Effectiveness, Safety, and Comparative Side Effects

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KEY POINTS

Effectiveness:
- More than 1 million pregnancies occur every year in the United States among people using contraception.
- Contraceptive effectiveness is one of several key factors that most people consider when choosing their method of contraception.
- When discussing contraceptive effectiveness in the context of comprehensive person-centered counseling, grouping methods into three effectiveness categories can be useful to facilitate understanding:
  - The category with the most highly effective methods includes intrauterine devices (IUDs), contraceptive implants, and permanent contraception, which entail the lowest risk of pregnancy with either perfect or typical use ($<$ 1%); this very low risk applies to all users.
  - Methods in the second effectiveness category include injectables, pills, patches, and rings. These also have a very low risk of pregnancy when used correctly and consistently ($<$ 1% with perfect use), but with typical use, these methods have pregnancy rates between 4% and 7%, with variability influenced by age, coital frequency, and many other factors.
  - Methods in the third effectiveness category include condoms (internal and external), diaphragm, withdrawal, sponge, fertility awareness–based methods, spermicides/vaginal pH regulators, and the cervical cap. These methods have the highest pregnancy rates during both perfect use ($\geq$ 2%) and typical use ($\geq$ 8%) with even greater variability for individual user.
    - However, limited, moderate-quality evidence suggests that some specific fertility awareness–based methods may be as effective as the second category of methods.

- The simultaneous use of two different methods can lower pregnancy risk and, if a condom is one of the methods, can also reduce the risk of transmission of sexually transmitted infections.

Safety:
- While all medications and devices have risks and benefits, in the vast majority of cases, pregnancy confers a greater risk than use of a contraceptive method. Screening for personal health risk factors, as well as discussing reproductive desires, is important when selecting a contraceptive method.

Side Effects:
- Contraceptive side effects, including changes in bleeding patterns, are a major cause of method nonuse, dissatisfaction, and discontinuation. Beneficial side effects, or noncontraceptive benefits, may motivate individuals to use a method consistently.

Individuals must weigh many factors when deciding which contraceptive method or methods they will use. The best method of contraception for an individual or couple is one that is safe and that is consistent with their preferences for particular contraceptive characteristics, their reproductive desires, and their values. Contraceptive decision making can be challenging. A method that is not effective for an individual or couple can lead to an unintended pregnancy. A method that is not safe for the user can lead to unacceptable health risks. A method with intolerable side effects, or that does not fit well into the individual's life, is not likely to be used correctly or consistently, increasing the risk of failure, and will detract from the user's general well-being.

Most people will use a variety of contraceptive methods throughout their lives. When choosing a method or methods, individuals' choices are based on many factors, with side effects/safety and effectiveness being mentioned most frequently, followed by ease/frequency/duration of use, and other factors, according to a recent systematic review by the World Health Organization (WHO).[1] Other factors include access, reversibility, timing of the return of fecundity after discontinuation, positive contribution to sex or at least noninterference in sex, menstrual bleeding changes, costs, ability for discreet use, and other characteristics. Through counseling, you can help your client choose the method best suited to their priorities. (See Chapter 4, Person-Centered Reproductive Health Conversations and Contraceptive Counseling.)

Information on levels and trends in contraceptive use in the United States is based on the National Surveys of Family Growth (NSFG), periodic surveys conducted by the National Center for Health Statistics in which people who self-identify as female ages 15 to 49 are interviewed about topics related to childbearing, family planning, and maternal and child health. Among the 72.7 million women of reproductive age (ages 15 to 49), about 65% (47 million) were using some method of contraception, according to the most recently available NSFG, collected in 2017–2019.[2] Among the 35% (25.2 million) who were not currently using a method, about one-fifth were sexually active and not seeking pregnancy. The remaining four-fifths had had a hysterectomy, were trying to become pregnant, were pregnant, were interviewed within 6 weeks after the completion of a pregnancy, or had not had intercourse during the 3 months prior to the survey.[3] Most sexually active women not seeking pregnancy

use a contraceptive method, but between 6% and 17% of all women not seeking pregnancy (~5.1 million) are not using any contraceptive method.[4-6]

Today, the most popular contraceptive methods in the United States are fallopian tube surgery (previously referred to as female sterilization;13.2 million), oral contraceptive pills (10.1 million), external (formerly referred to as male) condoms (6.1 million), intrauterine devices (IUDs; 6 million), vas surgery (formerly referred to as male sterilization; 4.1 million), withdrawal (also called coitus interruptus; 2.7 million), and implants (1.7 million) (**Table 5-1**). Fewer than 1 million women use rings, patches, or methods in the combined category of diaphragms, cervical caps,

Table 5-1 Number of US Women 15–49 Using Each Method and Percent Using Among Women at Risk of Unintended Pregnancy

Method	Number of women 15–49, in millions[*]	% Using among sexually active women not seeking pregnancy[†]
Fallopian tube surgery (Female sterilization)	13.2	23.9
Oral contraceptive pill	10.1	16.4
Male (external) condom	6.1	13.2
IUD	6.1	12.0
Vas surgery (Male sterilization)	4.1	8.5
Withdrawal	2.7	5.8
Implant	1.5	2.6
Injectable (Depo-Provera)	1.4	2.1
Fertility awareness–based method[‡]	1.2	2.6
Emergency contraception	1.0	0.2
Contraceptive vaginal ring	0.6	1.2
Transdermal patch	0.2	0.4
Other method[§]	0.1	0.2
No method	25.2	11.0

[*]"Contraceptive users" does not restrict to those who have been sexually active in the previous 3 months. Table shows only most effective method used at last sex.
[†]"Sexually active women not seeking pregnancy" includes all women who report sexual activity in the previous 3 months; are not currently pregnant, seeking to become pregnant, or postpartum; and are not noncontraceptively sterile.
[‡]Fertility awareness–based methods include periodic abstinence, cervical mucus tests, temperature tests, or calendar rhythm.
[§]Includes diaphragm, female condom, cervical cap, spermicides, and other methods.

Modified from https://www.guttmacher.org/fact-sheet/contraceptive-method-use-united-states; data derived from the 2017–2018 National Survey of Family Growth.

spermicides, and internal (formerly referred to as female) condoms, though data do not reflect the several new methods that have become available since these data were collected.

The most recent information on contraceptive use by age is from the 2015–2017 NSFG. We believe these patterns likely hold in the most recent data, as the overall method mix has not substantially changed.[3] The contraceptive methods women use differ substantially by age, as shown in **Figure 5-1**. Almost three-quarters of adolescents 15–19 use pills (45%), implants (16%), or injectables (12%), while fewer than 10% of women over age 40 use these methods. The vast majority (79%) of women 45–49 who are using contraception rely on permanent methods: fallopian tube surgery (61%) or vas surgery (18%). Condom use is highest among women in their 20s and early 30s (18% to 20%), and slightly lower among 15- to 19-year-olds (14%). Use of withdrawal (7% to 11%) and fertility awareness–based methods (FABMs) (2% to 4%) are also highest among women 20–34. Fewer than 1% of women in any age group report other coitally dependent methods, including the diaphragm, sponge, or spermicides, as their most effective method.[5]

Use of the external (male) condom, withdrawal, FABMs, and "other" methods is greater than indicated in Table 5-1, because some people use these methods in
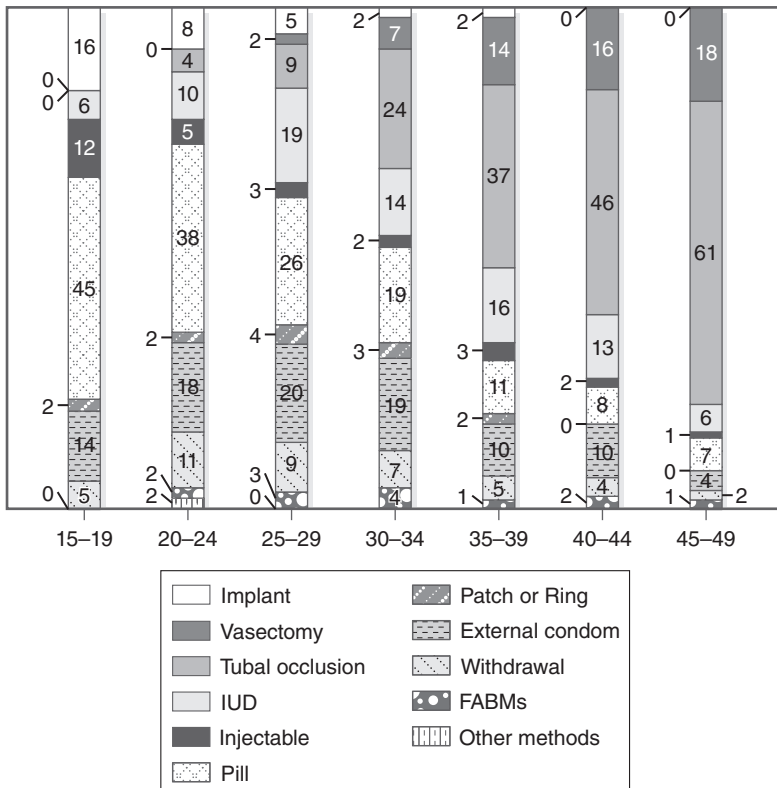

Figure 5-1 Method mix among all women using contraception by age.

addition to another method. In the NSFG, women were asked to report all contraceptive methods used in the current month for any reason (for protection against either pregnancy or STIs). When more than one method was reported, only the most effective method is coded as the current method. The most recent data available on multiple method use come from the 2013–2015 NSFG.[7] When data on the most effective method used was recoded to capture all use of the external condom in the month of interview, the fraction using external condoms among all users 15–44 at risk rises by 48%, from 14.5% to 21.4%. When the data are recoded to capture all use of withdrawal, the fraction using withdrawal rises by 96%, from 8.1% to 15.8%. The percentage using FABMs increases 48%, from 2.2% to 3.2%.

Couples' use of the mix of methods shown in Table 5-1 resulted in an estimated 1.2 million pregnancies in 2017, 21% of the total (5.7 million) pregnancies occurring that year. The 11% of people sexually active, not seeking pregnancy but not using contraception resulted in an additional 1.4 million pregnancies (25% of total pregnancies). People actively seeking pregnancies accounted for only slightly over half (54%) of the total pregnancies. Nearly half (46%) of pregnancies were reported to be mistimed (wanted later) or unwanted (not wanted at any time), resulting in 2.6 million unintended pregnancies per year.[8] Thirty-seven percent of these pregnancies occurred among individuals who reported using contraception.[8-10]

Effectiveness: "How Well Will It Work?"

