Evidence to Action for Strengthened Family Planning and Reproductive Health Services for Women and Girls Project

Emergency Contraception

Four Country Case Studies on the Introduction and Scale-up of Emergency Contraception





E2A Overview

The Evidence to Action Project (E2A) is USAID's global flagship for strengthening family planning and reproductive health service delivery. The project aims to address the reproductive healthcare needs of girls, women, and underserved communities around the world by increasing support, building evidence, and leading the scale-up of best practices that improve family planning services. A five-year Cooperative Agreement awarded in September 2011, E2A is led by Pathfinder International in partnership with the African Population and Health Research Center, ExpandNet, Intrahealth International, Management Sciences for Health, and PATH.

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Acronyms

BFPP Bangladesh Family Planning Program

CLAE Latin American Consortium for Emergency Contraception

DHS Demographic and Health Survey
E2A Evidence to Action Project
EC Emergency Contraception
ECP Emergency Contraceptive Pill

FEMCON Forum for Emergency Contraception (Bangladesh)
FIGO International Federation of Gynecology and Obstetrics

HIP High Impact Practice

IAWG Inter-Agency Working Group (for Reproductive Health in Refugee Situations of the

World Health Organization)

ICEC International Consortium for Emergency Contraception ICPD International Conference on Population and Development

IPPF International Planned Parenthood Federation

IUD Intrauterine Device

LNG ECP Levonorgestrel-only Emergency Contraceptive Pill MECC Mexico Emergency Contraception Consortium

NGO Nongovernmental Organization STI Sexually Transmitted Infection

UN United Nations

UNFPA United Nations Population Fund

UPA ECP Ulipristal Acetate Emergency Contraceptive Pill
USAID United States Agency for International Development

WHO World Health Organization

I. Emergency Contraception: A Critical Component of the Contraceptive Method Mix

Women's and couples' ability to decide the number and spacing of their children is central to public health and reproductive rights. Despite the fact that family planning is one of the most cost-effective public health interventions, an estimated 41% of pregnancies worldwide are unintended and 222 million women still have an unmet need for modern contraception. Fulfilling this unmet need would prevent 79,000 maternal deaths and 1.1 million infant deaths. Although use of modern contraceptive methods has increased during the last decade in the developing world, the percentage of women with unmet need living in the poorest countries has increased (from 67% to 73%), signaling the need to ensure adequate family planning services, particularly in the poorest countries where population growth and the desire for smaller families are driving the unmet need for contraception.

Access to a wide range of methods—including hormonal and non-hormonal methods, pre-coital and post-coital methods, reversible and non-reversible methods, and provider-dependent and non-provider dependent methods—is essential given women's diverse contraceptive needs. As the only available post-coital contraceptive method, emergency contraception (EC) is critical to a comprehensive method mix. EC provides a way of preventing pregnancy after unprotected sex, failure or ineffective use of another contraceptive method, or forced sex. EC is also an important method choice for women who have infrequent sex and prefer not to use an ongoing method of contraception.

The term 'emergency contraception' includes several kinds of emergency contraceptive pills (ECPs) as well as insertion of a copper-bearing intrauterine device (IUD). Although research to date has not demonstrated a population-level effect on unintended pregnancy from expanded EC access,⁶ the impact on individual women is clear: if used correctly, the World Health Organization (WHO)-recommended regimen of ECPs can reduce a woman's risk of pregnancy by between 52-94%, and the IUD inserted within five days of unprotected sex is 99% effective in preventing pregnancy.⁷

Prior to the mid-1990s, there was little global attention to EC as a contraceptive method. Around that time, the Consortium for Emergency Contraception (now the "International Consortium for Emergency Contraception" (ICEC)) was formed and sought to achieve three objectives: to garner manufacturing support for a dedicated EC product; introduce EC in four model countries (Indonesia, Kenya, Mexico, and Sri Lanka); and develop resources and materials needed to promote access to EC.8 Over the years, as the demand for EC has grown and more products have been registered, EC has increasingly been emphasized and embraced as an essential part of family planning best practices by international health organizations and donors. In 1999, the WHO added EC (in the form of a single 1.5 mg dose of levonorgestrel) to its Model List of Essential Drugs, which is meant to guide countries in their selection of drugs and drug procurement.9

Although much has been written about EC and its importance as a contraceptive option for women, much less information has been shown regarding its introduction and scale-up in different country contexts. This is not surprising given the lack of documentation that often exists during implementation of various activities and programs; introduction and scale-up tend to evolve organically with many actors taking leading roles at different times and not always communicating with one another. As a result, this process does not always lend itself to easy recording along the way and countries are left with few resources from which to learn when trying to implement a particular activity themselves.

I.I Purpose of the Report

This report seeks to address this challenge and add to the existing literature on EC by illustrating ways in which governments, nongovernmental organizations (NGOs), and the private sector have worked

together and separately to introduce and scale up EC within their respective countries. There has been very limited use of the IUD as EC in low-income countries and, as such, this report focuses on ECPs, though in some cases throughout the report the terms "EC" and "ECPs" are used interchangeably.

While each country is different and variations exist regionally, this report attempts to address these issues by examining the introduction and scale-up of ECPs in four geographically disparate countries: Mexico, Bangladesh, Kenya, and Senegal. Different cultural contexts and health systems exist within each of these countries, but all four have been able to introduce and scale up EC with varying degrees of success and range. Although each case is unique, there are some broader lessons to be learned from each that may be useful to other countries attempting to introduce or scale up EC. To some extent, these cases have already been used as examples to inform other ECP scale-up efforts in the regions they represent; this report seeks to broaden the reach of these lessons to the global community.

After completing a comprehensive literature review, an analysis of the four country case studies was conducted using two frameworks: the ICEC 9 Steps and the WHO Building Blocks. These frameworks lend a useful lens when examining the different components of each case and help to identify the components that were critical to facilitating success as well as significant gaps and barriers. Following the case studies, a further analysis compares and contrasts the various elements within each effort that led to successful introduction, and later, scale-up.

Drawing from the case studies and cross-country analysis, this report concludes with a recommendations section which highlights some of the most significant elements that led to success and recommends how others could implement them. These recommendations are intended to be applied by the various actors involved in the EC introduction and scale-up process, including governments, NGOs, and the private sector, with the ultimate goal of improving quality EC service provision to women globally.

I.2 Current Global Context

The global policy and funding context has experienced a number of significant events over the last several years, making the current environment conducive to efforts to promote greater access to EC worldwide. Specifically, the following milestones have occurred:

- In 2009, USAID launched the Global Health Initiative which included a focus on family planning in its efforts to improve public health. The first principle of the Initiative was a "focus on women, girls, and gender equality" and specific guidance around this principle included a programmatic recommendation to include provision of EC as part of gender-based violence screening and response programs.¹⁰
- 2. In 2011, USAID began accepting WHO prequalified hormonal contraception—including EC—for procurement for field programs (joining UNFPA which had already done so).
- 3. In 2011, USAID published a brief on "High Impact Practices" (HIPs) for family planning. HIPs are evidence-based recommendations for maximizing investments in a comprehensive family planning strategy. EC is included in the list of methods recommended for provision by community health workers and pharmacists and drug-shop keepers.
- 4. In 2012, EC's importance was highlighted by the United Nations (UN) Commission on Life-Saving Commodities for Women and Children, which identified 13 underutilized commodities to focus on, including three reproductive health commodities: female condoms, contraceptive implants, and emergency contraception. ¹² Technical reference groups are working to implement specific strategies to increase utilization of these life-saving commodities; WHO is leading the EC group. ¹³
- 5. In 2012, the London Family Planning Summit led to groundbreaking commitments to family planning by donor and developing country leaders, international agencies, civil society, and the

- private sector. The Summit renewed momentum around family planning, and Family Planning 2020 is building on the conference and carrying the agenda forward.
- 6. In 2012, the UN Child Survival Call to Action and the global initiative "Committing to Child Survival: A Promise Renewed" included family planning as a critical evidence-based intervention in their roadmap for ending preventable child deaths.¹⁴
- 7. In 2013, WHO released clinical and policy guidelines on "Responding to intimate partner violence and sexual violence against women" that recommend offering EC to sexual assault survivors presenting within five days of sexual assault.¹⁵

EC has come a long way over the last couple of decades, with the creation of dedicated EC products, inclusion on lists of essential medicines, increased awareness and use, mainstreaming into some public health programs, and much greater availability on the shelves of pharmacies and drug shops in many countries. However, much remains to be done in order to fully integrate EC into health systems and ensure all women have access. The commitment and participation of the public and private sectors, international organizations, donors, and civil society are critical to the success of national EC programs and the realization of EC access for all.

1.3 Women's Right to Emergency Contraception

While international norms and guidelines that support reproductive rights, such as the Convention on the Elimination of All Forms of Discrimination against Women, the International Conference on Population and Development (ICPD) Program of Action, and Millennium Development Goal 5 do not explicitly mention EC, it is clear that offering a wide range of contraceptive methods to meet women's and couples' needs is integral to fulfilling reproductive rights.

The often-cited ICPD Program of Action has several objectives related to family planning, including: 'to make quality family planning services affordable, acceptable, accessible to all who need and want them, while maintaining confidentiality.' The focus on quality in this statement implies offering a range of methods, as laid out in the most-cited quality of care framework for family planning services developed by Judith Bruce in 1990, which includes 'choice of methods' as one of its six elements.

In an effort to affirm women's right to EC, Weisberg and Fraser (2009)¹⁸ have identified a number of specific rights that are relevant to EC access and availability, including:

- ✓ Women's right to healthy, satisfying, non-procreative sex
- √ Women's right to accurate information about contraception
- ✓ Women's right to choose from as broad a range of contraceptive options as possible, which must include EC
- ✓ Women's right to make an informed choice among all safe and effective contraception options, free from unreasonable state and medical intervention
- ✓ Women's right to obtain EC over the counter without intrusive questioning
- ✓ Women's right to use ECPs as frequently as she deems necessary
- ✓ Rights of providers who have a conscientious objection to provision on religious or moral grounds

The last right highlights the potential conflict between the rights of the provider and the rights of the client. Weisberg and Fraser argue that principles of doing no harm and taking action to help individuals tip the balance to the client's rights over those of the provider. Reports of 'provider refusals,' where pharmacists, doctors, or other health providers withhold information about the existence of EC as an option, are a violation of clients' rights to receive the full range of contraceptive information and methods. Many providers who oppose EC do so because of misinformation and misperceptions, pointing to the need for additional training and sensitization for service providers.

1.4 Importance of Emergency Contraception for Specific Populations

EC should be available and accessible to all women who may need it and to men who may need access for their partners. However, there are some specific populations for whom EC is particularly important and who require more targeted interventions. These populations are described below. Also explained are the reasons each group needs EC, successful approaches that have been undertaken to provide EC, and key challenges that have been faced in providing EC to each selected sub-population.

A review of lessons learned about EC programs from regions where conservative groups have challenged the introduction of EC points to the tendency of policy makers to feel more comfortable with a "low-profile, rights-based approach starting with segments of the population in very high need, such as rape victims and women living in refugee camps." Though ensuring access to EC for these populations is critical, it is also important not to abandon other efforts to integrate EC more broadly into health systems and to find ways to move beyond implementation with special populations towards broader access.

I.4. I Young Women

Young women typically have less knowledge about reproductive health and more limited access to contraceptives in general than older women and are therefore less likely to be using an ongoing contraceptive method, even if they are married. In addition, young women are especially vulnerable to sexual coercion and forced sex and often have difficulties negotiating use of condoms and other contraceptives. They also often face increased discrimination from pharmacists and health care providers; as one example, almost half of pharmacists in a study in South Africa did not think ECPs should be given to women younger than 18.20 Young women may also be subject to additional legal barriers such as prescription requirements that are not mandated for older women. More work is needed to test the effectiveness of clinic, pharmacy, and community-based strategies for ensuring EC access to young women in the face of these challenges. The ICEC recommends a focus on privacy and confidentiality, accessible locations, flexible hours, and reasonably priced services, as well as over-the-counter policies for people of all ages and youth-oriented marketing strategies.²¹ Recent examples of youth-oriented EC work include promotion of youth-friendly services in Mozambique and Ethiopia,²² and PATH's RxGen project to improve the quality of pharmacy EC services offered to youth.²³

1.4.2 Sexual Violence Survivors

The UN Office on Drugs and Crime collects national data from police reports on sexual violence. In 2010, statistics from 60 countries found reported rape rates ranging from 0.0 to 92.9 per 100,000 population (with the majority between I and 30 per 100,000 population);²⁴ actual rates are likely much higher due to known problems with underreporting. EC is a critical part of post-rape services as it allows women the chance to prevent unintended pregnancy and the subsequent health risks, particularly in settings where abortion services are legally restricted. In order to provide EC and other services to survivors in a timely manner, it is essential to provide services not only in health care settings but also at other first points of institutional contact, such as police facilities. Recent clinical and policy guidelines published by WHO in 2013 recommend provision of EC to all women who present for services within five days of a sexual assault¹⁵—a major milestone in efforts to ensure EC access for survivors of sexual violence. Some governments including Kenya, Bolivia, Ecuador, South Africa, and the United States have national guidelines on sexual assault that explicitly recommend EC provision;²⁵ work in many settings to expand EC access has been done in the context of services for survivors of sexual assault.

