Update on New Contraceptive Choices

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Abstract

- **Objective**: To review new contraceptive methods and to provide information to facilitate informed decision making with regard to choosing contraception.
- **Methods**: Qualitative review of the literature.
- **Results**: An assortment of new methods offer a broad variety of contraceptive choices. Hormonal methods include the transdermal patch, vaginal ring, extended-regimen and drospirenone-containing oral contraceptive pills, Plan B emergency contraception, hormonal injection and implant, and the levonorgestrel-releasing intrauterine system. Sterilization via Essure placement and new barrier devices are also discussed. Provision of information on effectiveness and elicitation of patient preferences are the most important goals in contraceptive counseling.
- **Conclusions**: Current contraceptive methods are generally safe and easy to use. Patients need to have an accurate understanding of risks to make an informed choice.

Half of all pregnancies in the United States are unplanned, and in approximately half of unintended pregnancies, contraception was used at the time of intercourse [1]. The success of a contraceptive method in preventing pregnancy can have as much to do with user behavior as with the inherent efficacy of the method. Patient adherence to prescribed medications is notoriously poor, and contraception is no exception [2]. For example, as many as 50% of oral contraceptive users miss at least 1 pill per cycle. With perfect use, the failure rate for the pill is 0.3%; with typical use, however, the failure rate is closer to 8% [1].

This article reviews contraceptive methods that have become available since 1999 or that are pending approval for use in the United States. Generally, newer methods of contraception are designed to make adherence easier for patients. This review is also intended to serve as a guide to facilitate informed decision making for patients and practitioners.

Hormonal Methods

Transdermal Patch

The transdermal contraceptive patch (Ortho Evra, Ortho-McNeil Pharmaceuticals, Inc., Raritan, NJ) was introduced in the United States in 2002. It is pharmacologically similar to combination oral contraceptives but is applied topically. The regimen requires only 3 weekly applications per month, compared with 21 days of active pill-taking. The patch is a small (2 cm²), thin, adhesive square that releases 150 µg of the progestin norelgestromin and 20 µg of the estrogen ethinyl estradiol daily into the systemic circulation. The patch can be applied to the upper outer arm, lower abdomen, upper torso, or buttocks. It should not be applied to the breasts. The patch may be less effective in women who weigh 90 kg (198 lb) or more [3]. Obese patients who are seeking hormonal contraception should be counseled to use other hormonal methods or to consider a backup method when using the patch.

In 2005, the U.S. Food and Drug Association (FDA) released an advisory regarding the use of Ortho Evra. This warning was based on the results of an open-label randomized trial that compared the pharmacokinetics of ethinyl estradiol from the contraceptive vaginal ring (15 µg ethinyl estradiol/day), the transdermal patch (20 µg ethinyl estradiol/day), and a combined oral contraceptive (30 µg ethinyl estradiol/day) [4]. Analysis of the ethinyl estradiol area under the concentration versus time curve after 21 days on 1 of these methods showed that subjects on the patch were exposed to 60% more ethinyl estradiol than subjects who were on the pill (n = 24; 8 in each of the 3 arms). This study does indicate that women on the patch are exposed to more ethinyl estradiol than subjects who use a 30-µg pill or the ring, but this pharmacokinetic study was not designed to reveal whether patch use is associated with any increased risk of vascular events.

Two recent case-control studies that employed insurance claims data and medical record review to compare incidence rates of nonfatal deep venous thrombosis between patch users and oral contraceptive users obtained conflicting results, with 1 study finding no difference in risk for venous thromboembolism between pill and patch groups and the other finding an increased risk in patch users (odds ratio, 2.05) [5,6]. The evidence to date is insufficient to support a change in clinical practice. Ortho Evra should continue to be used without restriction in those patients for whom combined oral contraception is indicated.

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A Cochrane systematic review found that the patch was similar to combined oral contraceptives in efficacy [7]. Patch users in clinical trials reported significantly more cycles of correct use than oral contraceptive users. In a prospective study of 1417 women, the number of cycles with perfect dosing was significantly higher with the patch than with daily oral contraception [8]. This trend persisted across all age-groups. By contrast, among oral contraceptive users the percentage of cycles with perfect dosing increased only with increasing age of subjects, so that older women were more likely to continue the pill than were younger women. Consequently, the data show that for younger women the weekly patch facilitates better adherence to contraception.

