

Intrauterine Devices (IUDs) in Developing Countries:
Assessing Opportunities for Expanding Access and Use

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“A deeper commitment to contraception, including the IUD, can ease the burden of many health problems in every country. Foundations can highlight the leverage that contraception offers for lessening those burdens. They can advance advocacy at the highest levels and partner with other donors in a common strategy, thus leveraging the investment of USAID and the private sectors commitment.”

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FORWARD

At the beginning of 2006, the Hewlett Foundation's Population Program sought an assessment of the potential of the IUD as a contraceptive method in developing countries and ways to improve IUD availability, acceptance, and effectiveness. A team of three consultants—Amy E. Pollack, John Ross and Gordon Perkin—conducted an analysis during the first part of 2006 on: (1) public health benefits of the IUD; (2) programmatic factors influencing IUD use; (3) supply issues, including analysis of public-private partnerships; and finally (4) options for Foundations considering support for IUD programs. This report is primarily geared toward the donor community, especially private foundations, and may also be of interest to program planners, researchers, and advocates.

EXECUTIVE SUMMARY

I. Overview

The intrauterine device (IUD) has long been recognized as an inexpensive, highly effective, long-acting, reversible method of contraception. Even though it is ideal in so many ways, the history of its development reflects continual adaptations to minimize the side effects that lead to early discontinuations, and to maximize both contraceptive and non-contraceptive health benefits. The IUD should play a greater role than it does today in parts of the world, and especially sub-Saharan Africa, where fertility rates, unintended pregnancies, and unmet need for contraception are high. Those same parts of the world struggle against severe health problems and health system shortcomings that highlight the non-contraceptive (health) advantages of a hormonal IUD if it could be deployed widely. However, despite past efforts, many parts of the world in greatest need have surprisingly low rates of IUD use. Understanding the clinical, setting, and programmatic barriers should inform future investments for the global expansion of IUD use and new IUD product development.

This report initially reviews the history, clinical aspects, and some of the broad “setting” characteristics that have most likely influenced IUD use. The second section analyses programmatic issues that have equal or greater influence on overall use. The third section analyzes supply issues, examining options for increasing uptake of the TCu 380A or expanding the marketplace through either a new IUD or greater access to the LnG IUD currently unavailable in developing countries. Finally, we present an assessment of options for Foundation support for expanding IUD uptake in the future based on our findings. The report is meant to be an inclusive review of both published and unpublished findings. Although we were asked specifically about recommendations as they apply to sub-Saharan Africa, the report is not limited in that regard. We include our recommendations for development and introduction of a new IUD for the public sector that would be cost-effective and offer new health benefits. A time frame for development and clinical assessment of a new IUD is included in the report (see Table 12 on page 54).

II. Current IUD use

WHO estimates that approximately 160 million women worldwide use IUDs today. China has an estimated two-thirds of these users, or 96 million. Only a small percentage of current users are in eastern or western Europe or other industrialized countries (10%). The remaining 24% are in developing countries other than China, concentrated in Vietnam, Egypt, Indonesia, India, Uzbekistan, and Turkey. These six countries alone contain half of all users in developing countries excluding China.

A remarkable geographic pattern of IUD users exists. Most developing countries fall into clusters, which show widely different determinants of use. In the former USSR republics, the absence of other contraceptive options was paired with strong clinical capacity; in China and Vietnam it was government control; in North Africa and the Middle East it was an aversion to sterilization, considerable clinical capacity, and a cultural acceptance of the IUD. In Latin

American and most of Asia, however, the pattern is more idiosyncratic. Where clinical services and trained providers are inaccessible and other method options sometimes exist, IUD uptake is negligible, as is the case across all of sub-Saharan Africa.

III. Clinical characteristics that influence IUD use

Several types of IUDs exist, however the most widely available IUD is the TCU 380A. It is highly effective and long acting, easy to insert, and has a low complication rate. No new IUD is likely to offer a significant improvement over its essential qualities. However, side effects that lead to early discontinuation, such as increased bleeding or menstrual pain, could be improved upon, and would likely improve its continuation rate. That would also increase the pool of satisfied clients (improved provider training and better client counseling should have a similar effect, on any IUD).

The Mirena Lng IUD, its wider distribution limited by cost more than anything else, compares favorably with the safety and efficacy profile of the TCU 380A, although it is more difficult to insert and has a shorter approved duration of use. Moreover, studies that compare the two IUDs suggest that despite a decrease in irregular and menstrual bleeding, continuation rates are lower than with the TCU 380A, which may reflect user concerns about induced oligomenorrhea or amenorrhea and a different risk ratio faced by developing country women. A Lng-induced decrease in uterine blood loss related to either menses or other intrauterine abnormalities (especially in the peri-menopause) could provide an important therapeutic public health benefit, especially in sub-Saharan Africa where anemia rates are remarkably high. However, evidence that the Lng IUD could significantly impact the multifactorial type of anemia present in the region is very limited to date.

Several newer hormonal IUDs are under development, which include design changes to improve ease of insertion and possibly alter associated pain or bleeding pattern. Duration of use remains limited compared to the TCU 380A's 10-year approval (tested for 14 years). Through new product development, a negotiated public sector price should be possible that would remove the cost barrier to expanding the IUD market, with a greater diversity of products.

IV. Setting and programmatic characteristics that influence IUD demand and use

Our review of setting and program issues that have influenced IUD use historically points to both conditions for "success" and barriers for "failure." Invariably, the capacity of the health sector is key, that is, socioeconomic and infrastructure conditions that constrain access to services. Equally, policy positions and the vigor with which they are enforced matter greatly, such as, the shared commitment to the IUD at central, clinic, and provider levels including resources for ongoing training, information and education, and consumer marketing). The private medical sector cannot be ignored; it has its own life and can be independently important. Cultural forces are relevant in some cases. All these factors influence the contraceptive method mix.

"Demand" for a specific method therefore cannot be understood in isolation. While IUD prevalence is high wherever IUD access is high, "access" is usually a marker for other program features as well. USAID's IUD revitalization project notes the transition in Kenya's method mix away from IUD use and toward injectable use, without an increase in total contraceptive prevalence. Sterilization use also declined in the same period (1998-2003). For these clinical

methods, it is impossible to know whether the declines reflect the increasingly stressed health care delivery setting, the influence of myths about IUD safety, or the appeal of the injectable's special features. Ultimately, clinic based services that require a trained provider and a medical procedure (whether a pelvic exam or surgery) rest on a different infrastructure and programmatic commitment than commodity supply and distribution, whether for pills, condoms, or injectables. Although some countries in Asia or Latin America neglect the IUD, every country in sub-Saharan Africa does so, with only very slight differences by education or residence categories. In addition, although the IUD is considered a safe and effective method for use by HIV infected women, it provides no STI protection and its promotion has been called into question where improved barrier methods are badly needed.

In recognition of the underutilization of the IUD, two distinct programmatic efforts are underway. Certain USAID cooperating agencies have, through various funding streams, organized to revitalize the IUD through both operations research and program/IEC initiatives, focused chiefly on sub-Saharan African countries but with exceptions in other regions. Preliminary results confirm the nature of "macro" level barriers that exist within the health sector. However, the growing private sector in some countries may present an opportunity for growth and should be closely followed. While these social marketing, social franchising, or private clinic services may not reach the lowest socioeconomic quartile, they can, through consistent commodity supply and trained, less biased providers, expand IUD use within their own markets. Increasing the pool of users in that way may quicken interest and familiarity with the IUD in general.

V. Affordability of a hormonal IUD and its influence on access and supply

In recognition of the significant health benefits of the hormonal IUD, the question was raised as to whether public sector pricing (removal of the cost barrier) of either the existing Mirena Lng IUD, a generic version, or a new hormonal IUD could not only provide public health benefits but also catalyze increased interest in IUD use. Based on current manufacturing limitations a public-private sector partnership would allow for a public sector price of under USD \$5.00 for one option only- the development of a new IUD. Although this option would require an up front investment to support certain aspects of the necessary clinical research, it would allow for a re-design to address design issues associated with the Mirena. The product price differential, in comparison with the TCU 380A, would be minimized if spread over the first five years of use.

Introduction of this new IUD could be 5 to 10 years away, and would be a strategic investment requiring long-term vision and donor commitment. Such an investment would be highly likely to succeed in providing a new, highly effective contraceptive option with associated significant health benefits to women worldwide at a low public sector investment in return for an acceptable public sector price. In the foreseeable future, however, it is clear that, a new IUD will not change the landscape of negligible IUD use in sub-Saharan Africa.

VI. Recommendations

Development of an affordable hormonal IUD: This should be an area of consideration for long-term investment, even though there is a lack of evidence regarding the public impact that would significantly impact use in sub-Saharan Africa. The innovation is one that promises to change or save lives if deployed on a large enough scale; it offers the potential of expanding IUD

use in regions other than sub-Saharan Africa. It should be noted that obtaining a guaranteed public sector price is probably a time-limited option, one that requires a prompt commitment if this objective is to be realized.

If this recommendation is endorsed, key areas of support could include preparation for case studies in selected countries matched to: 1) WHO clinical trial sites; 2) potential for both private and public sector expansion; 3) acceptability for ICA donated Mirena LnG. The published case studies would support advocacy efforts at the national level once trials are completed and introduction is underway.

Large scale support for promotion or expansion of IUDs in sub-Saharan Africa: Efforts should focus on continued support for those organizations working with USAID on revitalization projects. Key areas of support could include: 1) full project evaluation of the revitalization projects, beyond the possible termination of vulnerable USAID funding; and 2) documentation and widespread dissemination of evaluation findings from these projects to inform further investments and program innovation.

Support for Private Sector: Continued or new investments to support expansion of IUD use in the private sector in selected countries. Again, documentation and widespread dissemination of program results to inform further investments and program innovation is recommended. A specific investment in social marketing/franchising projects with the intention of further describing private sector capacity and replicable models is worth considering.

Identify a grantee to design a collaborative project taking into account currently completed or proposed case studies of IUD availability, acceptability, and use, and identify 2-4 additional countries to prepare for the new hormonal IUD introduction.

Research Priorities: Consider supporting the following: Operations research demonstrating service delivery implementation and demand for the method would be a contribution to the literature and inform some settings where advocacy requires an evidence base. Research of the significance of amenorrhea in different populations and how to counsel and communicate about the advantage of the new IUD to both providers and clients.

INTRODUCTION

The intrauterine device (IUD) has long been recognized as a highly effective, long-acting, reversible method of contraception. Ideal in so many ways, the history of its development reflects the widespread interest in continual revision of the device concept in an effort to minimize side effects leading to early discontinuation, and maximize both contraceptive and non-contraceptive health benefits. In parts of the world where fertility rates, unintended pregnancy, and unmet need for contraception are high, the IUD should play a greater role in providing a safe and highly effective contraceptive option than it does today. Despite past efforts, parts of the world in greatest need have surprisingly low rates of use. This may be because both clinical aspects of the IUD (foreign body, associated menstrual changes) and programmatic barriers (the need for the commodity, a procedure, training, and a motivated provider) collide and dilute the ideal aspects of the contraceptive impact itself.

This paper reviews the history, geographic distribution, and clinical aspects of IUDs that influence IUD use. The second section analyzes programmatic issues that have equal or greater influence on overall use. The third section addresses supply issues, examining options for increasing uptake of the TCu 380A or expanding the marketplace through either a new IUD or greater access to the LnG IUD currently unavailable in developing countries through lower pricing. Finally, we will present an assessment of options for Foundation support for expanding IUD uptake in the future based on our findings. We include our recommendations regarding development and introduction of a new IUD for the public sector that would be cost effective and offer new health benefits. A time frame for research and development is included in the report (see Table 12 on page 54).

History of IUD development and use

IUD use was first reported in the 1800's and in 1902 Hallwig designed a pessary that had a stem extending into the cervical canal that was marketed for self-insertion. This was followed by Richter's silk and catgut ring covered in nickel and bronze wire and then Pust, who developed another ring for intrauterine use, utilized during WWI. Problems with infection attributed to the tail string led to the next innovation, the Graefenburg ring, in 1930. Contraception in Germany was highly discouraged; Graefenburg was exiled, leaving the problem of high expulsion rates unaddressed. In the 1960's there was revived interest in the IUD and a plastic device with an inserter was developed. The first reported international conference on IUDs took place in 1962, where different products were compared and the Lippes Loop was presented, followed shortly by the Tatum T with added copper (contraceptiononline 2006). The Dalcon Shield, introduced in 1970 was designed to decrease expulsion, however high rates of infection attributed to its multifilament tail led to its discontinuation and the stigma associated with IUD use in the US is still prevalent today.

Trends in IUD use in the rest of the industrialized world are not as dismal but remain disappointing. Based on 2004 United Nations data, Eastern and Western Europe represent 4-5% of global IUD use, despite a greater diversity of types of IUDs that have been approved for use than in the US (Wildemeersch 2003). IUD use in the United States is very low; estimated at 2%

in 2002 (Mosher, 2004). Recently, an increase in evidence supporting the use of the LnG IUD for non-contraceptive benefits such as treatment of menorrhagia in the peri-menopause has led to uptake in use preferentially in older women (Hurskainen R 2004). In addition, the manufacturer reports increased uptake in the US in the same demographic market for treatment of menorrhagia or for use in menopausal women as hormone replacement therapy (Bronenkant L., personal communication 2006). This increase in use does not appear to have influenced provider bias against use in younger contraceptors in the US, at least not yet. Unlike the situation in the global public sector markets, the cost differential between the TCu 380A and the Mirena LnG IUD is small in non-subsidized developed country markets.

WHO estimates that approximately 160 million women worldwide use IUDs today. China has an estimated two-thirds of these users, or 96 million. Only a small percentage of current users are in eastern or western Europe or other industrialized countries (10%). The remaining 24% are in developing countries other than China, concentrated in Vietnam, Egypt, Indonesia, India, and Uzbekistan, and Turkey – those six countries alone contain half of all users in developing countries excluding China (see **APPENDIX 1**).

A remarkable geographic pattern of IUD users exists. All developing countries fall into the following clusters, which show widely different determinants of use rates. They also help to identify programmatic reasons for greater or lesser uptake. The percentages below reflect the population of women using contraception.

1. The former USSR Republics: the five Central Asian Republics have high use (25- 56%), as does the cluster of Moldova, Belarus, Ukraine (19% - 34%) and most probably Russia. Why? We can speculate that in the absence of hardly any contraception, the IUD entered the scene as fitting the established medical infrastructure, the weakness of the private sector, the unreliable supply lines for pills or injectables, and the pressures to replace abortion with an alternative. Formal IUD targets did not play a role.
2. At the other extreme are China and Vietnam, also with high use (36% - 38%) but for different reasons. In these countries, intense policy and programmatic pressures for the method (along with sterilization in China) operated. Other options, with the exception of abortion, were less available. Consequently, little is known about what public preferences would have been if a range of contraceptive choices had been available.
3. In the Middle East, including Egypt, Turkey, Jordan, Syria, Lebanon, and Tunisia, use is moderate to high (15%-36%). Again, formal targets did not play a role. The antipathy towards sterilization left a vacuum for long-term protection, and the medical communities were sufficiently strong to provide services. In Egypt at least, the private medical sector took up provision of the IUD. These countries are also more urbanized than many others, a factor contributing to higher IUD use.
4. The IUD experience in Latin America is mixed. Cuba is an exception with a very high rate of 44% using the IUD; it has a unique medical system. Eight countries including Mexico, Honduras, Costa Rica, Bolivia, Colombia, Ecuador, Paraguay, and Peru have moderate user rates of 10%-14%. Others are low, especially Brazil, where the IUD is almost unknown at only 1% using it. The reasons for the uneven pattern across Latin America are obscure.

5. The Asian pattern is one of low to negligible use, apart from China and Vietnam. Few countries exceed 4% using IUDs, including the highly populated countries of India, Bangladesh, and Pakistan. The reasons differ greatly, from India's preoccupation with sterilization to Pakistan's program wide weaknesses to Bangladesh's low clinical capacity. Broadly, adoption rates are very low, however there are states in India where IUD prevalence reaches 7% (reasons remain unclear) and in Pakistan a social marketing franchise program (PSI's Green Star program) is slowly expanding IUD use through the private sector. Low user rates of 6%-8% are found in Iran and Indonesia. A decline from 13% to 6% occurred in Indonesia over some years as the injectable rose sharply.
6. Across all of sub-Saharan Africa there is consistently low use: no country exceeds 3%. Further, the main subgroups according to age, family size, education, and residence are consistently low, so low that use pervades the whole population. Causes of low use are apparently multiple: neglect of the method at the policy/program level, poor infrastructures and low clinical capacity, damaging rumors, female prejudices against an intrauterine foreign body, fear of infection or other complications, and either misinformed or reluctant providers. In any case, the universality of the IUD absence is striking compared to other regions.

In summary, the global pattern of IUD use is a disparate one, and reflects very different causes at work. The overall effect, for total contraceptive use, presents a pattern that is somewhat less puzzling than the odd geographic pattern for each individual method. As a rule, whatever contraceptive option is easiest to obtain, for whatever reasons, tends to dominate.

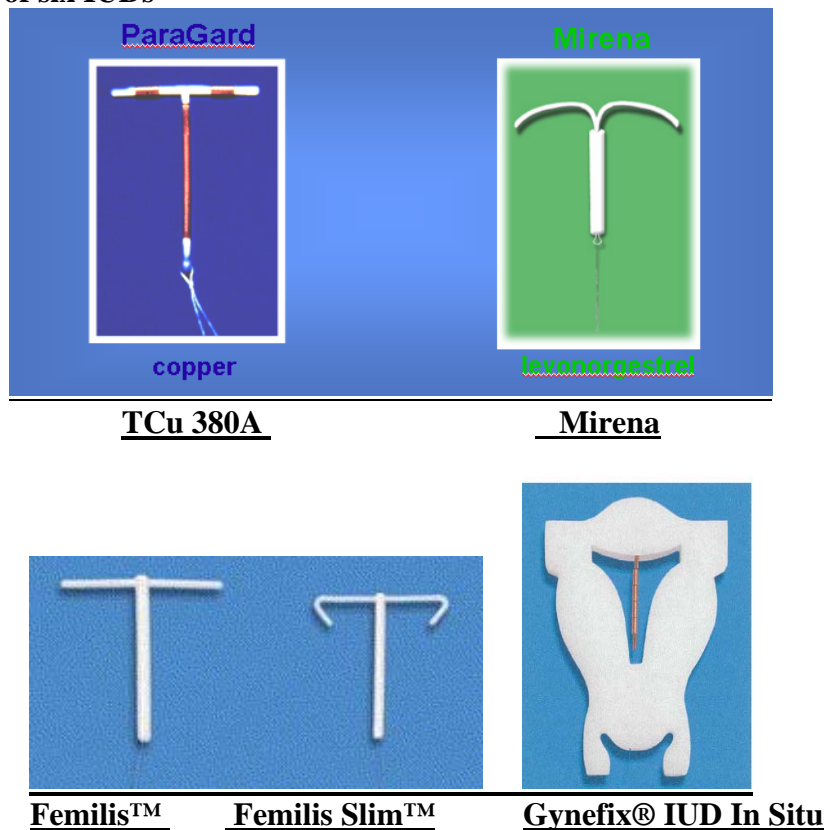
SECTION I CLINICAL CHARACTERISTICS OF THE MOST AVAILABLE IUDS

1.1 Types of IUDs

Two highly effective intrauterine devices (IUDs) are available in the global market today. The TCu 380A (TCu 380A)(ParaGard, Duramed Pharmaceuticals, Inc., Cincinnati, Ohio) and the levonorgestrel intrauterine system (LnG IUS or IUD)¹ (Mirena, Berlex Inc., Montville, New Jersey) are currently available in over 100 countries. Figure 1 provides images of these two IUDs. The TCu200, and multiload Cu 250 and 375 are still listed on the UNFPA commodities list but because of the proven higher effectiveness of the TCu 380A in comparison, and WHO's recognition of it as the first choice among the copper bearing devices, these alternatives will not be specifically addressed in this paper (WHO 1997).

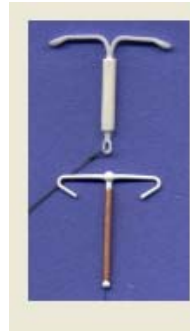
Several other IUDs, also shown in Figure 1, are currently under development or have been introduced in Europe including the Gynefix IUS and the mini Gynefix IUS (Van Kets H, 1997), FibroPlant (Wildemeersch 2002), the Femilis™ and Femilis™ Slim (Wildemeersch 2005), and the Flexi-T (Prosan).

Figure 1. Images of six IUDs



¹ Mirena® is referred to as a levonorgestrel-releasing intrauterine system, 20 ug/day. The product monograph specifically indicates that the use of the term “intrauterine system” should differentiate it from the intrauterine contraceptives (IUDs) of the past. In this document we will refer to either Mirena, or the LnG IUD (in this case the same thing unless indicated otherwise).

Figure 1 (continued).



Mirena (above) and Flexi-T (below) for size comparison

1.2 TCu 380A IUD – Advantages and Disadvantages

The TCu 380A is a polyethylene device with barium sulfate added to allow for visualization by x-ray. The device measures 36 mm long by 32 mm wide, with a 3 mm bulb at the base of the stem. Each of the horizontal arms is covered with a copper sleeve and copper wire is wound around the length of the vertical stem for a total surface area of copper of about 380 mm². A monofilament double strand polyethylene string is tied to the bulb at the base for use in removal. The Cu T380A has a 7 year shelf life, and is approved for 10 years of use. Figures 2 and 3 outline advantages and disadvantages of this IUD.

Mechanism of Action

IUDs in general work by preventing effective sperm function and therefore fertilization (Rivera, 1999). The TCu 380A releases copper ions and causes an inflammatory response with associated local increase of prostaglandins, white blood cells, and change in the normal fluids present in the uterus and tubes (WHO 1987; Saleem 1996).

Figure 2. Advantages of the TCu 380A

- Highly effective
- Protective against ectopic pregnancy
- Probable protective effect against endometrial cancer
- Long lasting, convenient and safe
- Cost effective

Adapted from Contraceptive technology 2004;
Hubacher and Grimes 2002

Effectiveness

The TCu 380A is well known for its high efficacy- the aspect of contraceptive effectiveness attributed to the method itself. Pregnancy assays that are highly sensitive and measure the lowest

levels of human chorionic gonadotrophin (HCG) in the blood indicate that fertilization and implantation do not occur in TCU 380A users (Wilcox, 1987). Because the IUD is not user dependent, once placed correctly, effectiveness is high with a failure rate of less than 1 per 100 woman-years and cumulative failure rate at 12 years of 2.2% per 100 women (Sivin 1987). This rate is comparable to the cumulative 10-year failure rate of female sterilization in the US of 1.9 per 100 women.(Peterson 1996). The TCU 380A is FDA approved for 10 years of use however studies indicate that it is effective for 12 years (WHO 1997) and unpublished data indicates the same high efficacy in a small study population after 20 years of use (Sivin 2006 pre-publication communication).

Ectopic Pregnancy

The 12-year cumulative ectopic pregnancy rate of 0.7 makes the TCU 380A protective against ectopic pregnancy compared with non-contraceptive users. (Franks 1990).

