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SPECIAL REPORT

Mifepristone for Early Medical Abortion: Experiences in France, Great Britain and Sweden

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In September 2000, the Food and Drug Administration (FDA) approved mifepristone (also known by the trade name Mifeprex or its original French name, RU-486) for use along with a prostaglandin for ending pregnancies up to 49 days from the onset of a woman's last menstrual period. The FDA-approved protocol involves the administration of 600 mg of mifepristone followed two days later by 400 mg of oral misoprostol administered at a medical facility. Many abortion providers soon adopted the method, at least on a trial basis, but it is not universally available. As of early 2002, two-thirds of providers belonging to the National Abortion Federation (NAF) were offering the method to eligible patients.[1] NAF members perform about half of all abortions in the United States; they include the majority of Planned Parenthood Federation of America facilities that provide abortions. The brief U.S. experience with mifepristone leaves many questions unanswered about its ultimate level of acceptance: How many abortion providers and physicians who have not previously offered abortion services will provide medical abortions using mifepristone? What proportion of abortion patients will choose medical abortion? How will the availability of mifepristone affect the overall abortion rate?

Other questions concern the appropriate protocols that most providers in the United States will ultimately use for early medical abortion involving mifepristone. Experience in other countries indicates that protocols can vary in mifepristone dosage, the gestational limits that determine whether women are eligible for the method and whether the prostaglandin used to stimulate uterine contractions is administered at a medical facility or at a woman's home.

The experience of European countries can shed light on these issues. Mifepristone is approved for use in most of Europe,[*] and three countries have had a decade or more of experience with its use: France, Great Britain[†] and Sweden. In this report, we synthesize information from national abortion statistics, professional guidelines and interviews with experts in these three countries to describe levels of mifepristone use for early medical abortion,[‡] practice protocols and factors that have affected mifepristone's acceptance. We also discuss the implications of these experiences for

acceptance and use of mifepristone for early medical abortion in the United States.

PROTOCOLS FOR EARLY MEDICAL ABORTION

Though reference to mifepristone as the "abortion pill" makes early medical abortion sound like a simple procedure, it actually involves the administration of two drugs on separate days, a span of several days before the abortion occurs and up to 2-3 weeks of bleeding and spotting. Both in the United States and in Europe, protocols can vary according to whether providers use registered regimens (those formally approved by a country's regulatory authority) or alternate regimens, developed to improve effectiveness and efficiency, and to minimize side effects.

REGISTERED REGIMENS

Registered regimens largely reflect the state of research at the time the drug was approved for use—1988 in France (although the regimen was changed in 1992), 1991 in Great Britain and 1992 in Sweden. France, Great Britain and Sweden have similar registered regimens for early medical abortion. Their protocols involve administration of 600 mg of mifepristone (three 200 mg pills) to a woman at a licensed medical facility. Mifepristone, an antiprogestin, prevents the lining of the uterus from holding onto the fertilized egg, which leads to embryonic demise. Two days later, the woman returns to the facility, where she takes a prosta-glandin, which stimulates uterine contractions that expel the products of conception. The approved regimens in Great Britain and Sweden provide that the prostaglandin gemeprost be administered vaginally. In France, the prosta-glandin—either misoprostol or gemeprost—may be administered orally or vaginally. Women in these countries also must remain at the facility until they expel the products of conception or, if they are not expelled, for a minimum of three hours after the prostaglandin is administered.[2] The protocols call for a follow-up visit 1-2 weeks later to confirm that the pregnancy has been terminated and that the woman has had no complications.

One important variation in the registered protocols is the eligibility period. Mifepristone is approved for early abortion up to 49 days from the onset of the last menstrual period in France and up to 63 days in Great Britain and Sweden. However, because medical abortions at 50-63 days from the onset of the last menstrual period can be less effective and more painful than those performed earlier, physicians in Great Britain[3] and Sweden[4] recommend mifepristone predominantly for abortions earlier than 49 and 56 days, respectively. Some providers in these two countries discourage or do not provide medical abortion at 50-63 days' gestation.