"How well will it work?" is a question frequently asked about any method of contraception. Although this question cannot be answered with certainty for any specific couple, clinicians and counselors can help clients understand something of the difficulty of quantifying effectiveness. In this chapter, we use the term *efficacy* to refer to data on how well a method works with perfect (consistent) use of that method. Efficacy reflects how well a method prevents pregnancy in clinical trials when study participants use the method correctly and consistently as defined by the manufacturer's instructions. We use the term *effectiveness* to indicate how well a method works with actual, real-life, typical use. Effectiveness varies according to many factors including the intrinsic efficacy of the method, whether the method is easy to use correctly, and user characteristics such as age and frequency of intercourse. These factors can vary significantly in different populations. Our current understanding of the literature on contraceptive efficacy during perfect use and effectiveness during typical use is summarized in **Table 5-2**.

It is useful to distinguish between measures of contraceptive effectiveness and measures of the risk of pregnancy during contraceptive use. Many people, including clinicians and clients, prefer positive rather than negative statements; instead of the negative statement that 20% of individuals using a method become pregnant during their first year of use, they prefer the alternative positive statement that the method is 80% effective. Strictly speaking that is not correct; it does not follow that the method is 80% effective, because it is not true that 100% of these individuals would have become pregnant if they had not been using contraception. However, no study can ascertain the proportion who would have become pregnant had they not used the contraceptive method under investigation. Our best estimate of the probability of pregnancy during 1 year of intercourse with no contraception is 85% (see No Method Section on p. 144). Therefore, we focus attention on pregnancy rates or probabilities of pregnancy during contraceptive use, which are directly measurable. When the risk

Table 5-2 **Percentage of Users Becoming Pregnant During the First Year of Contraceptive Use in the United States (Perfect Use and Typical Use) and Internationally (Typical Use)***

Method	% of Users Experiencing an Unintended Pregnancy within the First Year of Contraceptive Use			Effectiveness Category
	Perfect Use[a]	Typical Use, United States[b]	Typical Use, International Population-based Survey Estimates[c]	
Implant	0.1	0.1	**0.3**	Category 1 < 1 pregnancy per 100 women in 1 year with either perfect or typical use
Vas surgery	0.1	0.15		
Fallopian tube surgery	0.5	0.5		
Intrauterine contraceptives				
LNG-releasing IUDs[d]	0.3	0.4		
Copper-bearing IUD	0.6	0.8	**1**	
Depot-medroxyprogesterone Acetate (DMPA, DepoProvera) Injectable	0.2	**4**	**2**	Category 2 1–7 pregnancies per 100 women in 1 year with typical use
Oral contraceptive pills (combined or progestin-only)	0.3	**7**	**6**	
Transdermal patches	0.3	**7**		
Contraceptive vaginal rings	0.3	**7**		
Fertility awareness–based methods[e]				This group of methods spans effectiveness Categories 2 and 3.
Sensiplan	0.4	2		
Natural Cycles		7		
Clue	3	8		
Standard Days	5	13		
Billings	3	23		
Calendar rhythm	NA	**15**	**19**	

Method	% of Users Experiencing an Unintended Pregnancy within the First Year of Contraceptive Use			Effectiveness Category
	Perfect Use[a]	Typical Use, United States[b]	Typical Use, International Population-based Survey Estimates[c]	
External (male) condom	2	**13**	**9**	Category 3 More than 8 pregnancies per 100 women in 1 year with typical use
Sponge (both parous and nulliparous)[f]	12	17		
Diaphragm[g]	16	17		
Withdrawal	4	**20**	**17**	
Internal (female) condom	5	21		
Vaginal pH regulator (Phexxi)	12	21		
Spermicides	16	21		
Cervical cap (FemCap)	22	22		
No method[h]	85	85		

Emergency contraceptives: Use of emergency contraceptive pills or placement of an IUD after unprotected intercourse substantially reduces the risk of pregnancy. (See Chapter 10 Intrauterine Devices [IUDs]).

Lactational Amenorrhea Method: LAM is a highly effective, temporary method of contraception.[i] (See Chapter 17, Coitus Interruptus [Withdrawal, the Pull-Out Method].)

[a] Among couples who initiate use of a method (not necessarily for the first time) and who use it perfectly (both consistently and correctly) for the first year, the percentage who experience an accidental pregnancy if they do not stop use for any other reason. Most estimates in this column come from clinical data; see text for the derivation of the estimate for each method.

[b] Among couples who initiate use of a method (not necessarily for the first time), the percentage who experience an accidental pregnancy during the first year of typical use if they do not stop use for any reason other than pregnancy. Estimates of the probability of pregnancy during the first year of typical use for withdrawal, the male condom, the pill, and Depo-Provera are taken from the 2006–2010 National Survey of Family Growth (NSFG) corrected for under-reporting of abortion. See text for the derivation of estimates for the other methods.

[c] Among couples who initiate use of a method (not necessarily for the first time), the percentage who experience an accidental pregnancy during the first year if they do not stop use for any reason other than pregnancy. Estimates in this column are based on population-based Demographic and Health Survey data from 15 countries, not adjusted for under-reporting of abortion. All estimates in this column are calculated using life tables. See text for details.

[d] For details rates for specific LNG-releasing IUDs, see text.

[e] Multiple FABMs exist with varying features; a subset are shown here. See Chapter 15, Fertility Awareness-Based Methods, for additional detail.

[f] Estimates are for all sponge users. For nulliparous women, the typical-use pregnancy rate is 14% and the perfect use pregnancy rate is 9%. For parous women, the typical use pregnancy rate is 27% and the perfect use pregnancy rate is 20%.

[g] With spermicidal cream or jelly.

[h] This estimate represents the percentage who would become pregnant within 1 year without using contraception. See text.

[i] However, to maintain effective protection against pregnancy, another method of contraception must be used as soon as menstruation resumes, the frequency or duration of breastfeeds is reduced, bottle feeds are introduced, or the baby reaches 6 months of age.

*Bold estimates are from population-based surveys.

is framed as the probability of *not* becoming pregnant, i.e., 100 minus the pregnancy rate, this may be good marketing, but it overestimates the true effectiveness because no population is certain to conceive during 1 year of not using contraception.

Data Sources and Methods for Estimating Contraceptive Effectiveness

Pregnancy rates during contraceptive use come from two different types of studies: (1) analyses of population-based survey data like the NSFG, which samples the total US population to reflect the actual experience of a representative sample of contraceptive users with differing demographic characteristics, and (2) clinical trials, which enroll a select group of individuals whose experiences may not be generalizable to the wider population. Both typical- and perfect-use pregnancy rates can theoretically be measured in clinical trials. However, for methods with a sufficiently large number of users, experts generally rely on—and we have used whenever available—typical-use rates calculated with survey data for several reasons, beyond the generalizability issues mentioned above. First, population-based survey data capture the lived experiences of contraceptive users outside a clinical setting. These real-world estimates are the most relevant for patients interested in understanding how effective contraceptive methods would be for them. Second, the behavior of people in clinical trials is most likely affected by frequent contact with investigators and study staff, particularly for methods that are highly user-dependent. Such frequent "reminders" about their contraceptive use may make trial participants more likely to use the method correctly and consistently than they would outside of a trial setting, potentially biasing pregnancy rates downward.

Population-based survey estimates are not without their flaws. The two largest sources of population-based contraceptive effectiveness data—the NSFG in the US, and the Demographic and Health Surveys (DHS) internationally—are surveys that collect data retrospectively. These surveys ask respondents about their current contraceptive use, recent pregnancies and births, and then ask respondents to think back about which contraceptive method they were using each month for the past 2 to 3 years (NSFG) or 5 to 6 years (DHS). Retrospective data collection, especially about events that occurred far in the past, is potentially subject to recall bias, both intentional and unintentional.[11-13] If interviewees do not accurately recall the dates of their contraceptive use and reasons for discontinuation, including discontinuation because they became pregnant, typical-use pregnancy rates could be inaccurate. Additionally, researchers expect respondents to omit at least some pregnancies that occurred during contraceptive use, and especially those pregnancies that resulted in induced abortion. For this reason, pregnancy rates estimated from NSFG data are often adjusted for under-reporting of abortion.[*][14]

Pregnancy rates from population-based surveys and those from clinical trial data are sometimes calculated differently. The "gold standard" is to use single-decrement

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[*] US-based estimates, drawn from NSFG data, are adjusted for under-reporting of abortion using additional data from a survey of US abortion patients. Such adjustment for abortion is not currently feasible for DHS data, due to limitations in estimation of abortion in many international settings.

Evidence suggests that more than half of abortions are not reported in NSFG data.[15] If interviewees are less likely to report episodes of contraceptive use that ended in a preg-

life-table methods that calculate the cumulative incidence of pregnancy among a group of contraceptive method users, beginning from method initiation and continuing through the 12th full month of use for a 1-year pregnancy rate.[19] Life tables allow for inclusion of varying durations of contraceptive use without introducing the problems associated with the Pearl Index (see below). These life-table rates are statistically unbiased and standardized to represent the experience of an average user within the study sample during 1 year of use. This approach is used with all estimates presented in this chapter.

Many clinical trials use an approximation of the life table method called a Pearl Index which, despite its well-known shortcomings, remains the standard method used by the US Food and Drug Administration (FDA) to analyze clinical trial data. The Pearl Index is calculated by simply dividing the number of pregnancies during contraceptive use by the number of years of exposure to the risk of pregnancy contributed by all participants in the study.[†] This measure can be misleading when one

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nancy that was then aborted, pregnancy rates during contraceptive use will be too low. Researchers who use NSFG data to produce typical-use pregnancy rates therefore make adjustments to attempt to counteract such under-reporting. To adjust the most recent estimates of pregnancy rates presented in Table 5-2, researchers used information from the 2008 Abortion Patient Survey (APS), a nationally representative survey of abortion patients that includes information on contraceptive use at the time of pregnancy.[16] Briefly, researchers apply weights to the few episodes of contraceptive use that are reported to end in pregnancy followed by abortion, "weighting up" those contraceptive episodes to reflect the likely number of abortions after failures that occurred in each subpopulation (for details see Sundaram et al.[17]).

The correction for under-reporting of abortion may produce estimates that are too high because patients in abortion clinics (surveys of whom provided the information for the correction) tend to over-report use of a contraceptive method at the time they became pregnant (social desirability bias). Moreover, those interviewed for the NSFG also might over-report use of a contraceptive method at the time of an unintended pregnancy that led to a live birth. Evidence for this suspicion is provided by uncorrected first-year probabilities of pregnancy of 3.7% for the IUD and 2.3% for the implant (methods with little or no scope for user error) in the 1995 NSFG; these probabilities are much higher than rates observed in clinical trials of these methods.[18] Such overreporting of contraceptive use is unsurprising; individuals may feel less stigmatized in acknowledging an unintended pregnancy if reported as stemming from contraceptive failure versus from contraceptive nonuse. Thus, biases in opposite directions affect these estimates. Pregnancy rates based on the NSFG alone would tend to be too low because induced abortions (and contraceptive failures leading to induced abortions) are under-reported, but they would tend to be too high because contraceptive failures leading to live births are over-reported. We reason that the former bias is the more important one.