Non-contraceptive health benefits

The TCU 380A is a non-hormonal method that provides an option to women with contraindications to oral contraception or other hormonal methods, and an equally effective option to women who are not sterilization candidates. There are now two studies that report a statistically significant protective effect against endometrial cancer in copper IUD users (Hubacher D and Grimes DA 2002).

Figure 3. Disadvantages of the TCU 380A

- Provider dependent method
 - Spontaneous expulsion
 - Perforation
 - String loss
 - PID risk with insertion
 - Does not protect against STI/HIV
- Adapted from Contraceptive Technology 2004

Expulsion / Perforation/ String loss

Although the IUD is highly effective, proper placement is critical to long-term effectiveness. Spontaneous expulsion of the TCU 380A occurs in 2-10% of users within the first year (Zhang J 1992). Rates were higher in adolescents (and decreased with increased age), women with heavy menstrual flow, and women with a history of cramping pain (dysmenorrhea), with a 30% chance of repeat expulsion (Bahamondes 1995). Expulsion can be “silent” (without any pain) or associated with bleeding and cramping. WHO’s RHR 2003 technical report includes interim data from ongoing multicenter IUD safety and effectiveness studies. The cumulative net expulsion rate is reported as 11.2 per 100 women after 10 years and this rate is consistent with their previous 12 year published study of the TCU 380A of 12.5%, with most occurring in the first few years (UNDP/UNFPA Contraception 1997).

Perforation² is rare and occurs at the time of insertion. In experienced hands the estimated perforation rate for copper IUDs is 1 per 1,000 (WHO 1987). There is no evidence that the IUD “migrates” out of the uterus following normal insertion. The myths prevalent in parts of Africa may be the result of outcomes from poor insertion resulting in undetected perforations (Grimes, 2004A). Because copper causes inflammation and can cause scarring in the abdominal cavity near the bowel, bladder and ovaries the copper bearing IUD should be removed. This is most easily accomplished via laparoscopy, however, in places where no skilled provider is available, abdominal surgery may be required.

Lost strings can signal a perforation, undetected expulsion or simply ascension of the strings into the uterine cavity. Where ultrasound is available, identification of the IUD in the uterus and guided removal using local anesthetic at the cervix is possible. When ultrasound is not available the provider must assume an undetected expulsion and either explore the uterus blindly, and/or provide an alternative contraceptive method. There is no published data on rates for lost strings.

All IUDs are provider dependent methods. Both expulsions from improper placement and perforation rates can be minimized by use of standardized training and skilled providers (Chi, 1993; Harrison-Woolrych 2002). Published studies do not report widely on the impact of using less experienced providers on rates of either of these complications. However, provider shortages in many geographic locations, and in particular, in sub-Saharan Africa, make this more of a challenge than simply investing in better guidelines development and training.

PID

By far the most controversial issue related to IUD use has been concern that the IUD increases the risk of pelvic inflammatory disease. In the WHO-sponsored IUD trials, the risk of upper genital tract infection was limited to the first 20 days after insertion (Farley TM 1992). A recent systematic review of the literature attempted to assess the added risk of PID following IUD insertion in women with cervical Chlamydia or gonorrhea (Mohllajee 2006). This analysis is complex because of both the nature of the problem and by necessity, the study design; Chlamydia infection is often asymptomatic and it is not possible to randomize infected and uninfected women for IUD placement. Taking into account both cases - the overall increased risk of PID in the modern IUD user has been estimated based on observational studies and appears to be low, even in environments where the background prevalence of STIs (Chlamydia and/or gonorrhea) is high, ranging from 0.6 per 1,000 women (International Collaborative Post-marketing Surveillance of Norplant. 2001) to 1.11% in Nigeria (Sinei 1990) and 1.9% in Kenya at 30 days after insertion of the TCU 380A IUD (Walsh 1994). Because the rate of PID in infected non-IUD users is unknown in these groups, it is impossible to determine the added risk (Shelton 2001).

It is important, however, to consider that almost all other contraceptive methods (condoms as more inclusive barriers, and hormonals and sterilization against PID) do provide some protection against STIs or PID. The copper IUD does not.

² Perforation is a hole in the wall of an organ; in this case the IUD is accidentally inserted into the wall of the uterine muscle.

HIV positive women

Limited research reporting on safety of the copper IUD used in HIV infected women suggests that complication rates are comparable in HIV infected and non infected IUD users.(FHI 2005).

Nulliparous or nulligravid woman

Although there is no contraindication to use of the TCu 380A in a women who has never been pregnant or given birth (WHO medical eligibility criteria category 2)³, there may be a higher rate of mechanical problems associated with use. Expulsion rates are higher in adolescents, probably most related to their nulliparous state (Bahamondes 1995). Insertion is also more difficult related to the small diameter of the cervical canal (Grimes 2004). Use of oral non-steroidal anti-inflammatory drugs prior to insertion or even cervical dilators overnight can help prevent vasovagal reactions to insertion but these interventions may not be practical in all low resource settings.

Side Effects - Bleeding and Anemia

The most common medical indication for discontinuation of the TCu 380A is irregular bleeding. Irregular bleeding in the first several months of use is common but decreases over time. Women using the TCu 380A also often have heavier menses than the non-user. If the bleeding is significant, the health care provider needs to discern whether it is IUD-related or due to an undiagnosed pregnancy, an infection, or another intrauterine disorder. This in itself is an added intervention, and in a compromised health service delivery setting where access to providers is severely limited presents a barrier to IUD selection and continuation.

Iron deficiency anemia can be caused by poor nutrition and/or blood loss in industrialized countries, however it is more broadly multifactorial in developing countries with high prevalence of malaria, hookworm and other chronic disease and infections (HIV included). Actual blood loss associated with TCu 380 use is less than with older model IUDs. The marginal impact on hemoglobin level, studied in populations with normal levels of 12g/dl or greater, is small in the range of -0.5 g/dl occurring during early use may equilibrate over time with longer use (Andrade AT, 1987). The WHO listed Cu IUDs as category 2 –advantage outweighs risk for use in women with anemia. In any event, the TCu 380A does not decrease blood loss associated with menses or other intrauterine disorders. It is unclear what impact the small but steady increased menstrual blood loss associated with use has in a population with a high endemic rate of multifactorial anemia.

1.3 The Lng IUD - Advantages and Disadvantages

The Mirena is a plain plastic T-shaped frame, 32 mm long and wide and impregnated with barium sulfate making it radiopaque. The steroid reservoir around the stem is a cylindrical mixture of 52 mg of levonorgestrel and polydimethylsiloxane, covered by a membrane that allows for release of 20ug/day of LNG. Removal strings are attached to the base. MIRENA has a

³. Medical Eligibility Criteria for Contraceptive use (2004)(MEC) is one of the World Health Organization's two evidence based guidelines on contraceptive use, intended for policy-makers, program managers, and the scientific community. A designation of category 2 is "a condition where the advantages of using the method generally outweigh the theoretical or proven risks".

3-year shelf life and is effective for at least 5 years. Figures 4 and 5 outline the advantage and disadvantages of this IUD.

Mechanism of Action

Mirena is a steroid releasing device that acts locally to cause high levels of levonorgestrel in the endometrial tissue that lines the uterus, but low levels of systemic hormone. It has a minor effect on ovarian function. Both factors of high local impact and low systemic absorption are important in understanding the ultimate advantages of any levonorgestrel-releasing IUD. Local effects include thickened cervical mucus that slows the passage of sperm and a direct suppression of the endometrium causing it to atrophy (dry up) and become unresponsive to estrogen. The progestin effects also cause a decrease in sperm motility in both the uterus and the tubes. This is the result of the same sterile foreign-body reaction noted associated with the T Cu 380A that impedes ovum and sperm transport and fertilization; the LnG IUD also induces production of a glycoprotein that inhibits sperm-egg binding (Mandolin 1997). Together the local effects are responsible for its highly effective contraceptive action (Jensen 2005) and other non-contraceptive effects.

Figure 4. Advantages of the LnG IUD

- Highly Effective
- Protective against ectopic pregnancy
- Possibly protective against PID
- Decreases menstrual/uterine blood loss
- Causes amenorrhea in >20% of users
- Safe, long lasting, convenient

Adapted from Contraceptive Technology 2004

Effectiveness

Multiple randomized multicenter studies have confirmed the long-term efficacy of the LnG IUD and report a 1 to 7-year failure rate of 0 to 1.1 in women across all age ranges including those most fertile in the group under 25 years of age (Jensen JT 2005). In several large studies (Table 1) there was no significant difference in contraceptive efficacy between the T Cu 380A and the 20 ug per day LnG IUD.

Table 1. Principle clinical trials documenting the contraceptive efficacy of the LnG IUD

Principal clinical trials documenting the contraceptive efficacy of the 20- μ g per day LNG IUS					
Study Design	Study Duration (y)	No. Using LNG IUS/ Women-Years	Comparative Copper IUD	Number Using Comparative Method/ Women-Years	Pregnancy Rates: LNG IUS vs Comparative Group (P Value)
Multicenter European Trial, Luukkainen et al, 1987	1	1821/1555	Nova-T	937/777	0.1 vs 1.0* (P < .006)
Toivonen et al, 1991	3	1821/3850	Nova-T	937/1964	0.3 vs 3.7* (P < .001)
Andersson et al, 1994	5	1821/5815	Nova-T	937/2776	0.5 vs 5.9* (P < .001)
Study of the Indian Medical Research Council, Baveja et al, 1989	3	475/882	Several copper IUDs	1430/2925	0 vs 0.3-1.6† (NA)
Population Council Study, Sivin et al, 1990	5	1124/2912	T 380 Ag	1121/3189	1.1 vs 1.4* (NS)
Sivin et al, 1991	7	1124/3371	T 380 Ag	1121/3758	1.1 vs 1.4* (NS)

* Gross cumulative pregnancy rates per 100 women.
† Net cumulative pregnancy rates per 100 women.
LNG IUS indicates levonorgestrel intrauterine system; IUD, intrauterine device; NA, P value not available; NS, not statistically significant.

Taken from Jensen 2005

Ectopic Pregnancy

Because of the LnG IUD's high efficacy rate, it is also highly protective against ectopic pregnancy when compared to non-contraceptive users. The US ectopic pregnancy rate is estimated to be 3-4 per 1,000 women-years in non-contraceptors compared to an estimated rate of 0.2 per 1000 women years in LnG IUD users (Sivin 1991)

PID

As stated previously, PID rates are low among TCU 380A users and the same is true for LnG IUD users. Rate comparisons against the TCU 380A are shown in Table 2 and are favorable in large trials. In another trial in Scandinavia PID was diagnosed in 0.9% of over 2,000 study subjects using the LnG IUD compared to the overall incidence of PID in the general population of 2.1%. (NDA 21-225; Kani J 1992). This in itself is not enough to determine a protective effect but suggests that there is no added risk. The fact that there is biologic plausibility for protection because of the added barrier provided by progestin induced thickening of cervical mucous is important, an effect also noted in oral contraceptive users (Jonsson 1991). In addition, atrophic changes of the endometrium also caused by the local progestin effect may be protective (Hubacher and Grimes 2002).

Table 2. Selected health benefits/disease protection from using the levonorgestrel IUD

Condition/Study	Major Finding	Type of Study
Pelvic inflammatory disease		
European Trial		RCT w/Nova T copper IUD
Andersson et al. (30) (1994)	5-year PID rate: 2.2 (copper) vs. 0.8 (LNG)*	
Toivonen et al. (31) (1991)	3-year PID rate: 2.0 (copper) vs. 0.5 (LNG)*	
Multicontinent Trial		RCT w/T380 copper IUD
Sivin et al. (7) (1991)	PID rate did not differ significantly at intervals up to 7 years	
ALO on Papanicolaou smear		
Merki-Feld et al. (32) (2000)	ALO incidence: 20% (copper) vs. 2.9% (LNG)*	Retrospective cohort LNG-IUS users vs. ML375 copper IUD
Hemoglobin		
European Trial		Cohort from RCT
Ronnerdag and Odland (33) (1999)	Mean increase of 1.35 gm/dl over 12 years for LNG†	
Andersson et al. (30) (1994)	2.6 gm/dl decrease (copper) vs. 1.6 increase (LNG) at 5 years*	RCT w/Nova T copper IUD
Multicontinent Trial		RCT w/T380 copper IUD
Sivin et al. (7) (1991)	0.3 gm/dl increase (copper) ‡ vs. 1.4 increase (LNG) ‡ at 7 years	
Sivin et al. (34) (1987)	0.2 gm/dl decrease (copper) ‡ vs. 0.5 increase (LNG) ‡ at 2 years	
* Statistically significant difference between devices (P value ≤ .05).		
† P value not reported.		
‡ Statistically significant changes from baseline (P value ≤ .05).		
RCT = randomized controlled trial; ALO = actinomyces-like organisms.		

Taken from Hubacher and Grimes 2002

HIV positive women

The LnG IUD does not offer any known protection against cervical infection from sexually transmitted diseases, or any protection against the acquisition of HIV. Although it is unlikely that the IUD's progestin effects add risk for acquisition or transmission of HIV, the specific impact of locally released progestin (as opposed to oral contraceptives or injectables) has not been studied. The issue of impact of progestin contraceptives more broadly and HIV acquisition was addressed recently at an Africa regional meeting where unpublished data were reviewed and found to be difficult to interpret in general application⁴. Based on the current WHO Medical Eligibility Criteria (WHO Medical Eligibility Criteria 2004), progestin contraceptives, including the IUD, are not contraindicated in HIV+ women. The LnG was not specifically addressed.

Bleeding and anemia

The LnG IUD's local effects caused by the impact of levonorgestrel on the endometrium leads to a measurable decrease in menstrual blood loss (Anderson 1994, Suvisaari J, Lahteenmaki P 1996) and an increase in hemoglobin levels over time. Four studies address actual measures of decreased blood loss as indicated in Table 2. The data from these studies also show a decrease in hemoglobin levels with TCu 380A IUD use. The significance of the measurable increase or decrease is unclear in populations with multifactorial anemia as described above.

The impact of endometrial suppression on menstrual blood loss in LnG IUD users is notable

⁴ Hormonal Contraception and HIV: Science and Policy; Africa Regional Meeting Nairobi 19-21 September 2005. World Health Organization. Available at: http://www.who.int/reproductive-health/stis/hc_hiv/nairobi_statement.pdf

within the first 2 months of use and sustained. In one single-center follow-up study, 25% of 250 women had irregular spotting as opposed to normal menses at 6 months post insertion, and 44% had amenorrhea. At 24 months, 11% of women continued to have irregular spotting and 50% of women reported amenorrhea (Hidalgo M 2002). Two large multicenter randomized trials reported an amenorrhea rate of 17% at one year and 30% at 2 years (Bavega 1989, Sivin 1994).

Quantifying and characterizing menstrual pattern changes is difficult in diverse populations. Although there is an unquestionable decrease in the volume of menstrual blood loss, the irregularity of the resulting bleeding pattern (referred to as “breakthrough bleeding”) caused by thin walled blood vessels in the affected endometrium reported in LnG IUD users can be considered a disadvantage. Irregular spotting is most significant during the first few months of use. Discontinuation rates are affected by both initial but also persistent irregular bleeding (WHO ATR 2003) because of both provider and client concern that the bleeding reflects a problem that needs to be diagnosed and resolved (Jacobson 2006, Davie 1996). The changes in menstrual pattern are rapidly reversible with IUD discontinuation (Xiao B 2003).

The LNG IUD has most recently been successfully marketed and used to treat menorrhagia. The above studies address the issue of menstrual disruption in the normally menstruating woman. However, local application and impact of progestin on the endometrium is an important intervention for women who bleed too much due to age related changes of the endometrium or certain benign but problematic pathologic changes. Most of recent publications on LnG IUD use point to the almost perfect therapeutic match for women approaching or in menopause. Several studies indicate that the LNG IUD provides a non-surgical alternative to ablative therapy or hysterectomy for many women with dysfunctional uterine bleeding, uterine myomas, and adenomyosis (Stewart 200, Fedele 1997), These are problems that a percentage of all women suffer from regardless of ethnic background or socioeconomic class. All surgical procedures carry associated risk, and this is especially true in developing countries.

Figure 5. Disadvantages of the LnG IUD

- Provider dependent method
 - Spontaneous expulsion
 - Perforation
 - String loss
 - PID risk with insertion (unknown)
 - Does not protect against STI/ HIV
- Adapted from Contraceptive Technology 2004

Expulsion/Perforation/String loss

It is difficult to estimate ease or difficulty of IUD insertion. That said, many providers acknowledge the greater level of insertion difficulty related to the insertion method design associated with the LnG IUD compared with the TCu 380A. Data do indicate that experience with insertion (numbers of insertion per provider) affects rates of perforation for all IUDs. This inverse relationship (less experience/higher perforation rate) is independent of whether the

provider is a physician versus mid-level provider (Harrison-Woolrych 2003) but points to the importance of ease of insertion by design.

Until recently most data regarding perforation and expulsion of the IUD were collected in expert centers and were specific to the copper IUDs. With increasing introduction and uptake, new data demonstrate not only the risk of both with the LnG IUD but also the risk of complications associated with the resulting intra-abdominal location, once thought to be of much less concern than with the copper IUDs. Other non-medicated, non-copper bearing IUDs used in the past (that had higher failure rates) were not considered a risk if left inside the abdomen following perforation. However, more like the copper bearing IUDs, the LnG IUD continues to release progestin following perforation and presents a problem. Although a perforation can go unrecognized for months or even years, intra- abdominal scarring or adhesion formation can occur and is considered an indication for removal (Van Houdenhoven 2006).

A recent retrospective study from the Netherlands reported a perforation rate of 2.6/1,000 LnG IUD insertions. Previous studies of uterine perforation related to several of the copper bearing IUDs estimated the incidence of perforation of 1 per 1,000. Risk factors for perforation include the experience of the provider however it seems that perforation is less likely to occur if a withdrawal rather than a push out technique (as is the case with the Mirena LnG IUD) is used (Van Houdenhoven 2006). This is important when considering investment in a generic Mirena vs. the development of a new device that addresses this concern.

PID

As reviewed above, there is a small increased risk of PID for the 20 days following IUD insertion. Studies documenting this did not include the LnG IUD, however, because this risk is believed to be related to vaginal contamination during insertion there is no reason to believe that the risk would be different for the LnG IUD.

1.4 Additional clinical considerations

IUD failure and intrauterine pregnancy

Although both the TCu 380A and the LnG IUD are very highly effective they still have failures. As mentioned, all failures should raise alarm about the possibility of ectopic pregnancy, a life threatening circumstance in environments where access to health care is minimal (such as rural parts of SSA, where, as an indicator of access to surgery, obstetric fistula rates are very high). In addition, an intrauterine pregnancy with an IUD in place requires removal of the IUD, adding some additional risk of miscarriage with removal. If the IUD is not removed, severe infection has been reported in the second trimester.

Postpartum and post-abortion IUD use

Both the TCu 380A and the LnG IUD are considered safe for placement immediately post partum and post abortion when no intrauterine infection is present. Although higher expulsion rates have been observed following postpartum and post second trimester abortion placement of

copper IUDs, expulsion rates are not higher following first trimester abortion (Grimes D. 2004). Data for the LnG IUD are not available, however because expulsion is probably the result of increased uterine irritability and contractility related to the delivery or the procedure one should expect the same.

For several decades the promise of expanding IUD uptake through immediate postpartum IUD services has led to targeted interventions. Experience shows that the added burden during hospital based deliveries (particularly for good counseling and informed consent) predicts an increase during the introductory phase but a lack of sustainability. This appears to be true across all strata of maternity care infrastructures. Given the complexity of public sector maternity service delivery in poorer settings (in Africa the need to introduce PMTCT and the severe provider shortage), it is unlikely that postpartum IUD services will take hold broadly (Jacobson R- EngenderHealth 2006, Chirenge M- Zimbabwe 2006 , Somelela N- IPPF, 2006 personal communications). Postpartum IUD use is common in parts of China and Egypt where IUD use is high, and Mexico where it is moderate and obstetric care is institutionalized. Overall, adding counseling and IUD provision to a weak obstetric delivery setting is a formidable task and should only be attempted where quality monitoring can be implemented to assure informed consent.

Abortion services are provided on a random basis in almost all developing countries, influenced by laws for the most part. In those countries where abortion is legal, and therefore more available and organized in the public and private sectors post-abortion IUD placement is a safe option. Although described in the literature in the study setting, these publications describe outcomes of clinical trials that examine safety and efficacy (Grimes DA 2004). Published literature on programmatic implementation is scant, probably because model programs are rare.

Discontinuation of IUD use: clinical considerations

On a population basis, side effects are identified as the primary cause for discontinuation of use of the IUD (See **APPENDIX 2** for one-year discontinuation rates for 19 countries). These side effects include irregular bleeding with both the copper bearing IUDs and the LnG IUD, and increased menstrual bleeding with the copper bearing IUDs and amenorrhea with the LnG IUD. However, removal rates due to bleeding pattern changes vary greatly among study populations. A recent study from Scandinavia reported very low rates of discontinuation at 5 year follow-up (2.1) (Pakarinen 2003) however other older studies that compare discontinuation with copper IUDs report 5 year rates of 20% (Sivin I 1990, Andersson 1994). This may be a reflection of different counseling practice rather than an inherent cultural problem.

One can assume that a certain amount of discontinuation is due to provider concern when these normal side effects occur, and the lack of good training that would enable them to discern the true need for removal, or adequate pre-insertion counseling to help the user discern in some cases. Either way, this is an attendant risk with both the TCU 380A and the LnG IUD. Where ultrasound or other diagnostics are unavailable the provider cannot differentiate between a lost IUD vs. lost strings, bleeding from infection vs. a normally irregular bleeding pattern, or in the case of a LnG IUD, method induced amenorrhea vs. intrauterine pregnancy or ectopic pregnancy. In the case of Depo-Provera induced amenorrhea, which occurs in roughly 60 % of users at 1 year, the short-term nature of the method and inability to “discontinue” at will has not appeared to hamper uptake. Discontinuation rates at one year are high but reasons for this are not

clearly method related and could be access related. For long-term Depo-Provera users, it can take up to a year to return to a regular menstrual pattern following discontinuation.

Table 3 represents six year interim results from a WHO sponsored multicenter trial designed to compare the TCU 380A and the Lng IUD⁵.

Table 3. Cumulative net probabilities of IUD use discontinuation
(Standard error) per 100 women after six years of use (interim data to 30 September 2003)

Reason for discontinuation of use	TCu-380A	Mirena	P value
Pregnancy	2.0 (0.5)	0.5 (0.2)	<0.001
Ectopic pregnancy	0.1 (0.1)	-	0.162
Intrauterine pregnancy	1.9 (0.4)	0.5 (0.2)	<0.001
Expulsion	8.2 (0.8)	7.5 (0.8)	0.51
Pelvic inflammatory disease	0.1 (0.1)	0.3 (0.1)	0.29
Menstrual disturbance	10.9 (0.9)	35.9 (1.4)	< 0.001
Amenorrhoea	0.5 (0.3)	23.6 (1.3)	< 0.001
Reduced bleeding	3.1 (0.5)	10.9 (1.0)	< 0.001
Increased bleeding	7.1 (0.7)	5.9 (0.7)	0.074
Total device-related removals	25.5 (1.1)	47.8 (1.3)	< 0.001
Lost to follow-up	7.9 (0.7)	5.8 (0.7)	0.036
Total woman-years	7421	6382	
Number of women completing 6 years	629	506	

Taken from WHO Annual Technical report 2003

Importance of the Continuation Rate

The significance of discontinuation rates should not be underestimated. A simple calculation provides an idea of the impact of early discontinuation of a method. Note that most users are past postpartum amenorrhea and so are fully fecund, so unless users quickly adopt an alternative method, which many or most do not, they are exposed.

