Essential Knowledge about the IUD

This section presents the latest biomedical, social science, and programmatic knowledge about the Copper-T 380A (TCu-380A) IUD as of January 2006.

The Toolkit organizers have tried to update information and reduce inconsistencies within the various documents contained in the Toolkit. However, if a statement contained elsewhere in the Toolkit is at variance with the information contained in this summary of essential knowledge about the IUD, the information in this section should take precedence.

I. Method Characteristics

Effectiveness
The Copper-T 380A IUD (TCu-380A) is a highly effective form of long-term, reversible contraception, with an associated pregnancy (failure) rate of 0.8 percent in the first year of use (Trussell, 2004). In a long-term international comparative trial sponsored by the World Health Organization (WHO), the average annual failure rate was 0.4 percent or less, and after 12 years of use the cumulative failure rate for women using the TCu-380A IUD was 2.2 percent, which is comparable to that of female sterilization (United Nations Development Programme et al., 1997).

Return to fertility
A woman’s ability to get pregnant returns immediately after an IUD is removed (Andersson et al., 1992; Belhadj et al., 1986).

Life-span after insertion of TCu-380A IUD
Long-term studies have shown that the TCu-380A is effective for at least 12 years after insertion (United Nations Development Programme et al., 1997). (Readers should be aware that the US Food and Drug Administration (FDA) has labeled the TCu-380A as effective for only 10 years (United States Food and Drug Administration, 2005). Note that some of the documents within the Toolkit may cite the effectiveness of the TCu-380A as 10 years; however, the IUD Toolkit guidance is that it is “effective for at least 12 years.”)
Mechanism of action
All research on this topic shows that copper IUDs prevent pregnancy (implantation of a fertilized egg) only by actions that precede fertilization (Alvarez et al., 1988; Croxatto et al., 1994). When this mechanism fails and fertilization does occur, there is no evidence that the embryos experience abnormal rates of pre-implantation development. It is hypothesized that copper ions, found throughout the fluids in the uterus and fallopian tubes of IUD users, alter the sensitive environment necessary for fertilization.

Side effects
Pain/cramping/menstrual irregularities
During insertion, some women may experience discomfort or cramping (Grimes, 2004). Cramps may continue for several days beyond insertion. Cramping, pain, and menstrual irregularities associated with IUD insertion or menstruation usually subside within a few months. Heavy or prolonged bleeding may be treated with nonsteroidal anti-inflammatory drugs such as ibuprofen (World Health Organization, 2004b). Thoughtful counseling about side effects and treatment options is critical since menstrual irregularities are the most common medical reason for IUD removal.

Bleeding/anemia
No significant changes in hemoglobin levels, or likelihood of anemia have been noted with copper IUDs (though menstrual blood loss is increased by about 50%). (Andrade et al., 1987); (Milsom et al., 1995); (Task Force for Epidemiological Research on Reproductive Health, 1998). Accordingly, copper IUDs can generally be used by women with anemia (World Health Organization, 2004a).

Non-contraceptive health benefits
Non-hormonal IUDs, such as the Copper-T 380A IUD, may protect against endometrial cancer and cervical cancer (Hubacher et al., 2002).

Perforation
Perforation of the uterus during insertion has been shown to be quite rare, with fewer than 1.5 perforations per 1,000 IUD insertions occurring in large clinical trials (Treiman et al., 1995); (United Nations Development Programme et al., 1997). The skill and experience of the provider is the most important factor that minimizes the risk of perforation (Harrison-Woolrych et al., 2003).

Expulsion
Expulsion of the IUD is uncommon. The skill and experience of the provider is the most important factor that minimizes the risk of expulsion (Chi, 1993). Cumulative expulsion rates of 2.4, 3.4, and 4.4 percent at one, two, and three years of use, respectively, have been reported among copper IUD users (UNDP et al., 1995). In the first year of use, expulsion rates vary from 2-8 percent (Treiman et al., 1995). Based on clinical experience, women are usually aware when they have expelled their IUD. Such expulsion is not dangerous for the user; however, the woman is no longer protected against pregnancy.

Expulsion rates tend to be slightly higher for nulliparous women (compared to parous
women) and for postpartum insertions (compared to interval insertions) (Grimes, 2004); however women with these conditions can still generally have an IUD inserted.