Patch users in clinical trials were significantly more likely to report breast discomfort than oral contraceptive users. However, a recently published randomized open-label clinical trial of 1489 women found that significantly more users were very satisfied with the patch than with oral contraception [9]. Improvements in premenstrual symptoms and emotional and physical well-being were greater with the patch than with oral contraception. Additionally, in this trial correct use of method was consistently better with the patch than with oral contraception.

A recent study that examined the implications of increased use on the cost-effectiveness of the patch compared with oral contraceptives found that use of the patch resulted in a savings of $249 and 0.03 pregnancies per woman over 2 years compared with oral contraception [10].

**Vaginal Ring**

A contraceptive vaginal ring (NuvaRing; Organon USA Inc., Roseland, NJ) was introduced in the United States in 2002. The ring releases 15 µg of ethinyl estradiol and 120 µg of the progestogen etonogestrel per day at constant rates that effectively suppress ovulation. Lower levels of estrogen exposure are associated with the ring than with the patch or pill [4]. NuvaRing is small, flexible, light-weight, and transparent. It is made of evatane, a vinyl polymer matrix, and use is not associated with an increase in vaginal infections [11]. Insertion and removal is done easily, it does not require fitting by a health care provider, and the ring does not need to cover the cervix. NuvaRing does not have to be removed prior to sexual intercourse. However, if users desire removal, it can be left out for up to 3 hours. In addition, concurrent use of tampons or antifungal medications do not appear to affect efficacy [12].

Each ring is intended for 1 cycle of use, which is comprised of 3 weeks of ring use and a 1-week ring-free period during which women experience a withdrawal bleed. Studies have shown that the ring has a high level of acceptability to users. There is less breakthrough bleeding during the initial cycles of use as compared to oral contraception [13].

A 1-year study of 2322 women who were followed for 23,298 cycles found that the ring was well tolerated, with a low incidence of adverse events (2.5%); 85% percent of women were satisfied with the ring, and 90% would recommend its use to others [14]. Another study of 1950 women found that 85% of women and 71% of partners never or rarely felt the ring during intercourse and 94% of partners never/rarely minded that the woman was using the ring [15]. Overall, 96% of women in this study were satisfied with the ring and 97% would recommend its use to others.

**Oral Contraceptives**

**Extended regimen.** Seasonale (Duramed Pharmaceuticals, Inc., Pomona, NY), which was approved for use in the United States in 2003, is a 91-day extended-cycle regimen of a combined hormonal oral contraceptive pill. It contains 84 days of 30 µg ethinyl estradiol plus 150 µg of levonorgestrel followed by 7 days of placebo. Women who use this method will have 4 withdrawal bleeds per year.

The advantage of such a regimen is avoidance of menses and menstrual-associated symptoms, such as dysmenorrhea, headaches, and bloating [16]. An extended regimen also minimizes menstrual interference with daily activities, work, and special events. Indeed, the traditional 28-day cycle (21 days of active pills and 7 days of placebo, which permits a withdrawal bleed) has no basis in biology. The developers of the first oral contraceptives adopted this regimen to mimic naturally occurring cycles to conform to social norms of the 1950s [17].

The physiology of combined oral contraceptives supports the safety of continuous administration. Combined oral contraceptives inhibit follicle-stimulating hormone and luteinizing hormone, which in turn prevents proliferation of the endometrium. Continuous pill administration results in a thin endometrium. A recent 1-year study that assessed the effect of Seasonale on the endometrial microstructure found that the majority of subjects (n = 50) had inactive or atrophic endometrium [18]. No significant pathology was found. In addition, the endometrium reverted quickly to normal cyclic changes in those subjects who discontinued hormonal contraception after the study period.

A recent crossover study of 3316 women found that continuous administration of oral contraception resulted in fewer missed pills than traditional administration, particularly on the first day and week of the cycle [19]. This is the time when breakthrough ovulation is most likely to occur. Extended regimens may therefore result in fewer unintended pregnancies.

