Long-Acting and Permanent Contraception: An International Development, Service Delivery Perspective

Roy Jacobstein, MPH, MD

Recent scientific findings about long-acting and permanent methods of contraception underscore their safety, effectiveness, and wide eligibility for individuals who desire them. This has led to new guidance from the World Health Organization to inform national policies, guidelines, and standards for service delivery. Although developing countries have made much progress in expanding the availability and use of family planning services, the need for effective contraception in general (and long-acting and permanent methods in particular) is large and growing because the largest cohorts in human history are entering their reproductive years. More than half a billion people will use contraception in developing countries (excluding China) by 2015, an increase of 200 million over levels of use in 2000. The health, development, and equity rationales that historically have underpinned and energized the international family planning effort remain valid and relevant today. Despite the other compelling challenges faced by the international health community, the need to make family planning services more widely available is pressing and should remain a priority. J Midwifery Womens Health 2007;52:361–367 © 2007 by the American College of Nurse-Midwives.

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INTRODUCTION

Over the past four decades, the organized international family planning effort has made great progress in expanding the availability and use of voluntary reproductive health and family planning services. Access to modern contraception has become recognized by the international community as a basic human right; however, obstacles and challenges remain.

Meeting the current needs for family planning is difficult. An even greater challenge will be to meet the contraceptive needs of the largest cohorts in human history to enter their reproductive years. There will be more than half a billion contraceptive users in developing countries (excluding China) by 2015, an increase of 200 million people over the number of people using contraception in 2000. Whereas the rates of modern contraceptive use in North America and Western Europe are over 70%, such use is still very low in East Africa (17%), Middle Africa (5%), and West Africa (6%).

Related to these levels of contraceptive use, maternal mortality is a great rarity in the developed world (e.g., two deaths per 100,000 live births in Sweden), whereas in the developing world, maternal morbidity and mortality is much more common. For example, there are one or more maternal deaths for every 100 births in 17 of the 36 countries in West, Middle, and East Africa. Women in sub-Saharan Africa face a one in 16 (6.25%) lifetime risk of maternal mortality and an even greater risk of maternal morbidity. By contrast, women in developed countries face a lifetime risk of maternal death of one in 2800 (.035%).

Recent scientific findings and new understanding about long-acting and permanent methods of contraception underscore their safety and effectiveness. This has led to new guidance from the World Health Organization (WHO), as well as continuing strong support by the US Agency for International Development (USAID) for family planning in general and for long-acting and permanent methods of contraception in particular. The methods considered “long-acting” in this context are intrauterine devices (IUDs) and implants; vasectomy and female sterilization are considered “permanent.” Injectable methods, such as Depo-Provera (Pfizer U. S. Pharmaceuticals, New York, NY), are considered “short-acting” because their lengths of action are only from 1 to 3 months.

WHO’s guidance documents are available to inform national policies, guidelines, and standards for delivery of family planning services, which in turn should help foster wider access to family planning services. Wider access to and use of family planning, especially of long-acting and permanent methods of contraception, which are the most effective contraceptives available, can substantially reduce the high levels of maternal mortality and morbidity in developing countries, as well as unwanted pregnancies and abortion.

In recognition of the pressing need to make quality, voluntary family planning services more widely available, the Office of Population at USAID designed the Access, Quality, and Use in Reproductive Health (ACQUIRE) Project, a 5-year, $150 million project that...
foci on facility-based services and clinical contraception, especially long-acting and permanent contraception.

**WHO GUIDANCE FOR FAMILY PLANNING USE**

WHO has developed evidence-based tools that help providers and clients choose an appropriate contraceptive method. These tools include a family planning handbook for frontline providers, a counseling tool, and two guidance documents: *Medical Eligibility Criteria for Contraceptive Use* and *Selected Practice Recommendations for Contraceptive Use*. The eligibility criteria and practice recommendations are based on systematic reviews of the latest clinical and epidemiological research. They are meant to inform and rationalize national service delivery guidelines, policies, standards, and practices, leading to improved access, quality, and use of the range of modern family planning methods. Updated guidelines and policies also can help reduce or eliminate unjustified medical policy and practice barriers.

