VIEWPOINT

The Checkered History and Bright Future of Intrauterine Contraception in the United States

By David Hubacher

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No method of contraception stirs quite as much heated discussion and debate as the IUD. The reasons the IUD has this distinction are simple: People's opinions have been shaped by a body of seemingly discrepant (and sometimes mythical) evidence, and the issues this evidence addresses are fundamental. How does the IUD prevent pregnancy? What is the true relationship of IUD use to pelvic inflammatory disease (PID) and infertility, and how does exposure to sexually transmitted bacteria modify or confound that relationship?

Clinical research conducted over the past 30 years provides clues to help resolve these important issues, yet the debates over the IUD's safety[1] and mechanism of action[2] continue to rage, and misperceptions abound. Some people, for example, believe that because the IUD rests in the uterus, it must be aborting early pregnancies. Others reason that PID and infertility that appear any time during or after use of an IUD are sure to have been caused by the invasive procedure. Still others believe that the IUD (like other foreign objects) lowers the body's natural defenses and facilitates the development of PID and infertility among women exposed to sexually transmitted bacteria.

Even weak research that supports these arguments can appear to make the claims irrefutable. Research that generates results counter to these assumptions has to be flawless, unchallengeable and repeated to have any lasting impact. Thus, although the most recent research has shown these assumptions to be unwarranted, the controversy continues.

BACKGROUND

The IUD was once a popular form of birth control in the United States: In the 1970s, nearly 10% of women who practiced contraception relied on the device;[3] today, fewer than 1% do.[4] The sharp drop in IUD use resulted from a combination of interrelated factors and events. The five most important factors were the following:

- the published account of cases of septic maternal death among women who became pregnant while using the Dalkon Shield;[5]
- the discovery that the Dalkon Shield was associated with an increased risk of PID;[6]
- the scientific, legal, governmental and media actions that unfolded to bring the Dalkon Shield manufacturer to declare bankruptcy and recall all devices;
- the business decisions that led other manufacturers to voluntarily withdraw their IUDs from the U.S. market; and
- the published research that linked IUD use and infertility.[7]

The events that transpired in the United States and their impact were uniquely American. In many European countries, IUD use is still an integral component of family planning; a comparative study of five countries (Italy, Spain, Poland, Germany and Denmark) estimated that the IUD accounts for 9–24% of all contraceptive use.[8] The rate of less than 1% in the United States is the lowest in any developed nation.

A DATA-FUELED CONTROVERSY

The data that fueled the controversy leading to the near-demise of the IUD were generated under unique circumstances in the 1970s and 1980s. U.S. Senate hearings in 1970 on the safety of oral contraceptives led many women to abandon that form of birth control and adopt the heavily marketed Dalkon Shield (introduced in 1971) and other devices.[9] Because these events occurred in the midst of the sexual revolution, many of the women who switched methods were probably not optimal candidates for the IUD because they were at risk of acquiring a sexually transmitted infection; this important warning was not sufficiently emphasized in contemporary publications on contraception.[10] The Dalkon Shield, a device with design flaws that exacerbated the dangers, should never have been marketed. The net impact was this: Women at risk who may have been significantly protected from PID by using the pill[11] were now using devices that provided no protection (or, in the case of the Dalkon Shield, increased the risk). A cohort effect was created when the number of women who experienced PID (and later infertility) and had used an IUD reached critical mass; this group continued to draw the attention of researchers for many years.

Methodological issues compounded the trouble for the IUD. Early research examining PID used inappropriate comparison groups, overdiagnosed PID in IUD users and did not control for the confounding effects of sexual behavior.[12] These and other problems plagued the two most important research efforts of the 1970s and 1980s: the United States–based Women's Health Study[13] and the Oxford Family Planning Association contraceptive study.[14] Finally, the landmark studies on IUDs and infertility[15] may have been affected by referral bias: Women who had used an IUD may have been more likely than women who had never done so to seek medical attention when a fertility problem appeared.[16] If referral bias occurred, the imbalance created by the overrepresentation of IUD users among infertile women would have skewed the data and exaggerated the risks associated with the device.