A Cochrane systematic review found that 28-day and extended cycles were similar in regard to contraceptive efficacy (pregnancy rates) and safety profiles [17]. There was no difference in correct use between the 2 methods. The
extended-cycle group did better with respect to menstrual symptoms such as headaches, tiredness, bloating, and dysmenorrhea.

Seasonique (Duramed Pharmaceuticals, Inc., Pomona, NY) is another extended-regimen pill that was very recently approved by the FDA. It is similar to Seasonale in that it contains an extended regimen of active pills (levonorgestrel/ethinyl estradiol 0.15 mg/0.03 mg). As with Seasonale, this method also reduces the incidence of menstrual periods to 4 per year. However, in place of Seasonale’s 7 days of inactive or placebo pills, Seasonique has 7 days of very low-dose estrogen (ethinyl estradiol 0.01 mg), so that all pills in the 91-day pack are active. This new product incorporates low-dose estrogen rather than placebo tablets in an effort to reduce symptoms of bloating, hormonal fluctuations, and breakthrough bleeding that may occur with traditional pills.

Seasonique’s approval was based in part on data from a randomized, multicenter, open-label clinical trial of 1006 sexually active women aged 18 to 40 years who completed 2488 cycles of the 91-day regimen [20]. Results showed that the overall pregnancy rate was 0.78. This was based on 7 pregnancies during the course of 1578 pill cycles for which no other form of birth control was used. The company that manufactures Seasonale and Seasonique also plans to introduce a very low-dose extended-regimen pill into the United States market.

Drospirenone-containing pills. Yaz (Berlex, Inc., Montvale, NJ), which was approved for use in the United States in early 2006, is a combined hormonal oral contraceptive that contains a low dose of ethinyl estradiol (20 µg) with drospirenone, a progestin that has antimineralcorticoid activity. It is a lower-dose version of Yasmin, another pill by the same manufacturer. Yaz’s dosing regimen consists of 24 days of active hormone pills and 4 days of placebo pills. Most current pill formulations contain 21 days of active pills with a 7-day pill-free interval. A shorter pill-free interval may improve side effects, like headache, that are related to estrogen withdrawal. Another potential benefit from the shorter pill-free interval may be reduced ovarian activity, thereby decreasing the chances of ovulation.

According to the manufacturer, Yaz demonstrated 99% contraceptive efficacy in a phase III clinical trial of 1027 women who completed 11,480 treatment cycles [21]. In that study, the drug also increased menstrual regularity while maintaining breakthrough bleeding rates similar to other low-dose oral contraceptives. During the clinical trial, 7 women withdrew because of irregular bleeding. Due to its recent introduction, no postapproval studies were available for review through MEDLINE.

Drospirenone, the progestin used in Yaz, has antimineralcorticoid activity comparable to a 25-mg dose of spironolactone. Although it has never been observed, the drug is theoretically associated with an increased risk of hyperkalemia in high-risk patients. Women taking angiotensin-converting enzyme inhibitors, angiotensin II receptor blockers, high-dose chronic nonsteroidal anti-inflammatory drugs, potassium-sparing diuretics, aldosterone agonists, or potassium supplementation, all of which may increase serum potassium, should have their serum potassium levels checked during their first pill cycle.

Generally speaking, the 21/7-day pill regimen is somewhat outdated. Consequently, clinicians can expect that new pills will be unlikely to have a 7-day pill-free interval.

Emergency Contraception: Plan B

The widespread use of emergency contraception has the potential to prevent 1.7 million unintended pregnancies and 0.8 million abortions per year [22]. Despite this, only 6% of American women report ever having used emergency contraception [22].

Plan B (Duramed Pharmaceuticals, Inc., Pomona, NY) was approved for use in 1999. It consists of two 0.75-mg pills of levonorgestrel, a progestin commonly used in birth control pills. Its primary known mechanism for activity is suppression or delay of ovulation. Studies have shown that interference with embryo implantation into the uterus is an unlikely mechanism [23].