The *Medical Eligibility Criteria* gives guidance on the safety and appropriate use of modern methods of contraception. The question addressed is, “In the presence of a given medical condition or client characteristic, can a particular family planning method be used, and with what degree of caution or restriction, as reflected in four classification categories?” These classification categories represent gradations based on likely benefits and risks. The *Medical Eligibility Criteria’s* schema also distinguishes among providers “with clinical judgment” and “with limited clinical judgment” (Table 1). For providers with limited clinical judgment, Categories 1 and 2 become “Yes, use the method,” while Categories 3 and 4 become “No, do not use the method.” These distinctions and simplifications are helpful, particularly in the countries of sub-Saharan Africa and South Asia, where human resources for health care are scarce, and thus much of family planning service delivery must be provided by providers with relatively limited training.

The *Selected Practice Recommendations* functions as a set of frequently asked questions. Practice recommendations address common clinical issues that arise in the provision of modern contraceptive methods. Based on systematic review of available scientific evidence buttressed by expert consensus, the *Selected Practice Recommendations* addresses 33 common questions providers are likely to have about various modern contraceptives and advises on their safe and effective use. For example, “When can a woman have a copper-bearing IUD inserted?” or, “When can a man rely on his vasectomy for contraception?”

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**Table 1. WHO Medical Eligibility Criteria, Classification Categories**

<table>
<thead>
<tr>
<th>Classification Category</th>
<th>Provider With Clinical Judgment</th>
<th>Provider With Limited Clinical Judgment</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Use method in any circumstances</td>
<td>Yes, use the method</td>
</tr>
<tr>
<td>2</td>
<td>Generally use the method</td>
<td>Yes, use the method</td>
</tr>
<tr>
<td>3</td>
<td>Use of method not usually</td>
<td>No, do not use the method</td>
</tr>
<tr>
<td></td>
<td>recommended unless other</td>
<td></td>
</tr>
<tr>
<td></td>
<td>more appropriate methods are</td>
<td></td>
</tr>
<tr>
<td></td>
<td>not available or not</td>
<td></td>
</tr>
<tr>
<td></td>
<td>acceptable</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Method not to be used</td>
<td>No, do not use the method</td>
</tr>
</tbody>
</table>

From the World Health Organization.

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**THE COPPER INTRAUTERINE DEVICE**

The copper IUD (CuT 380A) has an effectiveness profile comparable to that of female sterilization, vasectomy, and implants. Three to eight women per 1,000 using the CuT 380A IUD become pregnant in the first year of use. A long-term international study sponsored by WHO found an average annual failure rate of 0.4% or less, and a cumulative failure rate after 12 years of use of 2.2%, which is comparable to that of female sterilization.

Copper-bearing IUDs have been shown to be very safe for most women (Category 1 or Category 2). This includes women who are: postpartum, postabortion, and farther from pregnancy or birth (i.e., “interval” IUD insertion); breastfeeding; HIV-infected; young and/or nulliparous; and unable to use hormonal methods. IUDs are highly protective against ectopic pregnancy via their high efficacy in preventing any pregnancy. Women who use copper-bearing IUDs have a 91% lower absolute risk of ectopic pregnancy than do women using no contraception. However, among women who do become pregnant while using an IUD, the relative risk of ectopic pregnancy is higher than in non-users, with an estimated 6% to 8% being ectopic. Still, this means that 92% to 94% of the rare pregnancies in IUD users will not be ectopic. While some women report increases in menstrual bleeding with copper IUD use, no significant changes in hemoglobin levels have been found. WHO thus advises that the CuT 380A can generally be used by women with iron deficiency anemia (Category 2).

Despite the findings that confirm the IUD’s high degree of safety and effectiveness, as well as its suitability for most women, efforts to ‘revitalize’ IUD use in developing countries family planning programs have many challenges. Providers tend to overestimate the IUD’s association with negative side effects and conditions. In addition, myths and misconceptions at the client and community levels remain widespread.
 PROVIDER CONCERNS ABOUT IUDs

Providers typically have three primary concerns about IUDs. Usually, these are that the IUD may: 1) cause pelvic inflammatory disease (PID); 2) cause infertility; and/or 3) be unsuitable for HIV-infected women.