ALTERNATE REGIMENS

All three countries permit the development of alternatives to registered protocols for approved medications. While registered mifepristone regimens are highly effective and safe, medical researchers and associations have developed alternatives that reduce time, cost and medication levels while maintaining efficacy rates and satisfaction among women.

Researchers have found that a 200 mg dose of mifeprisstone is as effective as a 600 mg dose for early abortions.[5]The 200 mg dose is also less expensive than the larger dose, and its use avoids giving women more medication than is necessary. In Great Britain,

the Royal College of Obstetricians and Gynaecologists (RCOG) recommends the lower dose for early abortions,[6] and most providers follow this practice.[7] A minority of providers in Sweden also use the smaller dose.[8]

Another alternative is to use the prostaglandin misoprostol instead of gemeprost because the former produces fewer side effects and is less expensive.[9] Providers in Great Britain and Sweden often use misoprostol for medical abortions before 49 days' gestation, but use gemeprost at 50-63 days because it is thought to be more effective for later terminations.[10]

Though France has been using mifepristone longer than the other countries, French providers are the least likely to deviate from the registered regimen. Some physicians are experimenting with lower doses of mifepristone, but this practice is not widespread. This is partly because providers are satisfied with the current regimen. Additionally, the French government closely monitors mifepristone supplies, and each 600 mg dose can be used in only one abortion procedure. According to Danielle Hassoun, head of the contraception and abortion center at Delafontaine Hospital, in Saint Denis, France, this means that if a provider uses 200 mg of mifepristone, the remaining two pills must be discarded or, at least, cannot be used to perform another medical abortion.

European countries' experiences suggest that the medical abortion protocol can safely and effectively vary in ways that could affect the method's availability.

Guidelines issued in March 2001 by the Agence Nationale d'Accréditation et d'Évaluation en Santé (ANAES), a professional organization of obstetricians and gynecologists sponsored by the French Ministry of Health, recommend 200 mg of mifepristone for use in medical abortion up to 49 days from the onset of the last menstrual period.[11] The guidelines also recognize that home administration of the prostaglandin and medical abortion up to 63 days' gestation are safe and can be practiced according to providers' and patients' preferences. Thus, some French providers may soon start using alternate regimens, and this, in turn, may increase mifepristone use in early medical abortion.

Ultrasound examination is not mandated, and the extent to which providers use it varies in the three countries. In Sweden, it is used for most abortions to confirm gestational age.[12] In France and Great Britain, some providers use ultrasound regularly, while others rely on it only when the products of conception are not expelled during the observation period or when there is a discrepancy between uterine size and the woman's reported date of her last menstrual period.[13] Great Britain's RCOG recommends that all providers have access to ultrasound, but believes that it is not essential to the medical abortion process.[14] A 2000 RCOG audit of abortion providers found that 44% of facilities offering early (surgical and medical) abortion routinely use ultrasound.[15]

MIFEPRISTONE AND TRENDS IN ABORTION

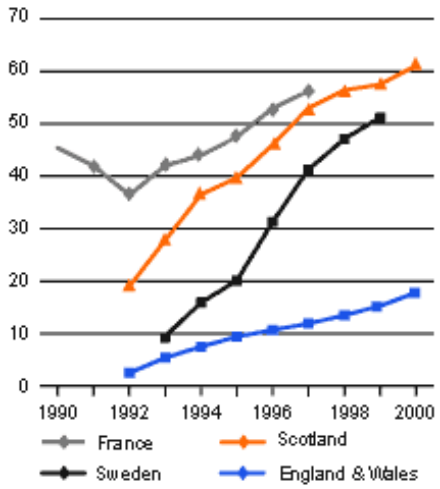
The availability of mifepristone does not necessarily translate into high levels of use or easy access to medical abortion. Different circumstances have resulted in varying levels of mifepristone use across the three countries and within each country.