The 1.5-mg dose can be taken by mouth either as a single dose or as a split dose 12 hours apart [24,25]. The single dose is recommended over the split dose because a single dose is simpler. Plan B may be taken up to 120 hours (5 days) after unprotected sexual intercourse, although efficacy is greatest if taken within 72 hours. A World Health Organization multicenter randomized trial of 4136 women showed that pregnancy rates were 1.5%, and that pregnancy rates did not differ among women who took Plan B as a split dose or single dose [24]. Plan B was well tolerated, with the main side effects being nausea (15%) and early menses (31%) [24,26]. A descriptive study of adolescent females who took Plan B showed that it was well tolerated [27].

A recent study of 120 women who used Plan B for emergency contraception found that those who used it during their first 3 weeks of their menstrual cycle had menses that arrived earlier and that were shorter than usual [28]. The earlier the pills were taken in the cycle, the more pronounced was this effect. However, the subsequent period was longer than usual. Intermenstrual bleeding occurred in only a small percentage of women studied.

Using cost data from a major HMO database, Trussell et al [22] showed that in a managed care setting, a single treatment of Plan B after unprotected intercourse saves $142 compared with no treatment. Advance provision of emergency contraceptive pills to women using barrier contraceptives,
spermicides, withdrawal, or periodic abstinence saves from $263 to $498 per woman annually [22].

**Hormonal Injection**

Depo-Provera (Pfizer Inc., New York, NY) contraceptive injection (150 mg/mL intramuscular depot medroxyprogesterone acetate [DMPA-IM] injectable suspension) is a highly effective, 3-month, progestin-only method that has been used internationally for decades. It was approved for use in the United States in 1992. In 2005, the FDA approved DMPA-SC 104 mg/0.65 mL, which is a subcutaneous, lower-dose formulation of DMPA-IM. Two large open-label studies assessed the 1-year contraceptive efficacy, safety, and patient satisfaction with DMPA-SC administered every 3 months (12–13 weeks) [29]. No pregnancies were reported in both studies, which included 1787 women in total. DMPA-SC was well-tolerated and incidence of adverse events, such as headache, weight gain, and intermenstrual bleeding, was similar to that reported previously for DMPA-IM. Of note, a recently published questionnaire survey of 176 current DMPA-IM users found that 67% would be interested in self-administering the subcutaneous injection [30].

Because of concerns about the effect of DMPA-IM on bone mineral density, the FDA last year issued a black box warning regarding its use. There are no available data that show whether the lower-dose DMPA-SC has a similar effect on bone mineral density.

The FDA's warning on DMPA-IM was based on partial data from a 7-year study that it commissioned. When the FDA made its recommendation, it did not take into account data from the same study showing that declines in bone mineral density were fully reversed within 2 years of DMPA-IM discontinuation. Other studies have also shown that declines in bone mineral density are completely reversed after discontinuation [31]. More importantly, there has been no increased incidence of fracture reported over the last 30 to 40 years of worldwide use [32]. Based on a review of available data, in July 2005 the World Health Organization issued the following policy statement: “With regard to bone metabolism, there should be no restriction on the use of DMPA, including no restriction on duration of use, among women aged 18 to 45 who are otherwise eligible to use the method” [33].

**Levonorgestrel-Releasing Intrauterine System**

The levonorgestrel-releasing intrauterine system (levonorgestrel IUS), known as Mirena (Berlex, Inc., Montvale, NJ), is licensed for use in 25 countries [34]. It was approved for use in the United States in 2001. Since then, clinicians and patients have come to appreciate levonorgestrel IUS for its noncontraceptive benefits, such as control of dysmenorrhea and menorrhagia secondary to uterine fibroids or adenomyosis. Mirena is indicated for contraception for up to 5 years in the United States and 7 years in Europe. Like the copper intrauterine device (IUD), Mirena is relatively maintenance-free. Users must deliberately have the device removed to become pregnant as opposed to making a daily, weekly, or monthly proactive commitment to avoid conception, as is the case with the pill, patch, or vaginal ring. Most important, IUDs, including Mirena, are as effective as sterilization for pregnancy prevention, and therefore are among the most effective contraceptive methods available.