The available evidence shows the TCU 380A having a better continuation rate than that of the current Lng. That is not the only criterion for preferring one device over another, but it is an important one and we think points to the need to invest heavily in counseling and clinical training with the introduction of a hormonal IUD. When one device returns women to an exposed state for unwanted pregnancy sooner than another (and surely all IUD users wish to avoid pregnancy), there will be more unfortunate events than with the inferior device. Here is a simple exercise to illustrate that.

Assume a population of 100,000 women subject to an annual pregnancy rate of 300/1000 women. If the difference in mean continuation between the TCU 380A and the Lng were 3.5

⁵ We are still trying to confirm where the trial is ongoing but we don't believe that there is an African site,

years vs. 3.25 years, the results of the 3 months of extra exposure to pregnancy are shown in the Table 4. If instead the difference were 3.5 years vs. 3.0 years, i.e. 6 months, the numbers would double. The truth may be somewhere between, but the point is that the continuation rate is very important. We do not know what the final, improved LnG device would do; hopefully it would compete.

Table 4. The consequences of additional exposure to pregnancy as impacted by continuation rates

If 3 months difference	If 6 months difference	
7,500	15,000	Extra pregnancies
2,500	5,000	Extra abortions if 1/3 of pregnancies are aborted
5,000	10,000	Extra births
50	100	Extra maternal deaths if the MMR is 1000/100,000 births
1,000	2,000	Extra infant deaths if the IMR is 200, or
1,250	2,500	Extra child deaths if the U5MR is 250
Plus	Plus	Extra orphans in a high-HIV environment

Adapted from Ross 2006

Anemia: Could the LnG IUD have a public health impact?

Anemia is defined as a reduction below normal in the concentration of erythrocytes or hemoglobin in the blood; a normal hemoglobin (Hb) level in women is greater than 12 g/dl . Anemia occurs when the equilibrium is disturbed between blood loss (through bleeding or destruction) and blood production, which can be affected by a large number of factors. Iron deficiency anemia, one type of anemia, is caused by a lack of iron stores. Other nutritional deficiencies contribute to the range of anemias found in developing countries, but anemia is multifactorial and significant contributors include hookworm, malaria and other chronic diseases that affect either red blood cell survival or production. Blood loss, as a cause of anemia, is not listed in the developing country literature. Post-hemorrhagic anemia, caused by large amounts of blood loss due to an accident or an obstetric event is not listed because if the patient survives, the body should be able to replenish stores. Although hemorrhage is listed as the greatest cause of maternal death, it is the underlying anemia that tips the scale and leaves women without capacity to survive the loss of even normal blood loss associated with delivery, causing more than 60,000 deaths per year (UNICEF 2004).

Iron deficiency anemia is listed by WHO as one of the top ten most serious health problems. In adults iron deficiency affects the workforce with an estimated productivity loss of up to 2% of GDP in the worst countries. It not only increases the risk of a bad obstetrical outcome but contributes to the risk of prematurity, and low birth weight. Children born to iron deficient mothers start life with lower stores inherited from the mother and have difficulty catching up. They enter the critical period from age 6-24 months, when breast feeding supplementation begins, without ability to recover to build adequate iron supplies for health and normal cognitive and psycho-motor development, affecting approximately 40-60% of the developing world's children.

Documentation of anemia prevalence across Africa is poor and derived from small studies. The distribution of up to 80% in coastal regions and 30-40% inland reflects the multifactorial nature

of the problem given the impact of malaria, hookworm, and socioeconomic factors. Although about half of all cases are probably attributed to iron deficiency anemia a report in 2001 that looked at strategies to address iron deficiency anemia suggested that iron supplementation and micronutrient replacement is likely to have less impact than expected unless coupled with treatment for malaria and hookworm. It is also likely that the HIV epidemic is contributing more to this picture than ever before. (MacPhail 2001; OMNI 2006).

Why is all of this important? It is true that a medicated IUD such as the LnG IUD would decrease menstrual blood loss. In the woman who is child spacing one might argue that this saving would help to build iron stores that could make a next pregnancy safer for both mother and newborn. However, in light of the complexity of the anemia ‘puzzle’ it remains unclear whether a decrease of menstrual blood loss and a potential marginal increase in hemoglobin in women who are child spacing would lead to lives saved.

In some countries where the uptake of Depo-Provera has been documented, the resulting amenorrhea provides a real time opportunity to look at any impact this might have on hemoglobin levels in select settings and should be further examined.

SECTION II PROGRAMMATIC ISSUES

II.1 Estimating demand and potential demand in an expanded market

If, by asking about demand, we are asking whether there is some untapped interest out there in adopting contraception, the answer is always yes. In every population there are at least some women, and men, who do not want the next pregnancy. That is evidenced by the unmet need figures, even though many women included in the “unmet need” category disagree and say they will not use a method. However, they are roughly matched by other women who say they intend to use a method, even though the surveys classify them as not having unmet need (this group is mainly spacers who want a birth within two years but not right now).

In any case, unmet need does not serve well as a gauge of likely contraceptive adoption over the next few years. In most countries, it is so large as to constitute an unrealistic outer limit of the market. Prevalence of contraceptive use seldom rises more than one or two percent of couples per year, and within that an individual method usually rises less. The global figure of 17% of married women with unmet need (**APPENDIX 3**) will fall only gradually as prevalence rises, and the grand total of 123 million women in need may even grow as populations increase.

As to “demand,” in no country are women vocally “demanding” the IUD, but in all countries there is at least some unexpressed potential for IUD use, and there is always a subgroup that would use the method if it were readily available and presented effectively. “Market” is a more useful concept than demand since it combines the element of programmatic push with the likely response by the client. A stronger program combined with a more favorable setting makes for a larger market. So to get a handle on the “potential demand”, or likely increase in IUD use, we need to consider the impact of strengthening a program along with the constraints of the setting. That is, equally strong programs applied in all regions will yield less in sub-Saharan Africa than elsewhere, but they will still yield something, and the yield will be greater where the program is stronger.

Demand is heavily affected by the quality and reliability of the program as a whole over time, which reflects the lack of resources in the setting. These lacking resources include: the absence of providers altogether, not just that of trained providers; poor stability in the entire commodity supply chain, not just that for IUD supply; and migration of public commodities into the private sector (theft) for all re-salable commodities, etc.

Historical Experience for Increases in IUD Use

One fix on the probable market for increased uptake of the IUD is to look at the past record in countries that have multiple surveys, to show the trends. Table 5 (page 29) details historical experience for increases in IUD prevalence for 26 countries. These are countries where a clear rise occurred, though the levels vary greatly, from very low in Nepal and Sri Lanka to very high in Egypt and Uzbekistan. The annual pace of increase also varies, from lows of around 0.100 point to highs of around 1.000. That is, from a tenth of a point rise per year to a full point rise per

year. For example, in Iran, the rise over five years was from 7.0% to 8.3% of married women using the IUD, for an annual rise of 0.260 point per year. Across all countries the median rise is 0.506, a half point per year. Egypt is an outlier at 1.422 points per year over a long period.

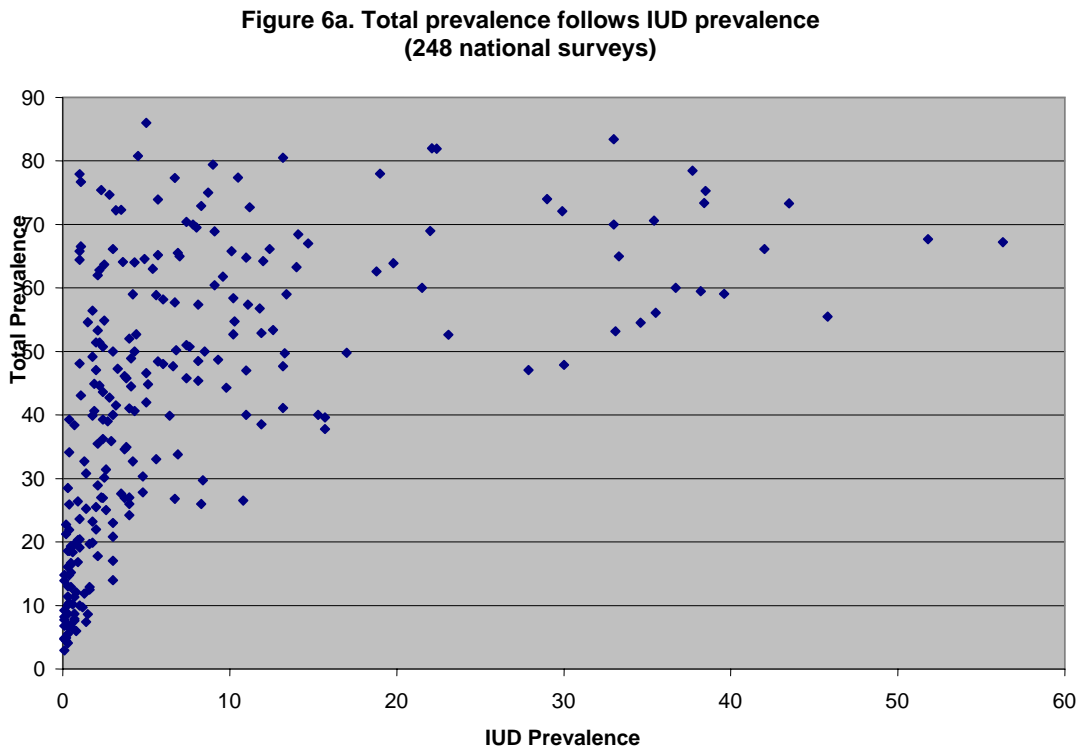
This gives rough bounds on what might be achieved in new national campaigns. The past IUD increases have of course occurred in the context of what total prevalence has done, which across all countries averages about 1.5 points per year, with an upper limit of around 2.5 points. A rise in IUD use can be partly due to substitution, with another method declining. For instance, in Egypt, pill use fell from 20% of women to only 9% during the IUD's steep climb. Or, the IUD rise can be accompanied by other increases, as in Tunisia, where pill use doubled from 5% to 11% while IUD use also rose.

Figure 6 below shows the relationship between total prevalence and IUD prevalence. Figure 6a provides data based on 248 surveys taken since 1980, giving the two prevalence rates, and Figure 6b is based just on 114 surveys in the 26 countries with increases. In Figure 6a, there is a cluster at the extreme lower left for near zero values on both prevalence rates (as in sub-Saharan Africa), showing a direct relation for numerous countries. On the right side of the chart are the outliers, for which both figures are very high –IUD prevalence and total prevalence averaging around 65%. Figure 6b is similar, but without the cluster of near zero values at the lower left and with fewer points.

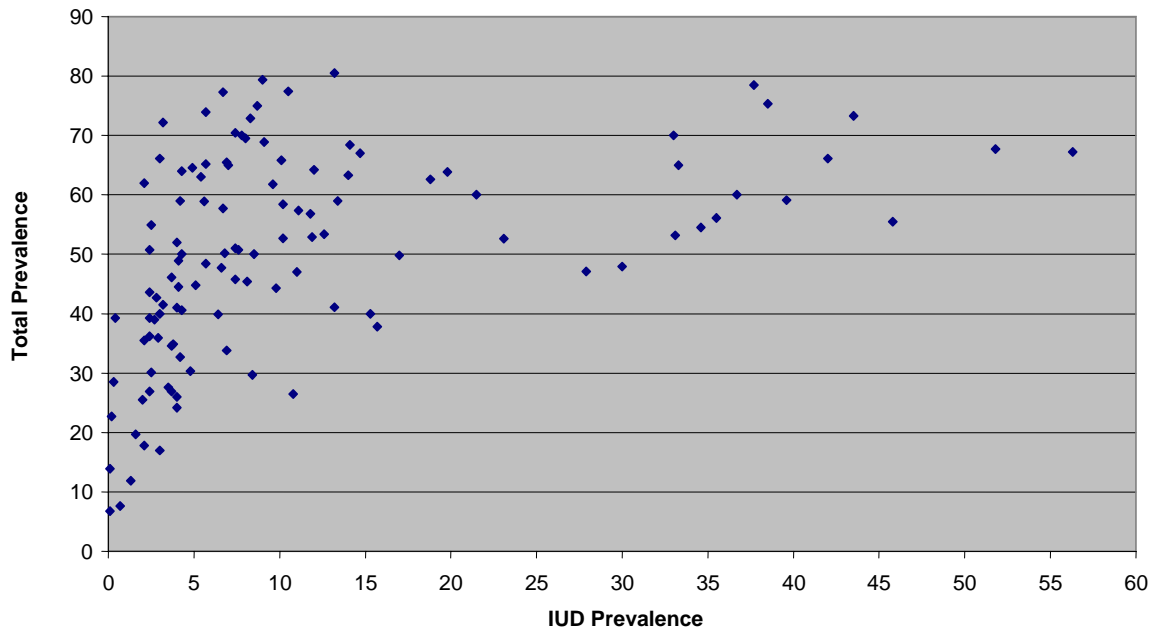
IUD use has been an important determinant of total contraceptive use in many countries, and IUD use can be expected to rise at no more than about a point a year at the national level. Therefore, an optimistic scenario for selected sub-Saharan Africa countries would be a rise from about 3% now to 13% over 10 years. That would be a substantial contribution but it would require an intensive campaign with providers, resting upon the appeal of a new IUD device that promises health benefits. To be acceptable in a policy sense, it would have to be folded into the context of multiple method offerings.

For a comparison, the injectable rose very rapidly in a few cases, but only moderately or not at all in other cases, as with the IUD. Peak cases are Indonesia (1.48 points/year from 1994 to 2002), and Namibia (1.37 points/year from 1992 to 2000).

Figure 6. Relation of Total Prevalence to IUD Prevalence



**Figure 6b. Total prevalence follows IUD prevalence in countries having past IUD increases
(114 national surveys)**



(Source: Macro DHS StatCompiler)

Table 5. Historical Experience for Increases in IUD Prevalence

	Dates	Increase in IUD Prevalence (%)*	Rise in Points/Year
ASIA			
Iran	1992-97	7.0 to 8.3	0.260**
Korea, Rep.	1982-97	6.7 to 13.2	0.433
Nepal	1986-01	0.10 to 0.40	0.020
Pakistan	1984-00.5	0.7 to 3.5	0.170
Philippines	1988-03	2.4 to 4.1	0.113
Sri Lanka	1987-93	2.1 to 3.0	0.150
Thailand	1981-93	4.2 to 5.7	0.125
Vietnam	1988-97	33.1 to 38.5	0.600
LATIN AMERICA			
Bolivia	1983-00	4.0 to 12.6	0.506
Costa Rica	1981-86	5.7 to 8.0	0.460
Cuba	1987-00	33.0 to 43.5	0.808
Ecuador	1982-89	6.4 to 11.9	0.786
Honduras	1981-01	2.4 to 9.6	0.327
Mexico	1982-95	6.6 to 14.7	0.623
Paraguay	1987-98	5.1 to 11.1	0.545
Peru	1981-91	4.0 to 13.4	0.940
MIDDLE EAST			
Algeria	1986-00	2.1 to 4.3	0.157
Egypt	1980-03	4.0 to 36.7	1.422
Jordan	1985-97	10.8 to 23.1	1.025
Kuwait	1987-96	3.7 to 6.8	0.344
Morocco	1980-03.5	1.6 to 5.4	0.162
Tunisia	1983-94	13.2 to 21.5	0.755
Turkey	1983-98	7.4 to 19.8	0.827
SUB-SAHARAN AFRICA			
Kenya	1984-93	3.0 to 4.2	0.133
CENTRAL ASIAN REP.			
Kazakhstan	1995-99	39.6 to 42.0	0.600
Uzbekistan	1996-02	45.8 to 51.8	1.000
*Percent of married women aged 15-49 using the IUD			
**Read: Iran's IUD prevalence rose by 0.260 point per year			
From 1992 to 1997, that is, from 7.0% to 8.3%.			

(Source: Macro DHS StatCompiler)

Projections for Users and Adopters: Examining the numbers

The historical experience just outlined affords one gauge of the IUD market; repeat surveys show that a working maximum is an increase of 1% per year in the proportion of married women using the IUD. If we take the median value, which happens to be half of that (0.5%), as a basis for illustrative projections, we can estimate the number of new adoptions per year per country, as in Table 6 below. A range around each number is readily obtained -- simply take half of each number to represent one-fourth percent rise per year (0.25%), or add half to the number to represent three-fourths percent rise per year (0.75%). If there is an interest in exploring a full one percent rise per year, double the number of adopters. (All this could be shown as alternative projections but the table below would become cumbersome.)

Table 6 shows first the IUD prevalence in the latest survey, with regional averages based upon aggregated numbers of users and women in the countries. The second column shows what IUD prevalence would be five years later, by adding a half percent per year (2.5% in 5 years). The next two columns give the numbers of married women and users, with users calculated as prevalence multiplied by women. The next to last column gives the estimated numbers of IUD adoptions needed to match the prevalence increase. There are three components to the adopters needed: (a) a half percent of married women to raise prevalence by the assumed amount, (b) adoptions to replace last year's dropouts from terminations, aging out, etc. (33% of last year's users), and (c) a 2% increase to allow for population growth. The final column compares adoptions to women to get the annual acceptance rate. (The top figure, for all less developed regions, is 6%, but that is for annual adoptions, not the net annual rise in prevalence of one-half percent per year. The difference is due to the three components just explained.)

Countries and regions differ sharply in their adoption rates because adoptions depend heavily upon the numbers required to replace last year's IUD dropouts. The assumed mean continuation period of 3.5 years (for the TCu 380A) implies the reciprocal, an annual loss from the using pool of 28%, and about 5% more who age out or end their marriage, for 33% total. Where users are numerous, as in high prevalence areas, dropouts are also numerous, driving up the adopters needed to maintain prevalence, quite apart from raising it. So adoption rates must be high where IUD prevalence is high to maintain this equilibrium. Both are maintained at a very low level in sub-Saharan Africa.

Each regional figure reflects the dominance of particular countries. East Asia's figures reflect China's high IUD use, whereas South America's figures reflect Brazil's very low use. Applying the assumed prevalence increase of a half percent to every country is crude of course, but the exercise yields the aggregate picture, with proper country weights by population, and it gives a useful order of magnitude. As noted above any total can be lowered or raised to assume an annual increase of a fourth percent or three-fourths percent, etc. Higher adoption rates have occurred in special projects, but national changes usually come about slowly. (The full table is in **APPENDIX 4**).

Table 6. Projections of IUD prevalence, users, and adopters at a half percent rise per year in IUD prevalence

	IUD Prevalence latest survey	IUD Prevalence after 5 yrs at 1/2% rise/yr	MWRA in 2005	Users in 2005	Needed Adoptions during 2006	Adoption Rate (% of MWRA) in 2006
LESS DEVELOPED REGIONS	15.5	18.0	941,040,280	145,843,807	56,625,597	6.0
Sub-Saharan Africa	0.9	3.4	98,386,639	863,068	799,185	0.8
Eastern Africa	0.6	3.1	39,189,647	241,773	282,019	0.7
Middle Africa	0.2	2.7	14,820,792	34,138	86,257	0.6
Southern Africa	1.8	4.3	5,415,300	98,728	62,224	1.1
Western Africa	1.3	3.8	38,960,900	488,429	368,685	0.9
Asia	18.4	20.9	706,783,937	130,074,064	49,840,287	7.1
Eastern Asia	35.7	38.2	305,269,089	108,967,781	40,318,875	13.2
S. Central Asia	3.3	5.8	291,899,852	5,723,599	3,497,101	1.2
SE Asia	10.0	12.5	98,398,283	10,214,179	4,128,239	4.2
Central Asia Rep.	46.3	48.8	11,139,713	5,161,575	1,893,219	17.0
N. Africa/Middle East	15.7	18.2	56,680,305	8,910,177	3,455,424	6.1
Caucasus	7.8	10.3	3,237,300	253,744	106,519	3.3
Latin American & Caribbean	7.6	10.1	75,952,099	5,742,755	2,424,181	3.2
Caribbean	19.6	22.1	4,860,620	955,012	364,288	7.5
Central America	11.5	14.0	23,921,700	2,752,683	1,099,564	4.6
South America	4.3	6.8	47,169,779	2,035,060	960,330	2.0

(Source: Appendix 4).

Intention to Use the IUD

Respondents in DHS surveys who are not using a method are asked whether they intend to do so, and if so what method they would prefer. Rather dramatic patterns appear across some 140 surveys when preference for the IUD is compared to the preference for the competing methods of pill and injectable (re-supply) or sterilization (long-term), all by region. (**APPENDIX 5** shows only the most recent survey for each country.)

Briefly, the patterns exactly parallel the use patterns. Hardly anyone in sub-Saharan Africa names the IUD, but many do so in the Middle East. The injectable is popular in sub-Saharan Africa, with a remarkable uniformity across the many countries. The injectable is decidedly unpopular (or less known) in the Middle East. In Latin America, it and the IUD are sometimes high and sometimes low. Sterilization is unpopular in the Middle East but very popular in Latin America. The pill is popular everywhere.

Geographically, the highly disparate pattern of method choice is as notable for future intentions as it is for current use, and it might remain so if nothing were to change. However, both use and intentions are amenable to change, as evidenced by the increased uptake of the injectable, although that is a much different kind of method and it reflected major exertions by public or private sector forces. In much of sub-Saharan Africa the injectable has been on the rise. From 1990-1994, UNFPA shipments of progestin-only injectables increased from 4.5 million to 16.7 million doses. USAID began providing supplies in 1992 to other countries. In some countries, such as Nepal, the injectable is supplied in pharmacies (Finger WR 1995). Myths about the injectable's impact on fertility were barriers at first; however it appears that efforts directed to

overcome those have succeeded in many places and the ease of administration has probably aided the continued rise in uptake.

II.2 Current strategies for an IUD revitalization

A critical question is whether a new IUD would be additive or a partial replacement? To address this question it is important to think through a strategy of expanded IUD use beyond the above calculations for a gradual increase in uptake balanced by annual discontinuations. First, consider a favorable opportunity for expansion, where the setting has a proven track record for delivery of services and the program, weak or strong, has demonstrated some commitment to the IUD. In that case, we can assume that there would be both an addition and some replacement to use of the TCU 380A, assuming that all other programmatic conditions were equal, such as cost and supply of the new IUD. But in cases where the setting is weak and hard to impact through a “vertical” introduction of a new IUD, any contribution of a new IUD would seem to be additive, assuming a vigorous provider initiative. In sub-Saharan Africa, if a new IUD were introduced and marketed as an improved method with clinical advantages it might migrate to the private sector first, leaving the TCU 380A in the public sector. This is of course hypothetical. Past experience with the introduction of new methods, such as NORPLANT, cannot be used to inform this equation because the LnG IUD, although new, is still an IUD and has the attendant associations and programmatic constraints. In any case, three strategy options follow.

