Contraceptive Security Brief

Emergency Contraceptive Pills: Supply Chain Considerations



A sign on the side of a building in the Henequenera zone of Yucatan, Mexico advertises emergency contraception.

To ensure the routine availability of emergency contraceptive pills, the managers of public health supply chains must take into consideration the unique characteristics of this important method.

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Emergency contraception is an important component of reproductive health programs, providing women with the only method that can be used to prevent pregnancy after unprotected sex or method failure. In addition to expanding the method mix, emergency contraceptives (EC) provide an important option in cases of sexual assault and as an opportunity to bridge clients to other reproductive health (RH) services. Despite the benefits, EC is often one of the least known, least available, and least used modern family planning method in developing countries.

While several contraceptives (i.e., progestin-only and combined oral contraceptives at higher dose and copper intrauterine device [IUD]) can be used in a special regimen as emergency contraception, a dedicated product "packaged and labeled specifically for EC use" is considered a best practice as it provides clear instructions for women and providers, helps reduce stigma, and legitimizes the method (International Consortium for Emergency Contraception [ICEC] 2011).

The inclusion of dedicated EC pills (ECPs) in RH programs provides women with an additional and important option for pregnancy prevention. However, the unique characteristics affect how the product is managed in public health supply chains. For example, forecasting is more difficult because programs often lack routine reliable logistics data for ECPs as they are a new method for many public sectors. In addition, demand is inherently unpredictable because ECPs are not intended for regular use as a family planning method, and their use is heavily contingent on client and provider awareness. Furthermore, as an underused method, they are often not mainstreamed into logistics reporting forms. Last, because ECP should be available through traditional and nontraditional outlets, there are challenges for the distribution system.

The ECP Market in Developing Countries

Commercial Sector

Most clients accessing ECPs rely on the commercial sector as their source of supply. The private sector offers flexible hours and geographical convenience, both of which are critical to ensure that clients can access ECP within five days after unprotected sex. The private sector also offers clients anonymity and confidentiality. While an important source of EC, the private sector tends to serve urban, wealthier segments of the population (ICEC 2011).

While private sector data are lacking, according to 2010 Contraceptive Social Marketing Statistics from DKT International, the market for socially marketed ECP grew in both number of countries (from 14 to 69) and sales (from 2.5 million to 8.8 million) between 2004 and 2010 (DKT International 2011).

Public and NGO Sectors

In addition to the private sector, the public and NGO sectors have an important role to play in the provision of ECP. Offering dedicated ECP in these sectors can ensure that quality EC is affordable and accessible to all populations and can serve as a way to bridge clients to other important RH services (i.e., HIV/AID/STI prevention and treatment, routine family planning, post-rape care, condom counseling, etc.).

However, according to a recent survey of 40 countries, while ECP was most often offered in the commercial sector (81 percent); fewer countries reported offering this method in the NGO (58 percent) or public (54 percent) sectors. (USAID | DELIVER PROJECT, Task Order 4 2011a)

Supply Chain Considerations for Emergency Contraceptives

As stakeholders continue to work to introduce and expand ECP provision in public and NGO programs, there are several important supply chain considerations to ensure its availability.

National Essential Medicines List (NEML)

Inclusion of drugs on a country's National Essential Medicines List (NEML) highlights their significance and can help ensure their availability by influencing funding allocations, program priorities, and prescriber protocols such as standard treatment guidelines, and may lead to benefits such as tax/duty exemptions. The status of a drug on the NEML is also often a prerequisite for public sector procurement.

Many countries still do not include emergency contraceptive pills on their NEML: in a 2011 survey, only 26 of 40 countries (65 percent) reported that ECP were included on their lists. It does appear that countries are recognizing the importance of this method and adding it to their respective lists when updates take place. For example, according to the survey, Rwanda and Senegal added EC to their NEMLs during the most recent list revision (USAID | DELIVER PROJECT, Task Order 1 2011b, p. 16).

Countries often rely on the WHO Model List of Essential Medicines to guide which medicines to include in their country list. The most recent WHO List includes the levonorgestrel EC pill (World Health Organization [WHO] 2011, p. 26).

Registration and Licensing Policies

As part of the quality assurance and monitoring process, countries require that all pharmaceutical products be registered by the national drug regulatory authority or a stringent regulatory authority (SRA). Registration influences which product and brand or generic equivalent of ECP a program can procure and sell.

The Emergency Contraception Website (www.not-2-late.com) has a database that inventories which brand names of dedicated ECP are registered in most countries. According to the database, 141 countries have at least one dedicated ECP registered and many have several ECP registered. The majority of the countries have the levonorgestrel EC pill registered.

To support countries in ensuring quality product selection in accordance with global standards, WHO has developed a prequalification program for reproductive health medicines. As of August 2010, WHO had prequalified Gedeon Richter's levonorgestrel two-pill ECP. Several ECP are also approved by other SRA such as the US Food and Drug Administration (FDA) or the European Medicines Agency (EMA). In addition, a number of manufacturers are also producing generic equivalents of ECP—some are currently going through the WHO prequalification process and being procured by international organizations and country governments.

Access and availability are also influenced by national policies such as licensing. National drug authorities determine whether ECPs are available with or without a prescription. As a way to reduce barriers to access, ICEC and other international agencies recommend that ECPs be available without a prescription. Currently, more than 60 countries allow clients to obtain this method without a prescription (ICEC 2011).

Procurement Price

As expected, the procurement price for ECP varies by manufacturer and according to brand, volume, specifications/special ordering requirements, mode of shipment, competition, and quality. In an effort to increase access to ECP, several manufacturers have offered preferential pricing for the public and non-profit sectors.