Mirena is made of polyethylene, a type of plastic. It is a 32-mm × 32-mm T-shaped device with a reservoir on the vertical stem that contains 53 mg of levonorgestrel mixed with silicone. Levonorgestrel 20 μg is released daily within the uterus, with negligible systemic distribution. The polyethylene of the T-body is compounded with barium sulfate, which makes it radiopaque. A monofilament brown polyethylene removal thread is attached to a loop at the end of the vertical stem of the T-body. Unlike the copper IUD whose contraceptive efficacy is primarily due to the spermicidal effect of copper, the contraceptive mechanism of levonorgestrel IUS is largely due to thickening of the cervical mucous by levonorgestrel so that sperm cannot ascend and therefore fertilization does not occur. In addition, levonorgestrel IUS supresses proliferation of the endometrium.

Insertion of Mirena must be done by a trained clinician. The cost of levonorgestrel IUS is approximately the same as for the copper IUD. Whereas the copper IUD is approved for use for 10 years, levonorgestrel IUS use in the United States is indicated for only 5 years. Consequently, levonorgestrel IUS can end up being twice as expensive as the copper IUD. Continuation rates for the levonorgestrel IUS are about the same or are somewhat lower than for the copper IUD [35,36]. The main reason cited for discontinuation by patients is amenorrhea. Because levonorgestrel IUS, unlike the copper IUD, is very effective at reducing menstrual blood volume, it should be considered for use in patients who have a history of painful and/or heavy menses. For women with menorrhagia secondary to uterine fibroids, levonorgestrel IUS is a first-line therapy and may delay or entirely reverse the need for hysterectomy. Due its suppressive effect on the proliferation of the endometrium, Mirena is also of benefit for those patients on estrogen or tamoxifen therapy. Estrogen exposure that is unopposed by progesterone can lead to endometrial hyperplasia and atypia.

In a Cochrane systematic review of 21 randomized controlled trials that compared levonorgestrel IUS to other forms of reversible contraceptives, reviewers found that users of levonorgestrel IUS were no more or less likely to become pregnant than women who used nonhormonal
IUDs or Norplant [34]. Pregnancy rates for IUDs are approximately 0.8%, which is comparable to the failure rate for surgical sterilization.

Sterilization

Approved for use by the FDA in 2002, the Essure micro-insert (Conceptus, Mountain View, CA) is a minimally invasive, transcervically placed device that occludes the fallopian tubes, thereby resulting in permanent sterilization. The micro-insert is a spring-like device that consists of a stainless steel inner coil, a nickel titanium (Nitinol) expanding outer coil, and polyethelene terephthalate fibers. Transcervical, hysteroscopic placement allows patients to avoid the risks usually associated with general anesthesia and laparoscopic sterilization, such as injury to bowel or abdominal wall vessels. Insertion can be done in an outpatient setting. During the implantation procedure, the physician inserts one of the devices into each of the 2 fallopian tubes. This is done with a special catheter that is inserted through the vagina into the uterus, and then into the fallopian tube under hysteroscopic visualization. The device works by inducing scar tissue to form over the implant, blocking the fallopian tube and preventing fertilization of the egg by the sperm. Scar tissue formation requires approximately 3 months. During that time women cannot rely on the Essure implants and must use alternate contraception. At the 3-month point, women must undergo a radiographic procedure, a hysterosalpingogram, in which dye is placed in the uterus and radiography is performed to confirm tubal occlusion. Once occlusion is confirmed, alternate contraception can be discontinued.

The FDA based its approval on the results of 2 effectiveness studies conducted by the manufacturer. In these studies a total of 632 women underwent Essure placement and after 1 year of follow-up, no pregnancies were reported. A 2-year clinical trial of 111 women who had Essure placed reported no pregnancies [37]. An independent cohort study found that of 55 women who underwent Essure placement, more were more satisfied and experienced a faster recovery and less pain than 22 women who underwent laparoscopic sterilization [38]. A recently published cost-comparison analysis at 1 institution found that Essure placement is considerably less expensive than laparoscopic sterilization, with hysteroscopic office placement of the Essure device costing $1374 versus $3449 for ambulatory laparoscopic sterilization [39].