Strategy Option No. 1. An increase in IUD use is most likely in countries where the method is already established, where its own prevalence is neither too low nor too high, and where total prevalence is neither too low nor too high. The reasoning is that prospects are unfavorable if the IUD has not taken hold after all these years, or where total prevalence has not started to rise (D.R. Congo, etc.). Equally, if IUD or total prevalence is already very high, additional rises are improbable.

Therefore, the matrix in Table 7 (page 34) isolates countries where both IUD and total prevalence are intermediate. They fall in the middle cells, with the 21 countries shown in **bold**. These deserve special consideration as the most promising sites.

However, the “middle-middle” strategy is only a starting point, and it cannot be the only guide. No country in sub-Saharan Africa makes the cut, and the only very large country included is Indonesia, so even if IUD use increases by a half point of prevalence a year in the 21 countries, there would be only a modest change for the developing world as a whole. Some of the other giants fall into the very low cells for either IUD prevalence or total prevalence or both. It is tempting to add at least a few large countries from the less favorable cells, and that is proposed in the following strategy.

Strategy Option No. 2. USAID is supporting an IUD revitalization effort (Acquire Project) that identifies eight sub-Saharan countries for special attention. These all fall into the last column and bottom two rows of Table 7 below (underlined). IUD use has not yet taken hold in these countries (although it was previously used more in Kenya than it is now). The large countries of Nigeria and Ethiopia are included, and three in East Africa (Uganda, Kenya, and Tanzania), where conditions are somewhat more favorable. Ghana is also included, along with Mali and Guinea. These choices necessarily reflected a blend of Mission interest, central priorities, and

available funding (MAQ country partnerships for Ethiopia, Mali, and Nigeria; Global Country Partnerships for Kenya and Uganda, and other sources for Ghana, Guinea, and Tanzania.) A mix of considerations is inevitable through any of the large donors, whereas foundations would be thought of as having somewhat greater freedom of action.

The question persists as to what to do, in an ideal world, about sub-Saharan Africa. Sheer need does not discriminate since it is universal. Probability of success is a more realistic criterion, and size also matters—so which countries in the region seem to be the best prospects? Coming down by size, Nigeria and D.R. Congo are large but extremely difficult. Ethiopia may be a more attractive site as it is more homogeneous and manageable, with large donor activities in train, and with a recent rise in prevalence. South Africa deserves consideration; there the injectable is at a world record level and may have topped out since no method can work for everyone. Next in size, after those just named, are the trio of Kenya, Uganda, and Tanzania, followed by Ghana and Mozambique, and then numerous smaller countries. Malawi may deserve particular consideration since its modern-method prevalence is nearly 30%, sterilization prevalence is 6%, and there is an active, committed NGO. Since sterilization has been marketed successfully to 6% in that setting, surely there is potential for the IUD. In any case, the countries just named include five of the eight in the USAID list, so there is considerable overlap.

Outside that region, if low IUD-prevalence countries of some size were to be considered, the list would include the Philippines, Bangladesh, Pakistan, Malaysia, Algeria, and Morocco.

Finally, some countries with high total prevalence but low IUD prevalence should be considered. If total prevalence is VERY high, as in Colombia (77%), little change is possible. However, Mexico, for example, has 68% total prevalence, of which 9% is for traditional methods, and IUD prevalence is only 14%. Equally, Ecuador has 66% total prevalence, of which a full 16% is for traditional methods, and IUD prevalence is only 10%.

Every country is a special case, and any general strategy must be tailored to country specifics. For example, a country undergoing decentralization may not be promising until local officials have chosen their priorities and settled new budgeting/planning procedures. The matrix below is simply a starting point for discussion and for strategy development, classifying countries that have demonstrated initial movement for both IUD use and overall contraceptive use, and identifying others that have yet to do so.

Table 7. Countries Classified by Total Prevalence and IUD Prevalence

Read: the high-prevalence countries in the top row vary greatly in the percent of couples using the IUD.

TOTAL PREVALENCE	IUD PREVALENCE					
	<u>42%-56%</u>	<u>29%-41%</u>	<u>15%-28%</u>	<u>5%-14%</u>	<u>0%-4%</u>	
Prevalence 66%-86%	Uzbekistan Cuba Kazakhstan	Viet Nam China		Reunion Mexico Korea, Rep Colombia Ecuador Peru Costa Rica Iran Nicaragua Hong Kong	Thailand Sri Lanka Mauritius Brazil Jamaica Puerto Rico Mongolia	
Prevalence 46%-65%	Korea DPR	Turkmenistan Kyrgyzstan Egypt	Jordan Tunisia Turkey Lebanon	Bolivia Paraguay Honduras Armenia Indonesia Kuwait Azerbaijan Panama Barbados Singapore	Algeria Cape Verde Morocco Saint Lucia Malaysia Bahamas Philippines Bahrain Dominican Republic Belize South Africa Dominica India El Salvador Bangladesh Zimbabwe	
Prevalence 25%-45%			Tajikistan Syria	Libya Georgia Qatar Saudi Arabia Guyana	United Arab Em. Pakistan Laos <u>Kenya</u> Lesotho Trinidad and Tobago Guatemala Namibia Suriname Sao Tome & Principe Botswana	Myanmar Swaziland Nepal Comoros <u>Tanzania</u> Central Af- Rican Rep Togo Zambia Congo D.R. Malawi
Prevalence 4%-24%					Yemen Iraq Guinea-Bissau Oman <u>Nigeria</u> Senegal Cambodia Bhutan Benin Burundi Gambia Mauritania <u>Ghana</u> Cameroon Sudan	Liberia Côte d'Ivoire Burkina Faso Eritrea Angola Madagascar Mozambique Afghanistan <u>Uganda</u> <u>Mali</u> <u>Guinea</u> Sierra Leone Niger <u>Ethiopia</u> Chad Rwanda

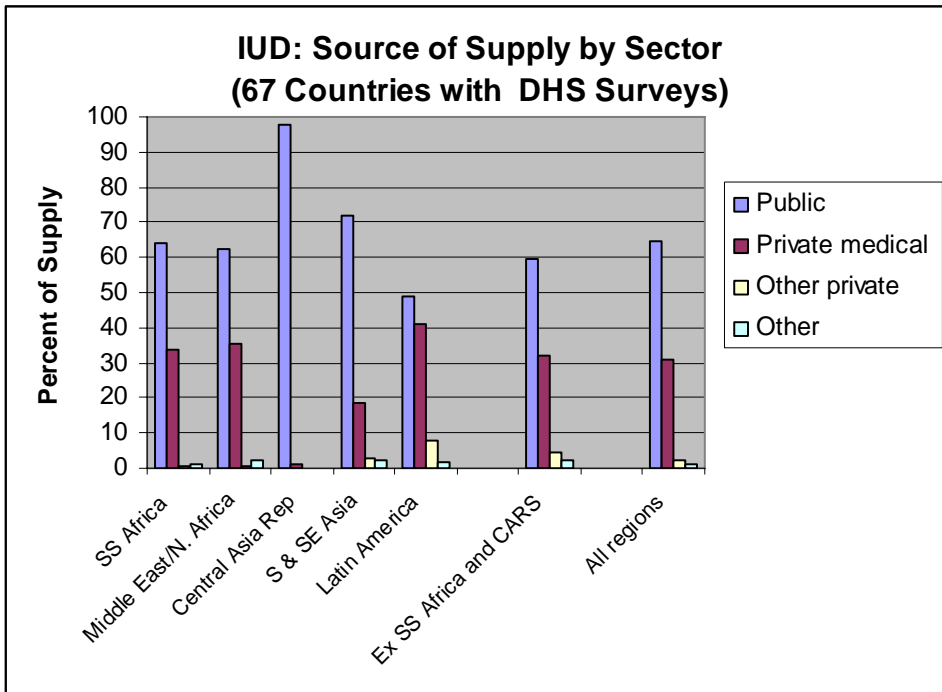
(Source: Macro DHS StatCompiler)

Strategy option No 3: the private sector. Here we explore the potential of the private medical sector for raising IUD use. Although we found in interviews that staff from DKT, MSI and PSI are all very enthusiastic about contraceptive social marketing broadly, and even about social marketing of the IUD, there is actually very little being done. This is probably because it is not an obvious fit. Distribution via social marketing franchising, a new model, provides IUD insertion training in the private sector. Although the idea is developed and described, programs are small, and measures of success are short-term and somewhat anecdotal; PSI has an active program in Pakistan (green Star) where despite a network of 10,000 providers, roughly 4,000 were women, and they distributed 74,000 IUDs through the network in 2005. This was considered an exceptional accomplishment although actual insertions are unknown. Their other significant program is Nigeria, where they sold 37,000 IUDs last year through social marketing, not franchising. These approaches should not be discouraged, and should be further explored, but their potential is not generalizable at this time. Below we try to narrow the playing field to identify opportunities to further explore social marketing, which in and of itself seems like a good model for certain countries.

First, what is the record so far? Figure 7 (page 36) shows the private medical sector to account for about 30% of IUD use (un-weighted mean of countries). The bars to the right are the most relevant; they exclude sub-Saharan Africa, where IUD use is trivial and the private sector also still small, and the Central Asia Republics, which are atypical. The private share is still low in South and Southeast Asia, at less than 20%, but it is a high 40% in Latin America. Concerning individual large countries, the private share for IUD use is 44% in India. IUD prevalence country-wide is 1.6% but further examination of 1999 StatCompiler data indicates prevalence of 6-7% in several states with diverse geographic distribution (Delhi, Arunchal Pradesh, Assam, Tripurna, Sikkim). Although this is low, the fact that a good percentage of share is private may indicate a private market in some states. Because of its size, the comments regarding country selection for expansion do not pertain. In Indonesia the same figures are 57% and 6%. In Bangladesh and Pakistan IUD prevalence is low, at 1% and 4% respectively. In Mexico, the picture may be brighter: 14% of married women use the IUD, but we lack information on the private share. In Brazil IUD use is trivial.

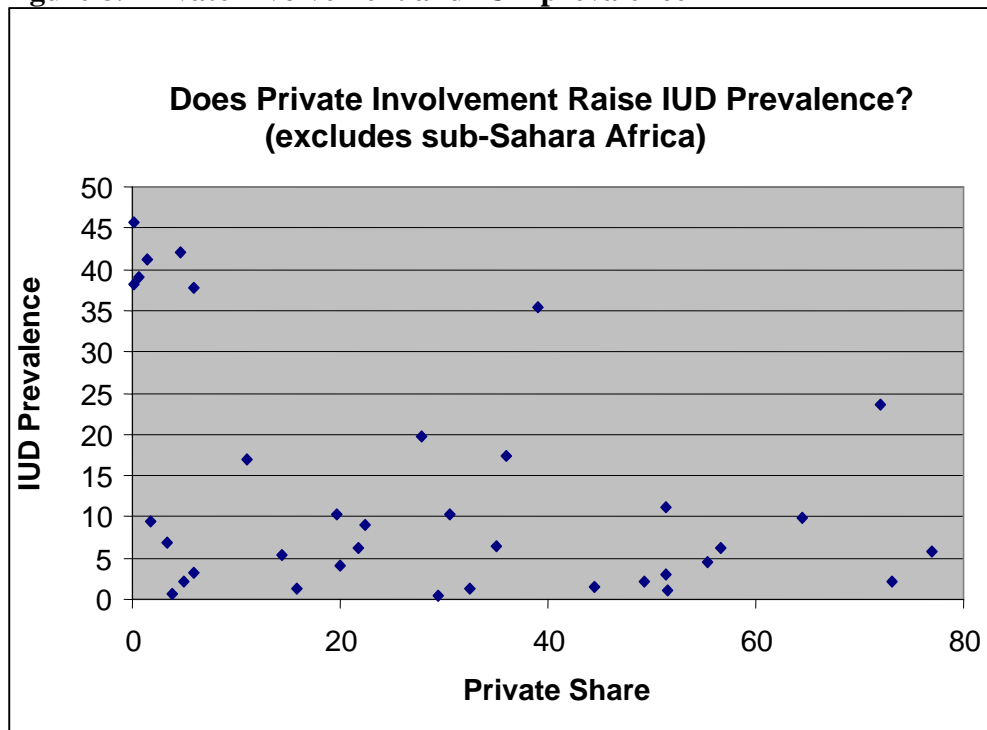
There are distinctly separate groups of countries when looking at private involvement and IUD prevalence, as shown in Figure 8 (page 36). The cluster in the upper left corner of the chart represents Vietnam and four Central Asia Republics, where IUD use is popular and is obtained entirely through government facilities (China is similar). High in the middle is Egypt, with a very active private sector: 35% of women use the IUD and, among them, 39% use the private medical sector. To the right is Jordan: 23% of women use the IUD and 78% is in the private sector.

Figure 7. IUD Sources of Supply by Sector



(Source: Macro DHS)

Figure 8. Private involvement and IUD prevalence



(Source: Macro DHS)

Figure 8 illustrates why it cannot be concluded that the larger the private share the higher is total IUD use. All the countries at the bottom of the chart, below 5% IUD prevalence, represent places where the private share varies greatly but where total IUD use is nearly trivial. Just above the 5% line are 13 countries, again with considerable variation in the share of the private sector.

But the real question is whether the private sector can be made more active and thereby raise total IUD use, *in particular countries*. This would also give women another channel through which to obtain the service and perhaps improve continuation, even if total adoptions stayed the same.

So what is the potential in particular countries for enlarging the private sector? We again recommend attention to selected countries as spelled out in Table 7 above. Prospects are better where contraceptive use in general is established and where the IUD has already won a fair share. Within such a country solid work is needed to detect legal and regulatory brakes on private medical initiatives. The supply system must be examined, as must the ease of advertising services. Given a careful assessment, advocacy efforts can then be targeted effectively. Where one or more NGOs or USAID Cooperative Agencies (CAs) offices are established they can do much to bring change about (see Table 13 and final recommendations for case studies on page 60). Table 8 below exemplifies diverse funding sources for private sector IUD supply.

Table 8. (DKT) 2004 Social Marketing Program Sales from all sources for IUDs

	IUD	Funding
Sub-Saharan Africa		
Ghana	3,650	USAID
Nigeria	41,020	DFID, USAID, private
Sub-total	44,670	
Asia		
India	55,641	DFID, USAID
Myanmar	2,882	DFID, UNICEF
Indonesia	19,830	KFW, Gates
Nepal	2,150	USAID
Pakistan	166,766	USAID
Sub-total	247,269	
LAC		
DR	35,577	USAID
Guatemala	5,357	USAID
Nicaragua	900	USAID
Peru	99	USAID
Sub-total	41,933	
2004 Total	333,872	

II.3 Programmatic requirements for effective IUD use

As described earlier, IUD delivery and uptake are heavily influenced by both “setting” (socioeconomic and infrastructure conditions that influence access to services) and “program” (shared commitment to the IUD at policy, provider and clinic levels, including resource allocation for training, information and education, and marketing to the consumer).

The issue of access is primary. Clearly, the IUD will not be greatly used if there is no access to it. National estimates for access exist in the “program effort scores” gathered in several cycles, most recently in 2004 (Ross, Stover, and Adelaja, 2006). These are based upon replies by expert observers in each country to a questionnaire that asked, among other things, approximately what proportion of women had “easy and ready” access to each contraceptive method. Those replies can be compared to the percentage of women in the same countries currently using the method. Allowing for some measurement error in the access measure (with over-estimates being more common than under-estimates), see Figure 9 below.

High levels of IUD use occur only where IUD access is quite common. At the upper right (box) we find eleven countries, also noted earlier, as making up three of the principal country clusters. Each cluster has its own causal dynamics, but high access is common to all three groups:

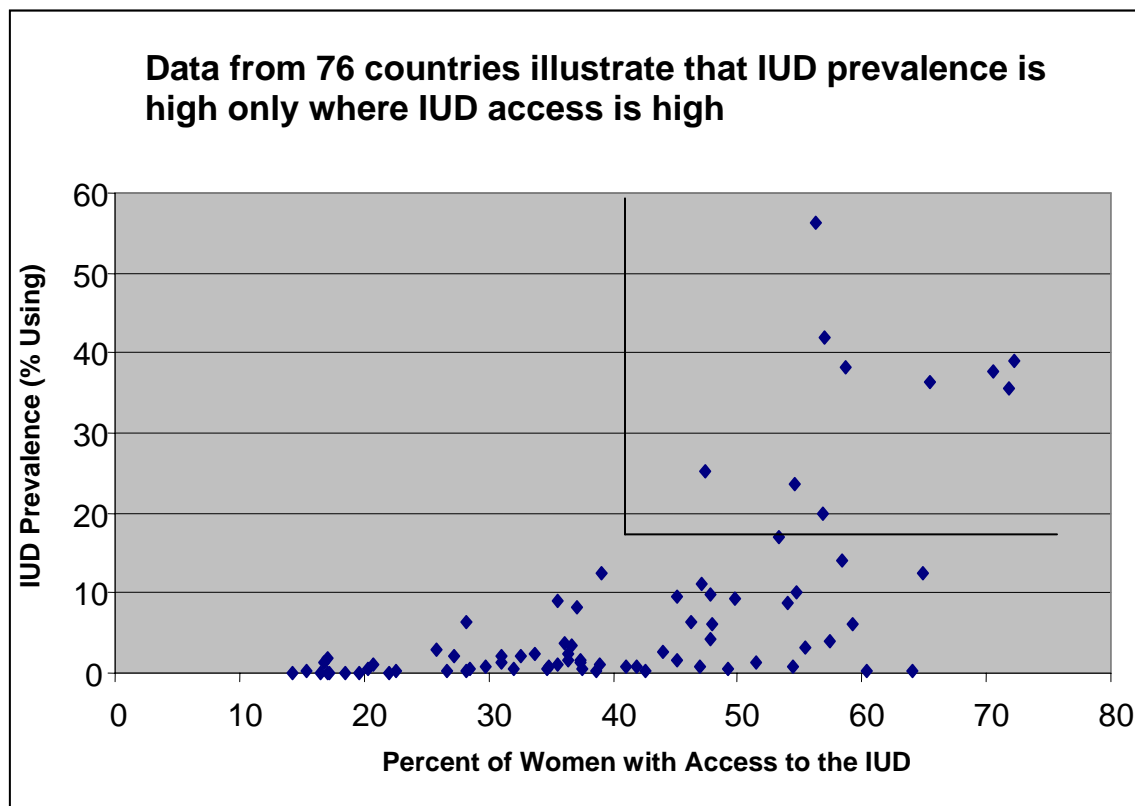
- China and Vietnam
- The five Central Asian Republics
- Egypt, Jordan, Turkey, and Lebanon

At the other extreme on the bottom of the chart is the entire body of sub-Saharan Africa countries, where use is negligible and access ratings tend to be low.

In practice, easy and ready access to the IUD rests on a composite of programmatic factors: the presence, in fairly close proximity, of a facility where both skilled personnel and supplies are present, where training for the method is current, and where the staff are motivated to suggest its use. Those in turn rest upon certain policy and programmatic features, and a failure in any one of these factors can render the IUD, or any other method, nearly inaccessible.

In many African countries, the simple ratio of providers to women is so low as to settle any question of broad, easy IUD access. In addition, the distraction of competing burdens can affect provider motivation. An IUD insertion often requires a follow-up visit, with some cases requiring provider action to address bleeding, do a removal, or counsel the client. Under time and caseload pressures the temptation may well exist to suggest the simpler injectable or pill.

Figure 9. Dependence of IUD Prevalence upon IUD Access



(Source: Ross, Stover, and Adelaja, 2006)

In summary, the five most significant influences on IUD uptake are:

1. **Low access** (discussed above).
2. **Absence or presence of competing methods:** as in the antipathy to sterilization in the Middle East which has left a kind of vacuum that the IUD has moved into, or the lack of both sterilization and re-supply methods in the former USSR, which has left an opening for the IUD to become the principal method. Likewise, easier access to competing methods such as pills or injectables. In both cases, there is not a provider shortage.
3. **Myths:** The bad reputation that has grown up around the IUD among the elites in some countries, together with unfavorable rumors of all sorts that hurt its image among potential users (vs. the satisfaction registered by many actual users). The myths regarding a foreign body placed inside of the body.
4. **The inherent drawbacks of the device:** the need for a clinic visit and a pelvic exam; changes in menstrual patterns; lack of complete invisibility (partner can detect the strings); early side effects; some failures/perforations; foreign body in the uterus.
5. **Medical barriers:** provider biases, fears and lack of motivation, e.g. in HIV areas reluctance to have bodily contact or touch bodily fluids; the need to deal with side effects and decision-making around removal and failures.

II.4 Ranking factors influencing programmatic initiatives supporting access and uptake

Teasing apart the exact ranking of influences upon programmatic stability and growth is nearly impossible given the multiple factors that interconnect settings and programs. Adding method-specific concerns to the equation increases the level of guesswork. However, we can discuss certain essentials as follows.

The currently available IUD is inexpensive. Insertion, although easy, still requires at least a mid-level provider. Failures are rare and not likely to present a significant barrier, so little change can be expected in either price, ease of insertion, or failures. However, discontinuations are common, and are related primarily to side effects of bleeding and pain. Decreasing these would substantially improve the overall reputation of the IUD and extend use time considerably while also attracting more new users by increasing the pool of satisfied clients. The difficulty of course is that a reduction in discontinuations rests upon either a modified device or large scale improvements in setting-related limitations such as training, supervision, direct to consumer IEC and marketing.

Kenya's experience affords some insights into important influences, drawn from work there with the USAID-funded revitalization project. The proportion of modern method users relying on the IUD dropped from 20.7% to 7.6% between 1989 to 2003, while use of the injectable jumped from 18.4% to 45.4%. Use of female sterilization decreased significantly over the same time period. During these sharp changes in method mix, overall use has stagnated. Does this represent the increasingly stressed health care delivery "setting", compromised by increasing levels of HIV/AIDS and the need to focus on treatment? Or, the migration of trained health care providers that has left huge gaps for both physicians and nurses? Or, more likely, both? A service delivery assessment indicated that along with these macro level influences, the losses in trained providers has probably led to a secondary decrease in provider knowledge and in accurate information for consumers. Given that the method technology has not changed for the worse over this period, one would have to assume that the problems are related primarily to the changing environment, at least in Kenya.

Returning to the initial question as to whether it is possible to rank the factors that impact IUD use, the answer is unfortunately negative, apart from noting that certain influences are necessary but by no means sufficient, such as access. The profile of determinants is so different from one country to another as to preclude a relative ranking of programmatic influences that is generalizable to all settings.

II.5 Successful and unsuccessful programs: lessons learned

If "success" means that the IUD is widely used, the lessons depend entirely upon which of the six clusters of countries we focus upon. Success in China and Vietnam rested upon a powerful push from the top. Success in the Middle East cluster rested not upon any top-down push but upon other factors, including the private medical sector's own availability, growth, and initiative. Success in the former USSR Republics reflected a vacuum of alternative contraceptives and a

widespread clinical infrastructure. In the mixed pattern throughout Asia and Latin America the lessons are very much country-specific.