Trends in Medical Abortion

More than half of abortions within approved gestational limits are performed using mifepristone in France (56%), Scotland (61%) and Sweden (51%).[§16] Mifepristone is least used for early abortion in England and Wales, where only 18% of eligible abortions are medical procedures.[17] Experts in all of the countries emphasize that there is substantial regional variation within their country. For example, as many as 60% of eligible early abortions involve mifepristone in some areas of Sweden, compared with 10% in other regions.[18]

In general, the proportion of early abortions involving mifepristone has increased steadily each year since its introduction (Figure 1, see below). The exception was that it fell in France in 1991 and 1992. This short-term decline, which occurred shortly after mifepristone's introduction in 1988, was possibly because in 1991, a death was attributed to sulprostone, the prostaglandin used at that time.[19] In 1992, France registered misoprostol as the approved prostaglandin, and since that time, early medical abortion has increased steadily.

FIGURE 1. Percentage of women eligible for early medical abortion who were prescribed mifepristone, four European countries, 1990-2000



Note: For France, eligible abortions refer to those performed up to 49 days from the last menstrual period; for the other countries, eligible abortions refer to those performed up to 63 days from the last menstrual period. *Sources:* **France**—Institut National d'Études Démographiques (INED), *Statistiques de l'avortement en France, annuaire,* various years, Paris: INED; and INED, 2001 (reference 16). **Scotland**—Elder R, 2001 (reference 20); and Information and Statistics Division, Scotland Online, 2001 (reference 16). **England and Wales**—Henshaw SK et al., 2000 (reference 23); and Office for National Statistics, *Abortion Statistics: Legal Abortions Carried Out Under the 1967 Abortion Act in England and Wales,* various years, London: Stationery Office. **Sweden**—National Board of Health and Welfare (NBHW), Center for Epidemiology, *Aborter,* various years, Stockholm, Sweden: NBHW; Hedberg C, 2001 (reference 16); and Henshaw SK et al., 2000 (reference 23).

When a country extends its gestational limits for early medical abortion from 49 to 63 days, the proportion of women seeking pregnancy termination who are eligible for the method grows. Extending limits may also lead to an increase in the proportion of all abortions that are medical abortions. In Scotland and Sweden, where the gestational limit is 63 days, the estimated proportions of all abortions that are early medical procedures are 54% and 33%, respectively.[20] In France, which permits medical abortion up to 49 days from the last menstrual period, 56% of eligible early abortions involve mifepristone, but these procedures account for only 11% of all abortions.[21] In England and Wales, however, 8% of all abortions are early medical abortions, although

the cutoff is 63 days.[22] This small proportion is likely a function of restrictive guidelines for service delivery, described below.

TRENDS IN EARLY ABORTION

Many providers require that a woman wait until at least the sixth week of gestation before they will perform a vacuum aspiration, although earlier aspiration abortions are becoming available. Medical abortions can be initiated as soon as a pregnancy is confirmed. Increased awareness of mifepris- tone abortion among women may lead them to seek abortion services very early in pregnancy to ensure that they are eligible. Hence, the availability of medical abortion may both allow and motivate women to obtain abortions at earlier gestations.

Since mifepristone was introduced, women have started obtaining abortions at earlier gestations. In France, the proportion of abortions performed at or before seven weeks from the onset of the last menstrual period increased from 12% in 1987 to 20% in 1997.[23] In Scotland, the proportion of all abortions that occur before 10 weeks' gestation increased from 51% in 1990 to 67% in 2000.**[24] In Sweden, the proportion of abortions performed before nine weeks increased from 45% in 1991 to 65% in 1999.[25] The increase has been less dramatic in England and Wales: Thirty-six percent of women who obtained abortions did so before nine weeks in 1990, and 43% did so in 2000.[26]

