Barriers to Prescribing the Copper T 380A Intrauterine Device by Physicians

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From a questionnaire sent to all obstetricians and gynecologists and all family and general practitioners in San Diego County, California, regarding the Copper T 380A intrauterine device, substantial barriers to prescribing it were identified. Of all physicians responding, 40% reported that they were not recommending the Copper T 380A to anyone, the single most common reason given being concern about medical liability. A lack of knowledge about the new device, a lack of intrauterine device insertion skills, and certain medical practice settings were also important barriers to prescribing it. The new intrauterine device is considered in the context of innovation-diffusion theory. Substantial amounts of education and training and improvement in the medical-legal climate are needed before current barriers to prescribing the new device are removed.

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The World Health Organization has stated that the new-generation copper-containing intrauterine devices (IUDs) are comparable in safety and efficacy to oral contraceptives.[1] Unfortunately, negative publicity associated with medical-legal issues caused major United States manufacturers to discontinue the domestic sale of IUDs in 1986, leaving only the intrauterine progesterone contraceptive device, Progestasert, on the US market. This discontinuation of sales of copper-containing IUDs has caused a decline in the number of women using IUDs from 2.7 million in 1973 to an estimated 1.4 million in 1985.[2]

In late spring of 1988 a new IUD, the Copper T 380A, became available in the United States under the trade name of ParaGard (GynoPharma, Somerville, NJ). This T-shaped IUD has the improved clinical characteristics of a failure rate of less than 1 pregnancy per 100 women-years-of-use[3,4] and a longer use interval of four years.[5] There has been concern, however, that nonmedical barriers to the prescribing of this new device by physicians may exist.

To identify possible barriers to prescribing the Copper T 380A, in the fall of 1988 we surveyed a sampling of physicians to examine their knowledge, attitudes, and practices regarding this new IUD.

Methods

We obtained a mailing list from the county medical society of all obstetricians and gynecologists and all family practitioners and general practitioners with an office address in San Diego County, California. The list contained 245 obstetricians and gynecologists and 651 family and general practitioners, for a total sample size of 896 physicians. They were given three opportunities to respond to a pretested mail questionnaire. Of the 896 physicians, 25 were excluded from the sample because we learned that they were retired, living out of the county, or deceased, leaving 871 possible respondents. Of these, we had a total of 473 responses for a 54% overall response rate.

Of our respondents, 78 or 16% said they did not provide family-planning services and, therefore, were excluded from further analysis. Thus, the final sample was 395, including 133 obstetricians and gynecologists and 262 family and general practitioners. Of these, 80% were in private practice, 13% were in health maintenance organizations (HMOs), 4% were in nonprofit health systems, and 3% were in governmental health systems.

To check for response bias, we made a telephone survey of a 10% sample of our nonrespondents. Of the 42 persons called, 4 had formally retired and 9 no longer had a business phone listing. Using a two-sample test for binomial proportions to compare our respondents and nonrespondents, we found no significant differences ($P > .05$) between the two groups in age, sex, practice setting, specialty, in providing family-planning services, or in the proportion who recommended the new IUD.

We asked physicians for their "current approach to the Copper T 380A IUD," giving four options to choose from:

- Recommend to no one.
- Recommend to selected patients but refer them to other physicians for insertion.
- Recommend to selected patients and plan to insert once the Copper T 380A is received.
- Recommend to selected patients and am currently inserting.

We used the χ^2 test to examine the association between the dependent variable, "current approach to the use of the IUD" and various hypothesized independent variables. To compare the probabilities of various groups *not* recommending the new IUD, odds ratios were calculated (Tables 1, 2, and 3). Confidence intervals (CIs) of 95% were constructed using the Taylor's series method.

Finally, we examined the reasons given by the 152 physicians who did not recommend the IUD to any of their patients.

Results

Only 17% of the respondents were currently inserting IUDs; 23% referred patients elsewhere for insertion, 21% planned to insert the device once they received it, but a full 40% did not recommend the IUD to anyone.