Barrier Devices

FemCap (approved 2003; FemCap Inc., Del Mar, CA), Lea’s Shield (approved 2002; Yarna, Inc., Union, NJ), and the Today Sponge (reintroduced into the U.S. market in 2005; Allendale Pharmaceuticals, Inc., Allendale, NY) are barrier methods that have recently become available. Barrier methods are generally less much less efficacious than hormonal methods for reducing risk of pregnancy. For example, in a clinical trial of 146 women studied for 6 months, 9% who used Lea’s Shield with spermicide and 13% who used it without spermicide became pregnant [40]. Pregnancy rates for the FemCap were also estimated based on a 6-month study. The failure rate was 18% [41]. Among sponge users 13% to 16% became pregnant in the first year of use [42].

Unlike the vaginal diaphragm, neither Lea’s Shield nor FemCap requires fitting by a clinician. However, a prescription from a physician or mid-level provider is required in order to obtain either of these devices. Patients then mail or fax the prescription to the manufacturer. The sponge is available over-the-counter at local pharmacies.

On the Horizon

Reversible Hormonal Implant

Implanon (Organon USA Inc., Roseland, NJ) is single-rod implant that releases 60 µg of etonogestrel, a progestin, daily. The product was first launched in Indonesia in 1998 and has had increasing popularity throughout Europe and Australia. FDA approval for Implanon was issued in July 2006, which means that this contraceptive method will be available to patients in the very near future through clinicians trained in implanting the device.

Contraceptive action is by complete inhibition of ovulation, and its effect lasts for 3 years [23]. Insertion and removal of Implanon is considerably easier and faster than for Norplant, which was a 6-rod system. Efficacy of Implanon is high; the reported failure rate has been zero [43]. The main reason for patient request for implant removal is irregular menses [44]. However, user acceptability is generally high at around 80% [45]. Several studies have shown that return to fertility is prompt, and that the implant has no effect on bone mineral density [46,47]. In addition, implants have been estimated to be more cost-effective than all other reversible methods of contraception except for the copper IUD [48].

Guide to Contraceptive Counseling

Given that most women ovulate on a regular basis for at least 30 years, contraception is paramount among their medical needs. Fortunately, contraception is the most effective preventive service available. Furthermore, current contraceptive methods are generally very safe and easy to explain and use.

For most women, efficacy of method is the most important factor in choosing a method of contraception [49]. In keeping with the recommendation of the World Health Organization, Table 1 is organized according to the methods’ effectiveness against pregnancy occurrence. We suggest using this or a similar table with patients as a framework for contraceptive counseling. Clinicians should make patients aware of the disparate levels of efficacy with regard to contraception and facilitate the decision-making process by directly
NEW CONTRACEPTIVE METHODS

Table 1. Contraceptive Methods Categorized by Effectiveness

<table>
<thead>
<tr>
<th>Contraceptive Method</th>
<th>Annual Rate of Pregnancy with Typical Use, %</th>
<th>Lowest Expected Annual Rate of Pregnancy, %</th>
<th>Most Common Side Effect</th>
</tr>
</thead>
<tbody>
<tr>
<td>Most effective (for all users)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male sterilization</td>
<td>0.2</td>
<td>0.1</td>
<td>Regret</td>
</tr>
<tr>
<td>Female sterilization (surgical, Essure)</td>
<td>0.5</td>
<td>0.5</td>
<td>Regret</td>
</tr>
<tr>
<td>Implant (Implanon)</td>
<td>0.0</td>
<td>0.0</td>
<td>Irregular menses Amenorrhea</td>
</tr>
<tr>
<td>Copper intrauterine device</td>
<td>0.8</td>
<td>0.6</td>
<td>Dysmenorrhea</td>
</tr>
<tr>
<td>Levonorgestrel-releasing intrauterine system (Mirena)</td>
<td>0.7</td>
<td>0.6</td>
<td>Amenorrhea</td>
</tr>
<tr>
<td>Hormone injection (Depo-Provera IM, Depo-Provera SC)</td>
<td>0.4</td>
<td>0.1</td>
<td>Irregular menses Amenorrhea</td>
</tr>
<tr>
<td>Effective*</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Combined progesterone/estrogen pill (Seasonale, Seasonique, Yaz), patch (Ortho Evra), or ring (NuvaRing)</td>
<td>5</td>
<td>0.3</td>
<td>Lighter menses</td>
</tr>
<tr>
<td>Minipill (progestin only)</td>
<td>5</td>
<td>0.5</td>
<td>Irregular menses</td>
</tr>
<tr>
<td>Least effective (for all users)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male latex condoms</td>
<td>14</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>Female condoms</td>
<td>21</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td>Cervical cap (FemCap, Lea’s Shield)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No previous births</td>
<td>20</td>
<td>9</td>
<td></td>
</tr>
<tr>
<td>Previous births</td>
<td>40</td>
<td>26</td>
<td></td>
</tr>
<tr>
<td>Spermicides (gel, foam, suppository, film, vaginal sponge)</td>
<td>26</td>
<td>6</td>
<td>Irritation</td>
</tr>
<tr>
<td>Withdrawal</td>
<td>19</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>Natural family planning (calendar, temperature, mucus)</td>
<td>20</td>
<td>1–9</td>
<td></td>
</tr>
<tr>
<td>No method</td>
<td>85</td>
<td>85</td>
<td></td>
</tr>
</tbody>
</table>