**Ectopic pregnancy**

Because they are so effective in preventing pregnancy, IUDs protect well against ectopic pregnancy. Women who use second-generation copper IUDs have a 91 percent lower chance of ectopic pregnancy than do women using no contraception, according to an analysis of 42 randomized trials published between 1970 and 1990 (Sivin, 1991).

In the unlikely event of pregnancy in an IUD user, that pregnancy is more likely to be ectopic than is a pregnancy in a non-user. Still, the pregnancy in an IUD user is far more likely to be normal than ectopic: only an estimated 1 in every 13 to 16 pregnancies, or 6 percent to 8 percent, is ectopic (Furlong, 2002).

**STI-related health risks**

**Pelvic inflammatory disease (PID)**

Rates of clinical PID are very low among IUD users—lower than previously thought and much lower than providers may realize.

A multinational study by the World Health Organization (WHO) of 23,000 IUD insertions with 51,000 years of follow-up found an overall rate of PID of 1.6 cases per 1000 women per year, that is, 998.4 per 1000 women per year did not get PID (Farley et al., 1992).

The risk of an IUD user developing PID appears to be increased only in the first 3-4 weeks after insertion; beyond this time the risk is similar to non-IUD users. The rate of PID during these first few weeks post-insertion is 7 PID cases per 1000 women per year. After 3-4 weeks post-insertion, an IUD user appears to be no more likely to develop PID than a non-user (Farley et al., 1992).

When PID in an IUD user does occur, the PID is caused by (recognized or unrecognized) sexually transmitted infections (STIs) with the organisms *Chlamydia trachomatis* or *gonococcus* (agent that causes gonorrhea), not by the IUD itself (Grimes, 2000).

In settings with a high prevalence (10 percent) of *Chlamydia trachomatis* or *gonococcus* among the population, the risk of PID attributable to the IUD is likely to be very small, estimated at 3 cases of PID per 1000 insertions (Shelton, 2001). With simple screening by history alone (based on a few key questions to identify an individual’s STI risks), the estimated attributable risk could be reduced in half, to 0.15 percent, or 1 case in 667 insertions (Shelton, 2001).

Even among women who have confirmed STIs at the time of IUD insertion, the chances of developing PID are low. A recent analysis of published studies compared the risk of PID in two groups: those with STIs at the time of insertion and those without STIs. The absolute risk of PID was low for both groups (0-5% for those with STIs and 0-2% for those without) (Mohllajee et al., 2006).

**Infertility**
Sexually transmitted infections with *Chlamydia* and *gonococcus* can cause PID which in turn can lead to infertility by damaging the fallopian tubes and causing occlusion. However, a single episode of PID is associated with only about a 1 in 8 (13 percent) occurrence of occlusion of the Fallopian tubes. More frequent episodes of PID are associated with higher chances of infertility (Westrom, 1975).

In a study examining the relationships between infertility, IUD use, and sexually transmitted bacteria, the risk of infertility due to tubal damage was not associated with previous IUD use, but rather to past exposure to *Chlamydia trachomatis* (Hubacher *et al.*, 2001).

**HIV/AIDS**

Use of the IUD is not known to increase the risks of female acquisition of HIV or to speed progression toward AIDS among HIV-infected IUD users.

IUD use by HIV-infected women does not increase genital shedding of the virus; therefore risk of HIV acquisition by an uninfected male partner should not be elevated either. (Richardson *et al.*, 1999).

Complications of IUD use are low among HIV-infected users, and are comparable to the complication rates among IUD users who are not HIV-infected, with 0.2-2 percent infectious complications and 7-10 percent overall complications (Morrison *et al.*, 1999); (Sinei *et al.*, 1998).

**II. Client Knowledge, Attitudes, and Behavior**

**Knowledge about the IUD**

Of the world’s major forms of modern reversible contraception (pills, injectables, condoms, and IUDs), IUDs are the least well-known; approximately 61 percent of respondents in Demographic and Health Surveys in the last five years are familiar with IUDs (Demographic and Health Surveys, 2005). Also, in some countries, many women are not aware of existing sources of IUD services (Zlidar *et al.*, 2003).

**Satisfaction with the IUD**

IUD users are more highly satisfied with their choice of contraception than are users of other reversible forms, according to research conducted in the US (Forrest, 1996).