Trends in Abortion Rates

Patterns in overall abortion rates, measured as the number of abortions (at all gestations) per 1,000 women aged 15-44, do not suggest that the availability of mifepristone has led more women to terminate their pregnancies. The abortion rates in France and in England and Wales remained stable from the year prior to mifepristone's approval to the most recent year for which data are available. There were 13 abortions per 1,000 women aged 15-44 in both 1987 and 1997 in France, and 16 per 1,000 in both 1990 and 2000 in England and Wales.[27] The abortion rate in Sweden fell from 21 per 1,000 in 1990—the year before mifepristone approval—to 18 per 1,000 women in 1999.[28] Scotland's abortion rate increased slightly between 1990 and 2000, from nine to 11 per 1,000 women.[29]

Many factors can cause fluctuations in abortion rates, including contraceptive use, political climate, economic conditions and the availability of providers. It is impossible to know what abortion trends in Europe might have been in the absence of mifepristone. Abortion rates might have declined more had mifepristone not been introduced, or mifepristone's introduction into environments where abortion services are fairly accessible might have had little impact on total use of abortion services. Nevertheless, the inconsistent trends in abortion rates across the study countries suggest that mifepristone has not had a large effect on overall numbers of abortions.

FACTORS AFFECTING AVAILABILITY

Levels of mifepristone use are affected by policies and practices that impact the financial aspects of abortion services and the conditions under which medical abortion can be provided.

Type of Facility and Medical Personnel Involved

In the study countries, abortion services are permitted only in public hospitals and in private facilities that meet certain requirements. In England and Wales, about half of abortions are performed in National Health Service (NHS) hospitals, and half in approved private facilities. Two nonprofit agencies, Marie Stopes International and British Pregnancy Advisory Service (BPAS), provide almost all abortions outside of NHS facilities.

Both public hospitals and private facilities in England and Wales were relatively slow in adopting early medical abortion. By 2000, only 46% of NHS hospitals that provided early abortions offered mifepristone.[30] Hospitals did not adopt the method more quickly because of the need for more bed space for women receiving the prostaglandin, a lack of trained staff, the low priority given to abortion services and the small abortion caseload in many hospitals.[31] Nevertheless, because many hospitals with large abortion caseloads offered mifepristone, 40% of eligible abortions in NHS hospitals used the drug.[32]

The private sector in England and Wales has been even slower to adopt medical abortion, in large part because of restrictions imposed by the health authorities. For example, until 2000, when more flexible guidelines were introduced, an overnight bed had to be available for each woman having a medical abortion. Non-NHS facilities accounted for 54% of all abortions in 2000, but for only 15% of early medical procedures.[33] Only 4% of eligible abortions in private facilities were performed with mifepristone.[34] The new guidelines may encourage more non-NHS units to offer mifepristone to more patients. According to Ann Furedi, director of communications at BPAS, the number of medical abortions performed in BPAS clinics increased 151% after the restrictions were lifted—from 1,052 procedures in 1999 to 2,644 in 2001.[35]

Similarly, private facilities in France, which provided 28% of abortions in 1997, have been slower than public hospitals to offer medical abortions.[36] Eighty-three percent of all public hospitals offered medical abortion services that year, and 23% of abortions at these facilities were performed using mifepristone.[††37] Only 40% of private abortion facilities provided medical abortions, and 13-16% of abortions involved mifepristone.[38] The reluctance of private providers to use mifepristone appears to be because insurance reimbursement is less generous relative to the amount of staff time involved.[39] Hassoun, of the Delafontaine Hospital, said that physician and staff salaries are higher in private facilities than in public ones, and insurance reimbursement rates are such that private facilities stand to lose money by providing medical abortions.