1.4.3 Refugees and Displaced Persons

In refugee camps and in crisis settings, including conflicts and natural disasters, many women are in particular need of EC. In these settings, contraceptive supplies may be disrupted, and women are often forced to move from their homes. Sexual assault and transactional sex increase significantly. WHO's

Inter-Agency Working Group (IAWG) for Reproductive Health in Refugee Situations developed the Minimum Initial Service Package to address the reproductive health needs of displaced women and girls, and EC is included as one of the services to be provided.²⁶ WHO has also included EC in the New Emergency Health Kit, a package of basic commodities delivered immediately to every newly identified emergency site.²⁷

In 2011, the UN High Commissioner for Refugees and the Women's Refugee Commission undertook a multi-country baseline study on knowledge and practices around family planning as well as the state of service provision in Djibouti, Jordan, Kenya, Malaysia, and Uganda.²⁸ While there was variation among the countries, knowledge and use of EC was very low in all settings, and EC was only available in the context of post-rape care. Another recent evaluation of EC provision in refugee camps and post-conflict settings in the Democratic Republic of the Congo, Ethiopia, Kenya, and Jordan by the International Rescue Committee revealed low levels of knowledge about EC among providers (only 25% knew the correct time period that ECPs can be taken) and identified the need for ongoing technical support, supply chain management, and interventions to identify survivors of sexual assault, in addition to provider behavior change interventions, in order to ensure EC access for women in these settings.²⁹ The 2011 IAWG meeting report identifies a number of obstacles to the use of EC in humanitarian response that mirror the general barriers to EC implementation already discussed, including: provider knowledge and attitudes, lack of dedicated ECP products (especially in Central Africa and the Middle East), and the failure to mainstream EC into family planning services.³⁰

2. Emergency Contraception: State of the Art

2.1 Clinical Aspects of Emergency Contraception

There are three types of EC: (1) dedicated ECPs, including levonorgestrel-only pills (LNG ECPs), ulipristal acetate (UPA ECPs), a progesterone receptor modulator, and mifepristone, another progesterone reception modulator;² (2) oral contraceptive pills containing progestin and estrogen taken in a specific timing and dosage sequence known as the Yuzpe method; and (3) the copper-bearing IUD. This section briefly reviews clinical and epidemiological evidence regarding ECPs, which have been proven safe and effective when taken as instructed by clinical guidelines. While dedicated products allow for the most efficient service delivery of ECPs, where they are not available, the Yuzpe method can be an

Box I: Mechanism of Action

How do ECPs prevent pregnancy?

- Primary mechanism: Disruption of ovulation
- May prevent the sperm and the egg from meeting
- Existing data do not support the theory that ECPs inhibit implantation of fertilized egg in the endometrium

ECPs do not have an effect on pregnancy and are not an abortifacient.

alternative. For more detail, there are a number of excellent resources that provide the latest on clinical aspects of ECPs, including the 2012 revised clinical guidelines by ICEC and the International Federation of Gynecology and Obstetrics (FIGO) (see Appendix 1).

2.1.1 Safety and Efficacy

There is strong evidence supporting the safety of all forms of ECPs for all groups of women, including adolescents. Frequent use of ECPs poses no known health risks, is considered safe, and no evidence exists suggesting harm to a developing fetus.³¹ WHO does not recommend ECPs as a regular or "ongoing" method of contraception because of the "higher possibility of failure compared with non-emergency contraceptives."³¹ There are no medical contraindications to using dedicated ECPs, according to WHO medical eligibility criteria.³² LNG ECPs reduce pregnancy risk by at least 50% (and up to 80-90%) for one act of unprotected intercourse, and UPA and mifepristone ECPs are more effective than LNG ECPs.³³

2.1.2 Impact on Sexual Behavior

A recent published opinion of the American Congress of Obstetricians and Gynecologists Committee on Health Care for Underserved Women (US) states that access to EC among adolescent and adult women is not associated with less contraceptive or condom use or more unprotected sex.³⁴ A meta-analysis of randomized controlled trials comparing advance provision of EC to standard access found that advance provision did not increase sexually transmitted infection (STI) rates or unprotected sex, or lead to lower condom use rates among women in several developed and developing countries.³⁵ Another recent systematic review of randomized-controlled trials providing data on safety and efficacy of advance provision of ECPs in several developed and developing countries also concluded that offering adolescent and adult women an advance supply of ECPs during routine reproductive health care visits is safe and increases use of ECPs after unprotected sex.³⁶

Despite clear guidance on the above clinical aspects of ECPs, myths persist globally (see Box 2).³⁷

^aThe use of mifepristone as an abortion pill has limited its acceptability as an ECP and it is only available in Armenia, China, Russia, and Vietnam as a dedicated ECP product according to the ICEC website (http://www.cecinfo.org/ec-issues/ec-medical-abortion/).

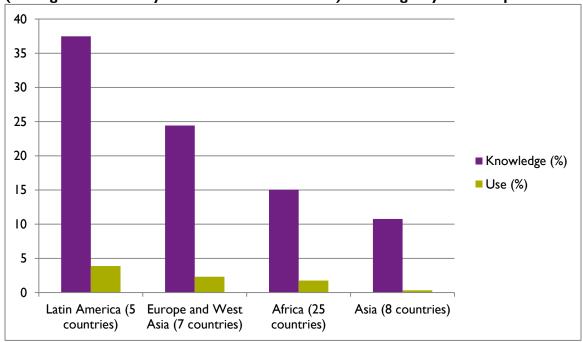
Box 2: Debunking the myths about ECPs

Concern/Misunderstanding		Evidence/Reality
Mechanism of action : ECPs act as an abortifacient	\Rightarrow	ECPs do not cause abortion or harm future fertility [ICEC and FIGO, 2012]
Impact on behavior: EC leads to risky sexual behavior	\Rightarrow	Access to EC among adolescent and adult women is not associated with less contraceptive or condom use or more unprotected sex [American Congress of Obstetricians and Gynecologists (ACOC 2012; Polis et al. 2007]
Safety : ECPs are not safe, especially if used multiple times or when a woman is pregnant	\Rightarrow	ECPs are safe and side effects are uncomm and generally mild. Repeat use is not harm ECPs do not have an effect on pregnancy or cause harm to a developing fetus if a woma is already pregnant [ICEC and FIGO, 2012; WHO 2012].

2.2. Knowledge and Use of Emergency Contraception

A recent review of Demographic and Health Surveys data from national household surveys in 45 countries analyzed trends in knowledge and use of EC from the most recent survey available in each country between 2000 and 2012.³⁸ Knowledge (among all women surveyed) and ever use (among women who had ever had sex) of EC are correlated; Latin America reported the highest knowledge and use of EC (34.8%, 3.5%, respectively), followed by Europe and West Asia (24.4%, 2.3%), Africa (15.0%, 1.8%), and Asia (10.8%, 0.3%) (see Box 3). In all regions, there was significant variation among countries.

Box 3. Regional variation in percent knowledge (among all women surveyed) and use (among women surveyed who have ever had sex) of emergency contraception³⁸



The global data related to knowledge of EC make clear that much more needs to be done to ensure all women are aware that EC is an option to prevent pregnancy after unprotected sex, method failure, or forced sex. Because ECPs are not viewed as a regular method of contraception and do not contribute to the national contraceptive prevalence rate (CPR), the 'ever use' indicator is less helpful in terms of monitoring whether women's contraceptive needs are met.

2.3 Service Delivery

When considering introduction, scale-up, and sustained implementation of ECP programs, it is essential to consider the various service delivery mechanisms and their unique roles in ensuring women's access to EC. These mechanisms—including public and private sector health services, pharmacies, and social marketing outlets—vary by country and region, depending on national policies and historical factors, and can serve to complement and reinforce one another.

The fact that, in order to be effective, EC must be used within five days of unprotected sex has implications for service delivery: women (and, in some cases, their partners) require rapid access, including on nights and weekends. Settings with limited hours or appointment requirements may limit women's access to EC. Provision of ECPs to women in advance of need has been tested and sometimes promoted. A meta-analysis of randomized, controlled trials comparing advance provision to standard provision found that advance provision increased use and led to faster use of EC,³⁵ and another more recent systematic review of randomized, controlled trials of advance provision also concluded that advance provision leads to higher use and does not appear to impact use of other contraceptive methods.³⁶ Thus, consideration of service delivery mechanisms must include both advance and standard provision of ECPs.

2.3.1 Commercial Sector

A number of companies throughout the world produce and distribute brand-name and generic dedicated ECP products. ECPs are sold in the private, commercial sector in virtually all countries that have a dedicated product. The 2012 ICEC Medical and Service Delivery Guidelines acknowledge the important role of pharmacies in disseminating information about EC to women and making ECPs accessible over the counter.³³ Though available figures are limited, commercial sales appear to be increasing and to outnumber EC procurement by donors and organizations listed in RHInterchange, the database of global contraceptive procurement maintained by the Reproductive Health Supplies Coalition.³⁹

2.3.2 Nongovernmental Sector and Social Marketing

As representatives of civil society, NGOs have an important role to play in terms of advocating for government fulfillment of its responsibility to coordinate and invest in efforts to expand access to EC. Aside from social marketing of EC, NGOs may directly provide services, as well as important technical assistance to the public sector in reaching special populations. For example, recent experiences in Mozambique and Ethiopia have shown that NGOs can play an important role in facilitating and contributing to increased access to EC in youth-friendly services and comprehensive services for survivors of sexual assault.²²

Some not-for-profits and NGOs promote and sell ECPs through a variety of social marketing approaches, including distribution of ECPs through commercial outlets as well as via public and private health care providers. Social marketing typically involves innovative branding and/or advertising of ECPs, as well as subsidies to make products more affordable to consumers in the developing world. According to 2010 contraceptive social marketing statistics from DKT International, their market for socially marketed ECPs grew in both number of countries (from 14 to 69) and sales (from 2.5 million to 8.8 million) between 2004 and 2010.40 However, a recent review highlighted the lack of published data on the incorporation of EC into family planning social marketing programs, and through interviews with

four major international social marketing organizations determined that only 33% of country family planning social marketing programs include EC.41 The authors identified the following barriers to incorporation of ECPs into social marketing programs: regulatory environments that pose barriers to product registration, legal restrictions that impact EC accessibility or sales, the influence of religious institutions and national governments who deem EC "politically sensitive," and lack of donor funding.41 Most importantly, enormous resources are required to socially market any dedicated family planning product (including obtaining the product, developing and printing packaging, maintaining warehouses, implementing sales and distribution strategies and channels, developing and executing advertising and marketing campaigns, collecting revenues, and performing the necessary accounting and monitoring functions). Social marketing is therefore not often justified given limited resources, known lack of demographic impact, and relatively poor efficacy of EC (as compared to correct and consistent use of pills and injectables, for example) in preventing unwanted pregnancies. Nevertheless, because socially marketed products are typically available at lower cost than commercial products in the private sector, this is an important route to consider (in the right setting) for expansion of EC access. This is true even in cases where ECPs are already widespread in the private sector, because commercially priced EC products may not be affordable to a large percentage of women.

2.3.3 Public Sector

The public sector has an important role to play in the provision of ECPs across many settings due to its responsibility for coordinating integration of EC into the health system—including the private, social marketing, and NGO sectors. Offering dedicated ECPs and raising awareness of them in the public sector is critical to efforts to integrate EC into a country's contraceptive method mix and also offers an important opportunity to bridge clients to other important reproductive health services (e.g., HIV/AID/STI prevention and treatment, routine family planning, and post-rape care). According to a recent survey of 40 USAID priority countries, however, ECPs were often offered in the commercial sector (81%), but fewer countries reported offering this method in the NGO (58%) or public (54%) sectors.⁴² In some cases, the focus on EC in the public sector is predominantly on sexual violence survivors.

2.3.4 Service Delivery Challenges

No matter the sector delivering EC services, programs have faced some common challenges. These include ensuring health care provider knowledge and attitudes are conducive to ECP provision and bridging ECP users to regular contraceptive methods.

Provider knowledge and attitudes: Even when appropriate policies are in place that support the availability of EC, until providers know what EC is and are comfortable offering EC, access for women will be limited. A review of EC program experiences from Africa, South and Southeast Asia, and Latin America and the Caribbean underscored provider training as vital for the introduction of EC and pointed to the importance of incorporating EC into pre-service training in comprehensive family planning counseling in addition to EC-specific workshops.¹⁹

An extensive literature review of provider-related barriers to EC access uncovered wide variation in EC knowledge, attitudes, and practices by provider type and in different country and provision contexts.⁴³ Provider knowledge of EC ranged from one-quarter to over 90% among the studies reviewed and a similarly wide range of correct knowledge existed when providers were asked about the period of time for EC effectiveness.⁴³ A few studies reviewed also asked providers about their beliefs regarding whether EC is an abortifacient and most found significant proportions of providers (between one-third to one-half) who believed EC is.⁴³ In terms of attitudes, in general, providers were more supportive of EC use in cases of rape than in situations of contraceptive failure or unprotected sex, and many believed that EC use increases promiscuity and sexual risk-taking.⁴³ The most conservative attitudes were found in relation to adolescents, with low rates of approval for EC provision to young women. The positive

correlation observed between knowledge and supportive attitudes is encouraging as it suggests more positive and supportive attitudes are possible through training.⁴³

Another aspect of provider knowledge and attitudes that has the potential to impact service provision is related to opinions about 'repeat' use of ECPs. As discussed above in the section on the clinical state-of-the-art, frequent use of ECPs poses no known health risks and is considered safe.³³ Access to EC is not associated with less contraceptive or condom use or more unprotected sex.⁴⁴ However, studies have revealed misconceptions about the safety of repeated use among providers. Negative attitudes towards frequent use conveyed in training materials and country provision guidelines have the potential to limit women's access to ECPs.⁴³

Bridging to other contraceptive methods: Because ECPs are not intended for ongoing contraceptive use, there is interest in using ECP provision as an opportunity to "bridge" women to other contraceptive methods and reproductive health services. Studies in Bangladesh and India have both shown increases in the proportion of women using a regular method of contraception after use of ECPs, from 72% to 93% in Bangladesh⁴⁵ and from 67% to 78% in India.⁴⁶ However, bridging has proven challenging in some cases, in part because programs have not fully addressed the fact that EC users are not a homogenous group and not all need bridging to longer-term contraception due to infrequent sex or already having an ongoing method.⁴⁷ Additionally, many women access ECPs in pharmacies because of the anonymity, convenience, and speed of this type of service delivery point; however, these same characteristics make it difficult to provide more extensive counseling on EC and other contraceptive methods or other reproductive health services.

2.4 Policy, Legal, and Regulatory Environments at Country Level

A number of national policies are important to introducing, supporting, and scaling up EC in the different sectors described above. These include registering a dedicated ECP in national essential medicines lists and national reproductive health guidelines, and addressing logistics systems issues for EC. In addition, ensuring there are no unnecessary legal or regulatory barriers to EC access is critical. National policy, legal, and regulatory environments are influenced by important global trends discussed in section one of this paper, which provides the historical overview of EC.

2.4.1 Registration of Dedicated Emergency Contraceptive Pills

As of April 2013, 144 countries had registered at least one brand of ECPs.⁴⁸ The Emergency Contraception website (www.not-2-late.com) maintains a database of the brand names of dedicated ECPs registered in most countries. The majority of these countries have registered the LNG ECPs.