Approximately 75-85 percent of women who choose the IUD keep it for at least one year (Rivera *et al.*, 1992); (Schmidt *et al.*, 1994). The continuation rate for IUDs is higher than the continuation rates for oral contraceptives, or injectables (though the factors that result in continuation among these various methods are not entirely comparable) (Sekadde-Kigondu *et al.*, 1996).

Myths and misconceptions in the minds of clients and communities about the IUD’s characteristics are widespread in many parts of the world and probably prevent greater use of the IUD. *Contrary to common myths and misconceptions*, IUDs do not “migrate” to distant parts of the body, do not have a higher failure rate than oral contraceptives, and do
not harm a fetus in the rare event of method failure (Grimes, 2004).

III. Counseling and Informed Choice

All couples and individuals have the basic human right to decide freely and responsibly the number and spacing of their children and to have the information, education, and means to do so. Under the Cairo Programme of Action, 180 governments have committed to “...provide universal access to a full range of safe and reliable family-planning methods...” (para 7.16) and to “...conform to ethical and professional standards in the delivery of family planning and related reproductive health services aimed at ensuring responsible, voluntary and informed consent...” (para 7.17) (United Nations Department for Economic and Social Information and Policy Analysis, 1994).

Greater contraceptive choice has been shown to improve uptake and use of all methods (Pariani et al., 1991); (Steele et al., 1999), therefore, it is important that women have access to an array of methods, including the IUD.

Good pre-insertion counseling on side effects has been shown to improve continuation rates of IUDs (Backman et al., 2002); (Zetina-Lozano, 1983).

Women who request an IUD, who are given the method, and whose husbands agree with their choice are less likely to discontinue use by 12 months than are woman who are not granted their initial choice and whose husbands do not agree with their choice (Pariani et al., 1991).

IV. Marketing and Communication

To maximize effect, demand-side communication and marketing activities should be coordinated and integrated with supply-side activities that are focusing on IUD availability (e.g., clinical and counseling training; secure logistics and supplies).

Consumer-directed information about the IUD can increase demand for and use of the IUD by effectively addressing common barriers to greater IUD use—low awareness of the method, low knowledge of its benefits; prevalence of rumors and myths, all of which contribute to poor image.

Clients who have been informed prior to a clinic visit about the IUD and its benefits may be more likely to ask their provider about it, thereby creating a “pull” that helps ensure its inclusion among contraceptive options presented.

In settings where the target audience’s awareness of IUDs is low, the primary needs are to raise awareness, provide correct information, and connect potential clients to qualified providers. Where awareness is high but negative information and myths are common, the objective is not only to provide correct knowledge but also to counter barriers by specifically addressing prevailing myths, rumors, and health concerns.

Formative research shows that benefits valued by IUD users include its being: “hassle-free” (no repeated clinic visits for re-supply; no need to remember a pill daily or return for
injections); a longer-term method that can be discontinued when the client desires, with immediate return to previous level of fecundability; non-surgical; safe and highly reliable; without hormonal effects (for the Copper-T); inexpensive over time.

Communications should specifically advertise sites where IUD services are available, linking clients to providers who are trained in proper insertion and can provide accurate, unbiased, and more detailed information, including proper counseling on side effects. Channeling clients to skilled providers ensures clients will be given the method if they want it, and have a more positive experience, leading to positive word of mouth.

Marketing efforts need to target not only potential clients, but also influencer groups, including spouses, community leaders, journalists, and providers. Communications should include provision of general information for providers who do not offer IUDs to support referral systems to providers who do provide them.

If using shorter communication formats (e.g., radio or television spots, posters), formative research should be used to identify the benefits as well as the negative aspects of the IUD as perceived by a particular (target) group, in order to create focused messages. Attempts to address multiple issues simultaneously may result in dilution of individual messages and less overall impact.

V. Training of IUD Providers

Providers play a pivotal role in the IUD’s availability and use. Providers not only conduct IUD counseling, insertion, and removal, they serve as “gatekeepers” whose attitudes and actions influence whether and how clients use IUDs. It is thus important to take a “provider perspective,” and to address the knowledge, skills, motivations, and needs of providers (see training section for details).