Within any cluster, IUD adoption is elevated if the essentials for service delivery are present, and depressed if they are not. This involves the usual list of physical access, training, supervision, public education, and so on. Proper counseling can be quite important; some studies show that continuation on a method is greater if a woman is informed about alternative methods and given the one of her choice.

The “commonality” question is an important one. In one sense, there is no commonality in what makes for IUD success due to the fundamental differences between the country clusters. In another sense, however, there are commonalities in the necessary conditions of clinical capacity, supplies, provider training, and links between women and facilities. The woman and the trained clinician have to meet in a facility with equipment and supplies. Some countries have lacked one or more of these conditions: poor transport for women, poor training, few clinicians, few facilities, little equipment, or poor supply lines. Where any single one of these is lacking, IUDs will not be inserted and IUD prevalence will be low.

Even if all necessary conditions are present they are not sufficient, as testified by certain Latin American and Asian countries that could have qualified but nevertheless have had very low IUD use. Brazil is the standout example. As to the “why” question, we can only speculate that a blend of national policies (formal or informal), views of the medical establishment, the religious environment, and ad hoc historical factors, account for the dominance of one method against another. In Brazil, the IUD never took off but sterilization did, on a sub rosa basis in the context of caesarian deliveries. Unique factors are present in each country. To actually change the IUD’s position in a place like Brazil, a significant policy and consumer directed marketing campaign would have to be implemented over an extended period of time.

It remains that, within any of the main clusters of countries, IUD use will tend to be greater where the essential conditions mentioned above are more favorable. Those in turn rest partly upon policy positions and the vigor with which they are implemented. International leverage can focus on the policy and medical establishments, in addition to direct programmatic assistance. For foundations, these efforts should be selective where moderate investments can have an impact.

II.6 Knowledge and acceptance of the IUD

It is important to consider what we know about acceptance of the IUD among donors, policy makers, program managers and providers, as well as what we know about subgroups of clients that may inform knowledge and acceptability. Lacking survey data on most of these groups, we can comment only generally. The principal donors are fully cognizant of the IUD due to their long history with it and in some cases, their expenditures for supplying it. However, their level of commitment varies, as does their appreciation of a better method mix for continuation rates and pregnancy prevention. The stand-out is USAID, with its prominent revitalization push, which has galvanized efforts by certain CAs and by some of the Missions. This project’s objective is to change the international context by alerting other donors and policy makers to the advantages of

the IUD; this high level of advocacy should not be underestimated in terms of global impact. It suggests that similar efforts by a few other major donors could be very useful and could significantly reinforce the USAID efforts (see recommendations in Section IV). Most other bilateral donors are not as specific in their foreign assistance as to focus on one method for one program for service delivery. Many participate in basket funding (see recommendations).

Policy makers are another matter; they are very diverse within the countries, as well as in the regional bureaus and missions of the UNFPA, USAID, and elsewhere. We have little empirical information, but it is clear that some policy makers have very little interest in the IUD or for that matter in contraceptive provision. Many of them have strong leverage or influence with ministries regarding service delivery initiatives, and they are the target group of any revitalization project.

Program managers and providers have been very little studied regarding their commitment to the IUD or to other methods, so, as with the above groups, they are difficult to quantify. However, it is clear from field impressions that both managers and providers in some countries can be sharply prejudiced against the IUD. Even where there is no overt prejudice against the method, its general lack of use in a country can induce timidity by providers, who fear mistakes and, under time pressures, may avoid pelvic examinations and prefer the easy alternative of the injectable at-hand. In other countries, the IUD may be the method of choice by providers, as in Vietnam, China, and the Central Asian Republics. Like anywhere else in the world, whatever providers are trained in and have considerable experience with, they migrate toward.

Clients also stand along as a group. For them, a wealth of information is available on both knowledge and acceptability (use). In sub-Saharan Africa, the IUD is little used when all couples are taken together, but the interesting question is whether use might be higher in the sensitive sub-groups. In general, IUD use increases with age and parity, and it usually varies by residence and education. Table 9 provides the results, based on 145 surveys in Macro's StatCompiler.

The picture for sub-Saharan Africa remains the same no matter what sub-group is examined: IUD use is uniformly very low. That is an unfavorable outcome, because if use was decidedly greater at the upper ages or parities, this would signal a basic acceptability that could gradually penetrate the other groups. Use is not as low in urban areas and among the best educated groups, but age and parity seem not to matter. They are somewhat confounded with rural residence, and the results might be slightly different if we examined age and parity within rural and urban areas separately, however the StatCompiler does not allow this. So while cross-tabulations might show slightly higher use in more specialized sub-groups, the overall levels are so low that the conclusion would likely be the same. That is, for program planning, the populations are uniformly starting at near-negligible levels. Table 9 shows that no subgroup in sub-Saharan Africa has significant IUD use.

Ever use of the IUD gives a picture for sub-Saharan Africa that closely parallels the dismal picture for current use, so it is not that the IUD was once popular and has fallen into disfavor or has lost out to competing methods. At least the age pattern makes sense: ever use rises a little and peaks at 3.9% to 4.0% for ages 35-44 (see Table 9; full country data are in **APPENDIX 6**).

Knowledge: In sub-Saharan Africa, the IUD is less known than any other method except vasectomy. The percent knowing about the IUD, at 42%, is well below the percent knowing of

female sterilization (53%). Of course knowledge of all methods is low in sub-Saharan Africa, but the differential is greatest for the IUD: there is a difference of 21 points between its average and the all-country average (42% vs. 63%). (Full country data for knowledge appear in **APPENDIX 7**).

In Tables 9, 10, and 11 below, the contrast is extreme between sub-Saharan Africa and the other regions—so extreme as to return our attention to the puzzle of causality. It is true that selected countries in Asia and Latin America also ignore the IUD, but every country in sub-Saharan Africa does so.

Table 9. Percent Using the IUD, by Age, No. of Children, Residence, and Education

Means*		All countries	Sub-Saharan Africa	North Africa/West Asia	Central Asia Rep.	South and Southeast Asia	Latin America
Total	Total	6.0	0.8	15.7	40.9	7.3	6.1
Age	15-19	2.0	0.1	4.5	10.3	2.6	3.2
	20-24	4.9	0.4	11.9	27.9	6.0	6.8
	25-29	6.7	0.7	17.1	40.8	7.7	8.2
	30-34	7.5	1.0	20.1	51.3	8.3	7.4
	35-39	7.2	1.3	19.7	51.8	8.3	5.8
	40-44	6.0	1.1	16.2	43.7	7.9	4.0
	45-49	3.6	0.8	8.3	26.9	5.5	2.4
No. of living children	None	0.3	0.0	0.2	2.1	0.2	0.6
	1	5.1	0.4	10.1	27.6	6.4	8.2
	2	7.9	0.9	19.9	45.9	9.4	9.7
	3	7.3	1.1	20.0	50.0	8.8	6.6
	4+	5.8	1.0	16.4	48.8	6.7	3.4
Residence	Urban	7.3	2.0	19.1	39.4	7.3	7.8
	Rural	4.8	0.4	11.7	42.1	7.2	3.1
Highest educ. Level	No education	3.6	0.2	10.2	32.4	5.2	1.9
	Primary	5.0	0.8	15.9	24.8	6.6	4.2
	Sec. or higher	8.9	3.2	21.3	41.0	9.1	9.8

* All countries receive equal weights.

(Source: Macro DHS StatCompiler)

Table 10. Ever Use of the IUD, by Age and Region

Means*	Sub-Saharan Africa	North Africa/West Asia	Central Asia Rep.	South & Southeast Asia	Latin America	All countries
15-19	0.2	6.1	11.5	3.2	4.9	2.8
20-24	0.9	18.3	38.3	9.0	12.2	7.9
25-29	2.0	29.7	61.7	14.3	17.9	12.6
30-34	3.1	36.4	75.1	17.2	19.4	15.2
35-39	4.0	36.8	76.0	17.9	18.2	15.5
40-44	3.9	33.4	72.7	16.9	16.2	14.4
45-49	3.4	26.1	62.0	14.1	13.2	11.8
Total	2.5	29.7	63.6	14.6	15.9	12.5

*All countries receive equal weights

(Source: Macro DHS StatCompiler)

Table 11. Knowledge of IUD and Other Methods, by Region

Means*	Sub-Saharan Africa	North Africa/West Asia	Central Asia Rep.	South & Southeast Asia	Latin America	All countries
IUD	42.2	89.6	98.2	81.2	78.0	63.4
Pill	72.2	93.0	79.8	91.1	89.9	81.7
Injections	65.4	68.8	60.1	82.3	80.2	71.5
Condom	63.0	64.2	78.3	79.4	79.2	69.8
Female steril.	52.6	74.4	50.3	84.6	84.2	67.0
Male steril.	19.0	19.1	21.1	69.0	52.5	34.6

*All countries receive equal weights

(Source: Macro DHS StatCompiler)

II.7 Status of other IUD revitalization program, research, and advocacy efforts

The work so far is an excellent start but it is only that. Most developing countries are not yet engaged, and the UNFPA, IPPF, EU, and other major players do not seem yet to be on board. Far more is needed if the IUD is to enjoy a major rejuvenation.

Most of the funding for current revitalization efforts has come from USAID, either centrally or from the Missions. Funds have gone to various organizations. The most active CAs in this work have been EngenderHealth, FHI, and the Population Council (separate summaries below). In some countries they have worked together, and they are closely involved in the MAQ (USAID's

Maximizing Access and Quality Initiative) working group. Much of the recent work concerning revitalization considerations has come from these organizations⁶.

EngenderHealth (EH) is using various USAID funding streams for activities in several countries, as well as doing extensive work centrally to marshal data and analyze biomedical aspects. Countries in which EH is involved either directly or through technical assistance to other CAs include the following (some of this involves MAQ funds and some Global Partnership funds): Kenya, Uganda, Nigeria, Mali, and Ethiopia. Using field support funds, Tanzania and Guinea are also included. FHI is active in Kenya and Uganda, with lesser activities in Ethiopia and Guinea.

EH and FHI are co-chairing an IUD Working Group through MAQ (which met March 27, 2006 in Washington); it developed the IUD Toolkit, with an associated CD Rom containing the content of the website for wide distribution⁷.

The operational details of projects in the countries vary a good deal, concerning guidelines, training, field experiments, etc. They also vary in geographic scope. Some, such as guidelines and policy work, are national; others work in a few provinces or local areas.

The Population Council is involved in several IUD activities. Three fall under the USAID FRONTIERS Project, one falls under the International Contraceptive Access (ICA) Foundation, and another falls under the Center for Biomedical Research's NICHD Contraceptive Development Center grant. All FRONTIERS efforts are focused on the TCU 380A, while the ICA is focused on the LNG IUD. CBR's research is focused on new technology.

- ◆ The FRONTIERS work is intended to strengthen health system capacity for IUD services. It is collaborating with FHI, EH, and University of Southampton, UK in several sites in Latin America, Africa, and Asia. Studies are on-going or recently completed in Guatemala, Honduras, Ghana, Kenya, and India. Additional assessments were completed by FHI in El Salvador, and by the University of Southampton in Nepal and China.
- ◆ The second activity is to follow-up earlier, completed efforts to extend coverage of IUD services through on-site training of nurses in rural areas in Guatemala and Honduras. This was scaled-up by the University Research Corporation (URC) in Guatemala and by EngenderHealth in Honduras through USAID bilateral programs. The intent is to document sustainability of the service models over several years and to examine counseling, insertion and removal, and infection prevention.

⁶ There are four presentations (PPTs) from EngenderHealth through its ACQUIRE Project, all by Roy Jacobstein.:

- "IUD 'Revitalization': Scientific, Programmatic, and Contextual Considerations," presented at the 2005 meeting of the American Public Health Association.

The next three presentations were given at the IUD Standardization Workshop, Webuye, Kenya, Nov. 2005

- "The Latest Scientific Knowledge and Guidance about IUDs: PID, Infertility, HIV/AIDS (and other provider concerns)."
- "The ACQUIRE Project and the IU(C)D 'Revitalization' Initiative."
- "Change Comes with Strings Attached: Thinking about Change in the Context of IUD 'Revitalization.'"

⁷ The IUD Toolkit is available online at www.iudtoolkit.org.

- ◆ The third activity is to cooperate with the MAQ activity (above). Several staff have collaborated in developing and/or reviewing elements of the web-based toolkit. Country case studies on Guatemala, Kenya and Pakistan are instructive of ways in which foundations might use diverse approaches to increase access to the IUD.
- ◆ The ICA Foundation is a partnership between the Population Council and Schering OY (Finland) and Schering AG (Germany). It provides LNG IUD donations of up to one percent of the unit sales of Mirena in developed countries (excluding US sales) to public sector counterparts in developing countries. In addition, counterparts have the option of purchasing additional LNG IUDs from the Foundation (matched to 3% of the unit sales, again excluding US sales) at the current public sector price of US\$40. The ICA Foundation is currently cooperating with partners in Brazil, Ecuador, Indonesia, Kenya, Nigeria and South Africa and donating LNG IUS to national counterparts.

II.8 Case-in-point: The USAID Kenya Mission

The USAID Kenya Mission is involved with IUD revitalization and has begun to report findings from some projects. FHI repeated a situation analysis in their work area and got results that agreed with an earlier situational analysis to explain low IUD use. The key obstacles were:

- Provider bias
- Pressures on time use
- Staff worries about infection
- Lack of IUD training for a long time
- Staff then lack confidence due to inexperience, so the injectable is easier
- The hierarchical character of the medical community, which, in turn, means an agency cannot simply conduct nurse training on the IUD and must generate buy-in at each level of the professional community.

As a next step, some field actions may be taken in the context of the above to pursue renewed clinical expertise, retraining, advocacy etc. The Kenya Mission reports that the MOH is not actively opposed to the IUD – it is just distracted by HIV/AIDS and Safe Motherhood; also the ‘plain vanilla’ FP program has receded. IUD retraining requires both interested women acceptors and IUD practitioners who are still active. Both are scarce. There is a history of stock outs that adds to the problem of consistent provider commitment. (The national program also suffered leadership changes, funding cuts, and supply problems).

Nationally, the IEC arm of the program weakened greatly about 8 years ago, decreasing any public stimulus for the IUD. Parallel: when Pepsi pulled out of Kenya Coca Cola thought it could relax on advertising, but then its sales fell. For FP incessant IEC, stimuli are needed as new couples come of age, etc.

An interviewee with the Family Planning Association of Kenya (FPAK) explained that IUD use declined partly because all funding fell some years ago including funds for training, so meaningful training ceased. Community mobilization also fell – most CBD agents were stopped

for lack of funds. FPAK used to provide all methods free but lost funding so it now charges about one-third of the real cost. Also, it is partly true that women do not like the IUD since they dislike the idea of a foreign object in the body, and some users had failures that caused distrust of the method.

To re-energize the IUD, several steps are essential:

- Training. Need better counseling by the providers in the clinics.
- Mobilize at the community level – especially by using CBD workers. They are trusted by the women (who dislike coming directly to the clinics).
- Fix commodity security; there were serious deficiencies in IUD supplies in 2004-05.
- Strengthen IEC in general with particular attention to unmet need and to the large numbers of women who want longer-term protection of at least 3-5 years.

“Do all that and the women WILL respond.” As to clinical capacity in rural areas, it was augmented earlier by the CBD workers, who were each attached to a local clinic, which was often just held in a tiny town or market crossroads.

In summary, many countries face classic constraints on adoption of any method: poor conditions for IEC, supply, training, counseling, and the local infrastructures required to contact women personally. These are probably accentuated in the case of the IUD, where clinical capacity – both specialized and ongoing insertion training and specialized equipment --play a large role. Moreover the profit motive in the private sector of maternity homes, etc. probably tilts toward the injectable in some countries since it offers repeat charges and is quick and easy.

SECTION III SUPPLY ISSUES

Overview

Considerable programmatic constraints influence both supply of, and demand for IUDs in developing countries. Although it is impossible to predict the opportunity that would arise if a new IUD were introduced that had specific health advantages, these cannot be adequately examined without some promise of reasonable public sector pricing for the new device as a start. The following section examines potential solutions to supply-related barriers to expanded hormonal IUD access.

III.1 Cost/Benefit

With an eight to 10 year potential life span, a LnG IUD priced at US \$5.00 would be competitive relative to other contraceptives. This pricing would make the LnG cost competitive with the TCu 380A in the market today because of the duration of use. According to a recent report from the Alan Guttmacher Institute (Vlassof 2004), the average costs of insertion, follow up, removal and overhead for an IUD is US \$22.38. This calculation does not include the cost of the device. If we project that a LnG IUD will be available to the public sector for US\$5.00 or less, the total comes to around US\$27.00 or \$9 per year with an average use of three years. The TCu 380A total costs would be slightly lower at US\$23 for three years, or US\$7.50/year.

Oral contraceptives are less per year of protection. If we look at the cost of oral contraceptives for three years, 39 cycles x \$0.25 is equal to US\$9.75. With an estimated cost for 12 re-supply visits at \$1 per visit, the total method cost for oral contraceptives would be just under \$22 for 3 years or \$7 per year of protection. This is probably an over-estimate though because of the marketing direct to the consumer, saving much of the cost of re-supply visits. DMPA is more expensive, with product costs of 12 x\$0.90 or US\$10.80 for 3 years. Visits to receive DMPA, would also be more costly since in most cases a clinic based health professional would administer the injection. An estimate of \$2 per visit for DMPA would bring the total cost for 3 years to \$35 or \$12 per year.

In terms of costs, using the above estimates the break point for the LnG IUD is around three years. If used longer, the cost of IUD per couple years of protection would continue to decrease relative to other methods requiring re-supply.

III.2 Product patents, intellectual property and licensing

Many of the issues relating to patents, intellectual property, and licensing would be avoided in a public-private partnership. The company would give preferential pricing to the public sector in return for subsidization of Phase 3 clinical trials or other development costs, all negotiated up front. The public sector would not need to have a non-exclusive license since devices would be purchased directly from the manufacturer.

III.3 Public-Private Partnership

The time would seem ideal for the development of a LnG IUD Public/ Private Partnership. At least three new LnG IUDs are in the development pipeline. Control (Ghent Belgium) has developed the Femilis TM and completed a small scale clinical evaluation with good results (Wildemeersch 2005) Another Belgium company is developing a generic Mirena device. The third LnG IUD is in early stage development by a US company.

Control and the US company have shown interest in discussing a public-private partnership. They are especially interested in providing a preferential price to the public sector in return for the public sector covering the significant costs of the Phase 3 trials.

It appears that the Mirena LnG has been registered in 107 countries across Asia, North and South America, and Europe. In Africa it has only been registered in South Africa and Egypt. The Concept Foundation, established some 15 years ago in Bangkok to act as a non-profit registration/distribution arm for the public sector, is willing and prepared to provide assistance with registration of a generic or second generation device (subject to the availability of funds). Where Mirena is not registered, or in the case of a new device, the per country cost is estimated at US\$30,000. This includes filing and registration but does not include the cost of labor or of obtaining the data in the file, which would vary from case to case.

The provision of funds to cover the costs of clinical trial liability insurance would be a further attraction. These costs could be significant if a US arm is included in the Phase 3 trial, which would be necessary for FDA approval. USAID purchasing requires approval by a stringent drug regulatory authority including either the FDA or the European Medicines Agency (EMEA).

Program Related Investments (PRIs) are essentially low interest loans with funds disbursed directly from a foundation to the company involved. A PRI would be attractive to at least one of the prospective partners. Funds would be used to develop the manufacturing infrastructure. The loan would be repaid from profits on devices the company sells in the private sector. There is some risk that the company will not sell enough devices in the private sector to generate significant revenue and could default on the loan.

Advanced Purchase Contracts (APCs) are agreements that guarantee the purchase of a minimum agreed upon number of devices (drugs or vaccines in other cases). This is usually based on demand forecasts. The APC reduces the risk to the manufacturer as they invest to expand production capacity. In this case, donors could agree to an APC of, for example, 200,000 devices per year for five years at the public sector price. This is of course more complicated than it sounds, and is not well tested yet, but should be further explored.

III.4 Supply Options

Generic Mirena

The Belgium company noted above, which has reverse engineered the Mirena device, has qualified a new polyethylene for the T and has proceeded through Phase 2 clinical testing. Since

it is a generic device, that is, identical to Mirena in dimensions and drug release, they believe that a demonstration of bioequivalency is all that is required for registration, obviating the need for time consuming and costly Phase 3 trials. Filing and registration for the generic device is expected by the end of 2007, according to the company. Public sector agencies could facilitate registration and the safe introduction of the device.

In addition to cost, there are several concerns that make the widespread distribution of a generic Mirena less attractive than it might first appear. As described earlier in the paper, Mirena has been reported to be "difficult to insert". The inserter that comes with the device is more complicated relative to other simple tube inserters. The arms of the Mirena are loaded into the insertion tube and require that the tube be inserted part way into the uterine cavity where the arms are deployed before proceeding to push the inserter tube the rest of the way to the fundus. One recent report described higher than expected uterine perforations (Van Houdenhoven 2006). The retrospective study from Holland reports an estimated incidence of uterine perforation of at least 2.6 per 1000 insertions, likely based on study design to be under-reported. Training providers in insertion would be an important component of any introduction effort as the insertion is different than insertion of the more familiar TCu 380A, which uses a pull technique.

In summary:

- The generic Mirena device might be ready for market in roughly 2 years.
- The biggest advantage is that Mirena's performance is well documented. If bioequivalence could be demonstrated, expedited approval by an appropriate drug regulatory authority might be obtainable.
- The estimated cost to the donors would be the cost of registration in developing countries, however the public sector pricing is not confirmed.
- The disadvantage is that the insertion is difficult and the introduction would have to place training emphasis on insertion technique. Poor placement may lead to higher expulsion rates than with the TCu 380A, but more data are needed. Available studies comparing the TCu 380A to the Mirena LnG to date suggest that the TCu 380A has a better continuation rate.

Femilis Device

The Femilis device (Wildemeersch 2005) is described as easier to insert while maintaining high efficacy and safety. The device employs "coaxial fiber technology" for steroid reservoir and release. Piet Wildemeersch believes the Femilis device will provide protection for ten years. This is not yet based on actual use experience.

Advantages include moving quickly into Phase 3 trials, working with an existing, albeit new, device. The Femilis is slimmer than Mirena and can be inserted through a simple tube in which the arms of the T remain outside the tube and self deploy when the device enters the uterine cavity. Disadvantages include a complex and expensive set of options to guarantee a low public sector price.

In summary:

- The Femilis IUD is more advanced in the development process than the US Lng IUD under development but requires further trials. It might be ready for broader introduction in 6-8 years.
- The advantage is product design with ease of insertion.
- Assuming similar progestin release to Mirena, there are no device-specific disadvantages, however, long-term performance has not been documented.