Forecasting and Quantification

ECP has unique characteristics that make it difficult to accurately forecast to meet program requirements. For well-established resupply methods, forecasts are typically based on historical consumption data or demographic data on contraceptive use (e.g., Demographic Health Surveys [DHS])so they can be quite predictable. Because ECP is not intended for routine use and usage is low, demand is unpredictable and there is no stable usage pattern. As a result, these data types are often not available or are unreliable for forecasting ECP. When ECP is newly introduced in a country, these challenges are further magnified. A recent analysis of forecast accuracy from several African countries confirms these challenges. According to the analysis, in 2009, ECP had the highest percent of forecast errors among all new and underutilized methods (A Forecasting Guide for New and Underused Methods of Family Planning, forthcoming 2012).

While there is no standard methodology for forecasting ECPs, stakeholders have used several approaches to address the unique issues:

- a. *Sales data*: For new programs, social marketing organizations base the initial forecast on a proportion of OCs sold in the country. As the program matures, the organization relies more on routine sales data.
- b. *Demographic data*: Another approach developed to estimate demand for both new and established programs uses population-based data. For new programs, the approach estimates the "maximum demand" as the number of ECPs needed based on both CPR for certain methods (traditional, male condoms, and OCs) and the number of women not currently using a method. For routine programs,

- this approach is refined to factor in supply and demand considerations (Program for Appropriate Technology in Health [PATH] 2004, p. F-15).
- c. Consumption data: When logistics data do exist for an established ECP program, they can be a useful data point for forecasting. For example, the average monthly consumption of ECP in a public sector program can help determine past trends and thereby estimate future requirements.

There are obvious limitations to each of these approaches and, in all likelihood, a combination of these and other data points should be considered when estimating the forecast for ECP.

Additionally, because of the issues with forecast accuracy associated with ECP, it is important for a program to ensure that forecasts are reviewed often and procurements are flexible and respond to any urgent needs.

Distribution

As part of comprehensive reproductive health programming, ECP is distributed to RH/FP service delivery points through existing supply chains. Through these supply chains, ECP would typically be distributed from the central level (central medical stores) to districts and then to health facilities. ECPs are also an important part of comprehensive sexual violence services and for programs focusing on specific populations (i.e., youth). As such, stakeholders must consider the supply chain and distribution system for nontraditional outlets such as hospital emergency rooms, refugee and IDP camps, pharmacies, prisons, schools, etc.

Routine Logistics Data

Logistics data are critical for programmatic, resource and policy decisionmaking—yet, reliable data on ECP are lacking in many countries. Because ECPs are not routinely used and client and provider knowledge is low, logistics data are not typically included in routine reporting and ordering forms. Ideally, ECPs should be integrated into routine reporting forms and information systems in preparation for its introduction into a program. Processes should also be developed to capture ECP data from nontraditional outlets, which typically do not report through routine health logistics systems.

Service Delivery

ECPs also require specific service delivery considerations. Often, service providers lack training and information on ECPs, so they can be an unintended barrier to client access to this method. Not only do providers need to have the clinical training, but they should also be trained in counseling, prescribing protocols, side effects, and how to correct myths and misconceptions. With proper training and information, service providers can use EC counseling as an ideal opportunity to bridge clients to other RH services, such as more routine family planning methods, post-rape care, condom counseling and services, and information on HIV/AIDS/STI.

Conclusion

Emergency contraception is an important component of reproductive health programs providing women with the only method that can be used after unprotected sex or method failure to prevent pregnancy. However, their unique characteristics impact how ECPs are managed in health supply chains. When introducing or implementing ECP in a country program, the following points should be considered:

• The public and NGO sectors are important sources of supply of ECPs and should ensure that ECPs are part of their program method mix.

- Including ECPs on a country's NEML can help ensure adequate financing, facilitate procurement, and may lead to benefits such as tax/duty exemptions.
- To address limitations in forecasting for ECP, a combination of approaches and data should be considered. Until ECP becomes a more established method in the public or NGO sectors, it is important to ensure that procurements are flexible and can respond to any urgent needs.
- Reliable data are critical for supply chain decision-making. Ideally, ECPs should be integrated into
 routine reporting forms and information systems when introduced into a program. Processes should
 also be developed to capture ECP data from nontraditional outlets.
- ECPs are also an important part of comprehensive sexual violence services and for programs targeting specific populations; therefore, they should be included in the distribution system for nontraditional outlets such as hospital emergency rooms, refugee and IDP camps, pharmacies, prisons, and schools.
- ECPs require specific service delivery considerations. As such, providers should be trained in the clinical aspects of ECP as well as in counseling, protocols, possible side effects, and logistics management.
- As a way to reduce barriers to access, ECPs should be available without a prescription.

For More Information

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- Contraceptive Social Marketing Statistics, 2010, http://dktinter.s463.sureserver.com/wp-content/uploads/2011/11/2010-Statistical-Mktg-Rpt.pdf
- International Consortium for Emergency Contraception, <u>www.cecinfo.org/</u>
- Resources for Emergency Contraceptive Pill Programming: A Toolkit, http://www.path.org/files/RH ec toolkit.pdf
- RHInterchange, www.rhi.rhsupplies.org
- The Emergency Contraception Website, <u>www.not-2-late.com</u>
- The Logistics Handbook: A Practical Guide for the Supply Chain Management of Health Commodities http://deliver.jsi.com/dlvr_content/resources/allpubs/guidelines/LogiHand.pdf
- WHO List of Prequalified Medicinal Products, http://apps.who.int/prequal/
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