2.4.2 Inclusion of Emergency Contraceptive Pills in National Guidelines and National Essential Medicines Lists

Inclusion of EC in government reproductive health guidelines is an important step towards integrating ECPs into the health system and family planning services as it sets the expectation that public and private sector providers counsel women about and provide EC, and creates standards that can be monitored for adherence. A recent review of EC programs in three regions pointed out that NGOs have played an important role in hosting international workshops to disseminate expert knowledge and advocate for regulatory and policy changes as well as offer technical assistance to update guidelines with EC information.¹⁹

In a 2011 survey, 26 of 40 (65%) USAID priority countries reported that ECPs were included on their national essential medicines lists.⁴² According to the ICEC website, to date there are a total of 58 countries known to include EC within their essential medicines list.¹⁰⁰

2.4.3 Emergency Contraception Logistics

ECPs pose unique challenges to contraceptive distribution systems for several reasons, as highlighted in a recent USAID Contraceptive Security Brief.⁴⁹ Forecasting demand for ECPs can be more difficult than for other contraceptive methods because demand is inherently unpredictable given that ECPs are not intended for regular use and because they are a new method in many public sectors. ECPs are also often not included on routine reporting and ordering forms because use is so low compared to other contraceptive methods. ECP distribution systems have the added challenge of making sure ECPs are available in a variety of outlets, not just within the health system (i.e., pharmacies, health care services, community health workers), but also in locations, such as refugee camps, prisons, and schools.

2.4.4 Legal and Regulatory Barriers

One common regulatory barrier to EC distribution is that some national drug authorities require that ECPs only be available with a prescription. The 2012 ICEC Medical and Service Delivery Guidelines recommend ECPs be available without a prescription: "Because no clinician screening or assessment is needed and women can decide on their own whether the treatment is needed, ECPs may appropriately be sold over the counter, as they are in most countries." According to the ICEC website, 17 countries allow direct over-the-counter access and 56 allow access from a pharmacist without a prescription. Another barrier to EC access is the existence of "conscience" clauses that give providers the ability to refuse to provide EC (and other reproductive health services) due to personal beliefs; these can limit women's timely access to EC when no mandate for referrals to other services exist. A desire to limit young people's access to EC also leads to age limits in some contexts. Legal challenges to EC distribution exist in some places due to the belief that EC is an abortifacient, particularly in Latin America—an extreme case being Honduras which banned free distribution and sale of ECPs in 2009. Finally, the limited capacity of regulators in many settings to monitor the quality of ECP products has been a problem in some instances.

3. Methods

The aim of this report is to identify elements of successful ECP program implementation through an indepth examination of four country case studies chosen to illustrate challenges and opportunities for introduction, scale-up, and sustaining ECP programs within health systems. Two complementary frameworks are used in the analysis to allow for an understanding of the initial introductory steps and, within the larger health system context, the necessary elements of successful scale-up and sustainability. The country case study analysis and recommendations in this report can be used to guide evidence-based integration of ECPs into health systems and help make access to ECPs a reality for more women around the world.

3.1 Country Selection

This section describes the systematic approach that the USAID-funded Evidence to Action for Strengthened Family Planning and Reproductive Health Services for Women and Girls (E2A) Project applied to select four countries that provide a good representation of the ECP program maturity trajectory from less mature (introduction phase) to most mature and sustainable, and the data sources and analytic approach utilized to enable a comprehensive understanding of successes and challenges in ECP program implementation globally.

E2A approached country case study selection in two stages. The selection criteria for the first stage were **availability** (EC availability at public and/or private facilities and supportive policies in place) and **accessibility** (women's knowledge and use of EC, public sector and social marketing distribution figures). E2A conducted a comprehensive literature review on global EC programs by searching the websites of WHO, USAID, Population Council, Pathfinder International, Guttmacher Institute, ECAfrique, K4Health, DHS, and PATH, looking for key documents including demographic information, public sector procurement data, social marketing statistics, and program and research reports. Literature was also reviewed from the ICEC website and ICEC country reports. This literature review revealed 19 countries with available EC programming information: Bangladesh, Democratic Republic of the Congo, Ghana, Egypt, India, Indonesia, Kenya, Mexico, Nepal, Niger, Nigeria, Pakistan, Peru, Philippines, Senegal, South Africa, Sri Lanka, Venezuela, and Zambia. Ten out of these nineteen countries met at least two of the availability and two of the accessibility criteria.^b

In the second selection stage, evaluating **regional representation** (South Asia, West Africa, East Africa, and Latin America) and **program maturity** (different stages of program implementation from those that are mature and sustainable to those in the process of scaling up) culminated in the selection of four countries: Senegal (West Africa, Program Introduction), Kenya (East Africa, Program Scale-up), Bangladesh (South Asia, Program Scale-up), and Mexico (Latin America, Program Sustainable). Looking at regional representation and various stages of program maturity provided a robust platform for guidance on why ECPs programs are sometimes not successfully implemented. Programs at earlier stages of maturity can provide a fresh view on steps taken to introduce ECPs, challenges faced, and how those various challenges were addressed.

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^b These were the most current data available at the time of this report's analysis in November 2013.

The table below displays relevant indicators for each of the four countries, highlighting the range of different contexts related to the four selection criteria, and provides basic demographic data.

Box 4: Country case studies: selection criteria and demographic indicators

Box 4: Country case studies			<u> </u>	
	Mexico	Bangladesh	Kenya	Senegal
Region	Latin America	South Asia	East Africa	West Africa
Relative Program Maturity (I=most mature)	I	2	3	4
Demographic data				
Population, women I 5-49 (millions)	32.4	47.4	11.1	3.7
Total Fertility Rate	2.3	2.3	4.4	5.0
Contraceptive Prevalence Rate (modern methods) (%)	66	52	39	12
% Urban	78	25	18	43
Availability of ECPs				
Policy support ²				
Essential Medicines Lists	Yes	No	Yes	Yes
Family planning norms	Yes	Yes	Yes	Yes
Pharmacy access	Behind the	Over the	Behind the	Behind the
	counter ³	counter⁴	counter	counter
Post-rape care guidelines	Yes	Unclear	Yes	No
Number of registered dedicated products	12	2	9	3
Public sector procurement	Data unavailable	Data unavailable	5,875,000 in 2009; ⁵ 300,000 in 2013 ⁶	Data unavailable
Social marketing ⁷	6 (2011) and 0 (2012)	N/A	886,200 (2011) and 271,950 (2012)	N/A
Private sector sales	6.8 million/year ⁸	Data unavailable	138,000/month in 2009 ⁹	90,000/year ¹⁰
Accessibility of ECPs ¹⁰				
Knowledge	76% (2009)	N/A	40% (2008-09)	13% (2010-11)
Use (ever use)	6% (2009)	N/A	2% (2008-09)	0.2% (2005)

I. Population Reference Bureau, "Data Finder," accessed July 29, 2013, http://www.cecinfo.org/country-by-country-by-country-information/status-availability-database; 2. ICEC, "EC status and availability database," accessed June 11, 2013, http://www.cecinfo.org/country-by-country-information/status-availability-database; 3. "Behind the counter" is ICEC's classification of locations where ECPs are available directly from a pharmacist without a prescription; 4. "Over the counter" is ICEC's classification of locations where ECPs are available without having to go through a pharmacist; 5. Jill Keesbury, Monica Wanjiru, and Katherine Maina, Mainstreaming Emergency Contraception Pills in Kenya: Policy Brief (Population Council, Kenya Ministry of Health, PSI, Hewlett Foundation, 2010); 6. Arthur Okwemba, "Ministry cuts e-pill orders as big stock goes to waste," Daily Nation, January 19, 2013; 7. DKT International, Contraceptive Social Marketing Statistics 2012 (Washington, DC: DKT International, 2013); 8. ICEC, "EC status and availability database"; 9. James Githinji, "EC Provision in Kenyan Pharmacies," Presentation to International Consortium on EC, 13-14 October, 2010; 10. Key informant from NGO sector in Senegal; 11. For Kenya and Senegal, knowledge and use data is from the DHS. EC was not included in the Bangladesh DHS. Mexico data is from 2009 nationally representative demographic survey conducted by the National Institute of Statistics, as cited on the ICEC website (http://www.cecinfo.org/country-by-country-information/status-availability-database/countries/mexico/).

3.2. Data Sources

In each of the four chosen countries, the authors reviewed published and grey literature and conducted interviews with key informants. Key informants were selected from the following categories to represent a diverse range of stakeholders and to elicit a comprehensive overview of the ECP program in each country: 1) ministry of health; 2) pharmaceutical company; 3) research organization; and 4) professional association. During the interviews, three attempts were made to identify and interview at least one respondent from each of these four categories. The figure below illustrates the methodology described in this section, while the table on page 20 (Box 5) summarizes the number and type of key informants interviewed for each case study.

Comprehensive Literature Review 19 countries with ECP programming information. Accessibility **Availability** women's knowledge, use; at public/private facilities; distribution figures supportive policies in place 10 countries meet at least 2 availability and 2 accessibility criteria. **Diverse Stages Diverse** of Program Regional Maturity Representation 4 countries illustrate diverse program maturity, regional representation. Senegal **Bangladesh** Kenya Mexico Data Data Sources Sources **Desk Review** published and grey literature **Key Informant Interviews** ministries of health research organizations professional associations

Figure I – Country Case Study: Selection and Data Sources

Box 5: Key informant interviews

Interviewer Category	Mexico	Bangladesh	Kenya	Senegal	Total
Ministry of Health	I	I	I	2	5
Pharmaceutical Company	0	0	0	0	0
Research Organization	2	2	2	1	7
Professional Association	0	0	I	0	I
Total	3	3	4	3	13

E2A developed a semi-structured interview guide after careful review of the literature to identify knowledge gaps related to ECP introduction and scale-up (see Appendix 2: Key Informant Interview Guide). Following pre-testing, the guide was revised. Interviews, in English and French when applicable, were conducted electronically via telephone, Skype, or email by two interviewers. Verbal consent was obtained prior to conducting each interview, and the interviewer took careful notes during each interview.

While it was initially deemed important to talk to representatives of pharmaceutical companies in each country, no respondent from this category in any of the countries was identified. Likewise, only one respondent from the "Professional Association" category was identified (Kenya) for interviewing in this study.

3.3 Analysis

Two analytical frameworks were used to guide the analysis of the four cases. The ICEC 9-Step Framework is an EC-specific, stepwise model that provides a framework for understanding the introduction of EC in a new country context. The WHO Health Systems [HS] Framework provides a more general, complementary framework relevant for understanding the necessary elements of successful scale-up and sustainable integration of ECPs in a larger health system context. Organizing available information for each of the four countries by each element of the two frameworks allowed for systematic identification of lessons learned related to introduction and health systems sustainability, as presented in the recommendations section of this report.

The ICEC 9-step Framework provides a specific series of actions countries can take to develop an evidence-based programmatic approach to introducing and ensuring EC availability and accessibility. As conveyed in the four case studies, the steps can be applied in different sequences depending on the country context where the EC introduction is taking place. The nine steps are summarized on the next page (see Box 6). The ICEC framework was designed to facilitate a participatory, flexible process of introducing EC, ideally in the context of strong family planning programs that offer a range of contraceptive methods.⁵²

Box 6: ICEC 9-Step Framework⁵²

ICEC 9-Step Framework	Description of steps
Step I – Assess user needs and service capabilities	Assess information and service needs of potential EC users, national regulatory requirements, and health service delivery capabilities.
Step 2 – Build support for EC introduction at appropriate levels	Involve a range of stakeholders, including government officials and community leaders, and take their priorities into consideration. Address any stakeholder concerns by providing evidence-based information.
Step 3 – Select a product	Choose a dedicated ECP product (pills packaged and labeled specifically for EC use) for registration.
Step 4 – Develop a distribution plan	Consider a variety of distribution channels: family planning program service delivery points (i.e., clinics and community-based distribution mechanisms), private sector mechanisms, emergency rooms, pharmacies, social marketing programs, schools, etc. Ensure contraceptive logistics system and record-keeping systems include ECPs and distribution channels are accessible and acceptable to clients.
Step 5 – Identify and meet clients' information needs	Identify current knowledge levels and consider a variety of mechanisms for informing women about EC: regular health care visits, mass media, Internet, advertising campaigns, folk media (e.g., local theater), or community-based organizations (e.g., churches, schools).
Step 6 – Train providers	Provide information to providers on ECPs and respectful, non-judgmental treatment of women. Include EC in overall training on family planning.
Step 7 – Introduce the product	Roll out distribution plan and publicize the launch.
Step 8 – Monitor and evaluate EC services	Assess user and provider perception of and experience with ECPs and service delivery mechanisms to inform adaptations to distribution and education strategies.
Step 9 – Disseminate evaluation results	Use monitoring and evaluation results to develop strategies for scaling up ECP provision.

The WHO Health System Framework describes common elements of all health systems and provides a useful guide for efforts to *scale up and sustain services* such as EC. This framework includes six building blocks that represent the basic functions of a health system needed to improve health outcomes (see Box 7).⁵³

THE WHO HEALTH SYSTEM FRAMEWORK

SYSTEM BUILDING BLOCKS

OVERALL GOALS / OUTCOMES

SERVICE DELIVERY

HEALTH WORKFORCE

INFORMATION

MEDICAL PRODUCTS, VACCINES & TECHNOLOGIES

OVERALL GOALS / OUTCOMES

IMPROVED HEALTH (LEVEL AND EQUITY)

RESPONSIVENESS

SOCIAL AND FINANCIAL RISK PROTECTION

SAFETY

Box 7: WHO Health Systems Framework⁵³

FINANCING

LEADERSHIP / GOVERNANCE

Source: WHO, "Everybody's business: Strengthening Health Systems to Improve Health Outcomes, WHO's Framework for Action," (Geneva: WHO, 2007)⁷⁵

First, service delivery refers to delivery of effective, safe, quality health interventions to those who need them in a timely and accessible manner with minimum resource waste; second, health workforce refers to staff who are responsive, fair, and efficient; third, information systems refers to a health information system that ensures production and use of reliable and timely information on health determinants, system performance, and health outcomes; fourth, medical products, vaccines, and technologies refers to equitable access to these resources that are high quality, safe, efficacious, and cost-effective, and used in an evidence-based, cost-effective manner; fifth, financing refers to adequate health funds that ensure people are able to use services and not experience financial catastrophe or impoverishment as a result; and finally, leadership/governance refers to strategic policy frameworks, effective oversight, coalition-building, appropriate regulations and incentives, system design, and accountability. Outcomes in this framework include improved health outcomes, equity, responsiveness, and efficiency of the health system, and social and financial risk protection.