In many countries where the DHS works, induced abortions are illegal. There is likely underreporting of failures terminated in abortion in international survey data too, but because no comparable data source to the APS exists internationally, there is no similar adjustment made to DHS-based pregnancy rate estimates.

† Specifically, the calculations for the Pearl Index are:

- If a study used monthly intervals, the formula is: (# of pregnancies / # of months of exposure) × 1200.
- If a study used cycle intervals, the formula is: (# of pregnancies / # of cycles of exposure) × 1300.

wishes to compare pregnancy rates obtained from studies with different durations of exposure to the risk of pregnancy during contraceptive use. The likelihood of pregnancy declines over time because those most likely to become pregnant do so at earlier durations of contraceptive use and exit from observation. Those still using contraception after long durations are increasingly less likely to become pregnant, so an investigator could (wittingly or unwittingly) drive the reported pregnancy rate toward zero by running the trial "forever."[‡]

Because estimates for different contraceptive methods in this chapter come from studies with different durations of exposure (e.g., 6 months, seven cycles, 1 year), and the purpose is to enable readers to compare estimates across contraceptive methods, we do not use any Pearl Index estimates in this chapter. We instead focus on life-table measures of pregnancy during contraceptive use, and use standard methods to extrapolate from shorter durations to a standard 12-month time period, so pregnancy rates for each contraceptive method can appropriately be compared to each other (see details under each specific method heading, below). These life-table measures are easy to interpret and control for the distorting effects of varying durations of use. Ideally, we would present perfect-use rates from clinical data and typical-use rates calculated with life tables from population-based survey data for all contraceptive methods. However, only five methods (injectables/DMPA, oral contraceptive pills, external condoms, calendar rhythm method, and withdrawal) had enough users in the most recent NSFG analyzed for contraceptive effectiveness to allow population-based estimates of typical-use pregnancy rates.[17,21] We therefore base the estimates for many of the remaining methods on clinical studies because there is no US-based alternative. In a few instances where robust data are not available from either NSFG or US-based clinical trials, we simply use the best available information (see below). We also include a column of typical-use pregnancy rates using international data from the DHS, which provides both a range of estimates across different populations, and the ability to produce population-based rates for seven contraceptive methods due to larger sample sizes.

Perfect Use

In the first column of Table 5-2, we provide estimates of the probabilities of pregnancy during the first year of perfect use. A method is used perfectly when it is used consistently and correctly as defined by a specified set of rules. For many methods in the third category, perfect use requires correct use at every act of intercourse. Some perfect-use pregnancy rates reported in the literature have been calculated incorrectly and are too low[22] (see Interpretation of Effectiveness Data, p. 135). We expect that our understanding of efficacy during perfect use will be enhanced by additional studies.

[‡] For example, two investigators using the NSFG could obtain Pearl Index pregnancy rates of 7.5 and 4.4 per 100 woman-years of exposure for the condom.[20] One (who got 4.4) allowed each study subject to contribute a maximum of 5 years of exposure while the other (who got 7.5) allowed each study subject to contribute only 1 year. Which investigator is incorrect? Neither. The two rates are simply not comparable.

Typical Use

In the second column of Table 5-2, we provide estimates of the probabilities of pregnancy (adjusted for under-reporting of abortion in the NSFG) during the first year of typical use of each method in the United States. Pregnancy rates during typical use reflect how effective methods are for the average person who does not always use methods correctly or consistently. Typical use does not imply that a contraceptive method was always used. In the NSFG and in most clinical trials, people are "using" a contraceptive method if they consider themselves to be using that method. Typical use of the condom could include actually using a condom only occasionally, and a person could report that they are "using" oral contraception even though they sometimes forget to take pills. In short, *use*—which is identical to *typical use*—is a very elastic concept that depends on an individual's perception.

The third column shows first-year typical-use pregnancy rates from international survey data. These data provide additional population-based survey estimates of typical use across a wide variety of populations from 15 countries in Asia, Eastern Europe, Latin America and the Caribbean, the Middle East, and sub-Saharan Africa selected for their relatively high calendar data quality.[23] Estimates generally align with, though are slightly lower than, estimates from NSFG data for contraceptive methods that can be measured with both data sources, as expected given that DHS-based estimates cannot be adjusted for under-reporting of abortion. The exception is for calendar rhythm, in which the DHS-based estimate is higher. This column also provides the only population-based survey estimates of pregnancy rates during implant and copper-bearing IUD use.

Interpretation of Effectiveness Data

In Table 5-2, we have relied on life table estimates derived from population-based studies wherever possible. Perfect-use estimates are almost exclusively from clinical trials. Typical-use estimates from population-based surveys are highlighted in bold in column two. We encourage readers to consider the unbolded, clinical-trial typical-use estimates to generally be lower than pregnancy rates that truly occur in a population. The differences between clinical-trial and population-based estimates can be assumed to be larger for methods in the second, and especially the third category, which are easier than methods in the first category to use incorrectly or inconsistently.

Given the challenges and utility of communicating point estimates of the various methods (see Pitfalls and Challenges of Communicating Pregnancy Risk, p. 153), many experts prefer to group methods into meaningful categories.[14] **Figure 5-2** uses the typical-use pregnancy rates to group contraceptive methods into categories, has been empirically tested both domestically[24] and internationally[25] for comprehensibility and adopted by the WHO,[26] and may be a useful counseling tool as part of comprehensive person-centered counseling (Chapter 4).[27]

Given the shameful history of some in the medical establishment coercively using permanent contraception, IUDs, and implants, there is near-universal agreement that providers should prioritize patient preference and avoid promoting particular methods or exclusively prioritizing contraceptive effectiveness during counseling. Promoting methods and directing patients toward any particular method damages trust and causes harm. Tiered effectiveness charts are a valuable visual aid to use during counseling to clarify comparative effectiveness. However, contraceptive
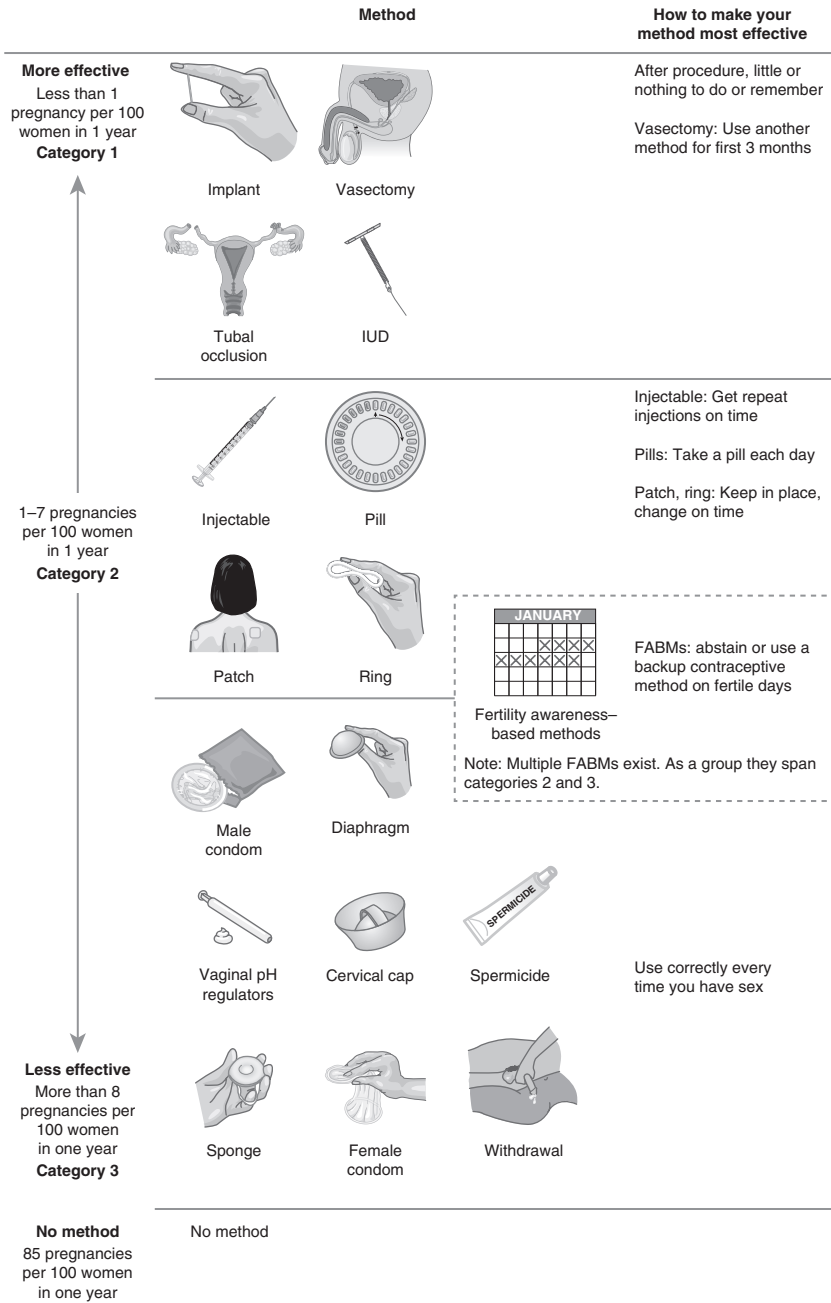
	Method	How to make your method most effective

More effective
Less than 1 pregnancy per 100 women in 1 year
Category 1

Implant | Vasectomy

Tubal occlusion | IUD

After procedure, little or nothing to do or remember

Vasectomy: Use another method for first 3 months

1–7 pregnancies per 100 women in 1 year
Category 2

Injectable | Pill

Patch | Ring

Injectable: Get repeat injections on time

Pills: Take a pill each day

Patch, ring: Keep in place, change on time

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Fertility awareness–based methods

FABMs: abstain or use a backup contraceptive method on fertile days

Note: Multiple FABMs exist. As a group they span categories 2 and 3.

Male condom | Diaphragm

Vaginal pH regulators | Cervical cap | Spermicide

Use correctly every time you have sex

Less effective
More than 8 pregnancies per 100 women in one year
Category 3

Sponge | Female condom | Withdrawal

No method
85 pregnancies per 100 women in one year

No method

Figure 5-2 Effectiveness Categories

counseling based on tiered effectiveness can prioritize effectiveness to an extreme that is coercive and undermines patient autonomy. Counseling on effectiveness should always accompany thorough discussions of other key characteristics important to an individual patient. Figure 5-2 is not meant to be the sole visual aid used during contraceptive counseling but rather a useful tool for clients interested in the effectiveness offered by various methods.

Methods in the top category have typical-use pregnancy rates below 1% and the perfect-use rates are nearly identical ($<$ 1%) because they do not require the individual to "actively" use the method regularly (monthly, daily, or with every act of intercourse). Importantly, the methods have similarly low pregnancy rates regardless of the population studied, statistical approach employed, or data source and thus apply to all users of these methods.