Pelvic Inflammatory Disease

Rates of clinical PID are very low among IUD users, between 0.6 and 1.6 cases/1000 woman-years of use after the first 20 days of use. That is, roughly 999 of 1000 women receiving an IUD do not get PID. When PID does occur in a woman who has an existing IUD, it is caused by *Chlamydia trachomatis* and *Neisseria gonorrhoeae* (or other sexually-transmitted organisms), not by the IUD itself. A large WHO study of 23,000 IUD insertions with 51,000 woman-years of follow-up found modest increased short-term risk of PID in IUD users: 7 cases/1000 women in the first 3 to 6 weeks post-insertion. After this time, PID risk appeared comparable to that of women not using an IUD. These findings are the basis for WHO’s practice recommendation that only one routine follow-up visit need be conducted, after the first menses or 3 to 6 weeks after IUD insertion, but that subsequent routine follow-up visits are not needed.

Providers working in countries with higher prevalence of sexually-transmitted infection (STI) and fewer resources for STI testing and treatment may wonder if these findings apply to their setting. No prospective studies exist, so inferences must be drawn from modeling studies. One such study using conservative estimates of each relevant variable found that even where STI prevalence is high (10%), in the absence of screening of any type, about one case of PID would occur in every 333 IUD insertions. This risk could be halved to one case in 667 insertions by simple screening for STI risk prior to IUD insertion. Even if these estimates are off by a factor of six, the study notes, estimated risk of PID from IUD use would still be less than 1% in high-risk settings. In addition, this risk should not be compared to zero, but rather should be weighed against the other sizeable risks a woman in such settings faces. The modeling study offers an additional view of these risks: if 25% of the IUD-associated PID causes infertility (twice the level associated with a single PID event), then without any screening, for every 2700 IUD insertions, one case of IUD-associated infertility would occur. In settings with a high prevalence of STIs, the consequences of denying IUDs to 2700 women would be 2160 pregnancies, at least 400 serious obstetrical complications, one to two deaths from pregnancy and childbirth, and unknown mortality and morbidity from unsafe abortion.

These considerations are often not borne in mind by family planning providers who, like medical practitioners everywhere, tend to be very fearful of the “harm of doing” but often don’t fully consider the “harm of not doing.”

Infertility

The second related provider concern is that the IUD might be associated with infertility, a personal tragedy everywhere, and in social context, highly disadvantageous to most women in developing countries. A well-designed study compared nulligravid, infertile women with primigravid women and found similar patterns of previous copper IUD use. Tubal infertility was not associated with IUD use per se, or with duration of use, reason for removal, or gynecologic symptoms during use. Rather, presence of antibodies to *C trachomatis* was associated with infertility.

HIV/AIDS

Recent evidence suggests that IUDs are generally safe in women with HIV/AIDS. Two cohort studies in Kenya found comparably low overall and infectious complication rates (7%–10% and 0.2%–2% respectively) following IUD insertion in HIV-infected women. The studies conclude that HIV does not appear to increase the risk of IUD-related adverse events, including PID. An ancillary study found cervical shedding of HIV, a proxy for increased infectivity to the male partner, is not increased with IUD use, and concluded that IUD use by HIV-positive women does not appear to increase the risk of acquiring HIV among their HIV-negative male partners. In response to this evidence, WHO has changed its guidance for IUD use by women with HIV and AIDS. Previously, for theoretical reasons only, IUD use by HIV-infected women had been Category 3. The concern had been that the PID risk might be increased because of the overall immunosuppressive effects of HIV. Now, use of an IUD in women who are HIV-infected or have AIDS is Category 2, except for the situation of IUD initiation in a woman with AIDS who is ill and/or on antiretroviral therapy, which is Category 3 (Table 2). One practice implication of these new classifications is that if a woman who has an IUD in place develops AIDS, the IUD may remain in place.