IMPROVED EFFICIENCY

Strengthening each component through a coordinated health system wide effort has the greatest potential for ensuring availability and access to EC. Box 8 displays the relevance of each of these six building blocks to national efforts to scale up and sustain ECPs.

Box 8. Relevance of EC scale-up and sustainability to WHO health system building blocks

WHO HS building blocks	Relevance for EC scale-up and sustainability
Service delivery	Is EC currently available and accessible to women who need it? Are services of high quality (e.g., is EC well integrated into other family planning and reproductive health services)?
Health workforce	How well-trained are providers (i.e., pharmacists, doctors, other medical personnel who counsel women on and offer women EC)? What is interpersonal and managerial quality of care? Is EC in the training guidelines for providers?
Information systems	Are information systems for tracking EC knowledge and use and product availability/demand sufficient?
Medical products	Are EC products up to manufacturing standards? How many registered products are there? Is EC included in the Essential Medicines List?
Financing	Does health system financing allow for affordable EC in public and private services?
Leadership/governance	Do health officials champion the need for EC and how is leadership generally in the health system (in terms of for example, accountability, oversight, and long-term planning)? Is EC in national family planning policy guidelines?

The information from the literature review and stakeholder interviews were analyzed utilizing the corresponding steps (Step I through Step 9) from ICEC's 9-Step Framework (Box 6) and the six elements of WHO's Health Systems Framework (Box 8) to illustrate the factors that contributed to success and failures as countries went through the phases of introduction, scale-up, and sustaining EC within their respective health systems. Each country case study provides a unique set of achievements and challenges that reflect regional, country, and cultural contexts.

3.4 Limitations

Our analysis of the four country case studies has several important limitations. First, the most up-to-date information on all elements of the ECP programs in these four countries may not be presented in this paper, due in part to difficulties in locating and conducting interviews with all four types of key informants in each country. For example, none of the country case studies benefits from the perspective of the pharmaceutical industry. Additionally, the report relies on information from key informants for some facts and figures related to ECPs distribution and sales. This kind of data is not verifiable due to the lack of published information.

In addition, while the qualitative nature of interview findings allowed us to explore in-depth issues related to ECPs introduction and scale-up, these four case studies do not necessarily represent those issues in other countries. While the criteria used for selecting the four countries allowed the sharing of

experiences and lessons learned from four very different contexts, the ability to transfer findings to other country contexts is limited given the unique social, political, cultural, economic, and historical factors in every country.

4. Country Case Studies

4.1 Mexico: Partners, Promotion, Products, Policies and Political Will

The Latin American Consortium for Emergency Contraception (CLAE) developed an index to describe the estimated percentage of potential users who have access to EC. The highest index score of 100% belongs to Mexico. How did Mexico—one of the four ICEC demonstration countries in the 1990s—achieve this and what does 100% access mean in reality? Mexico's story of introduction and expansion of EC provides a useful first case study as it is the most mature of the four EC programs reviewed in this report. Its level of maturity allows for a full exploration of the different stages of introduction, scale-up, and sustainability throughout the health system.

The EC introduction and scale-up experience in Mexico by the Mexican EC Consortium (MECC) led by the Population Council's Mexico office, and including a number of local partners is summarized in a book chapter from *Emergency Contraception: The Story of a Global Reproductive Health Technology.*⁵⁵ This and other available information published on Mexico's experience was supplemented by key informant interviews with three stakeholders: one representing the ministry of health and two from the non-profit research and technical assistance sector.

4.1.1 Introduction

Analysis: 9-step ICEC Framework

In 1994, the ministry of health was drafting family planning guidelines, including those related to the treatment and care of survivors of sexual assault. Some physicians and researchers attempted to get the "Yupze Regimen" of EC^c included in the family planning guidelines as a method women could use who forget to take their oral contraceptive pills, but came up against resistance from the ministry of health. One key informant named this time, "The pre-history of EC in Mexico."

An opportunity for funding and leveraging political will: Although the use of EC was considered very politically and religiously controversial in a country where Catholicism is the predominant religion and myths associating EC with being an abortifacient have been prevalent, an early USAID-funded project testing the feasibility and acceptability of including EC in sexual assault care levied the desire of state authorities to protect these survivors and introduce EC into health facilities. According to one key informant involved in this work, the big thing about this project is that it opened the gate for funding for EC. This was an important step in getting the product introduced into the country (Step 7), as well as beginning to build support for the product at various levels (Step 2). However, this project faced challenges to establishing buy-in from providers and supervisors. Their reluctance to provide the pills was rooted in a belief that they were an abortifacient. We faced the first round of providers and resistance and lack of knowledge and myths about EC, explained a key informant involved in this early work. Another said, "It took a long time. People were thinking this was abortion, which was then a crime in the code. Counselors were very reluctant but we ended up agreeing. We had a workshop and trained them to deliver EC, but we didn't see any effect in number of pregnancies. We made a very nice brochure. They started giving counseling, but they did not give the pills."

Assessing knowledge and attitudes: In 1997, a baseline survey of providers and clients in urban areas was conducted, showing that only about 30% of providers knew EC was a post-coital method.⁵⁷

^c The Yuzpe Regimen is a method of emergency contraception using a combination of estrogen and progestogen hormones and started within 72 hours of sexual intercourse.

d Liberalization of the abortion law in 2007 occurred only in Mexico City; abortion is still highly restricted outside of the capital.

Both users and providers overestimated EC's negative effects, although participants were "cautiously accepting" of the EC introduction (with a small minority opposing it). Only 18% of clients had heard of EC though they overwhelmingly reported that they would use it if needed. Providers favored EC distribution in medical settings while clients believed it should be more widely available (e.g., schools, vending machines) and advertised.⁵⁷ This assessment of user needs and service capabilities (Step I) proved critical to the introduction of EC in Mexico because it layered a good foundation to advocate for MOH support.

After disappointing attempts to convince local and international pharmaceutical companies to register a dedicated ECP, it was decided that introduction of EC would move forward, with emphasis on the Yupze regimen.⁵⁵ Pharmaceutical companies were concerned about potential controversy rooted in political and religious opposition from the Catholic Church, and Mexico did not have a registered ECP product until 1999.⁵⁸ One key informant stated, "I think we did the best thing we could do back then because if we had waited we would have lost a lot of time and opportunity. The message was it was out there and you have it in your hand and can use it. It would have been a strategic mistake to have waited."

Awareness and information campaign: Because EC was introduced in Mexico before an ECP product was registered, the distribution planning process was different from other contexts where a dedicated product has been integrated into an existing family planning system. Efforts to expand EC access focused primarily on provider training (Step 6) and information campaigns to raise public awareness about the Yupze regimen (Step 5). The awareness-raising and information campaign included a range of innovative efforts, including a media workshop to 'inoculate' the press and get free media exposure, marketing strategies on radio and television and through postcards, an innovative website, and a telephone hotline.55 The telephone hotline began in February 1999 and received more than 10,000 calls per month by late 2000.55 One key informant explained, "we started small and then we had promotions, hotlines, postcards... it was incredible. It was one of the best stories I can tell in my life—it was selling like red hot in the middle of nowhere. Women really needed it." Working through these information campaigns helped reinforce the introduction of EC and increase distribution. There were also early efforts to inform doctors, pharmacists, and factory workers about EC by mailing booklets and posters which reached approximately 18,000 physicians, 16,500 pharmacists, and 2,100 assembly plants.⁵⁹ Those reached responded positively, with most doctors and pharmacists reporting that they gave information to women in need of EC and discussed EC with their colleagues within three weeks of receiving the materials.⁵⁹ As one key informant stated about this project, "this was an unknown method, so we needed to disseminate information on this method. The Mexican media picked up the topic." Mass media involvement resulted in several articles, radio spots, and television programs. Another comment from this key informant about the project pointed to the potential to involve physicians in the work by giving them the opportunity to position themselves as experts on a new technology: "One thing that struck me—there are always people searching for new things to present. As part of the project we had a group of physicians who went and did presentations in different states. It was easy to find people to position themselves as experts. Physicians are always searching for new things that they can be knowledgeable about."

Training providers: Training providers was another essential component in the EC introduction process (Step 6). MECC partners trained a wide range of health care providers, including those employed at universities, Mexfam (an International Planned Parenthood (IPPF) affiliate), and the two main social security systems. Within the ministry of health, 600 federal-level providers were trained, who then went on to train roughly 12,000 state-level providers.⁵⁸

Building support: Another important aspect of the EC introduction included building support for the product at various levels (Step 2). In 1997, the MECC brought together a range of stakeholders, including universities, medical and nursing schools, the media, and eventually (after much persistence)

the pharmaceutical industry. ⁵⁵ The availability of peer-reviewed, Spanish-language publications in Mexican journals have lent credibility to the consortium's efforts. ⁶⁰

Monitoring and evaluation: The EC introduction included a monitoring and evaluation (M&E) component (Step 8). A follow-up to the small 1997 baseline survey was conducted in 2000 and found increased awareness of EC among providers (from 88% to 100%).⁶¹ Large national surveys from 2000 and 2006 revealed a doubling in EC knowledge among the public (from 31% to 59%) in those six years.⁶² According to another national survey in 2009, three-quarters (75.8%) of women know about EC and ever use was measured at 5.8% (and even higher in younger age groups—among 15-19 year olds, 22.2% reported EC use, and among 20-24 year olds, 12.9% reported use).⁶³

4.1.2 Transition from Introduction to Sustainable Scale-up

In 2004, EC was added to the family planning norms and remained despite constitutional opposition by anti-abortion groups.⁵⁸ ECP's inclusion in the norms was crucial for several reasons: it regulated ECPs provision in both public and private services, established standards and allowed for M&E, legally protected and obliged clinicians to supply the method, and facilitated access to dedicated products.⁶⁴ Introduction of ECPs to the Essential Drug List in 2005 was another important milestone in the scale-up process. One key informant noted, "once it's in there [the EDL] it's difficult to take away." In May 2010, Mexico's Supreme Court required the distribution of EC to rape victims.⁶⁵

4.1.3 Sustainable Scale-up

Analysis: WHO Health Systems Framework

In order to understand what happened in the years following initial introduction of ECPs in Mexico, and to glean lessons learned from the Mexican experience, the six elements of the WHO Health System Framework were used to organize information about the process of scale-up that culminated in Mexico achieving sustained ECPs availability and accessibility.

One key aspect of ensuring ECPs' sustainability in Mexico has been ensuring their availability through different **service delivery** points. Since 2003, when a dedicated EC **medical product** became available, according to one key informant, it is estimated that at least 30 million doses have been sold. One respondent pointed to the fact that with so many drug stores offering EC, there is widespread access: "Mexico is filled with drug stores. There are more drug stores than tortillerias and they are open practically all day and night." However, another key informant pointed to the difficulties of working with pharmacies to ensure quality and availability because, "the big pharmacy chains that dominate the market tend to be very conservative," and, as another key informant also pointed out, turnover in pharmacy staff also presents a challenge.

Given some of the challenges surrounding availability, one informant from the NGO sector pointed to the need for further evaluation in this area: "So much time after this introductory effort to get EC into the mainstream RH services and nobody has looked at it and tried to evaluate whether those efforts were effective. It is hard to design something, but even observational data would be useful." She also said: "In the public sector where these services are free or there is a sliding scale, it is a matter of treating this as a basic part of a package of care, but I'm not sure if that is taking place."

Another key informant highlighted that sustainability has been weak in the public sector because of its focus on special groups (i.e., youth or rape survivors). She suggested that focusing on alternative distribution mechanisms—such as schools or advance provision in health centers—is important: "Either we come up with alternatives to health centers or we work very hard on preventive prescription—every young person who comes to you for anything you give them a dose of EC or a prescription. Effectiveness comes down with time, so we shouldn't be giving through appointment in a public health center; either prescribe in advance or

we think of alternative ways to distributing, for example have boxes outside with both condoms and ECPs." Looking back on scale-up efforts, she reflects that more could have been done on this front though it was already challenging to convince doctors of the need for advance provision.

Another factor related to availability is the issue of **financing**. According to one key informant, although there are a variety of prices of ECPs in pharmacies "Some are cheap, but they could be cheaper."

Leadership demonstrated by key individuals in the ministry of health contributed to the successful scale-up and sustainability of EC. Dr. Julio Frenk, Mexico's minister of health from 2000-2006, most notably, was a critical champion of the EC scale-up process. As a strong advocate for EC and evidence-based policy, Dr. Frenk greatly influenced the ministry's decisions to support EC.

More recently, as one key informant from the NGO sector pointed out, there have been challenges to contraceptive access due to increasing federal government opposition to contraception. The recent passage of many state constitutional amendments in Mexico that grant defense of life starting at conception poses challenges to EC access as opponents define pregnancy as beginning with fertilization (rather than implantation) and use a biased interpretation of scientific evidence to argue that EC is an abortifacient. Ongoing challenges from anti-abortion groups persist. One key informant pointed out that those groups' efforts to restrict women's access to EC have become more sophisticated in their dialogue—using scientific language and misinterpretation of studies to convince professionals and the

public of the dangers of EC. She concluded that, "this all changes how we need to approach this [opposition from anti-choice groups] and how we respond."

4.1.4 Lessons Learned

A review of available literature and interviews with key informants revealed several key facilitating factors and barriers to Mexico's successful sustained implementation of EC throughout the country. These are summarized below.

"Getting EC into the norms provided another layer of political legitimacy and opened a bunch of pathways for providers and pharmaceutical companies to come in and grab this market."

- Researcher

Political will is invaluable: The role of the minister of health from 2000-2006, as a champion for EC was invaluable; as one key informant said, "People would say that the battle was won by civil society, but Dr. Julio Frenk at the MOH, he was instrumental. We have to thank him for the political will he had. ... These are things that I would include in recommendations to other countries: be brave, be coherent. These battles might cost a lot. This shows how evidence-based information is nothing without political will."

Supportive policies are essential to introduction and scale-up: The inclusion of EC in the family planning norms and on the Essential Medicines List were seen as key steps to institutionalizing EC into the Mexican health system in the face of controversy. As one respondent said, "getting EC into the norms provided another layer of political legitimacy and opened a bunch of pathways for providers and pharmaceutical companies to come in and grab this market... Before you knew it there were a ton of products around. And there was a lot of buzz." Having a dedicated product made a difference, in part, one person explained, because of the scientific evidence. "I am an OB/GYN and when I say it is safe I have evidence at hand. The discourse on safety was much easier to pass around with a dedicated product because of the evidence in the literature. The big change is the safety profile and peace of mind in saying to use it."