US Company LnG IUD

A US company is developing a new, "second generation" levonorgestrel IUD. This will be a slim device that can be inserted through a simple plastic tube. The flexible arms of the device remain outside the inserter and self deploy once the device enters the uterine cavity. A copper version of this device has been on the European market (UK and Netherlands) for several years with a good record.

There are a number of advantages to choosing this option. The device represents an easier to insert, second generation IUD, using a frame that is registered and sold in Europe as a Copper T version. No perforations have been reported with this device, although the manufacturers have no reason to research this as an outcome.

The major disadvantage is the timeline. It will take 3-4 years for the US device to complete the preclinical work required for advanced clinical study. This means that the device is unlikely to be widely available for at least a decade. The company has projected that the formulation, IND filing, toxicology, and pre-Phase 3 clinical studies would cost \$2-3 million over 3-4 years.

In summary:

- It could take up to a decade before there is widespread introduction of the device.
- The cost to donors would be estimated US\$8-10 million for Phase 3 trials and the cost of the US trial arm, which might be covered by USAID or NIH.
- The advantage is that the device design has been tested and does not appear to have insertion or perforation problems (to be verified during trials).
- There are not device-related disadvantages, but the time line makes this a long-term investment and strategy.

Purchase Mirena from Schering

There have been a number of contacts with Schering to negotiate a substantially reduced price for Mirena in the public sector. Schering expressed the need for training and counseling in association with Mirena. They are anxious to preserve the reputation of the product.

The Population Council and Schering have established the International Contraceptive Access (ICA) Foundation that can provide Mirena at a public sector price of \$40, compared to the US price of \$400. During 2006 the Foundation expects to donate 25,000 devices. There has been no indication that Schering is prepared to consider a significant downward revision in the public sector price.

In summary:

- There does not appear to be a public sector purchase option.

III.5 Timeline

WHO has prepared a budget and timeline for the Phase 3 multicentered trial of a new LnG IUD. The timeline extends over a nine-year period with a total cost (excluding a US arm) of \$7.7 million. WHO is proposing a side by side trial with Mirena. Ten centers would participate with a total of 400 subjects per site. One year is estimated for preparation, two years for recruitment, five years for follow up, and a final year of analysis. It is expected that a preliminary analysis of the data could be carried out during year five, when sufficient data on three years of use have accumulated. This would permit registration to proceed with initial approval for three years of use. This time of continued use would be extended as subsequent data on longer use become available (see Table 12).

Table 12. WHO Cost Estimate and a timeline for Phase III Clinical Trial of a New LnG/Mirena IUD

	Units	Unit cost	Preparation Year 1	2 year recruitment Year 2	Year 3	5 year follow up Year 4	Year 5	Year 6	Year 7	Year 8	Analysis Year 9	Total
Project manager / Epidemiologist	P5	50%	\$220,000	\$110,000	\$110,000	\$110,000	\$110,000	\$110,000	\$110,000	\$110,000	\$110,000	\$990,000
Secretary	G5	50%	\$110,000	\$55,000	\$55,000	\$55,000	\$55,000	\$55,000	\$55,000	\$55,000	\$55,000	\$495,000
Data collection/ management contract cost				\$300,000	\$50,000	\$50,000	\$50,000	\$50,000	\$50,000	\$50,000		\$650,000
Data monitoring cost	G6	10%	\$150,000	\$15,000	\$15,000	\$15,000	\$15,000	\$15,000	\$15,000	\$15,000	\$15,000	\$135,000
Statistical support cost: planning and preparation	P5	25%	\$220,000	\$55,000								\$55,000
Statistical support cost: analysis	P5	100%	\$220,000								\$220,000	\$220,000
Contract for product development												
TSA site cost with institutions for study			\$520,000	\$520,000	\$520,000	\$520,000	\$520,000	\$520,000	\$520,000	\$520,000		\$3,640,000
Coordination and GCP training meetings			\$50,000	\$50,000	\$50,000	\$50,000	\$50,000	\$50,000	\$50,000	\$50,000		\$350,000
Dissemination											\$100,000	
Site visits (number)			10	10	20	20	20	20	20	20		140
Site visit cost			\$2,000	\$20,000	\$40,000	\$40,000	\$40,000	\$40,000	\$40,000	\$40,000		\$280,000
Total				\$555,000	\$820,000	\$840,000	\$840,000	\$840,000	\$840,000	\$840,000	\$500,000	\$6,815,000
Management and administrative support		13%		\$72,000	\$107,000	\$109,000	\$109,000	\$109,000	\$109,000	\$109,000	\$65,000	\$886,000
Grand total				\$627,000	\$927,000	\$949,000	\$949,000	\$949,000	\$949,000	\$949,000	\$565,000	\$7,701,000
Notes												
control group		2000										
experimental group		2000										
n		4000										
sites		10										
subjects per site		400										
TSA cost per subject per year		\$130										
TSA cost per year		\$520,000										
Excludes product development cost												
For comparison, Implanon vs Jadelle study cost per subject per year averaged \$109												

(Source: WHO, personal communication with Dr. Paul Van Look, February 27, 2006.)

SECTION IV CONCLUSIONS AND RECOMMENDATIONS

IV.1 Conclusions

Our review confirmed that the currently available IUDs perform well as highly effective, reversible, long-acting contraceptive methods. Like all methods, the IUD has both strengths and weaknesses. It requires a clinical intervention and pelvic exam for placement and cannot be tolerated by some women because of side effects. For the majority of others, it provides years of uncomplicated protection.

The currently available TCu 380A is easy to insert and does not have a significant complication or expulsion rate; concerns about its relationship to pelvic infections have been resolved for the most part and WHO does not advise against use in HIV positive women. Although TCu 380A IUD users experience a temporary increase in menstrual bleeding, research shows that it is not significant over time. Removal of the device is technically easy and return to fertility is immediate.

The greatest barriers to higher use are due less to shortcomings of the device itself than to access and the necessity of clinic based care by trained and willing providers, who are all too rare in the least developed countries. Myths about IUDs migrating, or dislike of a foreign body, may be frequent barriers, but they are probably not as important as access issues. Long-term continuation of use is likely affected by counseling at insertion and provider comfort with management of side effects. Based on recent operations research and past experience (Frontiers in Ghana, Guatemala, Honduras; Amkeni/ EH and FHI in Kenya, Guinea), infrastructure capacity for ongoing training and counseling is critical for both uptake and continuation.

Additional, fundamental barriers are a lack of advocacy and political will to invest on a large scale in sustainable institutionalization of the IUD to maintain or increase use. It must be an integral part of available health services, and this makes Africa an unusually challenging environment for IUD revitalization. In places where even the essential vaccinations fail to reach large populations in need, a clinic-dependent contraceptive method is hard to sustain, and especially so in competition with easy-adoption methods such as the pill and injectables. For poor, young couples and women, the IUD does not compete well.

Nevertheless, the current TCu 380A is highly effective and relatively inexpensive at a public sector price and an investment worth considering by foundations. Probably because of this cost/benefit relationship, family planning advocates continue to seek means to invest in or explore expanded use where fertility rates are high. Despite this, the number of donors investing in “family planning” programs or a particular family planning method is currently small. Most bilateral and multilateral donors are investing in broader, integrated reproductive or even “health” programs, leaving un-earmarked funds to be deployed at the country or local level.

More and more, earmarked funds go toward prevention of infectious diseases. USAID appears to be the significant interested government donor yet many expect US family planning monies to decrease over the next few years. The future influence and role of the Foundations should be considered in this context. In the past, “foreign assistance” provided support for service delivery that might not be available in the future. Foundation replacement of this is out of the question, and so leveraging whatever there is, and catalyzing change at the national and global level seems more appropriate.

Cost aside, public health arguments for the introduction of a hormonal IUD are not yet firm. On a population basis, reductions in menstrual bleeding and in anemia rest on the LnG IUD’s impact per woman, on the distribution and level of anemia in the population, and on adoption of the LnG IUD by large numbers of anemic women. The marginal advantage of the LnG IUD on a population basis is unknown and not calculable with current information. However, with additional research it may prove to be substantial for some high-anemia populations, albeit less likely for SSA populations where anemia is multifactorial. Two other public health considerations should be weighed: its use for older women at risk of serious bleeding from other intrauterine problems, and the human rights argument that individuals who can benefit from it should have access to it. In these instances, women in Africa are no different than anywhere else at baseline, and probably in greater need because of the lack of access to safe surgical procedures to treat excessive uterine bleeding and intrauterine pathology. It is entirely possible that eventual availability of an inexpensive hormonal IUD marketed for its health benefits could gain acceptance first in an older population and ultimately in a younger population some time in the future when the environment can be more accepting of non-barrier methods.

Short-term prospects, over the next 5 years, for SSA are quite mixed regarding prospects for any IUD. Although revitalization efforts under USAID support appear to have increased uptake in sites with retraining, improved supply chains, and expanded education for clients, the sustainability of these programs remains unknown and their national adoption is yet to emerge. Intervention activities must be incessant due to discontinuations and to the movement upward of women by age and parity that makes for constant shifts in the relevant audience. A short-term increase of uptake in response to an intervention will not repeat if the intervention does not repeat. National commitment to a large IUD push will compete with provider shortages in health care and with the resource drains resulting from traumatic impact of the AIDS epidemic.

A deeper commitment to contraception, including the IUD, can ease the burden of many health problems in every country. Foundations can highlight the leverage that contraception offers for lessening those burdens. They can advance advocacy at the highest levels and partner with other donors in a common strategy, thus leveraging the investment of USAID and the private sectors commitment, such as MSI.

The longer term outlook hinges partly upon a calculus that compares a generic Mirena device available sooner (assuming that a lower price could be negotiated), to a potentially improved device that will require several years to develop. The question may be posed as to whether donors prefer a long-term vision for a new IUD that may take a decade to develop and bring to market, or accept the limitations of the generic Mirena as the best opportunity to add a new IUD to the method mix. Both of these can be posed against a concentration just upon the TCu 380A now widely available.

IV.2 Recommendations

The following recommendations do not take into account any funding level pre-determined by the participating Foundations, or particular country/regional interests other than those specifically expressed by the Hewlett Foundation.

1. Investing in a new hormonal IUD—A Long-term Goal

Our strong recommendation to the Foundations is to invest in bringing a hormonal IUD to an expanded market by taking advantage of an immediate opportunity to secure public sector pricing for the future through a partnership with a US company. This may be a time-limited opportunity and thus should be included in a timeline for long-term planning. Although funding for the WHO phase 3 clinical trial is requested, this funding of approximately 8 million USD will not be required for 2-3 years. Minimal interim funding to support the due diligence and the business plan and independent progress reports will be the short-term cost.

Our reasons for this include the following:

- a. We believe that the hormonal IUD represents a remarkable innovation in IUD design and utility.
- b. The current Mirena will likely not have a public sector price (at least as of today) but is now proving its potential in private markets.
- c. A new device would offer an opportunity to re-introduce the IUD as a long-term, highly effective method. In countries where contraceptive prevalence is in the middle range but IUD use is low, there is a significant opportunity for a new IUD.
- d. Investing in a new hormonal IUD while using a design that has already been tested as a copper releasing IUD for excellent performance and relative ease of insertion will minimize investment failure risk
- e. Improvements in the IUD will expand the universe of providers and reduce risk of perforation.
- f. The public health advantage of a hormonal IUD—specifically its impact on anemia—has not been tested in populations where bone marrow suppression is the cause of anemia. For many reasons it is unlikely that IUD uptake will significantly improve in the most compromised setting of sub-Saharan Africa, as explained below. It is true, however, that there should be a positive impact on anemia in a more general population of women. Therefore, we believe that there is a public health argument for investing in a hormonal IUD for use in low-resource settings other than sub-Saharan Africa and, that in the course of development over the next decade, opportunities in SSA could likely arise.
- g. The hormonal IUD has a quality of life impact given its secondary effects of reduction of menstrual bleeding and decrease of abnormal bleeding from intrauterine abnormalities. These health outcomes affect a percentage of women of all socioeconomic classes. This translates into fewer surgical interventions for bleeding and thus increased safety in places where surgery is impossible and/or unsafe, especially for the poor. It is impossible to say whether the health benefit

of the hormonal IUD would be enough to catalyze new interest even in SSA, but we agreed that the potential might exist in several countries within the next 5-10 years.

- h. We believe the US company to be a reliable and financially secure partner that understands the public sector and is willing to move forward on a Public-Private Sector Partnership.

2. Investing in the expanded use of the TCU 380A: Short-term goals

Uptake of the TCU 380A in the rudimentary setting of sub-Saharan Africa cannot be expected to improve appreciably in the foreseeable future. In light of that, and the resounding and universal pressures to give attention to barrier methods for HIV protection (such as the female condom), we have reluctantly concluded against recommending an ambitious new IUD revitalization program in sub-Saharan Africa.

That is not to say that current activities are misplaced. Foundation and USAID support for NGOs that are focusing on the IUD should be continued and encouraged for an extended period. Foundation support is especially important given the environment in Washington that predicts a continued decrease in general family planning support. Country-specific revitalization projects will only continue for another year or two with any certainty, so assuring funds to continue some of the activities and support for evaluation of the outcomes is well advised and could be done through continued general support for the involved NGOs. The results thus far show some short-term promise in attracting clients, however, data on sustainability is scant. One recent report from FHI's work in Kenya suggests that the investment cost in training providers and generating demand in that environment is high. This is consistent with our findings. However, continued involvement will provide the interested foundations with regular feedback and will identify any important opportunities that emerge; continued involvement will also provide lessons about IUD provision in difficult settings that can be transferred elsewhere.

3. Investing in the private sector

DKT, MSI and PSI all have moderate programs attempting to expand the private market for IUD use either through social marketing (product sales) or social market franchising (more than just about the product, this includes training and IEC that penetrates the private sector). Although these programs may never win a large market share they represent an opportunity to reach the "working poor". If these markets grow, it will represent, on a relative scale, significant expansion in some places. It is a model that needs to be further referenced in the literature and then might be more easily replicated (not only for IUD delivery). In the private sector, support for MSI to expand IUD services and service social marketing and to test post-abortion IUD provision in the context of the private sector is a good option. In fact, Dana Hovig (at MSI) refers to PSI's Green Star Pakistan service social market model when discussing MSI's strategy to expand IUD services. Literature on the success of sustainable private sector contraceptive commodity supply and uptake after donor subsidies are withdrawn is specific only to pills and condoms. The application of the

model to IUD supply and demand is relatively new but could be important (www.psp-one.com).

4. Foundation comparative advantage

Foundations' comparative advantage will be to invest in activities that USAID is not supporting or likely to support for one reason or another, whether in collaboration with others (USAID cannot support MSI), in choice of countries (some NGOs would not sign the GAG rule which ultimately limits FP funds), or in kinds of activities (such as post-abortion IUD insertion).

We favor action programs or case studies in countries where contraceptive prevalence is moderate, between 25-65%, and IUD use is lower than expected. The case studies should address both private and public sector expansion, to help determine more thoroughly what the country specific barriers are. These in-depth studies could be brief, but were still beyond the scope of this project as they require country visits. Examples of these are available on the Frontiers project website for Guatemala, Ghana and Kenya⁸. According to John Townsend of the Population Council, there are also proposals for India, Honduras, and Nepal.

Working with NGOs already active in family planning in the country to execute a strategy based on findings could prepare for the introduction of the new IUD in years to come. **Thus, matching countries to WHO's phase 3 trial sites would be best.** We checked on trial sites with Paul Van Look at WHO and recommend consideration of Mexico, the Philippines, and Indonesia. Brazil is currently included on their list among trial sites but the literature does not describe the barriers to IUD use there other than to suggest that sterilization takes up the long-term method portion of the users. We cannot be sure how introduction of the new IUD might be received.

IV.3 Specific Actions

Based on the above recommendations, the Foundations should consider the following actions/funding opportunities:

1. Identify a consultant or team to develop a business plan that creates a partnership between donors and the US company to support the research and development of a new hormonal IUD assuring low public sector pricing for the future.
2. Continue to support grantees who are already engaged in IUD revitalization projects. Also, plan for ways to assure continued support for projects now using USAID funds having a one-two year horizon, since those funds may well cease and the lessons of those projects may be lost due to premature termination. Continuity of funding can be critical to an accurate evaluation of success. A full evaluation component, carried through to capture the full experience of the projects, will inform future investments, both in the sub-Saharan Africa trials and in several countries elsewhere.

⁸ [www.popcouncil.com/pdfs/frontiers/FR_full reports/Guatemala_IUD.pdf](http://www.popcouncil.com/pdfs/frontiers/FR_full%20reports/Guatemala_IUD.pdf)

3. Consider a specific investment in social marketing/franchising projects with the intention of further describing private sector capacity and replicable models.
4. Identify a grantee (a) to design a collaborative project that takes into account currently completed or proposed case studies of IUD availability, acceptability and use, and (b) to identify 2-4 additional countries to prepare for the new hormonal IUD introduction (Table 13). Ideally the grantee would match several countries with between 25-65% IUD contraceptive prevalence and IUD prevalence above 5%, where health systems can accommodate increased IUD provision in both public and private sectors, acceptability for ICA donated Mirena LnG⁹, and potential WHO study sites. The case studies, and ultimately the projects, should be designed with intent to publish findings on several topics for use in high level advocacy once the new IUD trials are completed. These countries would be primed for introduction of the new IUD.

Table 13. Sample matrix of country case studies

Hewlett Case Studies	PopCo (Frontiers) Case Studies	Private sector Potential active	ICA	WHO Study site
	Guatemala			
	Ghana			
	Kenya	“		
	India (pending)	“	x	India
	Honduras (pending)			
	Nepal (pending)	“		
Mexico		MSI, DKT or PSI	x	?
Philippines		“	x	Philippines
Indonesia		“	x	Indonesia
Xx		“	x	Brazil
				Vietnam

IV.4 Research Priorities

The team did not design a research agenda. The recommended projects described above all involve research at either the clinical or operations level and seemed to be specific enough based on our findings and review of other ongoing activities through USAID with the following exceptions:

Although literature exists that describes the clinical safety and efficacy of post-abortion IUD, there is very little literature on actual programmatic implementation. These programs would

⁹ The ICA is prepared to make a long-term stable donation of LnG IUDs to one or two countries based on requests from the Hewlett Foundation. (John Townsend, email communication to Sara Seims May 23, 2006)

only be possible in well established “institutionalized” public sector services or in well organized private sector services where abortion is legal. Operations research demonstrating service delivery implementation and demand for the method would be a contribution to the literature and inform some settings where advocacy requires an evidence base.

If the Foundations decide to support the development of a new hormonal IUD, it will be critical to learn more about the significance of amenorrhea in different populations and how to counsel and communicate about the advantage of the new IUD to both providers and clients. This will also be important for marketing. Very little is known about attitudes and how effective counseling could impact both choice and continuation.

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SECTION VI APPENDICES

VI.1 APPENDIX 1: NUMBERS OF IUD USERS AND OTHER INDICATORS.

(Source: UN 2004; UN 2005)

Table 1. Numbers of IUD Users, IUD Prevalence, and IUD Share of All Use

Most IUD Users are in a few countries -- both globally and within each region.

Size counts: even the low-prevalence countries of India and Indonesia have large numbers.

Other countries, with high IUD prevalence, are small.

Countries at ceilings for either total prevalence or IUD prevalence are poor bets for IUD increases.

Those in a middle range may be of greatest interest.

Developing World Total	132,652,123
China	95,850,300
Rest of Developing World	36,801,823

TOP 40 COUNTRIES for No. of Users	Users	Percent (ex- China)	Cumulative Percent	TOP 40 COUNTRIES for IUD Prevalence	IUD Prev.	IUD Share of all Use
Viet Nam	4,954,177	13.5	13.5	Uzbekistan	56.3	78.5
Egypt	3,876,939	10.5	24.0	Korea DPR	48.5	59.3
Indonesia	3,249,234	8.8	32.8	Cuba	43.5	63.5
India	3,133,088	8.5	41.3	Kazakhstan	42.0	63.1
Uzbekistan	2,697,924	7.3	48.7	Turkmenistan	39.0	64.2
Turkey	2,432,034	6.6	55.3 HALF	Kyrgyzstan	38.2	48.0
Mexico	2,297,619	6.2	61.5	Viet Nam	37.7	43.4
Korea DPR	2,041,850	5.5	67.1 2/3	China	36.4	63.3
Korea, Rep	1,109,401	3.0	70.1	Egypt	35.5	40.8
Kazakhstan	1,101,020	3.0	73.1	Tajikistan	25.1	42.3
Iran	878,057	2.4	75.5 3/4	Jordan	23.6	35.8
Cuba	817,465	2.2	77.7	Tunisia	21.5	31.0
Pakistan	763,882	2.1	79.8	Turkey	19.8	30.6
Colombia	744,508	2.0	81.8	Lebanon	17.0	43.5
Philippines	418,137	1.1	82.9	Syria	15.7	21.3
Syria	414,291	1.1	84.0	Reunion	14.2	20.6
Nigeria	353,638	1.0	85.0	Mexico	14.1	16.4
Thailand	347,591	0.9	85.9	Korea, Rep	13.2	23.6
Peru	339,712	0.9	86.9	Bolivia	12.6	16.1
Turkmenistan	320,713	0.9	87.7	Colombia	12.4	18.1
Brazil	319,218	0.9	88.6	Libya	11.2	19.3
Bangladesh	315,048	0.9	89.5	Paraguay	11.1	15.3
Tajikistan	286,893	0.8	90.2 9/10	Ecuador	10.1	17.5
Kyrgyzstan	285,791	0.8	91.0	Georgia	9.7	15.5
Tunisia	284,311	0.8	91.8	Honduras	9.6	15.5
Saudi Arabia	197,148	0.5	92.3	Armenia	9.4	13.2
Ecuador	194,701	0.5	92.9	Peru	9.1	20.8
Morocco	183,387	0.5	93.4	Qatar	9.0	11.6
Algeria	157,207	0.4	93.8	Costa Rica	8.7	11.4
Jordan	151,214	0.4	94.2	Iran	8.3	14.1

Table 2. IUD prevalence, share of all use, and numbers of users, for all countries by region

This is a basic reference table: within each region countries are listed alphabetically.