PROGRAMMATIC CONSIDERATIONS ABOUT THE IUD: ACCESS

Access to the IUD could potentially be greater than access to female sterilization or vasectomy, because more service cadres can provide the IUD because it is a non-surgical method. Also, unlike sterilization, the IUD is a method quite suitable for women wishing to space births as well as those who have completed childbearing. From the standpoint of economic access, the IUD is the most cost-effective method after 1 to 5 years of use, depending on the study. Finally, IUD use for women who are HIV-positive is likely to become even
Table 2. Overview: Current (2004) Medical Eligibility Criteria for IUD Use in Clients with STIs or HIV/AIDS

<table>
<thead>
<tr>
<th>Category</th>
<th>Initiation</th>
<th>Continuation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Increased general risk of STI (high prevalent setting)</td>
<td>2*</td>
<td>2</td>
</tr>
<tr>
<td>High individual risk of STI</td>
<td>3†</td>
<td>2</td>
</tr>
<tr>
<td>Current chlamydial or GC infection, or purulent cervicitis</td>
<td>4‡</td>
<td>2</td>
</tr>
<tr>
<td>HIV-positive</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>AIDS</td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td>AIDS and clinically well on ARV</td>
<td>2</td>
<td>2</td>
</tr>
</tbody>
</table>

ARV = anti-retroviral therapy; GC = gonorrhea; STI = sexually-transmitted infection.
*Category 2: A condition where the advantages of using the method generally outweigh the theoretical or proven risks.
†Category 3: A condition where the theoretical or proven risks generally outweigh the advantages of using the method.
‡Category 4: A condition that represents an unacceptable health risk of the contraceptive method is used.

From the World Health Organization.3

The hormonally-induced decreased menstrual bleeding from levonorgestrel-containing IUDs may be an advantage in settings of high iron-deficiency anemia, such as in much of the developing world. Sociocultural aspects of menstrual bleeding and spotting might pose acceptability issues and underscore the need for good anticipatory counseling. However, the greatest impediment to current and likely future widespread programmatic use of the LNG-IUS in developing countries (where per capita income for all needs may be a dollar or less per day) is that the device is 30 to 80 times more costly (approximately $40) to developing country programs than is the CuT 380A ($0.50–$1.50).5

PROGESTIN-CONTAINING SUBDERMAL IMPLANTS

There are three progestin-containing subdermal implants. The first implant to be developed was Norplant, which is no longer being manufactured. Norplant had six levonorgestrel-containing capsules, and was used for up to 7 years. The two implants currently available internationally are Jadelle (Schering Oy, Pharmaceuticals, Turku, Finland) and Implanon (Organon USA Inc., Roseland, NJ). Jadelle contains two flexible, silicone-based polymer rods that are 43 mm in length and 2.5 mm in diameter; each rod contains 75 mg levonorgestrel, low levels of which are continuously released into the blood over Jadelle’s period of use, approved by the U. S. Food and Drug Administration (FDA) for up to 5 years. Implanon has one rod that contains 68 mg of etonogestrel, and is used for up to 3 years. While both implants have been approved by the FDA, only Implanon is available in the United States.

The effectiveness of these three implants are comparatively high, with failure rates of 0.1% to 0.2% or lower in the first year of use.25

Because they have fewer elements to be implanted than Norplant, Jadelle and Implanon offer faster and easier insertion and removal. In mid-2006, USAID entered into a 5-year procurement contract with the manufacturer Schering Oy for the provision of Jadelle. USAID’s cost will be $21 per set, with delivery from the manufacturer beginning in January 2007.

FEMALE STERILIZATION

Female sterilization is the most widely-used modern method of contraception in the world, in both developing and developed countries.26 Female sterilization can be performed postpartum, after spontaneous or therapeutic abortion, or as an interval procedure (unrelated in time to a pregnancy). The timing of the procedure influences both the surgical approach and the method of tubal occlusion.

more programmatically important in the next few years, as antiretroviral therapy continues to become more widely available in developing countries, and HIV-infected women of reproductive age live longer and healthier lives.

THE LEVONORGESTREL-CONTAINING IUD

Levonorgestrel-containing (or “levonorgestrel-releasing”) IUDs release 20 micrograms of the progestin levonorgestrel into the uterus daily. (Developers of this IUD refer to it as an intrauterine “system”: the LNG-IUS, helpful terminology which will be used here.) The LNG-IUS prevents pregnancy mainly via local hormonal effects in the uterine cavity: prevention of endometrial growth, thickening of cervical mucus, and inhibition of sperm motility and function. After an initial increase in spotting during the first few months, the LNG-IUS brings about a markedly significant reduction in bleeding and/or spotting. In women with normal menstruation, the LNG-IUS reduces blood loss by 75% at 3 months and reduces the number of bleeding days. After the first year of use, 70% to 90% of women using the LNG-IUS experience a reduction in monthly bleeding, and 20% to 30% of women experience no bleeding at all.24