A wide range of partners took part in making EC available: They worked together for at least a decade. 55 As one respondent explained, "partners, partners, partners—no one can do this alone. It takes a concerted effort through diverse groups working together towards a common goal." In particular, the media training conducted early on was seen as quite beneficial.

Simultaneously promoting supply and demand was critical: An innovative awareness and information campaign was highly successful as EC became mainstreamed in public discourse: "It was even mentioned in telenovelas," one person explained. However, one key informant reflected on messaging around EC and wished the communication had focused less on EC being something only for emergency situations and more on encouraging women to take it whenever they need it.

Evidence-based advocacy can be powerful: Advocacy with health care provider associations (e.g., medical schools, nursing schools, pharmacies, etc.) using peer-reviewed, published (in many cases, Spanish-language) evidence, lent legitimacy to EC and led to acceptance in professional communities despite strong opposition by the Catholic Church. This struggle continues as religious groups remain opposed to EC.

Need for flexibility in terms of product registration: It was too hard initially to get a dedicated product registered in Mexico, so it was important to begin with promoting the Yuzpe regimen. It was clear that things really took off once dedicated products were available.

4.2 Bangladesh: From registered product to national family planning strategy

The strong legacy of the national family planning program in Bangladesh, combined with the need for solutions to address high rates of unintended pregnancy and maternal mortality from unsafe abortion, created a facilitating environment for the successful introduction of EC throughout the country. Additionally, a strong, established field worker program reached rural populations. Ultimately, after initial introduction of a product and subsequent collaboration among many stakeholders, Bangladesh has become one of the first countries to systematically introduce ECPs in the public sector.

The ECPs introduction and scale-up experience in Bangladesh is summarized in a book chapter from *Emergency Contraception: The Story of a Global Reproductive Health Technology.* 66 This and other available information published on Bangladesh's experience was supplemented with key informant interviews with three stakeholders: one from the ministry of health and two from the non-profit research and technical assistance sector.

4.2.1 Introduction

Analysis: 9-step ICEC Framework

Initial introduction of ECPs in Bangladesh began with registration of an ECP product in 1995 (Step 3) by a private company motivated by the large unmet need for family planning and high maternal mortality ratios at the time.⁶⁶ The company advertised its product as a post-coital contraceptive method through newspaper advertisements (Step 5).⁶⁶ Despite the lack of initial opposition from any political or religious group, sales remained low and the need for a national strategy to raise awareness and improve EC access became apparent.⁶⁶

Creating a consortium: A second phase of introduction began in 1997 when the Population Council and Concerned Women for Family Development hosted a two-day workshop, bringing together a range of stakeholders to share EC information and develop future plans for expanding EC (Step 2). As a result, the Forum for Emergency Contraception (FEMCON) was formed by the 23 organizations involved in the workshop, and technical meetings were held with the National Technical Committee which had subsequently recommended formative research to inform introduction of EC into the Bangladesh Family Planning Program (BFPP).66 A critical aspect of these collaborations was the focus on evidence; as one key informant stated, "your documentation should be very scientific- convince them with rigor... you need to understand the context and need to go with full documentation and proof. It is based on evidence not emotion."

Building the evidence base: Multi-phased operations research (Step I) led by the Population Council and supervised by a committee representing the public and NGO sectors revealed limited knowledge of EC and ineffective, harmful practices by women to prevent pregnancy post-coitally, as well as an acceptance of and willingness to purchase the method.⁶⁷ Operations research with I2 health clinics in two districts in 2001 concluded that incorporation of ECPs into the national family planning program would be feasible.⁶⁸

Developing an information campaign: With evidence of acceptability and feasibility of ECPs introduction in hand, a dissemination plan (Step 4) was put in place to garner support of ECPs from medical experts, media, policymakers, program managers, and NGOs, leading to eventual introduction of ECPs into the BFPP by the Ministry of Health and Family Welfare in 2001 (Step 1).66 According to a key informant, the Bangladeshi national government was very supportive of EC early on in this process.

Monitoring and Evaluating EC Services: Assessing service delivery quality was built into the introduction (Step 8) and subsequent scale-up plans.⁶⁶ Rapid appraisals revealed good quality ECP services, and follow-up assessments found retained levels of knowledge from initial provider trainings; however, evaluations also found that EC was not incorporated into overall family planning counseling.⁶⁶

During nine workshops held after introduction of ECPs throughout the entire country, several needed policy and operations adjustments were identified (including the need for advance provision, a single-dose regimen, and more educational outreach activities), many of which were then implemented by the national family planning program (Step 9).66

4.2.2 Transition from Introduction to Sustainable Scale-up

Two phases of ECPs scale-up occurred: first, ECPs were introduced in the Dhaka division (covering a population of approximately 45 million) beginning in 2003; then, in late 2004, the second phase began and ECPs was introduced in the other five divisions of the country (population 89 million), with adjustments made as needed based on results of the introduction in Dhaka during Phase I.66 UNFPA supplied I.9 million packets of ECPs for distribution between 2000 and 2003.66

4.2.3 Sustainable Scale-up

Analysis: WHO Health Systems Framework

In order to understand what happened in the years following inclusion of EC in the national family planning guidelines in 2001, and to glean lessons learned from the Bangladeshi experience, the six elements of the WHO Health System Framework were used to organize information about the process of sustainable scale-up to ensure national ECP availability and accessibility.

In collaboration with technical support organizations, the government trained the **health workforce**, including health care providers and field workers during both phases of scale-up, and EC was incorporated into training guidelines for family planning providers. According to one key informant, the resources provided by international organizations to support training made this possible: "The government could not have supported training 42,000 workers." Unpublished surveys from 2009 with public and private sector providers, including pharmacists, revealed high levels of knowledge of EC and barriers to EC provision including lack of public awareness and inadequate supply. 69

A continuing challenge related to the health workforce, according to one key informant, is that some program managers are reluctant to provide information on EC to young people, resulting in a lack of knowledge among this population, and EC is not specifically mentioned in Bangladesh's current adolescent reproductive health strategy.⁷⁰ Another key informant commented that not all pharmacists are trained in EC.

Bangladesh has integrated ECPs into various **service delivery** points within their health care system—including, uniquely, provision by field workers. The major source of ECPs is the government family planning program. According to one key informant, field workers visit houses every two months and reach women otherwise unable to access health services. Evidence from Bangladesh that advance provision increases use of EC has been used to shift towards this method of provision in the public sector and increase access.⁶⁶ Additional work is needed to incorporate EC into services for sexual assault survivors in hospital and police settings. According to a situational analysis published in 2008, no uniform health service protocol was available for rape survivors and no police stations included in the analysis were counseling women on or providing EC, and many hospitals visited did not have ECPs in stock.⁷¹

ECPs are available in retail pharmacies without a prescription, and according to a recent analysis by ICEC, Bangladesh is one of few countries in the world where ECPs are 'truly' available over the counter without requiring provider interaction.⁶⁹ ECPs are also provided in NGO clinics and through social marketing programs.⁶⁹

In terms of the *information systems* building block, ECPs have been incorporated into health provider reporting forms and the central information management system, though the process of regular reporting took several years to get started.⁶⁶ According to Hossain and Khan, reports are sent to the Directorate General for Family Planning every six months, and between September 2006 and February 2007, at least 21,000 packets of ECPs were being distributed monthly nationwide.⁶⁶ While it is difficult to get precise sales data from the pharmacy sector, one key informant estimated that their sales are "not too much—they sell about 10,000-15,000 per month."

There are two dedicated ECP *medical products* now registered in Bangladesh.⁵⁰ According to one key informant, efforts are underway to incorporate the single-dose ECP regimen in the family planning guidelines in order to update them with the latest information available on simplified regimens for women seeking EC. Though no evidence is available on counterfeit ECPs in Bangladesh, the ICEC has pointed out that counterfeit drugs are generally a problem in the country.⁶⁹

According to key informants, *financing* to ensure contraceptive security, following the initial supply of ECPs from UNFPA, has been a challenge. The government is now budgeting for and purchasing ECPs, but there is sometimes a shortage of ECPs among field workers, in part because of complicated supply-management processes and delays in supply. In response to the shortage, public sector

"The government is still committed, but there is a need for continuous effort from other stakeholders, otherwise the government will lose interest."

- Researcher

distribution could be scaled back to only include facility-based distribution, which would greatly decrease the amount of ECPs distributed each month. In terms of affordability, initially clients were charged about US\$0.12 per packet of ECPs,⁷² though currently they are provided free of charge within the public system.⁶⁶ In pharmacies, ECPs are sold for a cost of about US\$0.72 per packet.⁶⁶

Leadership/governance and the level of support expressed by health officials for EC have a great impact on the long-term sustainability of an EC introduction. According to one key informant, continued technical assistance to the government was key to sustainable implementation of EC: "You may change the policy, you may demonstrate effectiveness, but unless you provide long-term technical assistance, it won't be sustainable. Otherwise, it slowly dies out." According to another key informant, while the government is supportive of EC, it can become "sluggish": "The government is still committed, but there is a need for continuous effort from other stakeholders, otherwise the government will lose interest." For example, refresher trainings for health care providers do not always include EC information without stakeholders reminding the government of its importance. This key informant suggested reinstating a stakeholder group (FEMCON is no longer active) to keep the pressure on. It is also interesting to note that EC is not specifically mentioned in the National Communication Strategy for Family Planning and Reproductive Health.⁷³

4.2.4 Lessons Learned

A review of available literature and interviews with key informants revealed several key facilitating factors and barriers to Bangladesh's successful sustained implementation of EC throughout the country. These are summarized below.

Partnerships and strategic planning among a variety of stakeholders are critical to ensuring long-term systematic policy change and sustained availability and accessibility: The involvement of policymakers and program managers in early operations research led to buy-in for EC implementation, and the collaboration of many stakeholders from the medical community, media, NGOs, etc., as well as a focus on evidence, led to broad support for EC.

Capacity building and sustained technical assistance and advocacy have proved critical to EC introduction: These components have ensured continuing governmental commitment to EC. In the current context, ensuring consistent, timely procurement and distribution of ECPs—as well as funding for training health care providers—has been challenging. According to key informants, contraceptive security will need to be a long-term focus, particularly considering the lack of continued funding from UNFPA.

Product registration is not sufficient: Eight years passed between the registration of the first ECP product in 1995 and the integration of EC into the national family planning program in 2003. Efforts described above by FEMCON to develop a national strategy for EC introduction were therefore critical.

Demand is still low due to the need for continued, evidence-based, awareness-raising activities: A brochure was developed and a radio campaign took place between 2006 and 2007, though both of these efforts failed to reach clients with comprehensive information about EC.66 Further work is also needed to fully integrate EC into routine counseling with all women—including adolescents and married women—about available contraceptive methods and into services for sexual assault survivors.

4.3 Kenya: Moving beyond pharmacies towards wider health system integration

Kenya, like Mexico, was one of the first ICEC demonstration countries in the 1990s, and the Kenyan EC Consortium (which included local and international NGOs, the ministry of health, the University of Nairobi, and a local pharmaceutical distributor) actively engaged government and pharmaceutical sectors at an early stage to gain buy-in. However, it was not until a second phase of investment and attention to EC scale-up in the mid-2000s that EC began to be mainstreamed into the entire health system. Knowledge about EC among public has increased significantly—from 24% to 40% in five years (between 2003 and 2008-9)⁷⁴—though access is still primarily restricted to urban pharmacies and sexual assault services, in part due to persistent stigma around EC and the belief that it promotes sexual promiscuity, abandonment of other contraceptive methods, and that it is an abortifacient.

Available information published on Kenya's experience about introduction and scale-up of EC was supplemented by four key informant interviews: from the ministry of health, Kenya Pharmaceutical Association, and two representatives of international NGOs.

4.3.1 Introduction

Analysis: 9-step ICEC Framework

The EC introduction experience led by the Kenya EC Consortium was explicitly guided by ICEC's 9-Step Framework. According to a key informant, careful work to gain buy-in from the government and professional associations (Step 2) paved the way for avoiding controversy surrounding initial introduction of EC. A dedicated ECP product had been registered in Kenya since 1992 (Step 3) and was already sold through the private sector prior to the government's EC introduction.⁷⁵ As part of the introduction, the Kenya EC Consortium worked with government and pharmaceutical partners to register a second dedicated ECP product, Postinor-2, in 1997.⁷⁵

Early government support: A baseline assessment of knowledge and attitudes among policymakers, public and private sector providers, clients, and university students in the late 1990s (Steps 1, 5) revealed low levels of EC knowledge (less than 50% of providers and 10% of clients were aware of the method).⁷⁵ Collaboration and discussion with the ministry of health and Poisons and Pharmacy Board led to ministry approval and support of the introduction project.⁷⁵ EC was also incorporated early on into national family planning guidelines.⁷⁵ According to a ministry of health key informant, the government was particularly interested in EC early on due to emergency situations in the country and the need for EC among survivors of rape.

Phased approach to introduction: The initial introduction strategy (Steps 4, 7) entailed a low-profile approach, first making ECPs available in limited clinics in Nairobi.⁷⁵ Eventually, more active promotion in pharmacies by the pharmaceutical sector took place and consortium materials were adapted for use in trainings (Step 6) with providers from several districts.⁷⁶ Consortium partners also developed and began testing brochures for providers and clients.⁷⁶

Evaluation demonstrating providers' increased knowledge and support: A 1999 evaluation of the introductory project (Step 8) that targeted providers and clients in the same locations as the baseline assessments showed a doubling in the proportion of women who had heard about EC (to 20%).⁷⁶ While only 3% of women at baseline received information about EC at a clinic, this had increased to 35% by 1999. More than three-quarters (88%) of the providers had heard of EC at the time of the evaluation compared to only 46% at the baseline survey. Asked about potential channels for distribution of the method, more than half (55%) of providers believed all family planning services should provide the

method while only 6% mentioned pharmacies as a potential distribution method (this is particularly striking given the direction that EC services in the pharmaceutical sector would take). Those conducting the study also noted that there were many comments about problems with maintaining ECPs stock and recommended a focus on sustainable procurement.

4.3.2 Transition from Introduction to Sustainable Scale-up

After being on the market for one year, 3,500 packets of Postinor-2 were sold monthly (in public and private sectors).⁷⁵ Despite the sales, several years after ECPs had been introduced, knowledge of EC remained low (the 2003 DHS recorded a 24% awareness level of EC among women).⁷⁴ Renewed attention to the need for post-rape care led to a returned focus on EC by the ministry of health, and in 2005, with the support of UNFPA, the ministry procured 700,000 units of ECPs for public sector distribution.⁷⁷

"The environment was right. People wanted to address it. It was emerging as a hot topic. I'm not sure it would have been as successful if it hadn't been on people's lips already."