Methods in the second category have typical-use pregnancy rates between 1% and 7% but substantially lower pregnancy rates during perfect use ($<$ 1%) illustrating these methods are highly effective if used correctly and consistently. Different sociodemographic subgroups can have widely varying typical-use pregnancy rates. For example, in the NSFG analysis by Fu et al., the rate for oral contraceptive pills ranged from 3.3% to 48.4% among different demographic groups.[28] The overall typical-use pregnancy rates for second category methods are not applicable to any one user and may not be useful to focus on during counseling; rather, their utility lies in grouping methods into categories.[14]

Finally, methods in the third category all have typical-use pregnancy rates above 8% and are generally not highly effective ($\geq$ 2%) even if used correctly and consistently. Again, none of the rates are applicable to any one user for counseling purposes but are sufficiently robust and useful for categorization, which is helpful to illustrate differences in comparative effectiveness.[14]

As a group, FABMs span categories 2 and 3, so are indicated as such in Table 5-2 and Figure 5-2.

Data Sources and Derivation for Effectiveness Estimates of Individual Contraceptive Methods

To update pregnancy rates for this chapter, we relied heavily on the approach and literature review of previous editions of this text. For pregnancy rates reported in population-based surveys we contacted investigators working with the current round of NSFG to make sure no additional pregnancy rate analyses have been published since the analysis referenced in the last edition.[8] We added population-based rates from a 15-country peer-reviewed paper published in 2019. For clinical trial data, we searched for systematic reviews as well as individual studies published since the last edition, and contacted authors of individual chapters to ensure we were basing our analysis on the most recent literature. We reviewed clinical trial data for several new methods of contraception, including the segesterone acetate and ethinyl estradiol vaginal ring (Annovera), the drospirenone-only pill (Slynd), a vaginal pH regulator (Phexxi), and the levonorgestrel and ethinyl estradiol transdermal patch (Twirla). We aimed to provide the best estimates of pregnancy rates for each major contraceptive category (e.g., oral contraceptive pills, levonorgestrel-releasing IUDs, contraceptive vaginal rings) rather than separate effectiveness estimates for every hormonal formulation and dosing regimen. The source and derivation for each estimate are described by contraceptive method category below, with additional

details provided in Appendix B: Method Efficacy Tables, which is included in the eBook (indicated by **B-** before the table number).

Perfect Use of Contraceptive Implant, DMPA Injectable, and Oral Contraceptive Pills, and Typical use of Contraceptive Implant. Information about the contraceptive implant Nexplanon is taken from studies of Implanon because the dose of etonogestrel is the same and no new efficacy studies were required for approval. Implanon failures are rare (**Table B-15**).[29] We took the pregnancy rate during typical use of Implanon (0.1%) from a multicenter study,[30] and set the probability during perfect use equal to that during typical use. In that same study, Jadelle, a two-rod contraceptive implant containing levonorgestrel and available in many countries outside the United States, had a 0% typical-use pregnancy rate in the first year and both implants had the identical cumulative typical-use 3-year pregnancy rate of 0.4%. In another recent trial comparing Jadelle to Levoplant, another two-rod implant containing levonorgestrel available outside the United States, both products had zero pregnancies during the first year of use.[31] The typical-use estimate of 0.3 in the third column reflects the real-life experience of several thousand women and is the best estimate we have of the (very low) implant pregnancy rate in the general population.[23]

The perfect-use pregnancy rate estimate of 0.2% for depot-medroxyprogesterone acetate (DMPA) is the weighted average of the results from the seven trials of the 150-mg intramuscular dose (90-day or 3-month) and the two trials of the 104-mg subcutaneous dose shown in **Table B-13**.[32-39] These trials yield a pregnancy rate estimate for perfect rather than typical use either because participants late for an injection were discontinued or because all pregnancies reported occurred during actual use (after one injection but before the next was scheduled). In the two trials of DMPA-SC, there were no reported pregnancies during perfect use in either study.[53,54]

Although the lowest reported pregnancy rate for the combined pill during typical use is 0% (**Table B-12**), more recent studies indicate that pregnancies do occur, albeit rarely, during perfect use.[40,41] Hence, we set the perfect-use estimate for the pill at the very low level of 0.3%. Perfect-use pregnancy rates for progestin-only pill formulations are generally slightly higher than those for combined pills (see **Table B-11**), though differences may not be statistically significant.[42] Whether the progestin-only pill is less effective than the combined pill during perfect use is unknown.

Typical and Perfect Use of Permanent Contraception. The weighted average of the results from the nine vasectomy studies in **Table B-17** analyzed with life-table procedures is a 0.02% partner pregnancy rate (perfect use) in the year following the procedure.[43-51] In eight of these studies, pregnancies occurred after the ejaculate had been declared to be sperm-free. This perfect-use estimate of 0.02% is undoubtedly too low, because clinicians are understandably hesitant to publish articles describing their surgical failures and journals would be reluctant to publish an article documenting poor surgical technique. The difference between typical-use and perfect-use pregnancy rates for vasectomy would depend on the frequency of unprotected intercourse after the procedure had been performed but before the ejaculate had been certified to be sperm-free. We kept the estimates the authors of previous editions of this text "arbitrarily set" at 0.15% for typical use and 0.10% for perfect use.

For current methods of fallopian tube surgery, there is almost no possibility of user error. Hysteroscopic methods are more subject to user error but are not currently available in the United States. The typical- and perfect-use pregnancy rate estimates (both 0.5%) are the pooled results from the US Collaborative Review of Sterilization, a prospective study of 10,685 individuals undergoing fallopian tube surgery (see **Table B-18**).[52] We are less concerned about publication bias with tubal than with vas surgery for permanent contraception because the largest studies of tubal surgery are based on prospective, multicenter clinical trials, not retrospective reports from one investigator. An increasing proportion of surgeons are favoring bilateral salpingectomy compared to other methods of tubal surgery in recent years, primarily due to evidence that a significant proportion of ovarian cancers originate in the distal fallopian tube.[53] Large prospective efficacy studies have not been performed; however, presumably this method is more effective than other methods of female permanent contraception.[54]

Typical and Perfect Use of Intrauterine Devices. All typical-use and perfect-use pregnancy rates for the hormonal formulations are low, below 1%, and to reinforce our caution not to put any emphasis on the differences among these very small probabilities, we have generalized the estimates to the average across the four formulations: 0.3 for perfect use and 0.4 for typical use. The formulation-specific rates are described below and in **Table B-14**.

The estimate for typical use of the copper-bearing IUD (0.8%) is taken directly from the largest study for Paragard.[55] Typical-use estimates for Mirena (52 mg LNG) (0.7%) and Skyla (13.5 mg LNG) (0.4%), come from the largest studies of these methods.[56,57] The typical-use estimates for Kyleena (19.5 mg LNG) (0.2%) and Liletta (52 mg LNG) (0.1%) are taken from the only studies of these methods.[57,58]

Perfect-use rates for IUDs are calculated for devices that remain in position, excluding pregnancies that occurred after expulsion. The estimate for perfect use of the Paragard (0.6%) was obtained by removing the pregnancies that resulted when the device was not known to be in situ from the numerator of the pregnancy rate.[59] The perfect-use estimates for Mirena (0.5%), Skyla (0.3%), and Kyleena (0.2%) were derived under the assumption that the same proportions of pregnancies during contraceptive use occurred when the device had been expelled (25%). No differences in the typical-use and perfect-use estimates for Kyleena are apparent due to the fact that only one significant digit is shown. The perfect-use rate for Liletta (0.1%) was obtained by removing the one pregnancy that occurred after an expulsion. None of these studies focused on postpartum or postabortion IUD placements, which have higher expulsion rates.[60,61]

Typical Use of DMPA Injectable, Oral Contraceptive Pills, External (Male) Condom, and Withdrawal. Our estimates of the probability of pregnancy during the first year of typical use for DMPA (4%), the oral contraceptive pill (7%), the external (male) condom (12.6%), and withdrawal (20%) are derived from the 2006–2010 NSFG corrected for under-reporting of abortion.[17] These current estimates are generally lower than the previous estimates derived from the 2002 NSFG (also corrected for abortion under-reporting), except withdrawal (19.9% vs. 18.4%). The most notable change in the estimated probability of pregnancy is for the male condom (12.6% vs. 17.4%).[62]

The NSFG does not ask for brand of pill; thus, combined and progestin-only pills cannot be distinguished. However, since use of the combined oral

contraceptive (COC) pill is far more common than use of the progestin-only pill (POP), the results from the NSFG overwhelmingly reflect typical use of COCs.[63] The pregnancy rates of progestin-only pills may be higher than that for combined pills since northindrone-containing progestin-only pills are probably less forgiving of nonadherence to the dosing schedule. (See Chapter 9, Contraceptive Implant.) However, DRSP-containing POPs suppress ovulation and are more forgiving of inconsistent pill use.[64]

Typical and Perfect Use of the Contraceptive Patch and Vaginal Ring. The typical-use (7%) and perfect-use (0.3%) estimates for transdermal patches (Xulane and Twirla) and contraceptive vaginal rings (NuvaRing and Annovera) were set equal to those for combination hormonal pills. It is possible that the patch and ring will prove to have lower pregnancy rates than the pill during typical use because of better adherence with the dosing schedule. However, such superior efficacy has not been demonstrated in randomized trials. Two large-scale systematic reviews and meta-analyses of randomized trials found no significant differences in efficacy between the patch, ring, and COCs,[65] nor between the ring and COCs.[66] Formulations of the patch (2.6 mg levonorgestrel and 2.3 mg ethinyl estradiol; Twirla) and the 13-cycle ring (delivering 0.15 mg segesterone acetate and 0.013 mg ethinyl estradiol per day; Annovera) that have become available since these systematic reviews were conducted so far do not show efficacy profiles that are substantially different than the formulations included in the reviews. Note that patches are restricted to use among people with body mass index (BMI) < 30. (See the section on differences in effectiveness by body weight, p. 151.)

Typical and Perfect Use of Fertility Awareness–Based Methods (FABMs). Numerous kinds of FABMs exist; each relies upon tracking different indicators (for example, day of menstrual cycle, or cervical secretions, or basal body temperature, or urinary hormones, or some combination of these) and using different rules for interpreting that information. Typical-use pregnancy rates for most individual FABMs are challenging to estimate in national surveys in the United States given relatively few users of each. Furthermore, several clinical trials have used inappropriate methodological approaches for calculating perfect-use pregnancy rate estimates. A systematic review published in 2018 identified at least 14 different FABMs for which published evidence exists[67]; additional FABMs have also come onto the market since then. As it would be impractical to list all FABMs in summary Table 5-2, we list a subset of FABMs (Sensiplan, Natural Cycles, Clue, Standard Days Method, Billings Ovulation method, and calendar rhythm); detail on effectiveness for other FABMs is available in Chapter 15.