	IUD Prevalence	IUD Share (% of users)	No. of IUD Users		IUD Prevalence	IUD Share (% of users)	No. of IUD Users
WORLD	13.9	22.9	145,114,411	ASIA, EAST			
DEVELOPED REGION	8.1	11.9	13,818,102	China	36.4	43.4	95,850,300
DEVELOPING REGION	15.0	25.3	131,269,968	Hong Kong SAI	5.1	5.9	58,793
				Korea, DPR	48.5	78.5	2,041,850
				Japan	na	na	na
ANGLOPHONE SS AFRICA				Mongolia	0.3	0.4	1,275
Botswana	1.3	3.2	2,285	Republic of Kor	13.2	16.4	1,109,401
Eritrea	0.4	5.0	2,219				
Ethiopia	0.1	1.2	9,453	ASIA, SOUTH CENTRAL			
Gambia	0.8	8.3	1,786	Afghanistan	0.3	6.3	10,674
Ghana	0.7	3.2	19,836	Bangladesh	1.2	2.2	315,048
Kenya	2.7	6.9	121,170	Bhutan	1.0	5.3	2,830
Lesotho	2.6	8.6	6,362	India	1.6	3.3	3,133,088
Liberia	0.6	9.4	2,338	Iran	8.3	11.4	878,057
Malawi	0.1	0.3	1,838	Nepal	0.4	1.0	17,184
Namibia	2.1	7.3	3,801	Pakistan	3.5	12.7	763,882
Nigeria	2.0	13.1	353,638	Sri Lanka	3.0	4.5	82,509
South Africa	1.8	3.2	74,996				
Swaziland	1.2	4.3	1,857	ASIA, SOUTHEAST			
Tanzania	0.4	1.6	20,913	Cambodia	1.3	5.5	23,331
Uganda	0.2	0.9	6,509	Indonesia	8.1	14.1	3,249,234
Zambia	0.1	0.3	1,366	Laos	3.0	9.3	26,791
Zimbabwe	0.9	1.7	16,278	Malaysia	3.9	7.2	139,302
				Myanmar	1.3	4.0	91,949
FRANCOPHONE SS AFRICA				Philippines	3.7	8.0	418,137
Angola	0.4	6.5	7,156	Singapore	5.0	8.1	35,105
Benin	0.8	4.3	8,484	Thailand	3.2	4.4	347,591
Burkina Faso	0.4	3.4	8,303	Viet Nam	37.7	48.0	4,954,177
Burundi	0.8	5.1	5,990				
Cameroon	0.6	3.1	13,627	CENTRAL ASIA REPUBLICS			
Central African Rep.	0.2	0.7	1,188	Kazakhstan	42.0	63.5	1,101,020
Chad	0.1	1.3	1,436	Kyrgyzstan	38.2	64.2	285,791
Côte d'Ivoire	0.4	2.7	8,563	Tajikistan	25.1	74.0	286,893
Congo D.R.	0.1	0.3	7,364	Turkmenistan	39.0	63.1	320,713
Gabon	na	na	na	Uzbekistan	56.3	83.8	2,697,924
Guinea	0.2	3.2	2,971				
Guinea-Bissau	2.3	30.3	4,761	MIDDLE EAST/ N. AFRICA			
Madagascar	0.3	1.6	7,033	Algeria	4.3	6.7	157,207
Mali	0.2	2.5	4,326	Bahrain	2.9	4.7	2,890
Mauritania	0.8	10.0	2,898	Egypt	35.5	63.3	3,876,939
Mauritius	2.8	3.7	5,872	Iraq	2.8	20.4	83,552
Mozambique	0.3	5.4	9,663	Jordan	23.6	42.3	151,214
Niger	0.1	0.7	1,898	Kuwait	6.8	13.5	19,584
Reunion	14.2	21.3	11,123	Lebanon	17.0	27.9	106,855
Rwanda	0.0	0.0	-	Libya	11.2	28.2	54,409
Senegal	1.6	12.4	23,528	Morocco	4.3	8.5	183,387
Sierra Leone	0.2	4.7	1,396	Oman	2.2	9.3	7,244
Togo	0.2	0.8	1,360	Qatar	9.0	20.8	6,300
				Saudi Arabia	6.6	20.8	197,148
CAUCASUS				Sudan	0.6	7.2	29,397
Armenia	9.4	15.5	54,238	Syria	15.7	43.5	414,291
Azerbaijan	6.1	11.0	89,914	Tunisia	21.5	35.8	284,311
Georgia	9.7	24.0	86,524	Turkey	19.8	31.0	2,432,034
				United Arab Em	3.7	13.5	13,357
				Yemen	3.0	14.4	80,042

Table 2, continued

	IUD Prevalence	IUD Share (% of users)	No. of IUD Users	IUD Prevalence	IUD Share (% of users)	No. of IUD Users
CARIBBEAN				WESTERN, Other		
Antigua and Barbuda	1.1	2.1	110	Canada	2.9	3.9
Bahamas	3.7	6.0	1,124	United States	0.7	0.9
Barbados	5.3	9.6	869			
Cuba	43.5	59.3	817,465	Australia	4.9	6.4
Dominica	1.7	3.4	204	New Zealand	3.4	4.5
Dominican Republic	2.5	3.9	33,604			
Grenada	3.0	5.5	1,081	EUROPE, EASTERN		
Haiti	na	na	na	Belarus	29.0	57.5
Jamaica	1.1	1.7	3,788	Bulgaria	6.8	16.4
Montserrat	11.0	20.9	220	Czech Republic	13.9	19.3
Puerto Rico	1.0	1.3	5,762	Hungary	17.4	22.5
Saint Kitts and Nevis	3.8	9.4	228	Poland	5.7	11.5
Saint Lucia	4.3	9.1	293	Moldova	34.5	55.3
Saint Vincent and the Grenadines	2.7	4.6	167	Romania	7.3	11.4
Trinidad and Tobago	2.2	5.8	3,278	Slovakia	11.0	14.9
				Ukraine	18.6	27.6
CENTRAL AMERICA				EUROPE, OTHER		
Belize	1.9	4.1	430	Albania	0.0	0.0
Costa Rica	8.7	11.6	66,876	Austria	7.3	14.4
El Salvador	1.5	2.5	14,015	Belgium	5.0	na
Guatemala	2.2	5.8	37,815	Bosnia and Herzegovina	7.9	16.6
Honduras	9.6	15.5	88,886	Denmark	11.0	14.1
Mexico	14.1	20.6	2,297,619	Estonia	35.9	na
Nicaragua	6.4	9.3	40,954	Finland	25.8	33.3
Panama	6.0	10.3	26,488	France	19.9	26.7
				Germany	6.0	8.0
SOUTH AMERICA				Italy	5.5	na
Bolivia	12.6	23.6	149,730	Latvia	19.8	41.3
Brazil	1.1	1.4	319,218	Lithuania	13.9	29.8
Colombia	12.4	16.1	744,508	Netherlands	3.6	4.6
Ecuador	10.1	15.3	194,701	Norway	24.1	na
Guyana	6.3	16.9	4,422	Portugal	3.6	5.4
Paraguay	11.1	19.3	96,607	Serbia and Montenegro	7.7	13.2
Peru	9.1	13.2	339,712	Slovenia	21.5	29.1
Suriname	1.7	4.0	1,156	Spain	7.6	9.4
				Sweden	20.0	25.6
OTHER				Switzerland	6.0	na
Cook Islands	3.3	na	99	United Kingdom	6.0	na
Papua New Guinea	0.1	0.4	924			

VI.2 APPENDIX 2: DISCONTINUATION RATES

(Source: Macro DHS StatCompiler)

APPENDIX 2: One Year Contraceptive discontinuation rates for 19 countries																
(Reasons for discontinuation are treated as competing risks, so reasons add to totals.)																
Dashes indicate absence of data. Means in the top row for all reasons are similar when done only for countries with data on all 3 contraceptive methods.																
IUD discontinuation rates have been falling in 8 countries (in bold).																
Reason for discontinuation	All reasons			Method failure			To become pregnant			Side effects, health			All other reasons			
	Pill	IUD	Injections	Pill	IUD	Injections	Pill	IUD	Injections	Pill	IUD	Injections	Pill	IUD	Injections	
Overall Means	47.3	17.5	51.5	5.3	1.6	2.8	7.3	1.7	4.7	19.9	10.8	28.4	14.8	3.3	15.6	
Sub-Saharan Africa																
Zimbabwe 1994	15.1	-	15.6	2.1	-	1.4	3.7	-	3.0	4.4	-	5.3	4.9	-	5.9	
Zimbabwe 1999	16.3	-	26.2	1.8	-	1.1	3.5	-	3.2	4.2	-	12.8	7.0	-	9.1	
N. Africa/ W.Asia/Europe																
Armenia 2000	-	6.5	-	-	1.4	-	-	0.6	-	-	4.1	-	-	0.5	-	
Egypt 1992	41.8	12.5	-	8.7	1.5	-	4.9	2.3	-	19.4	7.6	-	8.9	1.0	-	
Egypt 1995	46.2	14.2	52.1	6.3	1.3	0.6	6.9	2.7	2.2	20.1	8.3	29.0	12.9	1.8	20.2	
Egypt 2000	48.4	14.2	48.4	6.1	1.0	0.8	7.5	3.1	3.6	21.1	8.6	33.8	13.8	1.5	10.2	
Jordan 1990	63.5	20.9	-	8.2	2.4	-	10.5	4.4	-	30.2	11.0	-	14.5	3.2	-	
Jordan 1997	67.9	17.7	-	9.6	2.2	-	7.6	3.5	-	31.5	9.2	-	19.2	2.7	-	
Jordan 2002	55.4	12.8	55.2	9.3	1.4	0.0	10.0	2.7	8.3	23.1	7.2	40.8	12.9	1.6	6.0	
Morocco 1992	37.4	18.9	-	5.8	2.1	-	9.0	1.3	-	11.2	9.8	-	11.4	5.8	-	
Morocco 2003-2004 ⁽¹⁾	40.9	15.3	52.4	3.9	1.3	1.2	9.7	0.7	3.8	7.6	10.3	40.0	19.7	3.0	7.4	
Turkey 1993	55.1	10.1	-	6.3	1.0	-	5.6	0.8	-	22.5	6.1	-	20.7	2.1	-	
Turkey 1998	56.4	9.4	-	6.6	0.9	-	4.8	0.4	-	21.4	6.0	-	23.6	2.0	-	
Central Asia																
Turkmenistan 2000	72.8	11.7	-	6.6	0.8	-	12.3	3.0	-	27.0	6.6	-	26.9	1.2	-	
South & Southeast Asia																
Bangladesh 1993/94 ⁽²⁾	44.9	37.1	57.6	1.7	0.3	1.1	7.0	1.8	4.8	25.6	29.9	40.0	10.6	5.1	11.7	
Bangladesh 1999/2000 ⁽³⁾	46.3	34.3	50.1	2.9	0.0	1.3	7.6	2.0	3.8	22.0	29.4	36.6	13.7	2.8	8.3	
Bangladesh 2004 ⁽⁴⁾	46.3	-	48.7	3.9	-	0.4	8.3	-	5.2	20.7	-	33.6	13.4	-	9.5	
Indonesia 1991	29.9	15.7	32.8	2.6	1.2	1.5	8.9	1.4	5.0	10.8	7.5	16.8	7.6	5.5	9.5	
Indonesia 1994	33.8	15.2	29.1	4.1	1.8	1.6	10.7	0.9	4.5	10.9	8.4	15.0	8.1	4.1	8.0	
Indonesia 1997	33.9	12.3	23.5	4.1	1.4	1.6	10.4	1.4	4.2	11.4	7.4	12.2	7.9	2.1	5.5	
Indonesia 2002/2003	31.9	8.9	18.4	4.1	0.7	1.1	8.3	0.7	3.9	8.8	6.0	8.1	10.7	1.5	5.3	

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Philippines 1993	40.6	22.6	-	5.2	2.6	-	6.8	2.2	-	13.9	8.1	-	14.7	9.6	-
Philippines 1993	40.6	22.6	-	5.2	2.6	-	6.8	2.2	-	13.9	8.1	-	14.7	9.6	-
Philippines 1998	43.8	14.3	51.8	5.4	1.1	1.9	4.5	0.6	2.2	18.0	8.0	31.8	15.9	4.5	15.9
Philippines 2003	39.2	14.0	52.7	3.7	0.6	1.3	3.5	0.4	4.3	17.4	7.7	29.5	14.6	5.4	17.7
Vietnam 1997	33.2	10.3	-	7.9	1.4	-	3.7	0.8	-	10.2	7.2	-	11.5	0.9	-
Vietnam 2002	36.1	12.5	-	6.0	2.0	-	6.9	1.2	-	13.8	8.2	-	9.5	1.1	-
Latin America & Caribbean															
Bolivia 1994	58.9	11.9	78.2	5.1	1.6	4.6	4.4	1.0	9.4	36.0	7.6	38.5	13.4	1.7	25.6
Brazil 1991 ^(b)	51.1	-	72.7	6.7	-	3.1	6.7	-	5.9	21.0	-	39.7	16.6	-	23.9
Brazil 1996	44.8	-	63.7	4.8	-	4.7	5.0	-	4.5	11.8	-	27.4	23.3	-	27.1
Colombia 1990	44.9	20.0	63.7	5.6	4.5	9.4	8.5	2.3	5.4	17.0	10.3	31.6	13.8	2.9	17.3
Colombia 1995	52.4	19.1	67.4	6.4	3.2	5.5	7.9	1.3	4.8	23.5	11.6	34.3	14.7	3.0	22.7
Colombia 2000	49.7	16.8	62.1	6.2	3.7	5.1	7.0	1.2	4.9	17.0	9.2	28.4	19.5	2.6	23.6
Dominican Rep1991	63.4	37.6	-	6.5	1.1	-	14.1	4.0	-	24.2	26.9	-	18.6	5.6	-
Dominican Rep1996	59.2	32.7	-	7.0	3.8	-	10.3	2.3	-	24.9	21.1	-	16.9	5.5	-
Dominican Rep1999	60.4	-	-	3.2	-	-	7.8	-	-	26.2	-	-	23.3	-	-
Dominican Rep 2002	51.7	27.2	67.0	6.9	2.0	4.6	8.5	2.0	4.9	20.8	13.8	34.8	15.4	9.3	22.7
Guatemala 1995	46.6	18.5	56.0	5.3	0.0	2.5	6.1	3.8	4.2	21.4	8.1	19.7	13.9	6.5	29.5
Guatemala 1998/99	51.4	-	56.0	2.5	-	4.0	8.0	-	5.7	28.1	-	33.0	12.8	-	13.3
Nicaragua 1997/98	49.2	24.3	59.7	6.5	1.6	4.6	8.9	2.5	6.2	18.6	15.7	26.5	15.1	4.5	22.5
Paraguay 1990	60.0	15.5	71.2	2.7	2.2	7.9	7.2	0.8	8.3	31.3	8.8	33.6	18.8	3.8	21.4
Peru 1992	56.4	11.9	66.6	4.0	1.2	4.0	6.0	0.5	4.3	28.7	8.3	35.9	17.7	1.8	22.5
Peru 1996	53.8	17.4	53.6	5.4	0.5	2.6	3.8	1.3	3.3	27.9	13.3	30.0	16.7	2.3	17.7
Peru 2000	54.4	15.1	40.6	4.2	0.5	1.1	3.7	0.9	2.7	30.6	12.0	25.4	16.0	1.6	11.4

First-year contraceptive discontinuation rates due to method failure, desire for pregnancy, health reasons, or other reasons, according to specific method.

Note: Based on 5 years of calendar data. The rates apply to the 3 - 63 month period prior to the survey; exposure during the month of interview and the two months prior are excluded to avoid the biases that may be introduced by unrecognised pregnancies. These cumulative discontinuation rates represent the proportion of users discontinuing a method within 12 months after the start of use. The rates are calculated by dividing the number of women discontinuing a method by the number exposed at that duration. The single-month rates are then cumulated to produce a one-year rate. In calculating the rate, the various reasons for discontinuation are treated as competing risks. Methods with less than 125 months of exposure are not shown.

VI.3 APPENDIX 3. Numbers with Unmet Need by Region, Spacing/Limiting, and Marital Status, 2000 (in thousand)

(Source: Ross and Winfrey, 2002.) (see "Demand" section in text)

	Total	Latin America	Sub-Saharan Africa	Asia except China	Middle East/N. Africa
NUMBERS WITH UNMET NEED					
DEVELOPING COUNTRIES					
Currently Married					
Spacing	55,402	4,615	15,269	31,658	3,345
Limiting	49,803	6,473	8,281	29,484	4,961
Total	105,205	11,088	23,550	61,142	8,306
Not Married	8,442	749	4,447	2,508	619
All Women	113,647	11,837	27,997	63,650	8,925
Percent Distribution	100	10.4	24.6	56.0	7.9
OTHER AREAS					
Eastern Europe	3,594				
Russia	4,604				
Caucuses	633				
Baltic Rep.	219				
GRAND TOTAL	122,697				
PERCENTAGES WITH UNMET NEED					
DEVELOPING COUNTRIES					
Currently Married					
Spacing	9.0	5.7	15.7	8.5	6.3
Limiting	8.1	8.0	8.5	7.9	9.3

Total	17.1	13.7	24.2	16.4	15.6
Not Married	3.2	1.3	9.5	2.0	2.0
All Women	13.0	8.5	19.4	12.9	10.6
OTHER AREAS (a)					
Eastern Europe	10.7				
Russia	14.5				
Caucuses	14.3				
Baltic Rep.	11.5				

Note (a): Percents for last 4 areas pertain to women of all marital statuses

VI.4 APPENDIX 4. Projections of IUD Use.

(Source: Macro DHS StatCompiler and UN 2005).

See Text section on Projections.

APPENDIX TABLE FOR PROJECTIONS

Projections of IUD prevalence, users, and adopters at a half percent rise per year in IUD prevalence*

	IUD Prevalence latest survey	IUD Prevalence after 5 yrs at 1/2% rise/yr	MWRA in 2005	Users in 2005	Adoptions during 2006	Adoption Rate (% of MWRA) in 2006
LESS DEVELOPED REGIONS	15.5	18.00	941,040,280	145,843,807	56,625,597	6.0
Sub-Saharan Africa	0.9	3.38	98,386,639	863,068	799,185	0.8
Eastern Africa	0.6	3.14	39,189,647	241,773	282,019	0.7
Burundi	0.8	3.30	823,604	6,589	6,464	0.8
Comoros	0.4	2.90	100,732	403	647	0.6
Eritrea	0.4	2.90	610,160	2,441	3,920	0.6
Ethiopia	0.1	2.60	10,398,751	10,399	55,696	0.5
Kenya	2.7	5.20	4,936,540	133,287	72,133	1.5
Madagascar	0.3	2.80	2,578,798	7,736	15,648	0.6
Malawi	0.1	2.60	2,021,810	2,022	10,829	0.5
Mauritius	2.8	5.30	230,699	6,460	3,453	1.5
Mozambique	0.3	2.80	3,543,277	10,630	21,501	0.6
Réunionu	14.2	16.70	86,162	12,235	4,786	5.6
Rwanda	0.0	2.50	1,035,832	-	5,179	0.5
Uganda	0.2	2.70	3,579,840	7,160	20,448	0.6
Tanzania	0.4	2.90	5,751,154	23,005	36,945	0.6
Zambia	0.1	2.60	1,502,814	1,503	8,049	0.5
Zimbabwe	0.9	3.40	1,989,475	17,905	16,322	0.8
Middle Africa	0.2	2.74	14,820,792	34,138	86,257	0.6
Angola	0.4	2.90	1,967,852	7,871	12,641	0.6
Cameroon	0.6	3.10	2,498,280	14,990	17,828	0.7
Central African Republic	0.2	2.70	653,400	1,307	3,732	0.6
Chad	0.1	2.60	1,580,149	1,580	8,463	0.5
D.R. Congo	0.1	2.60	8,100,400	8,100	43,386	0.5
Gabon	na					
Sao Tome & Principe	1.4	3.90	20,711	290	207	1.0
Southern Africa	1.8	4.32	5,415,300	98,728	62,224	1.1
Botswana	1.3	3.80	193,312	2,513	1,861	1.0
Lesotho	2.6	5.10	269,158	6,998	3,837	1.4
Namibia	2.1	4.60	199,077	4,181	2,484	1.2
South Africa	1.8	4.30	4,583,115	82,496	52,284	1.1
Swaziland	1.2	3.70	170,200	2,042	1,578	0.9
Western Africa	1.3	3.75	38,960,900	488,429	368,685	0.9
Benin	0.8	3.30	1,166,507	9,332	9,155	0.8
Burkina Faso	0.4	2.90	2,283,363	9,133	14,668	0.6
Cape Verde	4.3	6.80	50,509	2,172	1,026	2.0
Côte d'Ivoire	0.4	2.90	2,354,817	9,419	15,127	0.6
Gambia	0.8	3.30	245,535	1,964	1,927	0.8
Ghana	0.7	3.20	3,117,042	21,819	23,353	0.7
Guinea	0.2	2.70	1,634,265	3,269	9,335	0.6
Guinea-Bissau	2.3	4.80	227,700	5,237	3,003	1.3
Liberia	0.6	3.10	428,577	2,571	3,058	0.7
Mali	0.2	2.70	2,379,545	4,759	13,592	0.6
Mauritania	0.8	3.30	398,516	3,188	3,128	0.8
Niger	0.1	2.60	2,088,193	2,088	11,184	0.5
Nigeria	2.0	4.50	19,450,107	389,002	235,735	1.2
Senegal	1.6	4.10	1,617,531	25,880	17,301	1.1
Sierra Leone	0.2	2.70	767,995	1,536	4,387	0.6
Togo	0.2	2.70	747,754	1,496	4,271	0.6
ASIA Total	18.4	20.90	706,783,937	130,074,064	49,840,287	7.1
Eastern Asia	35.7	38.20	305,269,089	108,967,781	40,318,875	13.2
China	36.4	38.90	289,657,500	105,435,330	38,983,265	13.5
China, Hong Kong	5.1	7.60	1,268,084	64,672	29,364	2.3
Korea DPR	48.5	51.00	4,631,000	2,246,035	822,743	17.8
Mongolia	0.3	2.80	467,500	1,403	2,837	0.6
Korea, Rep.	13.2	15.70	9,245,006	1,220,341	480,666	5.2
S. Central Asia	3.3	5.79	291,899,852	5,723,599	3,497,101	1.2
Afghanistan	0.3	2.80	3,913,800	11,741	23,749	0.6
Bangladesh	1.2	3.70	28,879,400	346,553	267,770	0.9
Bhutan	1.0	3.50	311,300	3,113	2,665	0.9
India	1.6	4.10	215,399,800	3,446,397	2,303,916	1.1
Iran	8.3	10.80	11,636,900	965,863	402,032	3.5
Nepal	0.4	2.90	4,725,600	18,902	30,357	0.6
Pakistan	3.5	6.00	24,007,723	840,270	419,175	1.7
Sri Lanka	3.0	5.50	3,025,329	90,760	47,437	1.6