Only 5% of all abortions in Sweden and fewer than 2% in Scotland are performed in private facilities, and provision of abortion services in the private sector has had little impact on the availability of medical abortion.[40]

In France, Great Britain and Sweden, both medical and surgical abortions must be performed by a physician. However, all three countries have developed practices to minimize physicians' involvement in medical abortion, thereby reducing staff costs and potentially the cost of the method for providers and patients, which could make it an available option for more women. Regulations in Great Britain are interpreted to allow nurses to administer the drugs as long as a physician prescribes them. As a result,

medical abortion services are largely supervised by nurses with physicians available if needed.[41] According to Swedish law, physicians are responsible for counseling women prior to an abortion and, in the case of medical abortion, for prescribing the drugs. Swedish midwives can administer both mifepristone and the prostaglandin. Midwives are usually responsible for pelvic examinations and postabortion checkups for both medical and surgical abortions.[42] In France, physicians confirm the pregnancy and conduct the follow-up visit, but nurses are often responsible for the other procedures involved in medical abortion.[43]

Waiting Periods and Other Delays

Because medical abortions are restricted to the first few weeks of pregnancy, delay in accessing services will reduce the number of women eligible for the method. Swedish women who undergo abortion counseling often are given a few days to evaluate the information they have received. But Swedish law mandates that abortion be provided without unnecessary delay, and informal waiting periods seldom impact access to medical abortion.[44]French law requires a seven-day waiting period before a woman can obtain a surgical or medical abortion. Crowded public facilities in some areas can further delay access for French women.[45]No waiting period is mandated in England and Wales, but waiting lists at NHS hospitals, which sometimes cause women to wait for more than three weeks, may eliminate medical abortion as an option for women, particularly if they lack access to a non-NHS provider.

Acceptance Among Medical Professionals

Provider and staff support of early medical abortion are key to whether the option is offered and women choose the method. Indeed, Furedi of Great Britain's BPAS asserts that staff support is "the absolute single main driver" explaining different levels of mifepristone use across providers. In all three countries, in some facilities, the option of medical abortion is facilitated and supported, and few women choose surgical abortion; in other facilities, the opposite is the case.[46] Medical professionals' positive experiences with the method can result in a medical culture that supports early medical abortion and encourages area providers to offer this option, while factors such as limited funding for abortion services and bureaucratic inertia may discourage providers from adopting new techniques.

The substantial reliance on early medical abortion in Scotland appears to be largely physician-driven. Scottish physicians have developed regimens that cost less to provide than the usual vacuum aspiration procedure, which, in NHS facilities in Great Britain, typically involves general anesthesia and a hospital operating room. Some NHS facilities in Scotland, and in certain regions of England, now adhere to a protocol that relies largely on medical abortion up to nine weeks' gestation and vacuum aspiration under general anesthesia from nine to 14 weeks.[47]

Swedish providers also are able to perform medical abortions at lower cost than vacuum aspiration.[48] However, there is no indication that the lower cost has influenced providers to recommend medical over surgical abortion. Instead, provider receptiveness depends more on the interest of a particular facility's department head and staff and the facility's capacity to serve medical abortion clients. According to Kristina Gemzell Danielsson, a physician with the Department of Women and Child

Health, Division of Obstetrics and Gynecology, in Stockholm, who conducts research on abortion, "once the staff of the department has gained experience [with] the procedure, the advantages of the treatment are appreciated."

Home Use of Prostaglandin

Women obtaining medical abortions in France, Great Britain and Sweden typically must make one more medical visit than do those obtaining surgical abortions; the extra staff time required may discourage providers from adopting mifepristone. In all three countries, there is some interest in allowing women to administer the prostaglandin at home, thereby reducing the number of office visits. The ANAES guidelines in France acknowledge that home administration of the prostaglandin is safe,[49] and studies of this practice are currently under way in Sweden and France. According to Furedi, home administration is under review by the Department of Health, and providers in Great Britain do not offer the option. BPAS is planning to undertake a study of home administration in 2002.

Postabortion Follow-Up Visits

According to the prescriber's agreement for mifepristone in the United States, a follow-up visit for mifepristone patients "is very important to confirm that a complete termination of pregnancy has occurred and that there have been no complications."[50] The concern is that a continuing pregnancy may result in birth defects, and that providers could be held legally liable. Potential providers may be deterred by the difficulty and expense of achieving a high follow-up rate.