Probabilities of pregnancy during typical and perfect use for Sensiplan (2% typical use; 0.4% perfect use), the Standard Days method (13% typical use; 5% perfect use), and the Billings Ovulation Method (23% typical use; 3% perfect use) are taken from the only clinical studies of these methods that also contain correctly computed perfect-use pregnancy rate estimates, and which were rated moderate quality in the 2018 systematic review.[68-70] The only study on Clue Birth Control,[71] and three of four studies on Natural Cycles,[72-75] have not yet been formally assessed for quality in a systematic review. For Clue, we use pregnancy rates used by the FDA (8% typical use and 3% perfect use). For Natural Cycles, we use the typical-use lifetable-derived pregnancy rate of 7% used by the FDA,

which also aligns with two recently published studies.[74,75] There is no published lifetable perfect-use estimate for Natural Cycles; the Pearl Index estimate cited by the FDA is 1.8.[76]

Estimates for calendar rhythm are derived from population-based surveys. In the 2006–2010 NSFG, among women who report using either "rhythm or safe period by calendar" or "safe period by temperature or cervical mucus test, natural family planning," over 80% of observations were for "rhythm or safe period by calendar," and 15% are expected to experience pregnancy while using one of these FABMs during the first year of use (after adjustment for under-reporting of abortion).[17] This specific 15% estimate was unpublished, because the 257 observations did not meet the prespecified minimum of 50 observations at each month for the first 12 months. It is substantially lower than the estimate derived from the previous (2002) NSFG (24%)[68]; it is unclear if this change relates to instability in the estimates given the small number of women reporting use of these methods, to improved use of these methods between the two survey periods, or to other factors. The international estimate of 19% is based on a sample of 7,859 women, and is not adjusted for under-reporting of abortion.

Perfect Use of the External (Male) Condom. Our estimate of the probability of pregnancy during a year of perfect use of the external condom is based on results from the only three studies of the external condom meeting modern standards of design, execution, and analysis.[77-79] In each study, couples were randomly assigned to use either a latex condom or a polyurethane condom. All three studies reported pregnancy rates during consistent use but only one reported pregnancy rates during perfect use[78]; in that study the six-cycle probability of pregnancy during perfect use (0.7%) was 70% of that (1%) during typical use. We assumed that in the other two studies the six-cycle probability of pregnancy during perfect use would also be 70% during typical use, assumed that the pregnancy rate per cycle during perfect use would be constant, extrapolated a 1-year probability from the six-cycle probability reported for the latex condom in each trial, and took as our estimate the median (2%, also the mean) of those three estimates. This estimate is consistent with an estimate based on studies of condom breakage and slippage.[80] Under the assumption that 1.5% of condoms break or slip off the penis and that individuals have intercourse twice a week, then about 1.5% of users relying on this method would experience condom breaks during the half-week that they are at risk of pregnancy during each cycle. The per-cycle probability of conception would be reduced by 98.5%, from 0.1358 to only 0.0020, if a condom failure results in no protection whatsoever against pregnancy, so that about 2.6% of users at risk for pregnancy would become pregnant each year.[81] Unfortunately, breakage and slippage rates did not accurately predict pregnancy rates during consistent use in one clinical trial of the latex and polyurethane external (male) condom,[77] and estimates of condom breakage and slippage during intercourse or withdrawal vary substantially across studies in developed countries, from a low of 0.6% among commercial sex workers in Nevada's legal brothels[80] to a high of 7.2% among monogamous couples in North Carolina.[82]

Typical and Perfect Use of the Sponge. Our estimates of the probabilities of pregnancy during the first year of typical and perfect use of the sponge correspond with results of a reanalysis of data from a clinical trial in which participants were

randomly assigned to use the diaphragm or sponge.[83] The probability of pregnancy during typical use was 17%. The probability of pregnancy during typical use among parous users (27.4%) was twice as high as that among nulliparous users (14.0%). The results indicate that within the first year of perfect use, the range of pregnancy rates with sponge use will be 11.4% to 12.0% among all users, 19.4% to 20.5% among parous users, and 9.0% to 9.5% among nulliparous users. We take as our estimate the midpoints of these ranges: 12%, 20%, and 9%, respectively.[84]

Typical and Perfect Use of the Diaphragm. Results are based on the only clinical trial of the Caya diaphragm (formerly called SILCS), used with contraceptive gel.[85] That study estimated a 6-month probability of pregnancy during typical use of 10.4%; from this we extrapolated a 12-month probability of 17.4% under the assumption that the probability of pregnancy during the second 6 months is 75% of that in the first 6 months (the median of the four estimates for the sponge, cap, and diaphragm).[86] During perfect use, we extrapolated the six-cycle probability of 7.9% to a 13-cycle probability of 16.3%, under the assumption that the per-cycle probability remains constant under perfect use. Unlike the sponge and cervical cap, effectiveness of the diaphragm does not appear to vary between parous and nulliparous users.[84]

The only other diaphragms currently available in the United States are Milex: Arcing and Omniflex. These are made of silicone and have been available in the United States since the late 1970s; before that time, diaphragms were made of latex. There are no published efficacy studies. The latest estimate of the probability of pregnancy during typical use of the Ortho (now discontinued) and Milex diaphragms is based on the 1995 NSFG; use of the Ortho diaphragm has virtually disappeared, and would not reflect the experience of current users of Milex.[28] A recent systematic review found no differences in effectiveness between newer and older types of diaphragms [87]

Perfect Use of Withdrawal. Our estimate of the proportion becoming pregnant during a year of perfect use of withdrawal (4%) is simply a guess based on the reasoning that the risk of pregnancy resulting from pre-ejaculatory fluid is modest. Although three studies found no motile sperm in the pre-ejaculate,[88-90] the most recent study did not replicate this result, perhaps because the samples were examined within 2 minutes of production.[91] In that study, 37% of participants produced pre-ejaculatory samples that contained motile sperm, and the sperm concentration and the percentage of motile sperm were similar in an individual's pre-ejaculatory and ejaculatory specimens. However, the volume of the pre-ejaculate and therefore, the actual number of sperm, in the pre-ejaculate was low.

Typical and Perfect Use of the Internal (Female) Condom. The typical-use pregnancy rate estimate for the internal (female) condom is based on the results of a 6-month clinical trial of the FC condom, formerly called Reality condom; 12.4% of study participants in the United States experienced a pregnancy during the first 6 months of use.[86] We extrapolated the 12-month probability of pregnancy for users of FC condoms in the United States (21%) under the assumption that the probability of pregnancy during the second 6 months is 75% of that in the first 6 months.[86] The probability of pregnancy during 6 months of perfect use of FC by US participants who met the adherence criteria stipulated in the study protocol was 2.6%. Those who reported fewer than four acts of intercourse during the month prior to any follow-up visit, who did not use at every act of intercourse, who

at any time reported not following the instructions, or who used another method of contraception were censored (results not included in calculations) at the beginning of the first interval where nonadherence was noted.[92] Under the assumption that the probability of pregnancy in the second 6 months of perfect use would be the same, the probability of pregnancy during a year of perfect use would be 5.1%. There have been no efficacy trials of the currently used second version of the internal condom (the FC2 female condom).

Typical and Perfect Use of Vaginal pH Regulators (Phexxi). Phexxi, a vaginal pH regulator consisting of lactic acid, citric acid, and potassium bitartrate (called Amphora in clinical trials), was approved by the FDA in 2020 for contraception. The sole published clinical study included 1,834 participants assigned to use 5-mg pre-filled vaginal applicators of the drug and found a seven-cycle typical-use pregnancy rate of 13.7%.[93] We extrapolate this to a 13-cycle pregnancy rate of 21% using the assumption that the per-cycle rate for cycles 8–13 is 75% of that for cycles 1–7.[86] There are no peer-reviewed estimates of perfect-use pregnancy rates with Phexxi, at the time of this writing. The Phexxi health care provider website refers to seven-cycle perfect use pregnancy rate of 6.7%.[94] Using the standard assumption that the per-cycle pregnancy rate during perfect use would be constant, we calculate a 13-cycle perfect-use pregnancy rate of 11.9%.

Typical and Perfect Use of Spermicides. Our estimate of the proportion of users becoming pregnant during a year of typical use of spermicides (21%) is based on a randomized National Institutes of Health (NIH) trial of five spermicides.[95] We extrapolated a 1-year pregnancy probability from the 6-month pregnancy probability reported for each method by assuming the probability of pregnancy in the second 6 months would be 75% of that in the first 6 months,[86] and took as our estimate the mean of the four estimates of products still marketed (excluding the 52.5 mg gel).

Our estimate of the proportion becoming pregnant during 1 year of perfect use of spermicides (16%) is based on the same NIH trial of five spermicides.[95] We assumed that the pregnancy rate per cycle during perfect use would be constant, extrapolated a 1-year pregnancy probability from the six-cycle pregnancy probability reported for each method, and took as our estimate the mean of the four estimates of products still marketed (excluding the 52.5 mg gel). Our estimate is considerably higher than would be expected from the extensive literature on the contraceptive efficacy of spermicides.

Six studies outside the United States,[96-101] in addition to several US studies,[22] have yielded very low probabilities of pregnancy during the first year of typical use of spermicides, much lower than any estimates for barriers with spermicides. The efficacy literature on spermicides in general is dominated by studies of suppositories, foams, and film; high spermicide efficacy is documented only in these studies. There are few studies of creams and gels used alone, and those with the lowest pregnancy rates are more than 30 years old (**Table A-3**). We consider it likely that the spermicide studies suffer from flaws in analysis or design that are not apparent in the brief published descriptions. For example, an FDA advisory committee was openly skeptical of one German study:[96] "the way in which the survey was designed and the manner in which the various incentives were offered" (physicians reportedly received a fee for completing q data forms) "would clearly make the data resulting from the survey unacceptable to any scientific group or regulatory agency."[102,103]

The first clinical trial of Emko vaginal foam is also one of the few studies to compute separate pregnancy rates for cycles in which the product was used at every act of intercourse and for cycles in which unprotected intercourse occurred.[104] The design of that trial was also quite sophisticated. Study participants were randomly assigned to six groups. Each group used three different spermicidal products for three cycles each. The six groups represented all possible permutations of orders of use of the three products. If the pregnancy rate for three cycles of consistent use (not perfect use, which requires both consistent *and* correct use) of Emko vaginal foam is extrapolated, then the implied proportion becoming pregnant in the first year of consistent use is 8.9%.

A randomized clinical trial comparing the efficacy of a film and a foaming tablet—the first trial of spermicides conducted according to modern standards of design, execution, and analysis—supports the conclusion that the pregnancy rate with spermicides is considerably higher than was previously thought.[105] In that trial, 6-month probabilities of pregnancy during consistent use were 28% for the tablet and 24% for the film, probabilities that were nearly identical to those during typical use and about the same as the 12-month probability of pregnancy during typical use of spermicides in the 2002 NSFG (the most recent estimate).[106]

Typical and Perfect Use of the Cervical Cap. The typical- and perfect-use pregnancy rates of the FemCap, the only cervical cap currently on the market in the United States, come from the Phase II/III randomized trial of 841 participants.[107] The study found a Kaplan-Meier 6-month typical use pregnancy rate of 13.5. We extrapolated to a 12-month typical use pregnancy rate of 22.3, under the assumption that the rate for months 7–12 is 75% of the rate for months 1–6.[86] The same study calculated a six-cycle perfect-use life-table pregnancy rate of 11.1. We extrapolated this to a 13-cycle perfect use pregnancy rate, under the standard assumption that the pregnancy rate during perfect use is constant, of 22%.