Rather than trying to train and support a large number of IUD providers, who often will have relatively few clients each and thus difficulty in maintaining skills, it may make more sense to identify currently or potentially active IUD providers and to support them in a more sustained fashion. Such providers tend to build up a satisfied clientele who attract other potential users. These providers can also serve as trainers, mentors, and role models (“champions”) for other providers. Similarly, training and program efforts can be focused on fewer, higher-quality, sites—“centers of excellence”—for training and service delivery, with an aim to subsequently expand and scale up once quality IUD services are flourishing.

With a competency-based training approach that first uses pelvic models during training before then proceeding to actual insertion, most paramedical providers achieve competency to provide clinical IUD services with as few as three insertions in clients (Ajello et al., 1994); (Montufar et al., 2005); (Villanueva et al., 2001). Paramedical providers can be trained at their own service sites, and many will continue using their skill after training is completed (Montufar et al., 2005).

A significant proportion of trainees who begin IUD training may not complete the training because of a lack of adequate numbers of IUD clients for training. Of those trainees who
do complete their training, many do not subsequently provide IUD services due to lack of confidence in their newly acquired skills, inability to identify women interested in the method, and/or lack of appropriate on-site supervision and follow-up (Katz et al., 2002); (Villanueva et al., 2001).

VI. Service Delivery
Who can provide the IUD?
In addition to physicians, other health care workers such as midwives, clinical officers, nurses, and auxiliary nurses, when appropriately trained and having shown they have the necessary skills, can provide IUD services with quality of care, safety, and client satisfaction comparable to IUD services provided by physicians (Eren et al., 1983); (Farr et al., 1998); (Villanueva et al., 2001).

Who can use the IUD?
Almost all women generally can use the IUD, including young women (under 20 years of age), nulliparous women, nulligravid women, HIV-infected women, and women with AIDS who are doing clinically well on antiretrovirals (World Health Organization, 2004a).

There are only a few conditions for which WHO recommends that the IUD should not be used (category 4), the common ones being pregnancy, postpartum or post-abortion sepsis, and current purulent cervicitis, PID, or chlamydial or gonorrheal infection (World Health Organization, 2004a). (Less common conditions for which the IUD should not be used include cervical or endometrial cancer, distorted uterine cavity, pelvic tuberculosis, and unexplained vaginal bleeding felt to reflect a serious underlying condition).

Use of IUDs by women at “increased risk” of STIs
IUDs can generally be used by women who might be judged as at “increased risk” of STIs solely because of certain epidemiologic or socio-demographic characteristics (World Health Organization, 2004a). Some examples of these characteristics include age (young), marital status (unmarried), level of education (low), or area of residence (a “high-STI setting”).

If a woman has a very high individual likelihood of exposure to Chlamydia or gonorrhea (e.g., she or her partner has multiple partners), IUD use is not generally recommended, as the risks of use will generally outweigh the benefits (World Health Organization, 2004a).

Use of IUDs in the presence of Chlamydia or gonorrhea
IUDs should not be inserted in the presence of current purulent cervicitis, or chlamydial or gonorrheal infection (World Health Organization, 2004a).

If a woman already has an IUD in place presents with current purulent cervicitis or chlamydial or gonorrheal infection, she should be treated with appropriate antibiotics, but there is no need to remove the IUD (treatment of the STI is sufficient) (World Health Organization, 2004a).
Use of IUDs by HIV-infected women
IUDs can generally be used by HIV-infected women or by women at high risk of HIV. IUDs can also be used by women with AIDS who are clinically well on antiretroviral therapy, as well as by HIV-infected women who already have an IUD in place at the time AIDS manifests itself (Fisher et al., 1986).

Use of prophylactic antibiotics before insertion
Prophylactic antibiotics are generally not recommended before copper IUD insertion. However, in some unusual circumstances (such as settings with a high prevalence of STIs and limited STI screening), prophylactic antibiotics may help reduce the incidence of PID (Grimes et al., 1999); (World Health Organization, 2004b), though this still remains unproven. Risk of PID is low with IUD use, with or without prophylactic antibiotic use (Grimes et al., 1999).

Availability and access
The greater the availability of IUD services, the greater the IUD use in a given country or geographic area (Ross et al., 2002).