PROJECTION TABLE CONTINUED

SE Asia	10.0	12.49	98,398,283	10,214,179	4,128,239	4.2
Cambodia	1.3	3.80	1,974,201	25,665	19,008	1.0
Indonesia	8.1	10.60	44,125,400	3,574,157	1,493,027	3.4
Laos	3.0	5.50	982,340	29,470	15,403	1.6
Malaysian	3.9	6.40	3,929,022	153,232	74,196	1.9
Myanmar	1.3	3.80	7,780,300	101,144	74,909	1.0
Philippines	3.7	6.20	12,431,100	459,951	225,898	1.8
Singapore	5.0	7.50	772,314	38,616	17,609	2.3
Thailand	3.2	5.70	11,948,449	382,350	195,859	1.6
Viet Nam	37.7	40.20	14,455,158	5,449,594	2,012,331	13.9
			98,398,283	10,214,179		
Central Asia Rep.	46.3	48.83	11,139,713	5,161,575	1,893,219	17.0
Kazakhstan	42.0	44.50	2,883,624	1,211,122	445,578	15.5
Kyrgyzstan	38.2	40.70	822,960	314,371	116,031	14.1
Tajikistan	25.1	27.60	1,257,300	315,582	118,634	9.4
Turkmenistan	39.0	41.50	904,576	352,784	130,114	14.4
Uzbekistan	56.3	58.80	5,271,254	2,967,716	1,082,863	20.5
N. Africa/Middle East	15.7	18.22	56,680,305	8,910,177	3,455,424	6.1
Algeria	4.3	6.80	4,021,585	172,928	81,670	2.0
Egypt	35.5	38.00	12,013,050	4,264,633	1,578,275	13.1
Libyan Arab Jamahiriha	11.2	13.70	534,377	59,850	23,979	4.5
Morocco	4.3	6.80	4,691,296	201,726	95,271	2.0
Sudan	0.6	3.10	5,389,417	32,337	38,459	0.7
Tunisia	21.5	24.00	1,454,613	312,742	118,609	8.2
Bahrain	2.9	5.40	109,612	3,179	1,680	1.5
Iraq	2.8	5.30	3,282,400	91,907	49,131	1.5
Jordan	23.6	26.10	704,810	166,335	62,739	8.9
Kuwait	6.8	9.30	316,800	21,542	9,253	2.9
Lebanon	17.0	19.50	691,415	117,541	45,302	6.6
Oman	2.2	4.70	362,189	7,968	4,648	1.3
Qatar	9.0	11.50	77,000	6,930	2,852	3.7
Saudi Arabia	6.6	9.10	3,285,801	216,863	93,632	2.8
Syria	15.7	18.20	2,902,677	455,720	176,750	6.1
Turkey	19.8	22.30	13,511,300	2,675,237	1,019,941	7.5
United Arab Emirates	3.7	6.20	397,100	14,693	7,216	1.8
Yemen	3.0	5.50	2,934,862	88,046	46,019	1.6
Caucasus	7.8	10.34	3,237,300	253,744	106,519	3.3
Armenia	9.4	11.90	634,700	59,662	24,413	3.8
Azerbaijan	6.1	8.60	1,621,400	98,905	43,317	2.7
Georgia	9.7	12.20	981,200	95,176	38,789	4.0
Latin American & Caribbean	7.6	10.06	75,952,099	5,742,755	2,424,181	3.2
Caribbean	19.6	22.15	4,860,620	955,012	364,288	7.5
Antigua and Barbuda	1.1	3.60	11,000	121	98	0.9
Bahamas	3.7	6.20	33,413	1,236	607	1.8
Barbados	5.3	7.80	18,037	956	431	2.4
Cuba	43.5	46.00	2,067,154	899,212	330,455	16.0
Dominica	1.7	4.20	13,200	224	146	1.1
Dominican Republic	2.5	5.00	1,478,582	36,965	20,552	1.4
Grenada	3.0	5.50	39,644	1,189	622	1.6
Haiti	na					
Jamaica	1.1	3.60	378,753	4,166	3,377	0.9
Montserrat	11.0	13.50	2,200	242	97	4.4
Puerto Rico	1.0	3.50	633,867	6,339	5,426	0.9
Saint Kitts and Nevis	3.8	6.30	6,600	251	122	1.9
Saint Lucia	4.3	6.80	7,498	322	152	2.0
Saint Vincent & Grenadines	2.7	5.20	6,784	183	99	1.5
Trinidad and Tobago	2.2	4.70	163,888	3,606	2,103	1.3
Central America	11.5	14.01	23,921,700	2,752,683	1,099,564	4.6
Belize	1.9	4.40	24,888	473	293	1.2
Costa Rica	8.7	11.20	845,558	73,564	30,416	3.6
El Salvador	1.5	4.00	1,027,742	15,416	10,627	1.0
Guatemala	2.2	4.70	1,890,752	41,597	24,262	1.3
Honduras	9.6	12.10	1,018,481	97,774	39,900	3.9
Mexico	14.1	16.60	17,924,684	2,527,380	989,371	5.5
Nicaragua	6.4	8.90	703,903	45,050	19,557	2.8
Panama	6.0	8.50	485,605	29,136	12,801	2.6
South America	4.3	6.81	47,169,779	2,035,060	960,330	2.0
Bolivia	12.6	15.10	1,307,165	164,703	65,170	5.0
Brazil	1.1	3.60	31,921,814	351,140	284,615	0.9
Colombia	12.4	14.90	6,604,507	818,959	324,572	4.9
Ecuador	10.1	12.60	2,120,508	214,171	86,848	4.1
Guyana	6.3	8.80	77,209	4,864	2,118	2.7
Paraguay	11.1	13.60	957,365	106,267	42,618	4.5
Peru	9.1	11.60	4,106,411	373,683	153,563	3.7
Suriname	1.7	4.20	74,800	1,272	827	1.1

* Regional figures are aggregates of country numbers so regional results weight countries by their numbers

VI.5 APPENDIX 5: Preferred method of contraception for future use

(Source: Macro DHS StatCompiler)

(columns do not add to 100 due to omitted methods)

	IUD	Injection	Pill	Female sterilization
Sub-Saharan Africa				
Benin 2001	3	44	21	2
Botswana 1988	14	27	47	3
Burkina Faso 2003	1	36	27	1
Burundi 1987	3	38	22	2
Cameroon 2004	1	24	18	3
CAR 1994/95	0	7	22	1
Chad 1996/97	1	32	46	1
Comoros 1996	2	40	25	3
Cote d'Ivoire 1998/99	2	44	30	1
Eritrea 2002	1	37	39	1
Ethiopia 2000	0	46	38	0
Gabon 2000	1	7	47	4
Ghana 2003	4	43	15	4
Guinea 1999	1	48	36	1
Kenya 2003	1	47	13	8
Liberia 1986	3	22	37	7
Madagascar 2003/2004	0	46	15	2
Malawi 2000	1	59	18	10
Mali 2001	1	39	47	1
Mozambique 2003	2	42	40	3
Namibia 2000	3	49	19	13
Niger 1998	1	29	49	1
Nigeria 2003	3	28	23	1
Rwanda 2000	1	31	18	3
Senegal 1997	7	18	28	2
South Africa 1998	4	48	24	15
Sudan 1990	6	8	60	3
Tanzania 1996	2	38	34	6
Togo 1998	3	40	14	1
Uganda 2000/01	1	46	21	6
Zambia 2001/02 (2)	1	31	42	6
Zimbabwe 1999	2	27	57	5
North Africa/West Asia/Europe				
Armenia 2000	28	0	11	-
Egypt 2000	39	7	14	0
Jordan 2002	53	2	15	4
Morocco 2003-2004	12	4	71	4
Tunisia 1988	27	8	17	15
Turkey 1998	37	9	10	6
Yemen 1997	20	10	34	5

Central Asia				
Kazakhstan 1999	72	2	13	1
Kyrgyz Republic 1997	73	5	6	1
Turkmenistan 2000	89	2	3	-
Uzbekistan 1996	84	4	5	-
South & Southeast Asia				
Bangladesh 2004 (7)	1	19	45	2
Cambodia 2000	4	34	26	1
India 1998/99	3	-	16	65
Indonesia 2002/2003	8	56	19	2
Nepal 2001	1	28	9	32
Pakistan 1990/91	7	16	13	17
Philippines 2003	8	10	48	10
Sri Lanka 1987	4	20	10	44
Thailand 1987	6	28	26	27
Vietnam 2002	60	1	14	1
Latin America & Caribbean				
Bolivia 2003	22	28	11	7
Brazil 1996	6	8	38	30
Colombia 2000	18	14	15	29
Dominican Republic 2002	6	16	28	36
Ecuador 1987	31	8	19	16
El Salvador 1985	6	17	33	29
Guatemala 1998/99	4	29	23	23
Haiti 2000	1	44	12	3
Mexico 1987	21	19	23	21
Nicaragua 2001	8	39	24	20
Paraguay 1990	12	14	27	5
Peru 2000	12	32	11	10
Trinidad & Tobago 1987	10	9	35	13

VI.6 APPENDIX 6. Percent of Married Women Ever Using the IUD, by Age and Region

(Source: Macro DHS StatCompiler)

BY REGION*	15-19	20-24	25-29	30-34	35-39	40-44	45-49	Total
Sub-Saharan Africa	0.1	1.0	1.8	3.1	3.9	4.0	3.7	2.6
North Africa/West Asia	6.7	19.7	31.5	38.3	40.4	36.1	30.1	32.5
Central Asia Rep.	12.5	38.2	60.4	75.5	76.4	73.6	65.1	63.9
South & Southeast Asia	3.1	7.6	12.0	14.4	15.3	15.4	13.4	12.8
Latin America	5.8	12.5	17.7	19.4	19.2	17.3	14.6	16.5
OVERALL MEANS	3.0	8.3	12.9	15.7	16.5	15.6	13.5	13.4

*Countries receive equal weights.

BY COUNTRY	15-19	20-24	25-29	30-34	35-39	40-44	45-49	Total
Sub-Saharan Africa								
Benin 2001	0.0	0.5	1.1	1.9	2.2	4.1	2.3	1.6
Botswana 1988	0.0	15.6	17.9	23.9	20.1	13.4	8.1	17.4
Burkina Faso 2003	0.2	0.1	0.9	1.3	1.9	2.4	2.6	1.2
Burundi 1987	0.0	0.4	0.7	0.9	0.5	0.6	0.5	0.6
Cameroon 2004	0.2	0.1	0.5	1.1	2.0	3.1	4.3	1.2
CAR 1994/95	0.0	0.1	0.1	0.2	0.2	0.6	0.3	0.2
Chad 1996/97	0.0	0.0	0.1	0.6	0.2	0.2	0.0	0.2
Comoros 1996	0.0	1.2	1.9	2.0	2.5	1.1	1.2	1.7
Cote d'Ivoire 1998/99	0.2	0.4	2.0	2.9	0.5	3.7	0.9	1.5
Eritrea 2002	0.0	0.1	0.8	1.6	3.4	4.0	3.0	1.7
Ethiopia 2000	0.0	0.0	0.3	0.8	1.1	0.5	0.4	0.5
Gabon 2000	0.0	0.1	0.4	1.2	1.1	3.8	5.5	1.3
Ghana 2003	0.0	0.4	1.5	3.2	5.1	6.2	5.0	3.2
Guinea 1999	0.0	0.2	0.2	0.8	0.5	0.8	0.2	0.4
Kenya 2003	0.1	0.9	2.7	10.3	14.4	17.0	14.8	7.9
Liberia 1986	0.0	2.2	2.3	4.0	4.7	3.3	2.8	2.8
Madagascar 1997	0.0	0.3	1.2	1.6	1.7	1.4	2.0	1.2
Madagascar 2003/2004	0.0	0.5	1.1	1.3	3.2	3.7	3.5	1.8
Malawi 2000	0.0	0.2	1.0	1.2	1.4	1.3	1.5	0.8
Mali 2001	0.0	0.2	0.3	0.8	1.0	0.8	0.9	0.5

Mauritania 2000/01	0.4	0.4	1.4	3.6	4.1	2.2	2.7	2.2
Mozambique 2003	0.1	0.4	1.3	2.4	5.7	5.0	2.7	2.2
Namibia 2000	0.0	0.4	1.8	5.2	8.6	8.3	7.6	5.2
Niger 1998	0.1	0.2	0.4	0.7	1.1	0.5	0.9	0.5
Nigeria 2003	0.0	0.5	1.9	1.6	3.1	3.8	4.0	2.0
Rwanda 2000	0.0	0.0	0.4	0.3	0.8	1.1	1.5	0.5
Senegal 1997	0.5	0.7	2.7	5.3	7.2	6.7	4.6	4.0
South Africa 1998	0.0	3.4	5.1	10.8	16.7	21.4	19.1	13.1
Sudan 1990	0.3	0.6	1.4	2.5	2.3	2.0	1.5	1.6
Tanzania 1999	0.2	0.5	2.8	2.4	1.0	1.2	5.5	1.9
Togo 1998	0.4	1.2	2.1	2.8	3.7	4.6	6.2	2.9
Uganda 2000/01	0.3	0.2	1.6	1.5	2.1	1.3	1.4	1.2
Zambia 2001/02 (2)	0.0	0.0	0.6	1.0	2.2	1.5	2.8	0.9
Zimbabwe 1999	0.3	0.7	1.3	3.1	6.1	4.2	6.5	2.7
MEANS	0.1	1.0	1.8	3.1	3.9	4.0	3.7	2.6
North Africa/West Asia/Europe								
Armenia 2000	2.8	7.5	16.5	26.1	28.1	20.5	16.3	19.6
Egypt 2000	21.2	44.4	62.7	67.0	66.3	61.5	52.9	58.2
Jordan 2002	4.4	22.7	41.5	57.5	63.7	61.9	57.1	50.2
Morocco 2003-2004 (3)	3.2	7.3	12.5	17.2	20.3	24.3	20.9	17.0
Tunisia 1988	4.8	28.1	39.5	43.9	40.9	35.3	27.5	37.0
Turkey 1998	9.6	23.4	40.9	46.4	52.8	42.3	30.5	38.9
Yemen 1997	1.1	4.5	7.2	9.8	11.0	7.1	5.4	6.9
MEANS	6.7	19.7	31.5	38.3	40.4	36.1	30.1	32.5
Central Asia								
Kazakhstan 1999	14.5	42.7	67.6	79.8	76.6	76.2	65.5	68.9
Kyrgyz Republic 1997	14.9	42.5	61.5	80.9	80.2	74.9	68.6	66.7
Turkmenistan 2000	7.6	32.5	52.3	69.0	74.4	76.7	67.3	61.4
Uzbekistan 1996	12.9	35.0	60.2	72.1	74.3	66.5	59.0	58.7
MEANS	12.5	38.2	60.4	75.5	76.4	73.6	65.1	63.9
South & Southeast Asia								
Bangladesh 2004 (7)	0.5	1.7	4.4	8.6	12.0	12.0	7.9	5.9
Cambodia 2000	0.3	0.8	2.8	3.9	4.8	3.8	3.6	3.3

India 1998/99	0.7	3.9	7.1	8.4	7.5	4.6	3.2	5.6
Indonesia 2002/2003	1.1	3.1	6.7	14.4	20.9	24.9	24.2	15.0
Nepal 2001	0.1	0.9	1.7	1.8	1.7	0.5	0.4	1.1
Pakistan 1990/91	0.4	1.4	4.1	4.9	4.1	3.6	1.8	3.3
Philippines 1993	3.1	5.7	7.2	9.0	8.5	8.6	7.7	7.8
Philippines 2003	3.6	6.2	8.2	11.2	10.9	11.9	9.4	9.6
Sri Lanka 1987	1.9	4.3	8.0	9.7	10.2	11.8	9.8	8.9
Thailand 1987	7.4	14.1	18.6	16.5	17.3	17.4	12.8	15.9
Vietnam 2002	15.4	41.4	63.6	69.5	70.6	70.2	66.4	64.9
MEANS	3.1	7.6	12.0	14.4	15.3	15.4	13.4	12.8
Latin America & Caribbean								
Bolivia 2003	6.0	16.6	24.0	27.4	25.1	21.0	19.0	22.0
Brazil 1996	1.3	2.0	3.3	5.2	3.8	4.1	4.1	3.8
Colombia 2000	13.3	25.9	34.8	36.3	41.1	34.7	35.4	33.9
Dominican Republic 2002	3.7	8.9	12.4	14.0	14.7	13.2	13.7	12.2
Ecuador 1987	7.2	16.3	24.8	23.5	19.3	19.9	9.1	19.3
El Salvador 1985	6.8	11.2	11.5	10.7	12.0	16.0	9.4	11.2
Guatemala 1998/99	0.7	4.5	6.7	11.0	12.2	6.5	11.5	7.9
Haiti 2000	0.0	0.1	0.2	0.4	0.4	2.3	3.1	0.9
Mexico 1987	17.5	28.2	31.6	27.0	22.2	22.0	12.6	24.9
Nicaragua 2001	9.2	17.5	28.1	32.3	33.5	26.3	21.1	25.1
Paraguay 1990	2.2	6.7	14.1	15.5	15.5	13.0	11.8	12.5
Peru 2000	4.8	17.2	26.3	33.9	35.3	31.4	24.3	28.0
Trinidad & Tobago 1987	2.9	7.8	12.3	15.6	13.9	15.1	14.5	12.4
MEANS	5.8	12.5	17.7	19.4	19.2	17.3	14.6	16.5
OVERALL MEANS	3.0	8.3	12.9	15.7	16.5	15.6	13.5	13.4

VI.7 APPENDIX 7. Percent of Currently married Women Who Know Each Method

(Source: Macro StatCompiler)

Regional Summary*	IUD	Pill	Injections	Condom	Female sterilization	Male sterilization
Sub-Saharan Africa	43.6	77.2	72.6	70.1	51.5	20.7
North Africa/West Asia	92.3	92.9	75.6	73.4	77.3	21.8
Central Asia Rep.	98.1	79.3	66.4	75.6	46.7	21.1
South & Southeast Asia	80.1	90.7	86.3	79.9	87.1	71.9
Latin America	80.8	92.7	85.7	82.7	85.0	56.4
OVERALL MEANS	64.6	84.0	77.0	74.7	65.7	35.9

*Countries receive equal weights

Country Detail	IUD	Pill	Injection	Condom	Female sterilization	Male sterilization
Sub-Saharan Africa						
Benin 2001	37.0	78.2	78.7	84.7	56.4	21.0
Botswana 1988	89.5	93.6	89.4	87.1	66.6	24.7
Burkina Faso 2003	41.2	81.8	76.1	84.7	27.2	16.0
Burundi 1987	23.8	42.4	57.4	14.9	14.6	3.6
Cameroon 2004	36.6	70.6	65.7	83.9	46.4	10.2
CAR 1994/95	12.9	44.7	36.3	58.7	48.5	25.9
Chad 1996/97	5.5	27.8	25.8	24.8	26.0	5.2
Comoros 1996	63.3	93.9	94.3	89.9	89.0	25.8
Cote d'Ivoire 1998/99	29.6	73.5	68.6	83.1	44.4	15.1
Eritrea 2002	23.9	78.0	73.6	75.2	23.2	6.3
Ethiopia 2000	10.2	81.9	69.6	29.2	23.9	4.7
Gabon 2000	38.3	86.2	57.4	92.2	54.1	17.7
Ghana 2003	65.1	89.7	91.8	94.7	74.3	45.4
Guinea 1999	15.3	63.2	54.9	55.1	32.5	3.9
Kenya 2003	74.6	93.1	93.5	91.6	80.3	52.1
Liberia 1986	31.3	61.1	42.4	26.2	41.7	5.9
Madagascar 2003/2004	34.9	76.5	78.2	72.0	35.2	24.4
Malawi 2000	70.4	94.9	95.5	92.2	87.5	60.2
Mali 2001	21.1	68.4	56.9	61.5	32.5	12.6
Mauritania 2000/01	33.8	63.6	56.8	33.8	15.6	6.1
Mozambique 2003	49.0	79.7	78.3	76.1	40.3	7.9
Namibia 2000	56.0	91.9	95.6	92.0	66.5	35.1
Niger 1998	32.8	68.4	63.1	40.0	42.0	10.5
Nigeria 2003	29.2	63.0	61.0	54.3	39.6	10.3
Rwanda 2000	38.4	83.3	87.7	90.0	61.1	17.8
Senegal 1997	54.4	74.2	57.7	66.7	58.2	6.8
South Africa 1998	79.5	95.4	96.7	89.1	77.8	44.1
Sudan 1990	39.0	69.9	45.6	17.8	44.1	5.1
Tanzania 1999	59.5	93.0	87.7	87.2	69.1	29.5
Togo 1998	75.2	76.5	87.3	86.1	62.8	23.1
Uganda 2000/01	52.7	94.2	93.1	87.9	79.1	39.3
Zambia 2001/02 (2)	45.7	96.2	86.9	95.5	76.9	24.6
Zimbabwe 1999	70.2	97.6	92.5	94.2	63.5	42.8

MEANS	43.6	77.2	72.6	70.1	51.5	20.7
North Africa/West Asia/Europe						
Armenia 2000	92.7	83.3	48.9	90.1	47.5	20.3
Egypt 2000	99.9	99.9	99.4	68.1	74.9	15.7
Jordan 2002	99.9	99.7	92.9	91.0	97.8	21.9
Morocco 2003-2004 (3)	97.6	99.8	96.4	88.9	94.2	9.0
Tunisia 1988	94.7	95.8	59.4	66.3	95.9	16.9
Turkey 1998	97.0	95.8	76.2	85.1	83.4	45.0
Yemen 1997	64.4	76.1	55.7	24.1	47.7	23.6
MEANS	92.3	92.9	75.6	73.4	77.3	21.8
Central Asia						
Kazakhstan 1999	99.1	88.8	59.7	94.6	58.4	31.3
Kyrgyz Republic 1997	99.6	73.3	67.1	85.2	59.3	-
Turkmenistan 2000	98.5	79.2	75.0	68.4	42.3	10.9
Uzbekistan 1996	95.0	75.7	63.7	54.1	26.8	-
MEANS	98.1	79.3	66.4	75.6	46.7	21.1
South & Southeast Asia						
Bangladesh 2004 (7)	85.7	99.9	98.7	92.4	96.3	73.2
Cambodia 2000	83.3	89.7	89.7	79.3	64.0	47.2
India 1998/99	70.6	79.5	-	71.0	98.2	89.3
Indonesia 2002/2003	87.4	96.4	97.1	76.3	63.6	39.0
Nepal 2001	54.7	93.4	97.3	91.0	99.1	98.2
Pakistan 1990/91	51.5	62.2	62.2	35.3	69.7	20.2
Philippines 2003	91.0	98.3	90.1	96.0	92.0	74.3
Sri Lanka 1987	83.4	93.4	84.3	73.3	98.1	91.5
Thailand 1987	94.7	98.7	97.2	88.5	97.8	96.0
Vietnam 2002	98.5	95.3	60.1	96.3	92.4	90.3
MEANS	80.1	90.7	86.3	79.9	87.1	71.9
Latin America & Caribbean						
Bolivia 2003	83.9	82.1	80.2	78.5	64.9	34.8
Brazil 1996	76.5	99.4	88.5	98.9	96.8	79.5
Colombia 2000	97.6	99.3	98.0	99.2	98.4	80.4
Dominican Rep. 2002	94.0	99.2	96.9	98.2	98.4	55.9
Ecuador 1987	79.5	84.8	65.6	51.0	77.5	18.7
El Salvador 1985	80.0	89.1	66.7	78.2	87.4	65.1
Guatemala 1998/99	54.3	79.4	72.9	60.0	76.3	58.4
Haiti 2000	40.0	97.2	97.3	94.8	72.4	51.5
Mexico 1987	86.7	91.2	86.7	66.6	85.8	67.1
Nicaragua 2001	89.7	98.2	96.9	94.7	90.5	64.7
Paraguay 1990	84.5	93.6	88.5	66.7	70.3	16.4
Peru 2000	94.1	95.4	96.1	91.9	93.2	79.8
Trinidad & Tobago 1987	89.6	96.3	79.4	96.0	92.9	60.6
MEANS	80.8	92.7	85.7	82.7	85.0	56.4
OVERALL MEANS	64.6	84.0	77.0	74.7	65.7	35.9