The cervical cap comes in different sizes for different parity/delivery status. Pregnancy rates (only available for typical use) appear to vary with parity, based on an unpublished study referenced in the FDA product insert. Nulligravid study participants using the 22-mm cap experienced a 14% pregnancy rate. The same rate of 14% was found among parous individuals who delivered nonvaginally, using a 26-mm cap. Parous individuals with vaginal birth(s) were assigned a 30-mm cap; their pregnancy rate during typical use was 29%.[108] A recent systematic review found no differences in effectiveness between newer and older types of cervical caps.[87]

No Method. Our estimate of the percentage of individuals becoming pregnant among those not using contraception is based on populations not using contraception (Hutterites), and on individuals in clinical studies who stopped using contraceptives because they wanted to conceive. **Table A-2** summarizes the studies of the 12-month probability of pregnancy among these individuals. None of these is ideal for our needs, since all but one were studies of those planning a pregnancy after stopping contraceptive use. What we want is an estimate of the fraction of individuals now using contraception who would become pregnant if contraception simply vanished and people did not alter their sexual behavior. Perhaps the most relevant is the study among Hutterites, an Anabaptist sect that does not use contraception, in which the estimate is 88.8%.[109] However, this is an estimate of pregnancies leading

to the first live birth among married cisgender women who reported no fetal losses. The proportion would be higher if those with fetal losses were included. However, this group of women was young, with a median age at marriage of 21, so presumably having a higher-than-average rate of fertility. Therefore, we arbitrarily lowered our pregnancy rate estimate to 85%. This estimate is certainly on the high end of the range of plausible estimates: 80%, 75%, and 70% are also plausible.

Available evidence in the United States suggests that only 40% to 60% of individuals at risk for pregnancy who do not use contraception (but who still wish to avoid pregnancy) become pregnant within 1 year.[62,110] However, such individuals are almost certainly self-selected for low fecundity, low frequency of intercourse, or perhaps they report no contraceptive use with a method but they are in fact preventing pregnancy with nonpenetrative sex or intermittently avoiding intravaginal contact with sperm during fertile times. They may not use contraception because, in part, they are aware that they are unlikely to conceive based on prior experiences of not getting pregnant despite not using contraception. The probability of pregnancy of 85%, therefore, is our best guess of the fraction of individuals currently using reversible methods of contraception who would become pregnant within 1 year if they were to discontinue contraception but not otherwise change their behavior. Individuals who have regular unprotected intercourse for a year without achieving pregnancy are clinically defined as infertile (but by no means are they necessarily incapable of pregnancy or childbearing).

Effectiveness Over Time

We focus attention on the first-year probabilities of pregnancy solely because probabilities for longer durations are generally not available. There are three main points to remember about the effectiveness of contraceptive methods over time.

First, the risk of pregnancy during either perfect or typical use of a method should remain constant over time *for an individual with a specific partner*, providing that underlying fecundity and frequency of intercourse do not change (both fecundity and coital frequency do generally decline as individuals age, but we assume they are held constant when calculating risk over the first year of use). It is possible, however, that the risk of pregnancy could decline during typical use of certain methods because the individual learns to use the method correctly and consistently.

Second, in contrast, the risk of pregnancy during typical use of a method will decline over time *for a group of users*, primarily because those users who are most prone to fail do so early, due to higher fecundity, incorrect or inconsistent method use, and/or higher coital frequency, leaving a pool of contraceptive users who may be at lower risk. This decline will be far less pronounced among users of those methods with little or no margin for imperfect use. The risk of pregnancy during perfect use for a group of users should decline as well, but this decline will not be as pronounced as that during typical use, because only the relatively more fecund and those with higher coital frequency are selected out early. For these reasons, the probability of becoming pregnant during the second year of use of a contraceptive method will be lower than the probability of becoming pregnant during the first year of use.[111]

Third, probabilities of pregnancy accumulate over time. Suppose that 10%, 6%, and 4% of people using a method become pregnant during years 1, 2, and 3, respectively. The probability of not becoming pregnant within 3 years is calculated

by multiplying the probabilities of *not becoming pregnant* for each of the 3 years: 0.90 times 0.94 times 0.96, which equals 0.81. Thus, the percentage becoming pregnant within 3 years is 19% (= 100% − 81%).

The *differences* among probabilities of pregnancy for various methods will increase over time. For example, consider the typical-use pregnancy estimates for the diaphragm (17%) with Phexxi (21%), a difference of 4 percentage points. Assuming that the typical-use pregnancy rates for a group of individuals decline by 2 percentage points each year, after 3 years, an estimated 39% of diaphragm users will have become pregnant, compared to an estimated 47% of Phexxi users. After 3 years, the difference in pregnancy rates between methods has doubled to 8 percentage points.

The number of pregnancies (contraceptive failures) in a lifetime have been calculated using previous NSFG surveys. Based on data reported in 1995, the typical woman who used reversible methods of contraception continuously from age 15 to age 45 would experience 1.8 pregnancies. Increased use of more effective methods of contraception will reduce this number; however, given that probabilities of pregnancy during contraceptive use accumulate over time, this figure will never be zero.

Simultaneous Use of Methods

Using two different methods at once dramatically lowers the risk of pregnancy, provided they are used consistently. If one of the methods is a condom, protection from sexually transmitted infection (STI) is an added benefit. It is worth noting that none of the methods in category 1 or 2 provides protection against STIs; patients who wish to effectively prevent both pregnancy and STI transmission may want to use a barrier and another method simultaneously. For example, perfect use of both condoms and spermicides together is highly effective for pregnancy prevention and protects against STIs. The probabilities of pregnancy during the first year of perfect use of external (male) condoms and spermicides are estimated to be 2% and 16%, respectively, in Table 5-2. It is reasonable to assume that during perfect use, the contraceptive mechanisms of condoms and spermicides operate independently, since lack of independence during typical use would most likely be due to imperfect use (either use both methods or use neither). The annual probability of pregnancy during simultaneous perfect use of condoms and spermicides would be 0.3%,[§] about the same as that achieved by the oral contraceptive pill (0.3%) during perfect use.[81]

Nearly one in five (18%) contraceptive users reported simultaneous use of at least two contraceptive methods at last sex.[112] Dual method use is an important strategy that can improve effectiveness, especially for patients who prefer not to use methods in category 1 or 2. During the postpartum period, counseling should also highlight the potential for dual method use with Lactational Amenorrhea Method (LAM).

Factors that Influence Reported Effectiveness

Our understanding of contraceptive effectiveness is influenced by four primary factors: (1) the inherent efficacy of the method when used correctly and consistently (perfect use), (2) the attributes of the method that facilitate or interfere with correct and consistent use (leading to imperfect use), (3) characteristics of the user, and (4) the quality of published evidence.

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§ The probabilities multiply, thus the calculation is $1 - (1 - 2\% \times 16\%) = 0.3\%$.

Inherent Method Efficacy

Inherent method efficacy refers to how effective the method is when used perfectly. Methods in the top category are inherently highly effective and user-independent: there is little for the user to do (or not do) that would affect method effectiveness. The inherent efficacy of combined hormonal contraceptives and injectables is also quite high, but these methods are user-dependent, requiring the user to repeatedly use the method on a daily, weekly, monthly, or every 3-month schedule. Methods in the third category have both lower inherent efficacy and are completely user-dependent, requiring correct use at each coital act.

Imperfect Use

Imperfect use refers to any use that is not consistent with the manufacturer's instructions. After inherent efficacy, imperfect use has the greatest effect on the probability of pregnancy while using a method. Examples of imperfect use include missed pills, delayed start of a new pack of pills, missed injections, or incorrect placement of a diaphragm. Reproductive desires are complex, nuanced, and change over time; some individuals may prefer not to get pregnant but do not have strong motivation to prevent pregnancy or use their methods correctly and consistently; some have ambivalence about pregnancy at a given moment, leading them to not use their method for a specific act of intercourse. Many factors that can result in imperfect use are often outside of an individual's control. Individuals may not receive adequate instructions or may receive incorrect information from a health care provider. Others may act on misinformation provided on social media platforms or by friends. There are many systemic issues that can lead to imperfect use, including barriers in obtaining contraceptive refills and lack of access to a health care provider.[113]

User Characteristics

Characteristics of the user can affect both inherent method efficacy and imperfect use. The pregnancy rate for any method will vary by user characteristics, but the impact will be greatest for methods with the highest pregnancy rates during typical use, either because the method has less inherent efficacy or because it is hard to use consistently or correctly. This section reviews several important user characteristics that impact contraceptive effectiveness, but this is not an exhaustive list. Less common factors, such as drug interactions and medical conditions, can also be important to consider for an individual.[114]

Age. Many studies have found that pregnancy rates decline with age, meaning contraceptive effectiveness essentially increases.[19,23,106,115,116] This association is certainly driven by biological fecundity and coital frequency, both of which usually decline with age (see Frequency of Intercourse). The decrease in pregnancy rates with increasing age may also reflect older users' increased familiarity with and ability to correctly use contraceptive methods. Because of these fertility rates decline with increasing age, those over age 35 are often excluded from calculations of method efficacy in clinical trials.