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ABBREVIATIONS USED IN TEXT

CI = confidence interval
HMO = health maintenance organization
IUD = intrauterine device

Family and general practitioners were much more reluctant to recommend or insert the new IUD than were obstetricians and gynecologists (Figure 1). Of the family and general practitioners, 47% did not recommend the new IUD as compared with 26% of the obstetricians and gynecologists. Thus, family and general practitioners were 2.6 times more likely not to recommend the new IUD than were their colleagues in obstetrics and gynecology (95% CI, 1.6 to 4.2). Even among those recommending the new IUD, most referred patients elsewhere for insertion. In fact, only 22% of family and general practitioners were inserting or planning to insert the new IUD compared with 65% of obstetricians and gynecologists.

Obstetrician-gynecologists and family and general practitioners employed by HMOs were particularly reluctant to get involved in prescribing and inserting the new IUD; 49% did not recommend it to anyone; they were 3.4 times more likely to not recommend the IUD than were their colleagues working for nonprofit or governmental institutions (Table 2). Furthermore, none of the HMO physicians were currently inserting the new IUD. Physicians working for nonprofit or governmental facilities were more receptive to the IUD, with 58% either already inserting it or planning to insert it. The number of physicians in private practice prescribing and inserting the new IUD was midway between these two groups.

Most physicians were not correctly informed about the improved clinical characteristics of the new IUD. We asked two questions to assess physicians' knowledge of the new IUD. When asked the pregnancy failure rate in women 25 years of age or older, only 27% of the physicians answered correctly. The percentage of correct responses did not differ significantly between the obstetrician-gynecologist and family-general practitioner groups. Next we asked how often the Copper T 380A should be replaced. Answers to this question differed between the two specialty groups: 55% of obstetricians and gynecologists responded correctly, as opposed to only 11% of family and general practitioners.

A low IUD knowledge score was strongly associated with a negative attitude toward the new IUD and a reluctance to recommend it (Table 2). Those who answered both questions incorrectly were 14.8 times more likely not to recommend the new IUD than were those who answered at least one correctly. Of the 35 physicians who knew the correct answers to both questions, only 1 (3%) said that he did not recommend the IUD, and 60% reported that they were already inserting it.

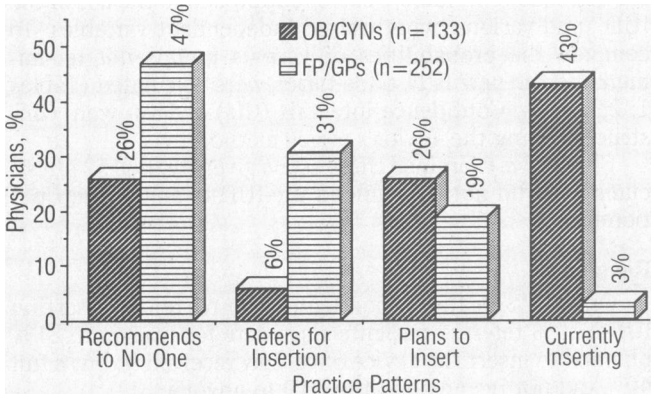

Figure 1.—The graph shows practice patterns of obstetrician-gynecologists (OB/GYNs) and family and general practitioners (FP/GPs) in prescribing the Copper T 380A. (The percentages for OB/GYNs add up to more than 100% due to rounding of numbers.)

Of the family and general practitioners, only 35%—as compared with 5% of the obstetricians and gynecologists—said that they had inserted 14 or fewer IUDs of all types. (The World Health Organization suggests that trainees need to do at least 10 to 15 IUD insertions under supervision before they have the skill and self-confidence to do it alone.[1]) None of these physicians with minimal experience in placing IUDs were currently inserting the Copper T 380A. Moreover, most of these physicians were not recommending the new IUD to any patients (Table 3).

Reasons Some Physicians Never Recommend the Copper T 380A

Of the 152 physicians who did not recommend the new IUD to anyone, only 136 indicated why. The most frequent reason was concern about medical liability (54 respondents, or 40%). Medical safety was the second most common concern of 41 (30%). A concern that the IUD may act as an abortifacient was the primary reason for 13 (10%).