- Researcher

Around this time, early concerns about controversy proved well founded, particularly regarding the issue of 'misuse' by young women. In 2004, a Kenyan newspaper published an article claiming that girls were eating ECPs 'like chocolates' and engaging in risky, unprotected sex. To test these assumptions, in 2005, ECafrique, a regional consortium housed at the Population Council, conducted a rapid assessment of EC use among 300 secondary, university, and out-of-school girls in Nairobi. Results demonstrated that while 74% knew about ECPs, less than 9% had actually used it. ⁷⁸The proportion of those who had used ECPs repeatedly in the past month was even lower, suggesting that there was no 'epidemic' of ECPs 'abuse' in Nairobi. Interestingly, according to one key informant, Kenya was able to take advantage of some of the controversy and coverage in the media: "The environment was right. People wanted to address it. It was emerging as a hot topic. I'm not sure it would have been as successful if it hadn't been on people's lips already. We were also building on the earlier efforts in EC while also responding to the new realities. We couldn't have done all this without the earlier groundwork, such as registering the product. There was a strong base to build on, as well as the public mystique around it."

In 2006, the Population Council, Population Services International (PSI), and the ministry of health launched a three-year initiative to support the ministry's efforts to expand ECP provision in the public sector and to strengthen private sector EC provision, as well as to spread the word more widely about EC and influence the public to be more informed and supportive of EC.⁷⁹ One of the goals of the initiative was to improve coordination among those involved with EC in Kenya; ECafrique supported national rollout, which included a two-day workshop on EC for senior health planners and policymakers from different parts of the country. An NGO, Marie Stopes Kenya, also began a social marketing program in its clinics.⁷⁷

The awareness-raising and information campaign (including national radio spots, printed advertisements and other mass media tactics, client brochures distributed in pharmacies and through community-level events, and a hotline) branded *Tulia* ("relax" in Kiswahili) targeted 18-30 year olds and sought to raise awareness and demand for EC.⁷⁹ Concerns rose about the campaign's portrayal of a mother speaking to her daughter about EC (as opposed to friends talking to each other—viewed as more culturally appropriate) and about the time slots for radio spots. This led to a temporary halt in the mass media campaign. With the support of the ministry of health and other national stakeholders, these issues were eventually addressed by PSI, and the campaign resumed.⁷⁷ ECAfrique also worked with media partners to help ensure correct, supportive reports on EC.⁸⁰ According to a key informant, well-planned, targeted, and executed media campaigns in Kenya are generally successful due to widespread

penetration of FM radio, television, Internet, and print, as well as a strong youth culture in the country that is open to new ideas and is 'media-savvy.'

As of 2008-9, according to the DHS, 40% of women were aware of EC (up from 24% in 2003).⁸¹ A baseline (2007) and endline (2009) survey evaluating the impact of the intervention and conducted in major towns and peri-urban areas found that 56% of women had heard of EC (compared to 24% in 2007) and 12% had ever used ECPs (compared to 6% in 2007).⁸² Though levels of knowledge among those already aware of EC did not appear to improve overall after the campaign, closer analysis revealed that exposure to the campaign was associated with an increase in knowledge that EC is not an abortifacient and is not meant to be a regular method of family planning.⁸² A study conducted in 2007 among people who had just purchased ECPs in pharmacies in five urban areas, though not generalizable to the Kenyan population and with disputed estimation methods, indicated that some women chose to use ECPs as a regular contraceptive method.⁸³ Further research is needed to determine whether this is common among Kenyan women and women in other sub-Saharan African settings.

4.3.3 Sustainable Scale-up

Analysis: WHO Health Systems Framework

In order to glean lessons learned from the Kenyan experience for other health systems, the WHO Health Systems Framework was used to organize information about Kenya's experience in working toward sustainable scale-up of their EC programs.

In terms of **service delivery** outlets, ECPs are available in public health facilities, youth centers, and sexual assault/rape clinics, though a large majority of women access them from behind the counter in pharmacies.^{75,84} Recent data from the Urban Reproductive Health Initiative, which included five urban areas in Kenya, confirms the previously identified trends of pharmacies being the primary source of ECPs: 96% of ever users of ECPs cited pharmacies as their preferred distribution source.⁸⁵ Available sales data indicate increasing demand for ECPs in the private sector, with sales rising from approximately 46,000 per month in late 2007 to more than 138,000 per month in mid-2009).⁷⁷ Qualitative research indicates urban and peri-urban Kenyan women prefer pharmacy access because it is convenient and confidential.⁷⁷

As part of the joint initiative to scale up ECPs in the mid-2000s, the Population Council, the Pharmaceutical Society of Kenya (representing university degree-holding pharmacists), and the Kenya Pharmaceutical Association (representing a wider group of pharmacy technicians) worked together to improve pharmacy services.⁸⁶ An intervention study in 2008 in 20 Nairobi pharmacies provided information to pharmacists on ECP provision, materials for counseling women on ECPs, and information on connecting users to other reproductive health services.⁸⁷ Despite a positive impact of the affordable, non-intensive intervention on pharmacist practices, the difference between intervention and control pharmacies was not statistically significant. The researchers recommended further institutional work to support pharmacists in providing reproductive health information to EC clients.⁸⁷ A presentation by the Secretary General of the Kenya Pharmaceutical Association in 2010 indicates that high staff turnover and non-professional counter staff, as well as women's desire for limited interaction with pharmacists, are barriers to quality counseling of pharmacy clients on EC.⁸⁸

In 2008, public sector distribution was about half that of private sector sales figures. A bias towards ECPs for sexual assault survivors appeared to exist, with 93% of ECPs distributed in the previous 18 months for sexual assault cases (according to a 2007 record review). The ministry of health key informant confirmed that the public sector mostly serves women who have experienced sexual assault, while other women—including young women mainly in urban areas—access ECPs through pharmacies. According to this key informant, ECPs are included as part of the family planning method mix in

adolescent-friendly health service programs, ⁸⁹ and to some degree in school life skills programs, though these efforts can be challenged by the negative public perceptions of EC as an abortifacient and the potential for young women to abuse it.

According to the ministry of health key informant, community health workers can provide ECPs, but it is not routine given their other priorities (skilled birth attendance, non-emergency family planning). A key informant from an international NGO pointed to the challenge of encouraging community health workers to offer ECPs given the belief that they will promote promiscuity and thwart their efforts to convince women of the merits of ongoing contraception. She suggested more work with community-based distributors in rural areas (e.g., medicine kiosks), but pointed to the same challenge of overcoming community bias while recognizing that a focus on sexual violence programs is most acceptable.

In terms of quality of care in public services, the key informant from the pharmaceutical association pointed out: "It would take radical changes for people to accept EC in the public sector. There is the perception that someone goes there because they are sick. Even people who go for FP don't go as freely. In the private sector, you walk in and walk out. In the public sector, you have to move your client card from one place to another, some products might not be available. And also the quality of the human resources in the public sector is an issue. How friendly are they to these people coming in? A girl may feel like she is being judged. There is a lack of trust. Generally because of the poor motivation in the public sector, they might project it to the clients." Another key informant echoed the point that young women do not access ECPs in public services partly due to poor treatment by nurses in the public health system and the perception that family planning is for married women. A 2013 Kenyan newspaper article reported that services designed to be youth friendly have not attracted as many young people as had been expected (and thus have not dispensed as many ECPs as estimated), though long lines to access services and problems with privacy and confidentiality were also cited. The key informant from the ministry of health suggested more be done to educate youth about EC.

A 2007 study revealed that while the large majority of the **health workforce** of family planning providers was aware of ECPs as a post-coital method of pregnancy prevention, only 54% displayed 'strong' counseling behavior (defined as counseling all clients or all likely clients) and in multivariate analysis higher levels of knowledge were associated with better counseling behavior. Based on these findings, the ministry of health increased efforts to train providers using contraceptive technology updates, pre- and in-service training, and a quick reference guide and job aid. EC was integrated into the Nursing Council curriculum for pre-service training of all nurses in Kenya in 2010 and into the curriculum for clinical officers in 2011.

In terms of *information systems* about ECPs, in 2008, the ministry of health revised the family planning register and included a column for ECPs, allowing for better record-keeping and sustainability of supplies.⁸⁶

There are currently nine registered, dedicated ECP *medical products* available and ECPs are included on the Essential Medicines List.⁸⁴ However, counterfeit medicines do exist, according to a 2010 presentation to the ICEC by the Secretary General of the Kenya Pharmaceutical Association.⁸⁸

In terms of *financing*, ECPs are provided for free by the public sector (with the exception of district and provincial hospitals).⁹³ Prices in pharmacies range from US\$0.60 to 2.60.⁸⁸ UNFPA also donates supplies to the ministry of health (over 1 million units between 2005 and 2010).⁸⁸ The ministry of health purchased a record 5,875,000 packets of ECPs in 2009.⁷⁹ This procurement resulted in huge excesses in unused ECPs stock due to lower than anticipated demand for EC in the public sector. A recent article (early 2103) in the *Daily Nation* newspaper indicated that the ministry of

health had decreased procurement for public sector facilities in 2013 to 300,000 due to a failure to accurately forecast demand and the expiration of many ECP packets on public sector shelves. Personal communication with a former technical advisor to the ministry of health revealed that the ministry had attempted to reduce wastage by providing ECPs to private pharmacies for sales at a substantially reduced price before their expiration dates, though this strategy did not succeed in eliminating the excess stock. According to this contact, the pharmacies sold these products for about one-half the price of the least expensive generic ECP available in Kenya at the time.

Leadership and governance are critical to ensuring continued support for ECs in Kenya's public sector. EC was included in the national family planning guidelines early in the process of introducing the method, and the 2010 revisions include strengthened guidance on ECPs.⁷⁹ EC was also included in the 2009 national guidelines on management of sexual violence in Kenya.⁹⁴ Advocacy efforts to ensure supply security have been critical.⁹⁴ However, key informants pointed out that while promoting family planning overall is a priority, EC does not always rise to the top in the shadow of larger efforts to increase contraceptive prevalence in the country. In terms of governance related to ECPs in other sectors, the two pharmaceutical associations have developed a protocol for selling ECPs, including a set of questions to ask when providing the method.

4.3.4 Lessons Learned

A review of available literature and interviews with key informants revealed several key facilitating factors and barriers to Kenya's efforts to introduce and sustain EC access throughout the country. These are summarized below.

Pharmacies are critical—but are not the only source for access to ECPs: Given the challenges to encouraging public sector and community-level distribution of ECPs, pharmacies have proven a critical source of access to ECPs for women in Kenya. However, it is also critical to continue efforts to expand access in the public sector, particularly for poor and rural women who may not have access (due to lack of availability or high cost) to commercial ECP products in the private sector. In addition, efforts must continue to find ways to reach youth through schools and adolescent-friendly public sector services.

Buy-in from health care providers and professional associations are necessary for scale-up: Buy-in from providers in multiple sectors (to ensure their nonjudgmental provision of ECPs, particularly to youth clients) will require more work to decrease stigma associated with EC and increase accurate information about the method. In light of the large proportion of women currently accessing ECPs in Kenyan pharmacies, it is particularly important to ensure pharmacies provide accurate, comprehensive information to women (even in the context of women preferring convenient, fast services); working with the pharmacy sector is key to accomplishing this goal. Support from the ministry of health, professional associations, and the pharmacy board was also critical to reviewing and re-launching the mass media awareness campaign in the face of public criticism regarding some aspects of the campaign.

Efforts to raise public awareness must continue: Though knowledge increased significantly over a short period of time in the 2000s, there is still much more work to be done to ensure all women who may, at some point in time need post-coital contraception, know about and can access ECPs. Important early efforts were made to obtain buy-in from key stakeholders and avoid national controversy over EC; however, EC stakeholders in Kenya must ensure that the public understands how ECPs work and their importance for women's health.

4.4 Senegal: Promoting emergency contraception in a low contraceptive prevalence context

This final case study provides an example of a country still in the early implementation stages of scaling up its EC program. Senegal's incorporation of EC into its national health system is less mature than the other country experiences described thus far.

Senegal's contraceptive prevalence rate of 12% is much lower than in the three other case study countries (see Box 4). Recognizing the consequences of the unmet need for contraception, Senegal's ministry of health has developed a multi-sector strategy that addresses maternal and neonatal mortality and includes family planning as a major focus. Recently there have been additional indications of increased political will and government commitment to family planning, such as the 500 million CFAs (or over \$1 million USD) designated by the Senegalese government for family planning at the 2011 International Family Planning Conference in Dakar.

There is little published documentation of the experience of EC introduction and scale-up in Senegal. We supplemented the limited published information with three key informant interviews: one with a representative of an international NGO and two with representatives of the ministry of health.

4.4.1 Introduction

Analysis: 9-step ICEC Framework

In 1998, EC was introduced into the national family planning training curriculum for health care providers⁹⁵ and in 2000 the national family planning program introduced ECPs.⁹⁶ However, it was not until 2005—when the Population Council's ECafrique program began working with the ministry of health on several initiatives—that a concerted effort was made to raise awareness of and increase access to ECPs throughout the country (Step 2). By 2005, a dedicated ECP had been registered in the country (Step 3).⁹⁵

Formative research on the possibility of expanded ECP access (Step I) in 2003 revealed areas of need for improved user and provider knowledge of EC—the large majority of contraceptive users and students in the study were unfamiliar with EC. ⁹⁷

A critical turning point occurred in 2005 when EC was incorporated into the ministry of health's operational and clinical guidelines, and ECPs were introduced into health centers (Step 4).⁹⁵ In 2006, a strategic evaluation of the family planning program (Step 8) identified low levels of knowledge about EC among providers, yet there was support both for the method and involvement of men in women's decisions about using EC. A situational analysis conducted in 2007 revealed that only 10% of clinics offered ECPs and that 37% of providers were not trained in ECPs provision.⁹⁵ These evaluations revealed the following barriers to EC promotion: limited information, fear, embarrassment, and cultural and religious constraints among potential users.⁹⁵

4.4.2 Transition from Introduction to Scale-up

Based on results of the initial evaluation of services described above, in 2007 the ministry of health scaled up training for service providers and community volunteers to educate clients about EC in eight regions (Step 9).95 A program was also introduced around that time to address adolescent sexual behavior and educate young people about ECPs through collaboration with schools, pharmacies and service providers.95 According to the key informant from the ministry of health, "for contraception there is not a difference on color, sex or age. The information is to be given to everyone about this."