Figure 5-3, which comes from a multicountry study using DHS data collected from women ages 15–49 in 15 low- and middle-income countries, demonstrates the substantially higher pregnancy rates among the youngest compared to older
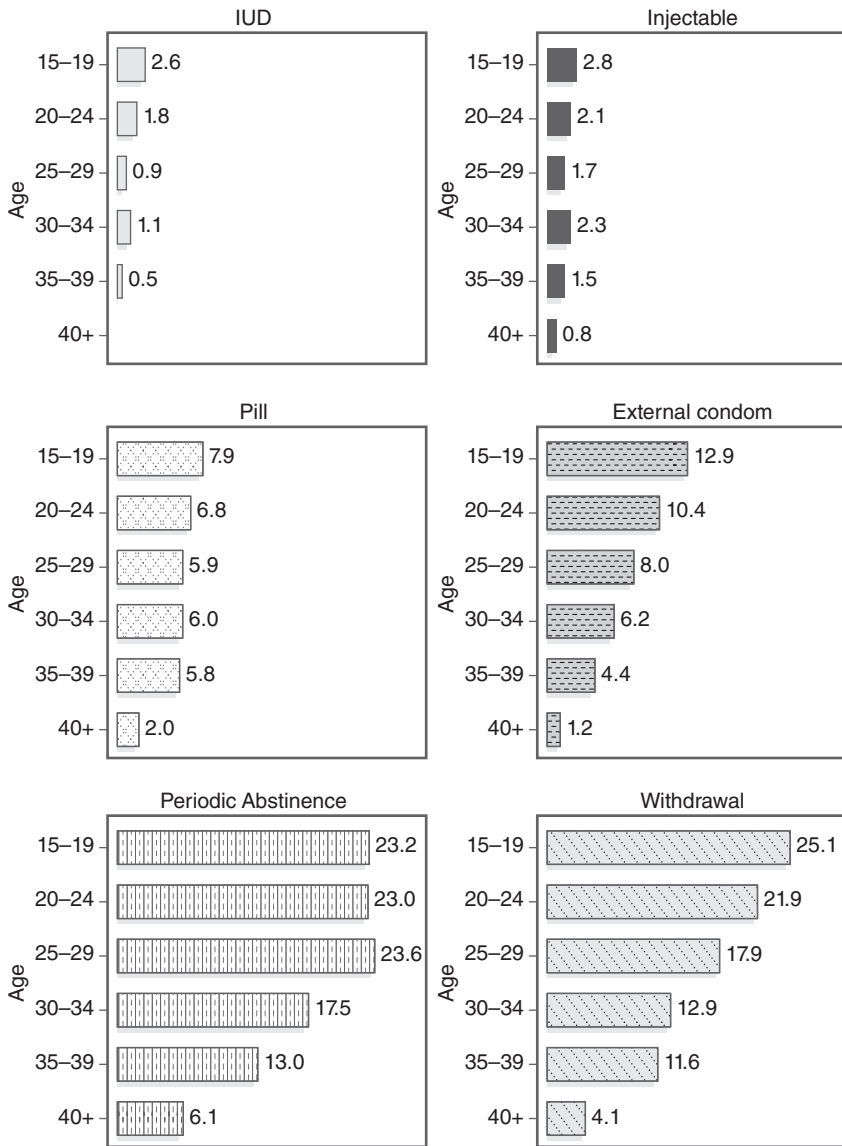
Figure 5-3 Typical-use 12-month pregnancy rates by age and contraceptive method from demographic and health surveys.

users, a pattern that holds across contraceptive methods.[23,117] Individuals aged 15–19 consistently experience the highest rates of pregnancy, and women older than 40 the lowest. Differences in pregnancy rates by age for users of the same method are substantial: 12.9% of condom users aged 15–19 experienced pregnancy in 1 year of use, more than 10 times the rate of women aged 40 and older (1.2%). The pregnancy rate for pill users is 8% for 15- to 19-year-olds, compared to 2% for

users older than 40. Periodic abstinence users (which comprise calendar and other fertility awareness–based methods) ages 15–19 experienced a 23.2% pregnancy rate, almost four times higher than the 6.1% of women in their 40s. Withdrawal users aged 15–19 have rates that are six times higher, compared to women in their 40s: 25% versus 4%. Though these are not US-based data, these patterns by age are largely consistent with multiple other US-based studies including those based on the NSFG, which has a smaller sample size that precludes analysts from calculating detailed age-specific rates.[17,19,28,106,110]

Frequency of Intercourse. Among those who use a method consistently and correctly (perfect users), the most important user characteristic that determines the risk of pregnancy is frequency of exposure to that risk through penile-vaginal inter-course. As definitions for intercourse vary widely, here we use this term generally to indicate actions with the potential for sperm to enter the uterus and fallopian tube(s). In a study in which users were randomly assigned to either the diaphragm or the sponge, diaphragm users who had intercourse four or more times a week became pregnant in the first year twice as frequently as those who had intercourse fewer than four times a week.[83] In that clinical trial, among women who used the di-aphragm at every act of intercourse, only 3.4% of those who had intercourse fewer than three times a week became pregnant in the first year, compared with 9.7% of those who had intercourse three or more times per week. Coital frequency for many people is strongly associated with age, declining as individuals and their partners grow older and with relationship duration.[118]

Biologic Fecundity. The probability of conception per coital act decreases sub-stantially with age.[119-121] The decline in ovarian reserve is moderate until a woman reaches her late thirties.[119] Risk of tubal factor infertility also increases with age among women who are exposed to STIs such as gonorrhea and chlamydia. The biologic fecundity and sperm quality of partners also decline with age.[122,123] Regular menstrual cycles are one proxy measure for fecundity. Women with regular cycles were 7.2 times as likely as women with irregular cycles (one or more cycles < 17 days or > 43 days) to become pregnant while using the internal (female) condom.[124]

Social Determinants of Health Such as Race and Income. Several stud-ies have found higher pregnancy rates during contraceptive use among Black and Hispanic users compared to non-Hispanic White individuals.[17,28,106] For example, in the most recent analysis of NSFG data, Black condom users experienced preg-nancy at more than twice the rate of White users (20.7 versus 8.7 pregnancies per 100 women, respectively).[17] Pregnancy rates during contraceptive use are also frequently found to be associated with poverty, with women in families with low in-comes experiencing higher rates.[17,23,28,106] These findings likely reflect differences in health care access, lower quality care, negative experiences with and lack of trust in health care providers, and many other barriers experienced by contraceptive users in these groups. In addition, individuals have varying levels of motivation to pre-vent pregnancy yet often do not feel supported in expressing their nuanced repro-ductive desires that may seem incongruent or ill advised to their provider. Hence, an individual may be categorized as, for example, a "condom user" but in fact may not feel a strong need to consistently protect against pregnancy. This person could be erroneously categorized as experiencing a pregnancy while using contraception

or as having an unintended pregnancy even though becoming pregnant is acceptable to (but perhaps not actively sought by) them. (See Chapter 4, Person-Centered Reproductive Health Conversations and Contraceptive Counseling.)

Access to Reproductive Health Services. Multiple studies have shown strong associations between access to reproductive health services, including insurance, and contraceptive use and continuation.[5,125] Patients cannot use methods consistently and correctly if they face transportation or cost barriers returning to clinics for repeat injections, to pharmacies for pills, and/or stores for condoms. Cost may also be a barrier to selecting certain methods, especially implants and IUDs, if patients cannot access sufficient insurance. Social norms, provider biases, dispensing patterns, and prohibitive policies and guidelines are also factors that can hinder access to reproductive health services.

User Motivation. Contraceptive users who are highly motivated to avoid pregnancy may be more likely to use a method consistently and correctly.[126,127] However, even if a current pregnancy would be unacceptable to someone, they would not have a reason to take steps to avoid pregnancy if they did not perceive that they are at risk of becoming pregnant.[128,129] Motivation to avoid pregnancy often changes over time and is related to the complex attitudes people have regarding pregnancy and their perceived risk of becoming pregnant in their specific circumstances. Pregnancy desires are not binary and cannot be accurately categorized within the limited designations of "intended" or "unintended"; a person can be relatively indifferent and report that they are not seeking pregnancy, yet if they were to become pregnant it would be acceptable to them (or they would be happy). Ambivalence can also arise depending on an individual's relationship, financial, or social situation including cost of childcare and missed career opportunities.

One study documenting the impact of user motivation comes from a comparison of perfect-and typical-use pregnancy rates with pregnancy rates observed among women using isotretinoin, which is effective in treating severe acne but is also teratogenic. To minimize pregnancies among women undergoing treatment, the manufacturer and the FDA implemented a pregnancy prevention program. Among 76,149 participants who reported using contraception, 268 became pregnant, yielding a rate of 3.6 per 1,000 20-week courses of therapy;[130] this rate, if constant for a year, would be equivalent to an annual probability of pregnancy of 0.9%. The estimated annual probabilities of pregnancy were 0.8%, 2.1%, and 2.6% among those who reported using oral contraceptives, diaphragms, and condoms, respectively. Thus, individuals using diaphragms achieved lower rates of pregnancy than we estimate would occur during perfect use, and those using condoms and oral contraceptives experienced about the same pregnancy rates that would be expected during perfect use. Pregnancy rates for individuals using any of these three methods, however, were substantially below rates generally observed during typical use; this finding would appear to indicate that users' understanding of the teratogenic risks of isotretinoin substantially enhanced correct and consistent use. It is also possible that participants in this study had lower than average fecundity (because acne is a marker for excess androgen production associated with anovulation[131]), that they lowered their coital frequency during treatment, or that they under-reported their number of pregnancies (and abortions).

Body Weight. Clinicians and patients often raise concerns that weight may decrease the efficacy of hormonal contraceptive methods. Pharmacokinetic data indicate differences associated with obesity, such as increased metabolic rate and volume of distribution, affecting time to achieve therapeutic contraceptive hormone levels and steady state hormone levels.[132] Unfortunately, early clinical trials for hormonal methods excluded participants with overweight and obesity due to the potential for greater venous thromboembolism (VTE) risk, limiting data on efficacy. For most hormonal contraceptive methods, effectiveness does not appear to be significantly associated with weight, despite small differences in hormone levels.[133] However, the levonorgestrel and ethinyl estradiol transdermal patches are contraindicated and should not be used in individuals with a BMI over 30 kg/m^2, given increased pregnancy risk in clinical trials.[134] Data on the effectiveness of the oral contraceptive pill among participants with a BMI > 30 kg/m^2 versus individuals of normal weight are inconsistent, with some studies showing an increase in pregnancy risk[135,136] and others showing no difference.[137] Body weight also affects medical comorbidities that are important to consider when determining which methods of contraception are safe for an individual.[114] Concerns about weight gain may also influence choice of methods.[138]

Quality of Published Evidence

When the published evidence is of poor quality, we cannot rely on it to help inform contraceptive decision making. The reasons for poor quality data range from simple arithmetical mistakes to improper design or execution or analysis of studies to outright fraud.[22]

Fraud. One well-documented instance of fraud involved the Dalkon shield. In a two-page article published in the *American Journal of Obstetrics and Gynecology*, a first-year probability of pregnancy of 1.1% was presented and the claim made that "only the combined type of oral contraceptive offers slightly greater protection."[139] It was not revealed by the researcher that some participants had been instructed to use spermicides as an adjunctive method to reduce the risk of pregnancy, nor that he was part-owner of the Dalkon Corporation. Furthermore, he never subsequently revealed (except to the A.H. Robins Company, which bought the shield from the Dalkon Corporation but did not reveal this information either) that as the original trial matured, the first-year probability of pregnancy more than doubled.[140]

Discrepancies in Presentation of Information. When comparing contraceptive method effectiveness, researchers compare typical-use to typical-use rates (or perfect-use to perfect-use rates). Similarly, effectiveness data presented in counseling tools and advertisements should use a standard 12-month rate used for all other methods to avoid confusing providers and clients alike. At the time of this writing, Phexxi's advertising presents a seven-cycle rate, rather than the 12-month or 13-cycle rate used by all other contraceptive methods, which has in some cases led to an erroneous understanding of Phexxi's effectiveness. The "health care professionals" portion of the Phexxi website, in very small font, states: "The effectiveness rates described above should not be compared to other contraceptive methods with different trial designs and study duration beyond 7 cycles".[141] However, the

consumer-facing portion of the Phexxi website does not provide any information explaining the rates are from a seven-cycle study and should not be compared to pregnancy rates of other methods that present annual pregnancy rates. As a result, several articles and websites have drawn incorrect conclusions based on the comparison. For example, a STEPS New Drug Review article compares the seven-cycle Phexxi pregnancy rates with a table of 1-year rates for other methods and assumes Phexxi is comparable in effectiveness to condoms (which are more effective, at 13% typical use).[142] If the 1-year 21% typical-use rate estimate was included in the table, Phexxi would be equal to other spermicides.