In Europe, however, there have not been problems related to follow-up visits. Estimates from regular practice (as opposed to clinical trials) in Europe show that the proportion of women not making follow-up visits after medical abortion ranges from 10% in France to 20% in Scotland.[51] Notably, in France, the proportion of follow-up visits women miss for surgical abortion is larger than that for medical abortion,[52] probably because the importance of return visits is stressed more strongly for medical abortion patients.

WOMEN'S CHOICE OF MEDICAL ABORTION

A woman's decision to choose medical abortion depends, in part, on the options available to her. For women in Great Britain and, to a lesser extent, in France, the choice of the type of early abortion is often between medical abortion and vacuum aspiration under general anesthesia. Women who do not want to be unconscious during the procedure or do not want to risk undergoing general anesthesia may see medical abortion as a more desirable alternative. In Sweden, women often can choose between medical abortion and vacuum aspiration with either local or general anesthesia.

In European countries, cost plays a small role in women's choice of abortion method. National health insurance or national health systems cover all or most of the cost of abortion services in Sweden and France, regardless of whether the provider is a public or private facility or physician. In Sweden, the cost to the patient for either medical or surgical abortion is no more than US $30.[53] In France, most women pay 20% of the charge for medical and surgical abortions, and health insurance covers the rest. Because of the cost of the drugs and staff time involved, the charge for medical

abortion is slightly higher than that for surgical abortion, and it usually is not enough to compensate for the relatively greater staff time and drug costs required for medical abortion. Providers receive only slightly higher reimbursement for medical than for surgical abortion. However, the out-of-pocket price difference of approximately $10 usually is not enough to limit women's choice. Women who access abortion services from private providers must pay the full charge and apply for reimbursement through health insurance, which they usually receive within a month.

Health insurance coverage varies more in Great Britain than in the other countries. In 2000, NHS paid for 98% of all abortions in Scotland, but for 75% of all abortions in England and Wales.[54] In Great Britain, services are free at NHS facilities and, for some clients, at nonprofit clinics under contract with NHS. Regional health authorities are responsible for allocating health service funds, and in some areas of England and Wales, abortion services have low priority. Long waiting lists at some NHS hospitals lead many women in England and Wales to turn to non-NHS facilities for abortion services. Though many procedures in non-NHS facilities are paid for by the state health system, approximately 50% of women obtaining abortions at these facilities (and 25% of all women obtaining abortions) pay for the services themselves because NHS-funded services are unavailable or inconvenient.[55] For these women, price may affect the choice of method. BPAS clinics charge approximately $378 for medical or surgical abortion, while clinics run by Marie Stopes charge $499 for medical abortion and $463 for surgical abortion.

The level of discomfort women experience with medical abortion can be more pronounced and typically lasts longer than that associated with surgical abortion. Most women who undergo medical abortion report some form of gastrointestinal discomfort, such as nausea, cramps, vomiting or diarrhea, which can last anywhere from a few hours to several days. Other potential side effects are headache, dizziness and chills. Bleeding that results from a medical abortion is typically heavier than menses and lasts an average of 8-17 days. Fewer than 1% of procedures performed up to 49 days' gestation result in bleeding heavy enough to require an emergency dilation and curettage.[56]

While a medical abortion takes longer and typically results in more side effects than surgical abortion, research on patients' evaluations of medical abortion in all three countries have found that the majority of women—often more than 90%—are satisfied with the procedure and would opt for the same method if a future termination were necessary.[57] Studies of women obtaining abortions in all three countries suggest that when given a choice between medical and surgical abortion, 57-70% opt for the former.[58]But greater satisfaction with medical abortion is not universal; two studies comparing women who had medical abortions with those who underwent surgical procedures found that those in the surgical group were more likely to indicate that they would choose the same method if they had to have another abortion.[59]