Modality of provision
IUD provision does not need to be limited to fixed facilities; mobile clinics can provide IUD services as well. In addition, community-based health workers can refer IUD clients to mobile or fixed facilities to increase access.

Timing of insertion
An IUD can be inserted in the first 12 days of the menstrual cycle, or at any other time, as long as a provider is reasonably sure that the client is not pregnant (White et al., 1980); (World Health Organization, 2004a). A pregnancy checklist based on criteria endorsed by WHO has been shown to be an effective tool for determining if a woman is not pregnant (Stanback et al., 1999). No additional contraceptive protection is needed after the IUD is inserted.

A woman does not need to wait until she is menstruating to have an IUD inserted (World Health Organization, 2004b); (White et al., 1980).

Postpartum insertion
Insertion of IUDs can be safely provided within the first 48 hours after delivery or otherwise at four to six weeks postpartum. Postpartum women often want reliable, long-term contraception soon after delivery (Thapa et al., 1992). For immediate postpartum insertion of the IUD, it is particularly important to provide good quality counseling to the client before labor and delivery to ensure that her decision is a voluntary and informed choice.

Postpartum IUD insertion requires different technique than interval IUD insertion. If performed by specifically trained providers, postpartum IUD insertion within 48 hours of delivery is safe and convenient, with no increased risk of infection, perforation, or bleeding. A relative disadvantage of postpartum insertion within the first 48 hours (compared to later postpartum or interval insertion) is a slightly higher risk of expulsion. Expulsion rates
following postpartum IUD insertion are lowest when the IUD is inserted within 10 minutes of delivery of the placenta, when the provider is skilled and experienced, and when the IUD is placed correctly, high in the fundus (Grimes et al., 2004); (World Health Organization, 2004a); (World Health Organization, 2004b).

Providing integrated mother and child services in a single visit six weeks after birth increases the use of contraceptive methods, particularly the IUD, and substantially reduces costs for both clients and providers (Coeytaux, 1989); (Medina et al., 2001). Women who are offered the IUD before being discharged from the hospital after the birth of a child are more likely to be using it both 40 days and six months later than are women who are not offered the IUD (Foreit et al., 1993).

Postabortion insertion
Postabortion clients often want immediate protection from future pregnancy. They need good quality counseling on their contraceptive options, and easily/readily available services (Núñez et al., 2005).

IUDs can be safely inserted immediately after spontaneous or induced abortion, except in women with pelvic infections or those who have had septic abortion (Chhabra et al., 1988); (Grimes et al., 2004); (Senlet et al., 2001); (World Health Organization, 2004a); (World Health Organization, 2004b).

Follow-up visits
Only a single routine follow-up visit after IUD insertion needs to be scheduled. This visit should take place after the first menses or three to six weeks following insertion. Additional routine follow-up visits are unnecessary and can be eliminated without a significant decrease in quality of care and with substantial cost savings (Bratt et al., 1998); (Hubacher et al., 1999); (Janowitz et al., 1994); (World Health Organization, 2004b). Rather, the client should be counseled to return at any time if she has any problems or concerns.

Medical barriers
Medical barriers (i.e., “policies or practices derived at least partly from a medical rationale that result in scientifically unjustifiable impediment to, or denial of, contraception”) are a significant problem impeding wider access to modern contraception, including IUDs (Shelton et al., 1992).

Many women who request an IUD are denied their choice based on eligibility criteria that are neither scientifically justified nor consistent with national guidelines. These medically unjustified criteria include marriage and spousal consent requirements, minimum or maximum age and parity restrictions, menstruation requirement, or norms that discourage uptake by requiring too many routine follow-up visits (Miller et al., 1998); (Shelton et al., 1992); (Stanback et al., 2001).

Provider perspectives
The perspectives of providers—their attitudes, motivations, needs, as well as their knowledge and skills—are an important variable in service delivery programs that should...
be considered (Shelton, 2001). For example, would a provider garner more “rewards” (e.g., greater prestige or income, or reduction of other duties) if s/he became more active in providing IUDs.

Inserting IUDs involves more work and has some other disincentives for providers. Thus, work needs to be organized accordingly to take account of these increased demands. Providers who demonstrate an interest in the IUD should be well supported.