4.4.3 Scale-up

Analysis: WHO Health Systems Framework

The WHO Health Systems Framework is useful in the early stages of EC scale-up in terms of health system strengthening support for the introduction of a new method. The WHO Health System Framework was used to organize information about the process of scaling up of ECP availability and accessibility in Senegal.

Service delivery of ECPs in the public sector is not yet widespread. According to recent routine service statistics, use of ECPs in the public sector is low (less than 2%%) and key opinion leaders in a 2012 Population Council study mention low availability of ECPs in public sector facilities. The ministry of health key informant identified a 'male factor' barrier: "If a young man comes to look for ECPs it is difficult for him because they [providers] say it is not right for him."

In terms of pharmacy access, ECPs are available without a prescription in pharmacies.⁸⁴ A recent qualitative assessment of availability and quality of ECP pharmacy services revealed a lack of pharmacist proficiency in ECP protocols, the need for more counseling of clients purchasing ECPs, and favorable opinions toward ECPs as they help (in particular young) people avoid unwanted pregnancy.⁹⁷ A key informant reported that sales estimates indicate that pharmacies sell around 90,000 units of ECPs per year. The ministry of health is currently working with the ministry of youth to introduce EC into schools, according to another key informant.

A recent study of providers' and key opinion leaders' knowledge, attitudes, and practice related to ECPs found that approximately one-third of the *health workforce* interviewed had not received family planning counseling training and that EC was not incorporated into family planning training.96 About 40% of providers overall had not received EC training and few reported counseling women on ECPs or knowing the mechanism of action for EC or eligibility criteria. This

"In Senegal the religious factor is very influential in people's behavior and they think giving EC to a woman is promoting abortion."

- Researcher

study also found persistent negative attitudes about EC, such as those related to access without a prescription and among certain populations. A key informant mentioned that providers at the health post level (where many women access services), and pharmacists need more training on how to counsel women on EC's mechanism of action. The ministry of health representative talked about ongoing efforts to train health care providers in maternity services and youth services, as well as community workers and pharmacists in ECP provision and family planning counseling in order to comprehensively strengthen the information sources for women about EC.

Information systems in the private sector to monitor ECP provision in pharmacies is lacking; a 2012 Population Council program brief recommends improving the logistics management system. ⁹⁶ The ministry of health key informant also commented on the general difficulty in monitoring health statistics in the country, in part due to union strikes.

In terms of *medical products*, there are three registered ECPs and ECPs are included in the Essential Medicines List.⁸⁴

Financing in the public sector has not yet posed a challenge to ECPs sustainability; a key informant commented that UNFPA provides ECP products to the public sector, but demand does not keep up with the stock: "We see stock in public sector doesn't move because providers don't talk about it. We have worked with the public sector but EC is not very integrated and providers do not give information in the public sector." Key opinion leaders in the Population Council 2012 study noted the high price of ECPs in private

pharmacies; prices ranged from 3,200 FCFA and 3,700 FCFA or approximately \$6.50-\$7.50e USD.84 The ministry of health key informant reported that the cost in the public sector is about \$1 USD.

Finally, **leadership and governance** will be integral to ensuring success of Senegal's current efforts to scale up EC. Key informants were very supportive—"officially, we have the commitment of the MOH for introducing EC." EC is in the national guidelines and training curriculum, but religious opposition and societal attitudes towards abortion have proven obstacles to widespread ECPs acceptance: "In Senegal the religious factor is very influential in people's behavior and they think giving EC to a woman is promoting abortion." A national debate about whether to include EC in post-rape care guidelines continues.

Senegal remains in an early stage of ECP introduction and scale-up in the public sector. Policies have been changed and products are available, particularly in pharmacies, but widespread access is not a reality. Knowledge of the method among women, which is still quite low at 13%97, must be improved. Additionally, the erroneous perceptions about ECPs must be addressed, in particular the beliefs that it is an abortifacient or is likely to increase risky behavior, especially among young women. The key informants both emphasized the need to continue working with other sectors, such as the ministry of education and maternal health services, to promote EC awareness and access.

4.4.4 Lessons Learned

A review of available literature and interviews with key informants revealed several key remaining challenges to Senegal's efforts to introduce and sustain ECP access throughout the country. These are summarized below.

Supporting public sector provision of ECPs: As with many countries, in Senegal, private pharmacists are the primary providers of ECPs, while its use by clients of the public health system is minimal. There is a clear need for further provider training to combat negative attitudes about ECPs. The recent, clearer evidence about the mechanism of action (see Appendix I) could help. Providers should be encouraged to regularly offer family planning (including EC) services. Senegal's training curriculum includes EC and it is well integrated into the family planning guidelines, but further training will help transform policy into practice. In addition to addressing provider misperceptions, working with religious leaders and networks could help to change attitudes. According to one key informant, "we need to work with religious networks who are very influential in Senegal and give the right information to these influential people."

Improving client knowledge: Larger-scale communications efforts are needed to improve knowledge. One respondent commented that "the main gap is the poor communication on EC in the country" and that there is a need for culturally sensitive messages.

Involving various stakeholders in a national EC promotion strategy: The ministry of health and the Population Council have collaborated on several activities to increase distribution and awareness of EC in Senegal. However, much remains to be done in terms of involving a variety of stakeholders—including community and religious leaders—in efforts to build a national plan.

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^e Currency estimation is from <u>xe.com</u>, July 29, 2013.

5. Comparative Analysis

The country case studies provide valuable guidance that countries can benefit from in their EC introduction and scaling-up programmatic strategy. This section describes the lessons drawn from the introduction and sustainable scale-up phases by synthesizing evidence across the four case studies (see Appendix 3 – Salient introduction and scale-up features across case study countries).

5.1 Introduction

Analysis: 9-step ICEC Framework

Experiences from the four case studies were analyzed independently for each of the nine steps to draw out the key lessons across a variety of country settings and introduction approaches. Lessons synthesized from the four-country analysis are presented below.

Step 1: Assess user needs and service capabilities

Formative research provided critical evidence about the need to raise awareness and address misinformation about EC. In Bangladesh, this formative work went a step further, including operations research on the feasibility of incorporating ECPs into the national family planning program. That operations research provided additional evidence that informed the strategy for introducing ECPs in the public sector and likely contributed to the strong and successful introduction. In Senegal, it was not until several years after initial introduction of EC into the national family planning program, when concerted efforts were made to expand access to ECPs, that formative research was conducted.

Lesson learned: Assessing existing information (or misinformation) of clients and providers through formative research early in the introductory phase is important so that approaches can be tailored appropriately.

Step 2: Build support for introduction at various levels

This step proved critical to the success of EC introduction. In Mexico, a strong consortium worked hard to involve a range of stakeholders—including, uniquely, media representatives—during early introduction efforts. In Mexico and also in Kenya, the existence of an EC consortium proved particularly critical to strategically garnering support for EC, a method stigmatized because of its erroneous association with being an abortifacient and promoting promiscuous behavior. The early support of government officials in Mexico and Bangladesh for the introduction of EC accelerated those countries' efforts to expand EC access. As in Kenya, Senegal has benefited from the involvement of ECAfrique in gathering a consortium to garner support for the product. Although Senegal remains in the early stages of program maturity, if the country continues to work with its consortium to dispel myths about EC and build support, greater long-term success is likely.

Lesson learned: In all cases, ensuring support for EC within the provider community and public at large by building multisector support has proven instrumental to successful introduction.

Step 3: Select a dedicated product

Registering dedicated ECP products occurred at different stages in the four case studies. In Mexico, the inability to register a dedicated product early meant that initial introduction efforts promoted the Yupze regimen as an alternative. Mexico's success in increasing access to EC before an ECP was available speaks to the ability of countries to move forward with EC introduction in the absence of a dedicated product. However, once a registered product did become available in Mexico, the EC program was more easily able to expand access.

On the other hand, in Bangladesh, where products have been registered since 1995, and in Kenya where EC products have been registered since 1992, registration of a dedicated EC product was critical to

EC's successful introduction. Senegal has only had an EC product registered since 2005, but given the histories of the other country case studies, it's likely that having a registered EC product will support the success of the introduction.

Lesson learned: The evidence-based recommendations that come with registered products lend legitimacy to ECPs. Besides showing government support and acceptability of the product, registering the product makes it available for procurement, an important element in ensuring access.

Step 4: Develop a distribution plan

This element of EC introduction had a stronger impact in some countries than others. In Bangladesh, operations research was undertaken for public sector distribution, while Kenya took a more modest approach, first making EC methods available at limited clinics, before expanding to active promotion in pharmacies and training more providers in the public sector. Both the Bangladesh and Kenya efforts successfully distributed EC products, using approaches tailored for their respective political and social environments. In Mexico, which at first lacked a registered product, efforts focused more on provider training and public information campaigns to drum up support for distribution. Senegal, still in a somewhat nascent phase of distribution, has officially introduced EC into public health centers and incorporated it into family planning guidelines. It remains to be seen how Senegal's distribution plan will unfold.

Lesson learned: Countries must adapt each distribution strategy to their respective environments and needs to ensure successful introduction.

Step 5: Identify and meet clients' information needs

Raising awareness about EC is critical to stimulating demand. While Mexico's widespread information campaigns led to increased demand for ECPs, even in the absence of a registered product, the experiences in Bangladesh and Senegal, which continue to experience low demand for ECPs among health services, speak to the pitfalls of an EC introduction strategy that does not include a strong awareness-raising component. Although those components were not a strong part of the initial EC introduction in Kenya, more recent efforts to expand EC access in the country have included awareness-raising efforts. In Mexico and Kenya, in particular, media coverage of controversy about EC helped generate awareness and demand for ECPs, suggesting that even negative attention to the method shows potential to harness media attention that boosts awareness. By contrast, in Senegal, initiatives to inform the public about the availability of EC products in both the public and private sectors has been less involved, and knowledge of the product's existence and how to use it remains much lower than in the other country experiences.

Lesson learned: Public knowledge about the availability of EC products and how to use them is necessary for increasing access to and use of ECPs.

Step 6: Train providers

Ensuring awareness and correct knowledge of EC among health care providers (nurses, doctors, and field workers as well as pharmacists and providers in police, school, and other sectors) supports the success of EC introduction efforts. In Mexico and Kenya, the case studies demonstrate the importance of gaining buy-in from professional associations for ECPs, particularly in the context of persistent provider stigma surrounding ECPs and the need for investments in provider training. The in-depth training of health providers in Mexico increased their knowledge of the product and supported EC's successful introduction, whereas in Senegal, lack of provider training and knowledge about EC remains low due to lack of training and guidelines.

Lesson learned: When EC providers are not trained on the method—whether they are professional health care workers or drug-shop keepers—knowledge about the product and thus the ability to provide it in a safe and effective way is severely undermined.

Steps 8&9: Monitor and evaluate EC services and disseminate evaluation results

The final two steps of the 9-Step ICEC framework suggest M&E of introduction efforts to assess user and provider perception of and experience with ECPs and service delivery mechanisms are significant to inform distribution and education strategies. While all four countries have, to some degree, monitored changes in knowledge and use among providers and clients over time, the explicit incorporation of such findings into subsequent scale-up strategies in Bangladesh provides an excellent example of successful incorporation of evidence into strategies for sustainable scale-up. As one of the strongest examples of successful EC introduction and scale-up, it's likely that Bangladesh's comprehensive inclusion of an M&E strategy from the very beginning was a facilitating factor in the comprehensive roll-out. Mexico has also been able to successfully use M&E to determine the effectiveness of EC introduction strategies by first conducting a baseline evaluation and then tailoring strategies to address findings, such as increasing media awareness campaigns to inform the public.

Lesson learned: The ability of a country to adapt its EC introduction strategy and address challenges as they arise depends firmly on the awareness of the situation on the ground, which requires good M&E.

5.2 Sustainable Scale-up

Analysis: WHO Health Systems Framework

The four country cases applied different approaches to the critical work of ensuring broad availability and accessibility of ECPs through multiple service delivery points in the health system, including public, private, and NGO sector health services as well as pharmacies and to special groups such as adolescents (e.g., through school systems), rural women, and survivors of sexual assault (e.g., through the police and hospital systems). For example, Bangladesh's successful experience with field workers provides a model for countries considering how to scale up ECPs to reach rural populations. And current efforts in Kenya and Senegal provide promising examples of efforts to increase access to ECPs among youth. In settings like Mexico and Kenya where the majority of access to ECPs continues to be in pharmacies, efforts are needed to improve access through the public system for all women (not just survivors of sexual assault). On the other hand, in settings like Bangladesh that have more successfully integrated EC in the public sector, work needs to be done to ensure availability for special populations, such as sexual assault survivors and young women. Several lessons can be gleaned about scaling up EC programs from the four case studies, which are discussed below.

Continued coordination among various stakeholders: The lack of a multi-stakeholder coalition in Senegal (beyond the collaboration between the ministry of health and the Population Council) has posed challenges for meaningful EC scale-up over the last decade or so. And while Bangladesh and Kenya formed EC consortia, the consortium in Mexico was unique in that it remained active for ten years to build on initial activities that occurred during an initial three-year period. The lessons learned from Bangladesh surrounding the need for continued advocacy to ensure government support of EC speaks to one important role of EC consortia in sustained scale-up efforts. In addition, in a context like Mexico's, where controversy over and challenges to EC have persisted, ensuring public support and supportive regulatory environments has been a continuous struggle.

Lesson learned: Stakeholder coordination beyond initial introductory efforts is critical to sustained scale-up and support for EC in the health system, even when supportive government policies, such as family planning service delivery guidelines or Essential Medicine Lists, are already in place.

Technical and financial assistance to governments: The Bangladesh case study illustrates the importance of supporting governments to train providers and ensure the supply of ECPs in the public sector. In Bangladesh, the continued success of public sector scale-up—including its field worker program—has been hindered by a lack of continued funding from UNFPA for ECPs supplies. Challenges in introducing information systems to track EC use and product availability and demand also illustrate the need for continuing technical support for governments and pharmacies.

Lesson learned: Technical and financial assistance to governments is necessary for the successful scale-up of EC.