Many gynecologists and the general public formed strong negative opinions about IUDs as the events of the 1970s and 1980s unfolded, and rightfully so. The messages coming out of the medical journals and courtrooms were powerful; unfortunately, it took irreparable harm to some women to avert more widespread tragedy. Reflection, new devices, and better knowledge and judgment about which women can safely use the method have led many gynecologists to voice renewed support for intrauterine contraception.[17] On what do these individuals base their opinions, and what new evidence is available to support their beliefs? Fourteen key research articles (Figure 1) published in the last 15 years dispel many of the common myths about IUDs and support the belief that with today's devices and proper patient screening, the IUD-related risks of PID and infertility are close to, if not at, nil.[18]

FIGURE 1. The main messages of key articles that dispel common myths about IUDs, 1987–2001

Citation	Main message
World Health Organization, 1987	The IUD is an important method of fertility regulation with high continuation rates and important advantages in convenience of use.
Wilcox et al., 1987	The IUD effectively interrupts the reproductive process before implantation.
Alvarez et al.,1988	The IUD prevents most fertilizations from occurring, but if it fails to do so, the IUD prevents fertilized ova from entering the uterus.
Wilson, 1989	Fertility is not impaired among women who have IUDs removed because of complications.
Sivin et al., 1991	Copper IUDs are as safe as levonorgestrel IUDs.
Farley, 1992	PID is an infrequent event after the first 20 days following IUD insertion.
Andersson, Odlind and Rybo, 1994	A five-year study showed that the LNG-IUS is a safe and effective contraceptive.
UNDP et al., 1997	A 12-year follow-up study confirmed the safety and efficacy of copper IUDs.
Sinei et al., 1998	IUDs are a safe form of contraception for HIV-positive women.
Walsh et al., 1998	Careful screening practices can eliminate insertion-related PID.
Hubacher et al., 2001	Copper IUDs do not increase the risk of tubal infertility, whereas exposure to *Chlamydia trachomatis* does.
Kadanali et al., 2001	The IUD interferes with sperm transport in the female reproductive tract.
Meirik, Farley and Sivin, 2001	Copper IUDs are safe and effective in relation to other methods.
Shelton, 2001	Even in settings with a high prevalence of sexually transmitted diseases, the theoretical risk of PID attributable to an IUD insertion is very low.

Source: reference 18.

WHY WE NEED THE IUD

The public health need for more widespread use of the IUD is revealed in one simple statistic—53% of unintended pregnancies in the United States are a result of contraceptive failure or misuse.[19] Because the IUD is almost impossible to misuse and is far less likely to fail than the pill, the condom or the injectable, a national increase in IUD use that comes at the expense of such methods would reduce the number of unintended pregnancies. If some women choose the IUD instead of relying on natural birth control methods or chance, the number of unintended pregnancies should also decline. An industry-sponsored survey of 7,000 U.S. women conducted in 1999 revealed that many current IUD users had switched from the condom (30%), the pill (22%) or withdrawal (12%).[20] Still, the IUD is not for everyone; women who use condoms to avoid sexually transmitted infections may be better off continuing with their method, because the IUD offers no protection.

EXPLAINING LOW IUD PREVALENCE

If the IUD is indeed a safe form of contraception for many women and if a public health need exists for such a method, what is preventing it from contributing more than 1% of total contraceptive use? Could it be that U.S. women simply do not want to use IUDs and are exercising an informed choice? Certainly that could be the main reason, but other factors may come into play, given the method's history and the role of various gatekeepers in controlling access to this method. Other possible explanations include the following:

- U.S. gynecologists and their patients are not getting accurate information about today's IUDs.
- U.S. gynecologists are uncomfortable with the thought of providing IUDs, either because of lack of adequate insertion training and confidence or because of fear of litigation.
- Manufacturers sell IUDs as a courtesy to women but are reluctant to spend advertising dollars promoting devices that compete with their more lucrative birth control products.
- Product labeling and consent procedures discourage many potential users from trying the method.
- The high initial cost is daunting for women who lack health insurance that covers it, and the possibility of an early removal makes the IUD a risky investment.

Evidence suggests that some of these reasons contribute to the low prevalence of IUD use. A 1991 survey of reproductive-age U.S. women revealed that only 16% had a favorable opinion of the IUD, 32% had little or no knowledge about it and only 21% felt that the term "safe" closely described the IUD.[21]

In the late 1980s, a survey of obstetrician-gynecologists and family physicians in San Diego County found that 40% were not recommending the copper IUD to anyone, citing concern about medical liability as their primary reason.[22] A recently completed survey of members of the American College of Obstetricians and Gynecologists found that although 95% of respondents thought copper IUDs were safe, 20% had not inserted an IUD in the last year; of those who had, 79% had inserted 10 or fewer. Twenty percent of the respondents thought the IUD was an abortifacient, and 16% believed that providing it would expose them to lawsuits.

Finally, respondents who feared litigation and believed that IUDs cause PID performed fewer insertions.[23] The response rate for this survey was only 50%; if respondents had a more favorable attitude toward IUDs than nonrespondents, the results would paint an overly optimistic picture.

A U.S. study on the economic value of contraceptive use[24] suggests that pharmaceutical company profits may be hurt if users of oral contraceptives switch to an IUD. The private-sector unit cost of a copper IUD was estimated at $184, while the total product costs for comparable protection (10 years) from oral contraceptives was estimated to be $2,520 ($21 per cycle). The same study also estimated the initial visit costs of the IUD and the pill to be $207 and $38, respectively; this difference can explain at least part of the reluctance to use IUDs among women without full health insurance coverage.