The LNG-IUS is effective for 5 years and has a somewhat lower failure rate than that of copper-bearing IUDs (0.1%–0.3% in the first year of use).8 Unlike copper-bearing IUDs, the LNG-IUS cannot be used to provide emergency contraception.24 WHO’s medical eligibility classification categories and practice recommendations for levonorgestrel-containing IUDs are the same as for copper-bearing IUDs, except for clinical considerations related to the hormone the IUD contains.3,4

Increases general risk of STI (high prevalence setting)
There is no new evidence about the effectiveness of female sterilization, but some aspects of its effectiveness bear mention, as they may seem “new.” Although female sterilization is intended to be permanent, and its effectiveness, like other long-acting and permanent methods of contraception, is very high, the risk of failure continues for years after the procedure and does not diminish with time. The Centers for Disease Control and Prevention reported cumulative pregnancy rates in the United States of 5.5 pregnancies/1000 women at 1 year, 13/1000 at 5 years, and 18.5/1000 at 10 years. That is, there were almost two pregnancies per 100 women by 10 years, though this risk varied by method and timing of sterilization, age, race, and ethnicity.

Female sterilization, like the IUD, is highly protective against ectopic pregnancy because it is so effective at preventing pregnancy. However, among women who do become pregnant after female sterilization, the relative risk of ectopic pregnancy is higher than it is in non-users, although risk varies substantially by method and timing of sterilization. In the aggregate, the 10-year cumulative probability of ectopic pregnancy after female sterilization by any method was found to be 7.3 per 1000 procedures. This means approximately one-third of female sterilization failures resulted in ectopic pregnancy, two-thirds in intrauterine pregnancy.

WHO ELIGIBILITY CRITERIA FOR FEMALE STERILIZATION

According to WHO, there is no medical condition that absolutely restricts eligibility for female sterilization, but some conditions and circumstances require additional considerations. For female sterilization (and vasectomy) only, the Medical Eligibility Criteria thus uses a different classification scheme, which also has four classification categories: A (Accept: “no medical reason to deny sterilization to a person with this condition”); C (Caution: “the procedure is normally conducted in a routine setting, but with extra preparation and precautions”); D (Delay: “the procedure is delayed until the condition is evaluated and/or corrected”); and S (Special: “the procedure should be undertaken in a setting with an experienced surgeon and staff, equipment needed to provide general anesthesia, and other back-up medical support . . . ”). High risk of HIV and being HIV-infected are both classified A; AIDS is classified S, with a clarification that the presence of an AIDS-related illness may require a delay in the procedure.

New Method of Transcervical Sterilization

In 2002, the FDA approved the use of a new transcervical sterilization device, Essure (Conceptus Inc., Mountain View, CA). Essure consists of two micro-inserts, which have a stainless steel inner coil, a nitinol outer coil, and polyethylene (PET) fibers. After hysteroscopic placement into the uterine end of each fallopian tube, where the micro-inserts remain anchored, tubal occlusion results from stimulation of tissue ingrowth by the PET fibers during the first few months post-placement. Backup contraception is needed for 3 months, after which time a hysterosalpingogram is performed to confirm occlusion. Essure is not available in family planning programs in developing countries, nor is it likely to become available, because of considerations of cost, practicality, and (the lack of) comparative advantage.

**VASECTOMY**

The effectiveness of vasectomy is comparable to the other long-acting and permanent methods. It is important to remember that vasectomy is not effective immediately after it is performed. Failure (pregnancy) rates with vasectomy are commonly quoted in the range of 0.2% to 0.4%, but failure rates as high as 3% to 5% have been reported from some countries. Failure may be caused by client behavior (incorrect use of backup contraception after the vasectomy for the recommended timeframe of 12 weeks), or may be because of a failed technique itself. This underscores the importance of good preoperative counseling, so men know that vasectomy failure does not equate to spousal infidelity.

