women's and couples need for short-term, long-term and permanent methods of contraception and, where relevant, for prevention of STIs, including HIV;
- Ensuring equitable access to contraceptive commodities for all who are at risk of unwanted pregnancy;
- Streamlined regulatory processes and national-level responses to increase opportunities for the introduction and use of all services and commodities to improve maternal and child health.

B. DATA SYNTHESIS

1. Contraceptive implants

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. Clients are satisfied with them because they are convenient to use, long-lasting, and highly effective. Implants, which are inserted under the skin of a woman's upper arm, prevent pregnancy for an extended period after a single administration. 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) with a cost ranging from $8 to $18.00 per unit.[2] The most common types include Jadelle (two rods each containing 75 mg of levonorgestrel, effective for five years); Sino-implant (II), which 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); Implanon 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.

Policy – Guidelines, protocols, technical

Implants are included in the WHO Essential Medicines list (2011) and specified as the two-rod levonorgestrel-releasing implant, each rod containing 75 mg of levonorgestrel (150 mg total). One rod implants are still not included in the WHO list. In addition, service delivery policies and protocols, are in place in many countries which support implant provision, including both two-rod and one-rod presentations. Given the different implant products that are available in diverse markets, technical requirements for competent training in counseling, insertion and removal of each product as well as related procurement processes is required to ensure that these commodities are provided appropriately. In some settings, policies allow task-shifting which permit lower cadres of health care providers (i.e. providers other than doctors such as nurses or midwives) to insert and/or remove implants. In Ethiopia since 2009, Health Extension Workers (HEWs) have offered Implanon at the community level through the Health Extension Program with nurses or midwives trained for removal.[3]

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[2] All amounts are in US dollars (US$)

[3] Under this scheme, female high school graduates are recruited and trained for one year (candidates must have completed grade 10 in school, need to be from the local community, and speak the local language).

Regulatory: Registration and distribution

Jadelle is prequalified by the World Health Organization. It has been registered in more than 47 counties worldwide with review underway in an additional 10 countries. It is distributed commercially by Bayer Pharma. Sino-implant (II) is registered in 19 countries worldwide and is under active regulatory review in 10 additional countries. In addition to the manufacturer's name for the product (Sino-implant (II)) the product is marketed under a variety of names by different distributors: as Zarin by Pharm Access Africa, Ltd., as TRUST by DKT Ethiopia, and as Femplant by Marie Stopes International. Implanon is prequalified by the World Health Organization and registered in approximately 80 countries. It is distributed commercially by Merck/MSD.

Financing and commodity costs

High commodity costs and a lack of supplies at the country level, due to lack of procurement or distribution networks within the country, contribute to unsatisfied demand for implants. Donors and governments may be more likely to purchase large quantities of short-acting, less expensive hormonal methods such as oral contraceptives (OCs) instead of more expensive, longer-acting methods such as implants. However, implants are more cost-effective in the long term than repeated use of short-acting methods.

Significant increases in procurement of contraceptive implants have been reported worldwide over the last several years. Data gathered by the RH Interchange show that in 2005 approximately 132,000 implants were donated in sub-Saharan Africa. By 2011, donations rose to more than 2.5 million. In 2011, Merck/MSD lowered the price of Implanon to $18/unit in developing countries. If sales volumes of 4.5 million units or more are reached by December 2012, the price will be reduced to $16.50, including retroactive price reductions. In addition, in March 2012, Bayer Pharma lowered the price of Jadelle to $18.00/unit in developing countries. Sino-implant (II) costs agencies seeking procurement approximately $8/unit.

For Jadelle**,** public-sector price agreements with organizations such as the U.S. Agency for International Development (USAID), the United Nations Population Fund (UNFPA), PSI and