TABLE 1.—*Rates and Odds Ratios of Physicians* Not *Recommending the Copper T 380A Intrauterine Device (IUD) by Medical Practice Setting (N=365)*

Practice Setting	*Rate**	*Odds Ratio†*	*95% CI*
Nonprofit or governmental	22	1.0	Referent
Private practice	39	2.2	0.8 to 6.3
Health maintenance organization	49	3.4	1.04 to 11.3

CI = confidence interval

*Per 100 physicians.
†Based on an index rate of 22 per 100 physicians working in nonprofit or governmental health facilities *not* recommending the new IUD to anyone.

TABLE 2.—*Rates and Odds Ratios of Physicians* Not *Recommending the Copper T 380A by Physician Knowledge About the New Intrauterine Device (IUD) (N=307)*

*Physician's Knowledge**	*Rate†*	*Odds Ratio‡*	*95% CI*
2 of 2	3	1.0	Referent
1 of 2	30	14.6	2.1 to 79.7
0 of 2	42	24.8	3.5 to 111.5

CI = confidence interval

*Number of correct reponses to 2 questions (efficacy and duration of use) about the Copper T 380A.
†Per 100 physicians.
‡Based on an index rate of 3 per 100 physicians with a perfect knowledge score *not* recommending the new IUD.

TABLE 3.—*Rates and Odds Ratios of Physicians* Not *Recommending the Copper T 380A Intrauterine Device (IUD) by Past Experience With Insertion of IUDs (N=383)*

Number of Insertions	*Rate**	*Odds Ratio†*	*95% CI*
>25	31	1.0	Referent
15-25	51	2.4	1.1 to 5.0
1-14	46	1.9	0.99 to 2.7
None	69	5.0	2.3 to 10.7

CI = confidence interval

*Per 100 physicians.
†Based on an index rate of 31 per 100 physicians who have inserted more than 25 IUDs of any type *not* recommending the new IUD to anyone.

Only 4 physicians (3%) answered that their major concern was that the new IUD was too expensive. Most of the remaining reasons related to a lack of information about the IUD.

Discussion

The most striking finding of this study is that 40% of the respondents did not recommend the Copper T 380A to anyone. Of further importance is that 23% more responded that they recommended the new IUD but referred their patients to someone else to insert it. This referral may well represent a barrier to women using the IUD because it means additional costs, inconvenience, and delays in getting birth control.

The introduction of the Copper T 380A can be viewed as a contraceptive innovation in that it is perceived by at least part of the medical community as new. Kotler points out that innovations are assimilated into a social system over time through a diffusion and adoption process.[6] Diffusion is the long-term process of the spread of a new idea from its source of invention all the way to its ultimate users or adopters. The adoption process is more circumscribed and focuses on the mental processes that persons pass through from the time they hear of an innovation until they become regular users.

Space does not allow for a full description of innovation-diffusion theory, but it may be helpful to summarize its basic tenets:

- People differ greatly in their willingness to try new products.
- Each person goes through a series of stages in the adoption process, including an initial awareness of the existence of the innovation, an interest in it and attempts to seek additional information, evaluation, individual trial on a small scale, and adoption.
- Opinion leaders play a large role in the adoption of new products.
- The nature of the innovation itself affects the rate of adoption.[6]

When the Copper T 380A IUD is considered in the context of innovation-diffusion theory, the results of our study take on a new perspective. This study suggests that we are in the midst of a technologic diffusion process as a new copper IUD is released into the medical system after a relative IUD hiatus of more than two years. This cross-sectional survey is like a snapshot of physician practices during the fall of 1988, about six months after distribution of the Copper T 380A began. At the time of the snapshot, 38% of the physicians who would be most likely to adopt this new contraceptive innovation—obstetrician-gynecologists and family and general practitioners—had progressed to the point that they planned to insert it, but only 17% currently had the Copper T 380A in stock in their offices.