In countries with low IUD prevalence, providers frequently do not mention the IUD in counseling sessions for family planning clients. When they do, they usually provide only minimum information about it. Lack of equipment, method stock-outs, lack of confidence in clinical skills, and lack of time are the main reasons given by providers for not offering the method (Brambila et al., 2003); (Katz et al., 2002). Even among health centers that do meet the conditions needed to provide IUD services (e.g., necessary equipment and appropriately trained staff), many do not do so (Brambila et al., 2003).

Provider myths and misconceptions
In many countries, potential providers of IUD services hold misconceptions about the IUD’s mechanism of action, side effects, and eligibility criteria (e.g., erroneously believing that it can cause cancer, greatly increases risk of PID, ectopic pregnancy, and infertility, or is inappropriate for HIV-infected women). Many also believe, incorrectly, that the IUD moves through the body or that it interferes with sexual relations because it can be felt by partners or can cause pain during intercourse (Gyapong et al., 2003); (Katz et al., 2002).

Cost considerations
The IUD, among the reversible methods, is the most cost-effective—in terms of both cost per unit time of protection and all program costs (including materials and staff time for initial and follow-up visits) (Chiou et al., 2003); (Hubacher et al., 1999); (Trussell, 1974).

Providing an IUD to a woman before she is discharged from a hospital after delivering a baby is less than half as expensive as providing the method at outpatient visits (Foreit et al., 1993).

VII. Supplies and Logistics
“Stockouts” of needed equipment and supplies are commonly reported in service programs. Thus attention to logistics and supplies is critical, because unavailability of either the IUD itself or of the other needed materials and equipment means IUD services are also unavailable. Needed materials and equipment include drape cover for woman, clean cloth for exam table, speculum, light source to view cervix, uterine sounds, tenacula, scissors, forceps, bowl/cup, disinfectant, antiseptic, a supply of gloves (sterile gloves not necessary), cotton, gauze, and sponges (Miller et al., 1998).

IUDs should be stored at room temperature (15-30°C) and protected from excessive moisture or direct sunlight.

Copper IUDs sometimes tarnish while in the sterile package; such tarnishing does not
affect IUD efficacy or safety and does not indicate that the package seal has been broken (Sivin I, 1992).

Shelf life should not be confused with insertion life. The shelf life of the copper T-380A is seven years from the manufacturing date, as long as the product has been stored properly and remains in the sterile package. IUDs that are not inserted within that time period should be discarded. As mentioned previously, once the IUD is inserted, it can remain in the uterus for at least 12 years

VIII. Key Guidance Documents

Medical Eligibility Criteria for Contraceptive Use (2004 edition) (MEC) is one of the WHO’s two evidence-based guidelines on contraceptive use, intended for policy-makers, program managers, and the scientific community to support national programs in preparing service delivery guidelines. The document reviews the medical eligibility criteria for use of contraception, offering guidance on the safety of use of 19 different methods for women and men with specific characteristics or known medical conditions. The recommendations are determined by expert consensus and are based on systematic reviews of available clinical and epidemiological research (World Health Organization, 2004a). For a summary of 2004 MEC, see the INFO Report, “WHO Updates Medical Eligibility Criteria for Contraceptives,” and FHI’s Quick Reference Chart.

Selected Practice Recommendations for Contraceptive Use (2004 edition), the companion guideline to Medical Eligibility Criteria for Contraceptive Use, provides guidance on the safe and effective use of a wide range of contraceptive methods. The recommendations, which answer 33 questions selected by the WHO, were determined by expert consensus and are based on systematic reviews of available clinical and epidemiological research. Eleven of the 33 questions address IUD use and related issues (World Health Organization, 2004b). For a summary of the 2004 recommendations, see the INFO Report, “World Health Organization Updates Guidance on How To Use Contraceptives.

Decision-Making Tool for Family Planning Clients and Providers (World Health Organization (WHO) et al., 2005).

Essentials of Contraceptive Technology (Hatcher et al., 2001) (currently being revised and updated).

A Pocket Guide for Managing Contraception (Hatcher et al., 2002).

IUDs: New Research, New Guidance (Populations Reports on IUDs).

The Copper Intrauterine Device as Long-Term Contraception from the U.K. Faculty of Family Planning and Reproductive Health Care Guidance (Penney et al., 2004).

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