The proper way to provide IUDs is to explain all the known risks in enough detail that the patient can make a truly informed decision about whether to have a device inserted. In addition, it is wise for legal purposes to have a patient sign the manufacturer-issued document stating that she understands the written and oral material, and that the decision to choose an IUD was her own.[25] The patient package insert for one device lists death as a possible adverse reaction.[26] Although it also states that the risk of death for oral contraceptive users who smoke is 2–80 times as high as the risk for IUD users, the net effect of this informed consent process may be to discourage many women from adopting the IUD.

IUD CHOICES

U.S. women have two choices for intrauterine contraception: the TCu380A (marketed as ParaGard by Ortho-McNeil Pharmaceuticals) and the levonorgestrel intrauterine system, LNG-IUS (marketed as Mirena by Berlex Laboratories). Though the two devices have similar rates of effectiveness, have similar shapes and dimensions, and are inserted into the same organ, they are vastly different forms of contraception because of what they do inside the uterus; the TCu380A sheds copper ions, while the LNG-IUS releases 20 mcg of levonorgestrel per 24 hours. This fundamental difference allows each woman to choose which side effects of intrauterine contraception are more acceptable to her. Women in whom the TCu380A produces noticeable side effects tend to experience increased menstrual blood loss and a higher frequency or intensity of cramps. In contrast, the LNG-IUS often causes intermenstrual spotting during the early months of use; later, it can cause dramatic reductions in total menstrual blood loss (resulting in amenorrhea in 20% of women).

ADVANTAGES OF THE IUD

Any strategy aimed at renewing interest in the IUD must begin by stating the advantages of intrauterine contraception over other reversible methods. The key advantages are that the IUD is very effective, lasts for five or 10 years (LNG-IUS and TCu380A, respectively), is inexpensive when the cost over its life span is compared with the cost of alternatives over the same number of years, requires practically no user maintenance and is completely reversible. In addition, the copper IUD has no hormonal effects, and the levonorgestrel-releasing IUD reduces menstrual blood loss.

For more than a decade, the IUD has been viewed as a method of last resort suitable to a very specific population of women—usually those with medical contraindications to other forms of birth control. This attitude toward the IUD does more harm than good, and the harm extends beyond the issue of unintended pregnancies. More widespread use of the IUD could have trickle-down effects that would increase the range of women's contraceptive choices and help achieve health goals such as the following:

- easing the burden of contraceptive use for women who are tired of ongoing regimens (e.g., daily pill, scheduled injections, precoital preparations);
- providing a long-term option for women who have completed their families yet do not want to be sterilized;
- offering a long-term option for women whose spouses do not want to get a vasectomy;
- providing a long-term option that prevents premature sterilization decisions and possible regret.

CATALYSTS FOR INCREASING IUD USE

The first decade of this century will be a pivotal time for intrauterine contraception in the United States. Gynecologists who remember inserting Dalkon Shields will be retiring and will be replaced by new physicians who did not live through the controversy of the past. Moreover, we now have a new generation of reproductive-age women who have little direct knowledge of that controversy. A fresh start could increase the prevalence of IUD use, and several factors could act as catalysts.

LNG-IUS

The introduction of the LNG-IUS in the U.S. market in January 2001 may turn out to be the most important event in an IUD revival. Thousands of health care providers have been trained over the past year in proper screening, insertion and follow-up care. As this new method is added to practices nationwide, many women will be getting information about intrauterine contraception for the first time in their lives.

The LNG-IUS is an ideal delivery system for many conditions that respond to progestin; European gynecologists are testing its therapeutic potential for treating heavy menstrual blood loss and for hormone replacement.[27] The advantage of this form of delivery is that the progestin is absorbed directly into the endometrial tissue, whereas other forms are systemic and cause undesirable side effects. Although the LNG-IUS was approved by the Food and Drug Administration as a contraceptive only, many U.S. gynecologists are likely to suggest off-label use to provide other health benefits. Ironically, this may prove to be a way for gynecologists and patients to become comfortable with the device and consider adopting it for its originally approved use.

Women Physicians and Other Users

Women physicians in the United States use IUDs at rates between two and five times the rates among age- and income-matched women in the general population.[28] If this medical endorsement were better known, many more women might try IUDs. Satisfied IUD users who talk to friends and family can also help improve the image of the IUD and ultimately increase prevalence. A 1999 survey revealed that the proportion of current IUD users who were satisfied with their method (96%) was equal to that among pill users.[29]

Importing Demand for IUDs

Rising immigrant populations from some Asian and Latin American countries may help increase demand for the IUD. Mexico provides the highest number of immigrants to the United States, and IUDs are the method of 21% of female contraceptive users in that country.[30] Requests from foreign-born residents for IUD services may prompt U.S. gynecologists and family practitioners to begin providing the method.