Vasectomy is a very safe and simple surgical form of contraception with few restrictions. Major morbidity and mortality with vasectomy is rare and there are generally no adverse long-term effects. Minor complications, such as postoperative pain, infection and bleeding, and chronic pain, occur at levels of 5% to 10%. There are fewer complications with the “no-scalpel” vasectomy technique, which entails a small puncture in the scrotum rather than an incision.

In developing countries reproductive health and family planning programs, vasectomy is typically provided under local anesthesia in an outpatient setting. Although vasectomy is safer, simpler, less expensive, and comparably effective compared to female sterilization, it remains the least known and least used modern contraceptive method in developing countries.

There is one new WHO recommendation with respect to vasectomy: a man should wait 12 weeks before relying on his vasectomy for contraception. WHO no longer recommends the alternative of waiting until after 20 ejaculations.

**THE ACQUIRE PROJECT**

To help meet the challenge of “keeping family planning on the radar screen,” USAID’s Office of Population designed the ACQUIRE Project. ACQUIRE is a 5-year, $150 million project, the aim of which is to increase the use of reproductive health and family planning services, with a focus on facility-based services and clinical contraception, especially long-acting and permanent contraception.
In 2003, USAID awarded ACQUIRE to a partnership headed by EngenderHealth that includes: the Adventist Development and Relief Agency International; CARE; IntraHealth International; Meridian Group International; and the Society for Women and AIDS in Africa. The partners have complementary expertise and experience that addresses reproductive health and family planning service delivery needs from the perspectives of health systems, providers, clients, and communities.

ACQUIRE operationalizes its mandate into three programmatic priorities: 1) expand contraceptive services and choices; 2) increase participation of clients, providers, and communities; and, 3) expand the number of service sites offering a range of reproductive health and family planning services. That is, “more methods and services to more people in more places.” ACQUIRE does this by providing service-oriented technical assistance to reproductive health and family planning programs in sub-Saharan Africa, Asia, and Latin America. In program implementation, ACQUIRE’s guiding principles emphasize: 1) The fundamentals of care (informed decision-making, clinical safety, and quality assurance and management); 2) Identification, adaptation, and use of proven, or “best” practices; 3) Taking a holistic, systems approach that pays attention to program elements on both the “supply side” (e.g., service site readiness and capacity, training needs, and security of contraceptive logistics and supplies) and the “demand side” (e.g., mass media and interpersonal communication, community involvement, and other behavior change interventions); 4) Use of data for decision making, especially locally-generated data; and 5) Participatory programming to foster ownership and sustainability.

ACQUIRE also incorporates considerations about the dynamics of behavior change into its long-acting and permanent contraception methods programs. The challenge is to turn the latest scientific knowledge and best practices in reproductive health and family planning service delivery into accurate perceptions and understandings—“truths”—held by clients, providers, policymakers, and programs, who will in turn, act upon these new truths with appropriate behavior change. The evidence-based, time-tested theory of the diffusion of innovations serves as a useful theoretical framework that helps identify best programming practices, which may facilitate the changes or innovations being fostered, such as greater access to and use of long-acting and permanent contraception by individuals who want to effectively space or prevent pregnancies.

Using what is known about effecting change leads to such implementation approaches as: identification and nurturance of “champions”; working from both a “client perspective” and a “provider perspective”; the use of satisfied clients in communication efforts; identification of causes and solutions of barriers to service provision; the use of messages that focus on the benefits of long-acting and permanent contraception as perceived by the potential user, not by the service system or ACQUIRE; and the design of initial/pilot efforts with scale-up (diffusion) in mind, planned from the start. This consideration of change also leads to more realistic program goals and timeframes, as it underscores the reality that “change takes time,” especially in medical/clinical settings, which are often conservative and change-resistant.

CONCLUSION

Recent findings and new understandings about various contraceptive methods, including long-acting and permanent methods, have led to new evidence-based guidance from WHO. There is a large and growing need in developing countries for effective contraception in general and for longer-acting and permanent methods in particular, because the largest cohorts in history are entering their reproductive years. The USAID-designed and funded ACQUIRE Project is working to increase access to and use of good quality, voluntary reproductive health and family planning services in developing countries in Africa, Asia, and Latin America. The health, development, and equity rationales that historically have underpinned and energized the international reproductive health and family planning effort remain relevant and valid today.

REFERENCES