NOTE: Methods discussed in this paper are in bold. (Adapted with permission from Steiner MJ, Dalebout S, Condon S, et al. Understanding risk: a randomized controlled trial of communicating contraceptive effectiveness. Obstet Gynecol 2003;102:711.)

*Effective for most users, but more effective when used correctly.

asking patients how effective they want their contraception to be and whether they are planning to become pregnant and, if so, how soon. In general, provision of information on effectiveness and elicitation of patient preferences are the most important goals for contraceptive counseling.

Patients can make informed choices only when they have an accurate understanding of risk. Risk of pregnancy is the most important variable in this decision-making process. With respect to safety, pregnancy presents far greater risks of morbidity and mortality than does use of hormonal contraception. This is particularly true of women with chronic medical conditions such as hypertension or diabetes.

For patients who wish permanently to end their fertility, the best options are surgical sterilization, Essure placement, or the IUD. For patients who wish to delay fertility for several years,Depo-Provera, the IUD, or an implantable device (Implanon) are ideal. The patch, the pill, and the ring should also be recommended. However, these methods require considerably more user involvement and because of this may make method failure more likely. Patients who are interested in delaying fertility for 1 year or less should consider using a combined hormonal method such as the patch, pill, or ring or a barrier method, such as condoms, with emergency contraception as a back-up. If after appropriate counseling regarding levels of contraceptive efficacy, patients insist on using a less efficacious method such as the diaphragm or
cervical cap, those patients should be encouraged to use condoms as well. In general, all women should be encouraged to use condoms, no matter what their contraceptive method. Lastly, all fertile women who are interested in contraception should be provided with an advance prescription for emergency contraception so that they do not miss the therapeutic window for this important intervention.

Despite the overall safety of hormonal contraception, a few women should not take estrogen-containing contraception, primarily due to cardiovascular or neurovascular risks posed by their use in these women. Table 2 describes these patient groups.

Other Important Considerations
Medications. Medications such as rifampicin, griseofulvin, and certain anticonvulsants (phenytoin, carbamazepine, topirimate, barbiturates) induce the cytochrome P-450 system and may render the birth control pill, patch, or ring less effective. Contrary to popular belief, the contraceptive effectiveness of combined hormonal contraception is not affected by most broad-spectrum antibiotics [50].

History of pelvic inflammatory disease. Pelvic inflammatory disease history within the past 12 months is a contraindication to IUD placement. However, nulliparity, history of sexually transmitted infection without pelvic inflammatory disease, and history of multiple sex partners are not contraindications to IUD placement.

Insurance status. For patients who have unstable insurance status and therefore may be unable to afford the cost of hormonal contraception, the IUD or sterilization can be a good choice.

Case Scenarios
Scenario 1
A 33-year-old moderately obese woman with poorly controlled hypertension without vascular changes and who smokes regularly presents for contraception. She also has a history of deep venous thrombosis after the delivery of her last child. There is no history of gallbladder disease, bleeding disorders, migraine with aura, or personal history of breast cancer. The patient requests the patch. She does not wish to become pregnant again for “a few years.”