Family and general practitioners and obstetrician-gynecologists differ in their approach to the Copper T 380A. Physicians in family and general practice were less knowledgeable about the improved features of the Copper T 380A. They had considerably less experience inserting IUDs, were less inclined to recommend the Copper T 380A, and were much less likely to be inserting it.

Physicians practicing in HMOs seem to be the least willing to recommend the Copper T 380A, and public-governmental sector physicians appear to be the most receptive to recommending it. Unsolicited written comments on the questionnaire from several HMO physicians showed concern within their organizations about the manufacturer's ability to withstand a possible barrage of legal suits and concern that HMOs might then become a "deep-pocket" target for liability suits.

Most physicians lacked current knowledge about the Copper T 380A. Nearly half (47%) answered that the pregnancy failure rate of the Copper T 380A was 3 to 5 pregnancies per 100 women-years-of-use, and more than a third (38%) answered that 3 was the maximum number of years the Copper T 380A is approved for use. These answers are correct for the second-generation copper IUDs such as the Copper 7 (G.D. Searle Co, Skokie, Ill). This lack of knowledge suggests that many physicians have not assimilated the new (and more favorable) information about the third-generation Copper T 380A. Because poor knowledge scores were associated with a reluctance to recommend the IUD, continuing medical education on this subject is a worthy objective.

The data suggest that a substantial minority of physicians lack experience in inserting IUDs and that these physicians are also particularly reluctant to recommend the new IUD even when they could refer patients to someone else for insertion. It would seem advisable to develop training programs for these physicians.

Physicians' Concern About Liability as a Barrier

Of special concern is the fact that 54 of the 136 physicians (40%) who did not recommend the Copper T 380A to anyone said the main reason was concern about medical liability. Thus, health decisions are being made on the basis of the fear of being sued and not on the basis of the medical benefits and risks.

Before about 1985, the increased incidence in pelvic inflammatory disease seen in IUD users was ascribed to the device itself. This may be true for the Dalkon Shield. Recent epidemiologic evidence suggests, however, that the increased incidence in pelvic inflammatory disease associated with copper-bearing IUDs is more appropriately ascribed to the previous practice of inserting IUDs without screening for behavioral risk factors for sexually transmitted diseases.[7-11] These same recent studies support the evidence that the copper-bearing IUDs pose a low risk of pelvic inflammatory disease or infertility to women whose sexual life-style—stable, mutually monogamous sexual relationships—puts them at low risk for sexually transmitted diseases. Responses to our survey imply that physicians do understand that the Copper T 380A represents a very small medical risk to selected patients, but they refuse to recommend it.

From a legal perspective, all prescription products are considered "unavoidably unsafe," which means that they cannot be made totally safe for all users.[12] Thus, the law directs that such products are reasonably safe if accompanied by appropriate warnings from physicians. In the case of IUDs and oral contraceptives, federal law goes further, requiring manufacturers to inform patients directly about the risks and benefits of their products. For the Copper T 380A, GynoPharma has produced an information brochure that functions as a detailed informed consent booklet.[13]

Limitations of Our Study

Although the questionnaire was pretested on medical practitioners, the internal validity of the survey instrument has not been repeatedly checked. For example, we learned that there is a certain ambiguity in the word "recommend." Several physicians commented that they never "recommend" any IUD, but that if other methods are contraindicated or unacceptable, they will prescribe an IUD as a second-choice method. Also, the study surveyed physicians

in only one locale, which makes generalizations regarding physicians throughout the United States questionable. Finally, nonphysicians such as nurse practitioners and midwives recommend birth control methods. Studies of their knowledge and practices regarding the Copper T 380A IUD would be important.

Summary

Our study suggests that there are important attitudinal, informational, and experiential barriers to the prescribing of the Copper T 380A IUD. An improvement in the medical-legal climate and substantial education and training are needed before current barriers will be removed. If this can be done, then women will be able to make contraceptive choices based on appropriate medical criteria, not extraneous barriers from medical providers.

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