Marketing the IUD's Advantages

U.S. women who want oral contraceptives can choose from 68 formulations represented by 46 product names.[31] The differences among the products are slight, yet companies spend millions of dollars each year marketing them to consumers. If even a fraction of the marketing dollars spent on oral contraceptives were spent to inform consumers about the advantages of IUDs, more women might choose the method. The arrival of the LNG-IUS might create market competition and increase advertising.

Alternative to Sterilization

The IUD has often been described as "reversible sterilization" because it offers a level of contraceptive protection similar to that provided by sterilization without exposing women to the risk of regret. In one study, the cumulative probability of expressing regret during a follow-up interview within 14 years after tubal sterilization was 20% for women aged 30 or younger at sterilization and 6% for women older than 30 at sterilization.[32]

Insurance Coverage

This issue continues to hinder access to all contraceptives nationwide. A recent study in Washington State revealed that fewer than half of health insurance carriers covered contraception of any kind.[33] From a managed care perspective, the IUD should be one of the first methods on the formularies for full coverage, because it proves to be the most cost-effective of all reversible methods.[34]

New Research

Clinical research may never fully resolve the debate of whether IUDs increase the risk of PID and infertility. The perfect study cannot be conducted because of ethical issues. However, an innovative pilot study involving randomization of contraceptive method (and hence avoiding the bias that accompanies choice) will soon be under way in Brazil, Guatemala and Vietnam.[35] If the pilot study is successful and a larger study is launched in the future, the incidence of PID will be the primary outcome.

Researchers in Europe have developed a new, frameless copper device that moves with the contortions of the uterus; theoretically, women who use this device will experience less menstrual bleeding and pain and will have a lower risk of expulsion than those using a standard T-shaped device. The device shows some promise in clinical studies,[36] although a recent review article concludes that it has no important benefits over the TCu380A.[37]

Research conducted under a National Institutes of Health grant is seeking to determine whether prophylactic use of ibuprofen during menses can improve comfort for women using the copper IUD and reduce the incidence of early removals caused by bleeding and pain. The double-blinded, randomized, controlled trial is being conducted in Chile.[38]

Years ago, researchers demonstrated that bacteria are introduced into the uterus at the time of IUD insertion.[39] Since then, we have come to understand that the amount, properties and type of bacteria (sexually transmitted or naturally occurring) and host defenses combine to determine whether sequelae such as PID and tubal infertility will occur in the absence of treatment. In the late 1990s, researchers in the United Kingdom obtained promising results when they conducted tests on guinea pigs to determine if strings laced with chlorhexidine (a common topical bactericidal agent) would reduce the extent of bacterial contamination of the uterus.[40] If this novel approach is successful in preventing infection in humans, it might remove the last remaining risk associated with IUD insertion.

CONCLUSIONS

Ten years ago, this journal published a viewpoint on IUDs that contained modified versions of two questions: How much, if at all, does the IUD increase the risk of PID and subsequent infertility? And if there is an increased risk, is it acceptable?[41] A good measurement on the first question is required to answer the second. What has become abundantly clear over the past decade is that the risk estimates from earlier research on these topics no longer apply and that new research has put the risks closer to, if not at, zero. For the nuts and bolts of service delivery, no simple answers exist, because the decision-making issues are moving targets: The risk of exposure to sexually transmitted pathogens, the risk of pregnancy, and the social, economic and health consequences of an unintended pregnancy vary tremendously in a patient population. Any risk of PID and infertility must be weighed in relation to these factors when a patient expresses interest in an IUD. For most women, the benefit of excellent pregnancy protection and ease of use will outweigh the very low risk of serious adverse effects.

If renewed interest in the IUD leads to inadvertent provision of the method to women at high risk of exposure to bacterial pathogens, the IUD stands to be falsely accused

of causing adverse health effects and may well be drawn into a controversy echoing that of a generation ago. Although research methods have improved, providing convincing evidence (particularly in a courtroom setting) that infertility may have developed before insertion or that bacterial exposure and sequelae may have occurred subsequent to insertion is still difficult. However, if the IUD is used only by women who are not at risk of a sexually transmitted infection, its reputation can flourish and the method can provide many couples with years of effective contraception.

All the factors outlined here—new research documenting safety, a clear public health need, many advantages over other reversible contraceptive methods, newly discovered noncontraceptive health benefits, a choice of two excellent devices, and favorable assessments (by contraceptive experts, women physicians, satisfied current users and women in other countries)—predict a bright future for intrauterine contraception in the United States. Together, these positive forces may well overcome barriers to IUD provision, rid the device of its tainted image and lead to expanded reproductive health choices.

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