Institutionalized health workforce training: EC has been institutionalized in pre-service training guidelines for family planning providers in all four countries. However, the evidence from Kenya of challenges related to quality of care in the public sector points to the importance of not only including technical information on EC in provider training, but also focusing on interpersonal quality of care, so that women (and men) feel comfortable accessing ECPs through various service delivery points. It is also important for EC providers to be trained at all service delivery points. While some people access ECPs at traditional public health facilities in Mexico, the rest of the case studies demonstrate that ECPs are most commonly accessed from private pharmacies, often from drug-shop keepers who often have limited knowledge and training. Regardless of whether clients choose to access ECPs from these private pharmacies for personal comfort or simply ease of access, it is critical to ensure that they are getting correct information from the provider.

Lesson learned: Initial provider training efforts during EC introduction in a country need to be scaled up and institutionalized, and address both technical information and quality of care, in order to ensure sustainable knowledge and support for EC among the health workforce.

Documenting efforts to introduce and scale up EC: The four case studies reveal the need for better documentation. As the authors of this synthesis report, it was necessary to consult key stakeholders to fill in informational gaps. Improved documentation would help both internal evidence-based scale-up efforts, and encourage the sharing of experiences between countries. There was a lack of information, in particular, related to the acceptability, efficiency, and accessibility of EC services and a need for documentation of unmet need for EC among various subpopulations of women.

Lesson learned: Filling in informational gaps, like those referenced above, would provide countries with more evidence to ensure that policy successes are translated into real access for women and that scale-up efforts equitably address the needs of all women.

Governance and leadership for introduction and scale-up: The involvement of leadership and governance in the EC scale-up process was significantly important at various levels in each of the country cases examined. In Mexico, for example, leveraging political will and the strong involvement of the minister of health, as well as other ministry officials, greatly influenced support for EC. In Mexico, the government was therefore able to include EC in family planning norms despite constitutional opposition by anti-abortion groups. In Kenya, the government took a more pragmatic approach in its relationship with EC roll-out; while not wanting to appear to 'endorse' a controversial family planning method such as ECPs, the government nevertheless quietly worked to ensure safety for people accessing the drug at private pharmacies and eventual expansion to public health facilities. In Bangladesh, government leadership took a very strong role in the scale-up of ECPs, creating guidelines for providers and including EC in norms for family planning and sexual violence. Senegal's leadership has also taken steps to make ECPs more widely available, but continues to face pushback from religious opposition.

With strong support in the government, it is possible to generate the political will necessary to combat this opposition, as we have seen in other case studies.

Lesson learned: Whether ECPs are accessed in a public sector facility or a private pharmacy; governments play an important role in coordinating the scale-up process.

6. Recommendations

The analysis of the experience with ECPs in Mexico, Bangladesh, Kenya, and Senegal illustrates factors that contributed to success and failure, as countries went through the phases of introduction, scale-up, and sustaining ECPs within their health systems. The use of the ICEC 9-step Framework and WHO Health Systems Framework enabled E2A to distil important lessons that can inform current and future efforts to introduce and scale up ECPs in various countries. While any introduction and scale-up of a product/service, such as ECPs, is context-specific and no universal guidelines can be written, analyzing the synthesized information across the four country experiences resulted in evidence-based recommendations that can be used to guide programmatic integration of ECPs into health systems, making access to ECPs a reality for more women around the world. Our recommendations follow.

Know and address the specific contraceptive needs of women

Conducting formative research to determine knowledge gaps, evaluating the information needs of clients and providers related to EC, and conducting operations research to determine the feasibility of introducing ECPs in various sectors creates an evidence-based foundation for introducing, and later, scaling up ECPs. Once informational needs have been identified, an information and education campaign, including information, education, and communication materials and behavior-change strategies, can be developed to raise awareness, and change attitudes and behaviors about EC among potential users—critical to ensuring that demand is stimulated alongside supply.

Approaches to scaling up ECPs should be comprehensive, including a focus on distribution through public, private, and NGO health services sectors as well as pharmacies. A focus on these services for special groups such as adolescents, survivors of sexual assault, and women in conflict settings are recommended. Moving beyond provision of targeting only sexual assault survivors in the public system has proven challenging in some contexts where pharmacy access remains the most common delivery point, but Bangladesh's experience suggests it is possible. The Bangladesh case study also points to the possibility of reaching rural populations through field workers.

Create an enabling environment for sustainability

As seen in Mexico, Kenya, and Bangladesh, creating a consortium of representatives from the public, private and NGO sectors who are supportive of EC can drive the introduction and scale-up of EC by building comprehensive support for the product among the government, public, and providers themselves. Working together to expand access and build support at different levels is particularly important in contexts like Mexico or Kenya where EC is stigmatized due to erroneous beliefs about its mechanism of action and effect on sexual behavior. Likewise, reaching the media with information about EC, even if the media coverage does turn out controversial as it did in Kenya and Mexico, generates awareness and attracts public attention to EC products, which can help to generate demand and drum up support.

Before EC is expanded beyond the introductory phase, it is important to identify sectors of relevance for a sustainable implementation as well as to involve leaders and governments in the ECP scale-up process at various levels. This is crucial for minimizing constraints and maximizing opportunities for the institutionalization of ECPs into national health programs. Supportive national policies, laws and regulations should also be put in place that address the health needs of specific groups including survivors of sexual violence, young people, and rural populations.

Assure quality, availability and distribution of dedicated products

Registration of dedicated products helps increase legitimacy of the method (and subsequent buy-in from providers, policymakers and communities), though Mexico's experience suggests that moving forward with ECP introduction using the Yupze regimen is possible. Beyond registration, continued technical and

financial support to governments attempting to sustain the scale-up of ECPs may be necessary; the case of Bangladesh, where lack of supplies has decreased the ability to meet women's demand for EC, demonstrates this need.

Improve the quality of service delivery by ensuring multi-sector approach to health systems strengthening

Providers must not only know about the availability of ECPs, but must possess correct knowledge about its clinical profile (mechanism of action, safety and efficacy) and drug regimen. Trainings should reach a comprehensive subset of health professionals, including nurses, doctors, pharmacists, and field workers as well as other sectors such as schools and police. A supervisory/technical group that can oversee and provide technical guidance is an effective mechanism to attain national coverage. Efforts to gain buy-in from professional societies are particularly central to institutionalizing EC in pre-service and in-service training programs. Provider trainings must address quality of care in addition to technical knowledge, ensuring user-friendly counseling services and high-quality communication between providers and women so that women and men are not discouraged from requesting EC.

Track and document scaling-up process

Monitoring the process of ECPs introduction should include an assessment of provider and user knowledge of EC and experience with ECP services. Concerted efforts to utilize such findings to design and modify scale-up efforts—as was done in Bangladesh—is critical to ensure program success. It is important to define the multi-sector health systems strengthening modalities that are being considered from the beginning. These might include policy recommendations (legislation, norms, protocols and guidelines); programmatic strategies (trainings, information systems, organizational processes, dissemination and advocacy plans) and costs/resource mobilization. The implementation of these multi-sector modalities must be carefully documented to track achievements and challenges.

Conclusion

The report illustrates, through an analysis of four country case studies, the multi-sectoral strategies that governments, NGOs, and the private sector can apply to introduce and scale up ECPs through different service delivery channels considering the unique context of each country setting. Our goal is for the information to be useful to the diverse community of individuals and organizations working to promote EC access globally—for special populations such as young women, sexual violence survivors, and refugees and displaced persons, as well as for all women and men in need of post-coital contraception.

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Appendix I: Summary Service Protocol, ICEC and FIGO

Indication: Emergency Contraceptive Pills (ECPs) are indicated to prevent pregnancy after unprotected or inadequately protected sex.

ECP Regimens: Three regimens are packaged and labeled specifically for emergency contraception.

- Levonorgestrel 1.5 mg, or levonorgestrel 0.75 mg taken twice 12 hours apart
- Ulipristal acetate 30 mg
- Mifepristone 10-50 mg

Take the pills within 5 days after sex, as soon as possible after the sex act.

How ECPs Work: The primary mechanism is disruption of ovulation. Other mechanisms have been postulated but are not well supported by data. No evidence supports the theory that ECPs interfere with the implantation of a fertilized egg. ECPs do not cause abortion of an existing pregnancy.

ECP Efficacy: The levonorgestrel regimen reduces pregnancy risk by at least half and possibly by as much as 80-90% for one act of unprotected intercourse. The ulipristal and mifepristone regimens are more effective than the levonorgestrel regimen.

Safety: ECPs have no known medically serious complications. Side effects may include altered bleed- ing patterns, nausea, headache, abdominal pain, breast tenderness, dizziness, and fatigue. ECPs do not appear to be harmful if inadvertently taken in pregnancy.

Precautions and Contraindications: ECPs have no medical contraindications. Do not take ECPs if you are pregnant because they will not work.

Clinical Screening: You do not need any examinations or laboratory tests before taking ECPs.

ECP Use After More Than One Sex Act: Take ECPs after each unprotected sex act; do not wait until a series of acts has occurred. Use only one ECP treatment at a time (e.g., within a 12 hour period).

Repeated ECP Use: Use ECPs as often as needed. However, deliberate use of ECPs as a regular, routine contraceptive method is not recommended because more effective methods exist for this purpose.

Drug Interactions: Concurrent use of some drugs may reduce ECP efficacy. However, the ECP regimen is the same whether or not you are using these drugs.

Follow-up after ECP Use: No scheduled follow-up is required after ECP use. But if you have not had a menstrual period by 3 weeks after taking ECPs, consider that you may be pregnant.

Starting or Resuming Regular Contraceptives after ECP Use: ECPs are not designed to provide contraceptive protection at sex acts that occur in the future. Using a regular contraceptive after taking ECPs is CRITICAL to minimizing your pregnancy risk. Start hormonal methods (oral contraceptives, patch, vaginal ring, injectables, implants, levonorgestrel intrauterine system) either immediately or after your next menstrual period; if you wait, use a barrier method such as condoms in the interim. Copperbearing IUDs provide highly effective emergency contraception, so you do not need oral ECPs if you get this type of IUD within 5 days after sex. Do not rely on fertility awareness methods until you have had at least one normal menstrual period.

Appendix 2: Key Informant Interview Guidelines

- I. How were you involved in the work to introduce and scale up EC in COUNTRY?
- 2. Why was COUNTRY interested in introducing and scaling up EC?
- 3. What was achieved in COUNTRY in introducing and expanding EC?
- 4. What were the main reasons for this success?
- 5. I'd like to ask about several specific elements in your EC programs.
 - a. Was an assessment conducted before introduction of EC? If so, how was this done? Did this help the program? If yes, how?
 - b. Did you try to build support for EC? At what levels? What worked well?
 - c. Was a specific EC product selected for programs in your country? If so, which product? Has this helped the program?
 - d. Which types of providers were trained in EC? What worked well in these trainings? What were the main barriers in training providers?
 - e. What policy changes were made for ensuring access to EC? How successfully have these policies been implemented?
 - f. Were there efforts to meet the needs of specific populations, such as victims of sexual violence or youth?
 - g. Have EC services been monitored and evaluated? If so, how? Is EC included in the HMIS? Do you know of any specific program adjustments based on the M&E?
- 6. What were the main challenges encountered? How were these challenges addressed?
- 7. How extensive are EC services in COUNTRY? Was a scale-up plan developed? If so, who was involved in developing it?
- 8. How well have program changes continued over time? What programmatic changes remain? What program efforts have ended? Have there been other changes in EC services over time?
- 9. What were the main reasons for successful continuation? What were the main reasons for changes not being continued?
- 10. What would you have done differently to improve sustainability?
- 11. What are the main gaps currently in EC programming in COUNTRY?
- 12. What is something from the EC work that you are particularly proud of?
- 13. What was something that happened in your work on EC in COUNTRY that surprised you?
- 14. What recommendations would you give another country that was planning to introduce and scaleup EC?

Appendix 3: Salient introduction and scale-up features across case study countries

Introduction – the nine-step ICEC Framework

	Step I Assess user needs & service capabilities	Step 2 Build support for EC at appropriate levels	Step 3 Select a product	Step 4 Develop a distribution plan	Step 5 Identify and meet clients' information needs	Step 6 Train providers	Step 7 Introduce the product	Step 8 Monitor and evaluate EC services	Step 9 Disseminate evaluation results
Mexico	Formative	EC consortium	Yupze regimen;	Provider	Radio, TV, print	University,		Follow-up	
	research		First ECP registered in 2003	trainings & information campaign	materials, media outreach, hotline, website	NGO and public sector providers	√	surveys with providers and public	-
Bangladesh	Formative research; operations research	EC forum	First ECP registered in 1995	Public sector dissemination	Newspaper advertisement	-	V	M&E in introduction plans	Policy and operations adjustments based on M&E
Kenya	Formative research	EC consortium	First ECPs registered in 1992 & 1997	Phased approach	Brochures for clients	Providers in several districts	V	Evaluation of introduction project	-
Senegal	Formative research	ECafrique	First ECP registered in 2005	Health centers & FP guidelines	-	-	V	Evaluation of provider knowledge	Results informed scale-up

Sustainable Scale-up – the WHO Health Systems Framework

	Service Delivery	Health Workforce	Information	Medical Products	Financing	Leadership/governance
Mexico	Pharmacies – wide availability; public sector – special groups	EC institutionalized in national curricula	-	ECPs on EML; 12 ECPs registered	Prices in pharmacies vary	EC in FP & sexual violence norms; strong past govt. support that is waning
Bangladesh	Public sector - field workers & clinics; pharmacies	Providers & field workers trained; EC in training guidelines for FP providers	ECPs in provider reporting forms and central information management system	2 ECPs registered	ECPs free in public sector; about \$0.72USD in pharmacies	Sustained technical assistance has encouraged govt. commitment
Kenya	Pharmacies; public sector – limited to sexual assault survivors; limited availability in youth- friendly services	Effort ongoing by Ministry of Health to increase provider training	FP register tracks ECPs	ECPs on EML; 9 ECPs registered; presence of counterfeits	ECPs free in public sector, except provincial and district hospitals; prices vary in pharmacies; limited procurement in 2013	EC in FP &sexual violence norms; pharmaceutical assoc. developed protocol for ECPs sales; advocacy necessary to ensure supply
Senegal	Not yet widely available in public sector; efforts to introduce in schools	Efforts ongoing to train providers, including community workers & pharmacists	Need for logistics management system	ECPs on EML; 3 ECPs registered	ECPs about \$1USD; in pharmacies - \$6.50- \$7.50USD; supply outweighs demand	EC in FP norms; inclusion in rape care guidelines debated; religious opposition trumps govt. support

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