IMPLICATIONS FOR THE UNITED STATES

Determining the most safe and effective protocol for using mifepristone for early medical abortion in many ways transcends issues related to a country's medical system or type of service delivery. Providers must determine the most effective dose of mifepristone and the most appropriate gestational limits, as well as who can administer

the drugs and where. Because France, Great Britain and Sweden have had time to practice the method and test variations in protocols, U.S. providers have looked to these countries' experiences to inform their own practices. Cross-national differences exist in the cultural contexts, types of facilities that provide medical abortion, availability of funding, cost of the procedure and amount of flexibility providers can exercise in varying from health guidelines and regulations. However, the experience in the European countries can shed light on some fundamental factors that may influence levels of acceptance and use of the method in this country in the coming years.

Acceptance of the Method Will Take Time

It could take a decade or longer for mifepristone to be fully recognized and integrated as a method of abortion. In each of the study countries, mifepristone use has increased gradually and continues to expand even after 10 years. Although the health care systems vary among the countries, in all cases it has taken time for them to adopt regulations and protocols appropriate to the new technology. In the United States, the number of facilities offering medical abortion and the proportion of abortion patients choosing the method are likely to increase gradually over a period of years as providers become more comfortable with the medical abortion procedure and as more women seeking abortions inquire about mifepristone. The European experience suggests that the addition of medical abortion at surgical abortion sites will not noticeably increase the abortion rate. If medical abortion services become available at previously unserved locations, however, more U.S. women may find it possible to terminate unwanted pregnancies.

Provider Knowledge and Acceptance Are Key

Physicians and facility staff are critical to determining whether women adopt medical abortion and how the option is presented to eligible patients. As providers gain more experience with medical abortion and interact with colleagues who have had success with the method, they are likely to become increasingly interested in providing this option for their patients. The European experience demonstrates that providers who are favorably disposed to the method find that larger proportions of patients make it their choice, while those whose attitudes are unfavorable have few patients who choose the method.[60]

In the United States, large abortion facilities, which account for most abortions, will play an important role in determining use and acceptance of mifepristone. Most of these facilities are part of networks, such as NAF and the Planned Parenthood Federation of America, that offer providers training and advice for integrating mifepristone into their practices. Emerging research indicates that acceptance among these clinics is substantial and that the proportion of eligible abortions involving mifepristone is increasing. For example, several Planned Parenthood affiliates offering mifepristone for early medical abortion report that more than one-third of pregnancies at eligible gestations (less than 49 days from the last menstrual period) are terminated using mifepristone.[61]

Protocols Can Be Flexible

European countries' experiences suggest that the medical abortion protocol can safely

and effectively vary in ways that could affect the method's availability. Preliminary reports in the United States suggest that some providers of medical abortion have begun to use alternatives to the FDA-approved protocol—for example, using the 200 mg regimen and permitting women to administer the prostaglandin at home.[62]

While medical abortion is approved only up to 49 days from the last menstrual period in the United States, some providers in Great Britain and Sweden allow women the choice of medical abortion up to 63 days from the onset of their last menstrual period. On the basis of clinical studies, some providers in the United States are extending use up to 63 days as well.[63] Staff oversight of medical abortion services can be flexible. For example, at many facilities in France, Great Britain and Sweden, nurses and midwives are responsible for many aspects of the medical abortion process. Physicians often play a less-important role than they do for surgical abortion procedures. If U.S. providers were to implement this practice, the cost of the method to patients could potentially be reduced, and the method could be available to more women. Experiences in Europe also indicate that early medical abortion is safe in terms of women's health even if some women do not return for a follow-up visit. Although 10-20% of women in Europe do not return for their follow-up visit, providers do not see it as a problem because these women have not returned seeking treatment for complications.