Recommendation. The level of efficacy for the patch is excellent, and return to fertility is usually within 2 months. There is no demonstrated increased risk for a cardiovascular event in a female smoker younger than age 35 years. However, her history of venous thrombosis and uncontrolled hypertension are significant risk factors that argue against both an unplanned pregnancy and use of estrogen-containing hormonal contraception. Additionally, if this patient weighs more than 90 kg, the patch may be less effective for her. This patient is not interested in further childbearing in the near future. IUD placement (copper-T or LNG-IUS), DMPA, or a contraceptive implant (Implanon) would all be good choices for this patient. Any future pregnancy should be planned with medical surveillance. This patient should also be encouraged to stop smoking.

Scenario 2
A 28-year-old slightly overweight woman with well-controlled type 2 diabetes without vascular changes presents for contraception. She has no history of gallbladder disease, bleeding disorders, thromboembolic event, migraine with aura, or personal history of breast cancer. She does not smoke. This patient requests the pill. However, she desires pregnancy within a year.

Recommendation. The pill is a highly effective method of contraception when used consistently. Because this woman is under age 35, her diabetes is uncomplicated, and she desires fertility within a year, the pill is a good choice. The patch or ring are also excellent options. The clinician should also recommend folic acid intake.

Table 2. Women Who Should Not Take Estrogen-Containing Contraception

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<thead>
<tr>
<th>Women age 35 and older who</th>
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<tbody>
<tr>
<td>Smoke</td>
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<tr>
<td>Have diabetes with or without vascular changes (retinopathy, nephropathy, neuropathy)</td>
<td></td>
</tr>
<tr>
<td>Have current hypertension</td>
<td></td>
</tr>
<tr>
<td>Have migraine with or without aura</td>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Women of any age who have</th>
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</thead>
<tbody>
<tr>
<td>Current ischemic heart disease</td>
<td></td>
</tr>
<tr>
<td>History of stroke</td>
<td></td>
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<tr>
<td>Migraine with aura</td>
<td></td>
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<tr>
<td>Diabetes with vascular changes (pill, patch, ring are safe for those without vascular changes)</td>
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<tr>
<td>Uncontrolled hypertension</td>
<td></td>
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<tr>
<td>Personal history of deep venous thrombosis/pulmonary embolism</td>
<td></td>
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<tr>
<td>Known thrombogenic mutation</td>
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<tr>
<td>Are less than 21 days postpartum</td>
<td></td>
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<tr>
<td>A personal history of breast cancer (family history is not a contraindication)</td>
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<tr>
<td>Symptomatic gallbladder disease</td>
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<tr>
<td>Active viral hepatitis (pill, patch, ring are safe for those in a carrier state)</td>
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<tr>
<td>Liver cirrhosis</td>
<td></td>
</tr>
<tr>
<td>Liver tumors</td>
<td></td>
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</tbody>
</table>
Scenario 3
A 42-year-old woman with history of monthly migraines without aura presents for contraception. The patient has a history of heavy menses that led to iron-deficiency anemia, for which she is on iron replacement therapy. Her older sister died of breast cancer last year. There is no history of gall-bladder disease, bleeding disorders, thromboembolic event, or personal history of breast cancer. She has no interest in further childbearing. She requests a copper IUD.

Recommendation. The copper IUD has an excellent level of efficacy. However, this form of contraception would be inadvisable in a woman who is on iron replacement therapy for anemia that is secondary to menorrhagia. The levonorgestrel IUD would be a good choice for this patient. Also with an eye towards treating her heavy menses, an estrogen-containing hormonal method such the pill, patch, or ring are also excellent options. Breast cancer in a first-degree relative is not a contraindication to use of these methods. DMFA could also be considered, but because this method is often associated with irregular bleeding, this method is not ideal for this patient. Because she expressed a desire for a permanent end to her fertility, surgical sterilization or Essure placement should also be discussed. These methods, however, will not treat her menorrhagia.

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Financial disclosures: None.

Author contributions: conception and design, YS, CW; drafting of the article, YS, CW; critical revision of the article, CW.

References

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