Cost Affects Access to Medical Abortion

While cost is often a minor factor in European women's choice between medical and surgical abortion, it is an important issue for many providers and affects their willingness to offer the method. Private physicians in France receive greater compensation for surgical abortion than for medical abortion, relative to the staff time involved, and are less likely to offer the latter. In Scotland and certain areas of England, where early medical abortion costs less to provide than surgical abortion, providers are encouraged to adopt a protocol that emphasizes the use of medical rather than surgical abortion during the first 7-9 weeks of pregnancy. While this increases access to medical abortion, it may do so by reducing access to the surgical option.

Costs to both patients and providers are likely to affect medical abortion services in the United States. Preliminary reports suggest that a majority of NAF members charge more for medical abortion than for surgical.[64] The higher cost is reported to be a product of the expense of the drug and the extra time spent in counseling and follow-up. This may restrict accessibility of medical abortion in the United States, because a majority of women pay out of pocket.[65] Home administration of misoprostol, lower doses of mifepristone,[‡‡] an increasing role of lower-cost midlevel practitioners and coverage of mifepristone by Medicaid and several large insurance plans suggest that cost may become less of an obstacle in the coming years.

CONCLUSION

The European experience suggests that early medical abortions can be safely performed at later gestations and under simpler protocols than the one approved by the FDA, and that acceptance of mifepristone by both providers and women will continue to increase in the United States for a number of years. Mifepristone has the

potential to make it less difficult for women to access abortion services, particularly if large numbers of physicians who do not currently offer surgical abortion start providing medical abortion services. While not all women prefer medical to surgical abortions, providing women the choice between the methods will increase satisfaction levels among women obtaining abortions. Finally, as knowledge of mifepristone abortion increases among women, they may seek abortion at earlier gestations to ensure that they are eligible for the procedure. Hence, the availability of medical abortion may lead to an increase in the proportion of all abortions that are performed at earlier gestations.

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*Mifepristone has been registered for use in 14 countries in Europe: Austria, Belgium, Denmark, Finland, France, Germany, Great Britain, Greece, Luxembourg, the Netherlands, Norway, Spain, Sweden and Switzerland. In addition to the United States, the drug has been registered in China, Israel, New Zealand, Russia, South Africa, Taiwan, Tunisia and Ukraine.

†Although Scotland is part of Great Britain, its abortion practice is different enough from practice in England and Wales that in some cases, we will discuss it as a separate country.

‡Mifepristone is also registered for use in second-trimester abortions in the study countries. However, because mifepristone is not approved for use in later abortions in the United States, we address only early abortions using mifepristone.

§In calculating the number of eligible abortions from statistical reports, we are limited by the gestational categories published. The criteria used were less than nine weeks from the onset of the last menstrual period in England and Wales, Scotland and Sweden, and less than five weeks of gestation (or seven weeks from the last menstrual period) in France. In En- gland and Wales, gestation is reported in completed weeks. Abortions at 63 days, though technically eligible, were not counted. In the other countries, it is not clear whether weeks are reported as completed weeks, ordinal weeks or nearest week. The figures may therefore be somewhat inaccurate because of variations in the ways physicians estimated weeks of gestation.

**Published statistics documenting early abortion in Scotland are for gestations through 69 days from the last menstrual period and, thus, include women who were not eligible for medical abortion. Unpublished data for gestations of less than nine weeks, a more accurate eligibility period, extend back only to 1992 (source: Elder R, 2001, reference 20). Nonetheless, they show a similar increase in women seeking early abortion, from 44% of all women seeking abortions in 1992 to 54% in 2000.

† In France, mifepristone is registered for use for cervical ripening prior to surgical abortion. Thus, the figures for abortions that involve mifepristone include abortion procedures at all gestations in which mifepristone was used for any purpose. For this reason, the proportion of all abortions that involve mifepristone (13-23%) is larger than the proportion of all abortions that are early medical abortions (11%).

‡ The Population Council is conducting a four-site study in the United States to evaluate the efficacy of a lower-dose mifepristone regimen in an effort to obtain approval for a regimen that uses 200 mg of mifepristone instead of 600 mg.