Other manufacturers, including those of basal body temperature mini-computer Daysy® have also made claims about effectiveness that were not based on a standard 1-year prospective methodology used in other studies.[143,144]

What Gets Published. The incentives to conduct research on contraceptive failure vary widely from method to method. Many studies of the pill and IUD exist because companies wishing to market them must conduct clinical trials to demonstrate their efficacy. In contrast, few studies of withdrawal exist because there is no financial reward for investigating this method. Moreover, researchers face differing incentives to report unfavorable results. The vasectomy literature is filled with short articles by clinicians who have performed 500 or 1,000 or 1,500 vasectomies. When they report pregnancies (pregnancy is seldom mentioned in discussions of vasectomy "failures," which focus on the continued presence of sperm in the ejaculate), their pregnancy rates are invariably low. Likewise, drug companies do not commonly publicize their failures. Even if investigators prepared reports describing failures, journal editors may not be likely to publish them. Current requirements to register trials (e.g., clinicaltrials.gov) aim to decrease publication bias.

Analytical Pitfalls

Several analytical pitfalls can snare investigators. Three of the most common are (1) comparing trials with different frequency of pregnancy testing, (2) the incorrect calculation of method failure rates, and (3) failure to follow up participants in a trial. Other, more technical, errors that have biased reported results are discussed in other publications.[145,146]

Inconsistent Frequency of Pregnancy Testing Across Studies. In population-based surveys and in older clinical trials, individuals reported whether they became pregnant in a specific month. By contrast, in some recent clinical trials, sensitive pregnancy tests were administered every month and whenever the participant had symptoms. The number of pregnancies (and hence the pregnancy rate) therefore increased because early pregnancy losses not clinically noted by the study participant are added to the number of observed pregnancies. More frequent pregnancy testing in the more recent contraceptive trials has resulted in higher pregnancy rates than would otherwise have been obtained and makes the results not comparable to those from older trials and population-based surveys.

Incorrect Calculation of Pregnancy Rates. Some studies separate pregnancies occurring during perfect and imperfect use to calculate "method" and "user" failure rates. Some investigators have calculated these rates incorrectly.

By convention, pregnancies that occur during a month in which a method was used improperly are classified as user failures (even though, logically, a pregnancy might be due to failure of the method, if it was used correctly on some occasions and incorrectly on others), and pregnancies that occurred with correct and consistent use are classified as method failures. But investigators do not always separate the exposure (the denominator in the calculation of failure rates) into these two groups.

For example, suppose that two method failures and eight user failures occur during 100 woman-years of exposure to the risk of pregnancy. Then the common calculation is that the user failure rate is 8% and the method failure rate is 2%; the sum of the two is the overall failure rate of 10%. By definition, however, method failures can occur only during perfect use and user failures cannot occur during perfect use. If there are 50 years of perfect use and 50 years of imperfect use in the total of 100 years of exposure, then the method failure rate would be 4% and the user failure rate would be 16%. The difference between the two rates (here 12%) provides a measure of how forgiving of imperfect use the method is. However, if investigators do not inquire about perfect use except when a pregnancy occurs, the proper calculations cannot be performed.

Loss to Follow-up. The standard assumption made at the time of analysis is that individuals who are lost to follow-up (LFU) experience pregnancy at the same rate as those who are observed. This assumption is probably innocuous when the proportion LFU is small. But in many studies the proportion LFU may be 20% or higher, so that what really happens to these individuals could drastically affect the estimate of the proportion becoming pregnant. Our strong suspicion is that those who are LFU are more likely to experience pregnancy than are those who remain in the trial. For example, one study found that the pregnancy rate for calendar rhythm rose from 9.4 to 14.4 per 100 woman-years of exposure as a result of resolution of cases LFU.[147]

Pitfalls and Challenges of Communicating Pregnancy Risk

Most people seeking contraception believe effectiveness is one of the most important factors—often the most important factor—when choosing a contraceptive method or methods.[148-152] Yet general knowledge about absolute and relative effectiveness is often low, and patients may underestimate the effectiveness of IUDs and implants, and overestimate the effectiveness of other methods.[153] People need correct information on effectiveness and relative effectiveness to make an individual informed choice. Yet, not all patients prioritize effectiveness and it is coercive for providers to overemphasize effectiveness based on their own priorities rather than on the priorities, preferences, and values of the individual patient.

Striking the right balance as well as the exact messaging around contraceptive effectiveness is challenging. The overall estimated perfect use and typical use pregnancy rates derived from US studies do not pertain to any individual in the US (or elsewhere), but rather represent the average effect of the mix of characteristics found in the population studied.[14] Moreover, the statistical approach used to estimate these rates as well as quality of the data make these estimates rather crude.

Keep these key points in mind when counseling about contraceptive effectiveness:

1. **Methods in category 1 are highly effective for all users**. Use of the top-category methods—IUDs, implant, vas surgery, and fallopian tube surgery—entails the lowest risk of pregnancy, and this very low risk applies to all users.

2. **Correct and consistent use of most other contraceptive methods results in a low risk of pregnancy**. However, effectiveness for individual users of these methods (Categories 2 and 3) varies substantially by age, coital frequency, and other characteristics that are often associated with each other.

3. **Counseling tools may help communicate pregnancy risks associated with different methods**. Tables of numeric risks, such as Table 5-2, are likely to be more useful for health care providers than patients. Informational graphics that group effectiveness rates into categories (Figure 5-2) may lead to more informed contraceptive choices for clients interested in method effectiveness by demonstrating relative effectiveness to potential users.

4. **Using two methods at once dramatically lowers the risk of pregnancy**, provided they are used consistently and in appropriate combination (e.g., two condoms should not be used at the same time). If one of the methods is a condom, protection from STI acquisition and transmission is an added benefit.

5. **No method of contraception is 100% effective**. Clients are sometimes told that pregnancies occurring during contraceptive use are their own fault because they did not use the method correctly or consistently. Contraceptive methods are imperfect and can fail even the most diligent user.

Safety

In general, contraceptives pose few serious health risks to the majority of users. Moreover, the use of contraceptive methods, including hormonal methods, is generally far safer than pregnancy. This fact may not be well understood: one study found that 75% of women believed COCs were at least as hazardous to a woman's health as pregnancy.[154] Contraceptive failure (pregnancy) is associated with risk: an individual must assess the likelihood of contraceptive failure and the dangers that a pregnancy would pose. Depending on where a person lives, they may face risks associated with delayed or unsafe abortion, or risks associated with pregnancy continuation and childbirth. These risks are all affected by an individual's health and sociocultural circumstances. Thus, people in many lower-income countries with higher pregnancy-related mortality rates will experience an even greater relative health advantage in using contraceptive methods. As people age, they are more likely to have health problems that can complicate pregnancy. Nonetheless, use of hormonal or device-based contraceptive methods (IUDs and implants), and permanent contraception, may entail potential risks.

Major Health Risks

Some contraceptive options, such as fertility awareness–based methods, are not associated with any serious health risks (beyond those associated with pregnancy via method failure). When it comes to the most serious outcome of all—death—the absolute level of risk is extraordinarily low for most people, and lower than the risks

associated with pregnancy and birth. Other major health risks, such as blood clots, cancer, anaphylactic reactions, or serious infections, are uncommon. People with underlying medical conditions may have greater health risks from contraception, yet also may have greater health risks from pregnancy. The US Medical Eligibility for Contraceptive Use provides information about the safe use of contraception for individuals with selected medical conditions. (See Appendix A: Summary Chart of US Medical Eligibility Criteria for Contraceptive Use available at the end of the book.)

Risk of Death with Combined Oral Contraceptive Use

Studies using data from the 1990s and earlier compared mortality among users and users of COCs. Some early studies found increased mortality risks among older users and smokers, and especially users who were in both groups.[155,156] Many early studies were based on older formulations using far higher doses of hormones (specifically ethinyl estradol) than found in pills used today. More recent large-scale analyses have found no increase in all-cause mortality associated with oral contraceptive use either in the short term or in the long term.[157-160]

Comparing Risks of Contraceptive Use to Risks of Pregnancy

It may be useful to weigh the low risks associated with COCs and permanent contraception against the risks associated with carrying a pregnancy to term and delivery. The risk of death associated with COC use is 0.06 in 100,000 among nonsmoking users aged 15–34, and 3 in 100,000 for those aged 35 to 44; for smokers aged 15–34, the risk is 1.7 in 100,000.[156] The risk of death among those undergoing fallopian tube surgery for permanent contraception is 1.5 in 100,000.[161]

The most recent data available, from 2019, show an increasing maternal mortality rate in the United States.[162] Among all women, there were 20.1 deaths due to maternal causes for every 100,000 live births. Risks are substantially higher for Black women and older women. The maternal mortality rate for non-Hispanic Black women was 44 deaths per 100,000 live births, 2.5 times the rate for non-Hispanic White women (17.9) and 3.5 times the rate for Hispanic women (12.6). Maternal mortality rates also increased with maternal age, from 12.6 for women younger than age 25, to 19.9 for those aged 25–39, and 75.5 for those aged 40 and older. The mortality risk for women aged 40 and older was 6 times higher than the rate for women younger than age 25.

The risk of death associated with legal abortion is low, approximately 0.6 in 100,000; this varies by gestational age and method (medication or surgical).[163,164] However, the risks of unsafe abortion are substantially greater. The risk of death is 55 per 100,000 unsafe abortions worldwide, accounting for 70,000 deaths per year.[165] As access to abortion is restricted, the proportion of individuals seeking unsafe abortion increases.

Cardiovascular Disease

Use of combined hormonal contraceptives (CHCs), including COCs, the patch, and vaginal ring, as well as injectable contraceptives, are associated with an increased risk of arterial and venous thromboembolism (ATE and VTE). The most serious thrombotic events, myocardial infarction (MI) and stroke, are extremely rare and much less common than deep venous thrombosis (DVT). Smoking significantly increases the risk of MI, especially in users older than age 35. However, evidence is mixed

regarding an increased risk of MI among CHC users of any age who do not smoke and do not have hypertension or diabetes.[166,167] The risk of stroke in normotensive nonsmokers younger than age 35 may not be increased by use of CHCs,[155,168] except potentially in those with certain medical conditions such as migraines with aura.[169] The risk of VTE is increased by certain contraceptive methods (two-to fourfold for DMPA, two-to sixfold for COCs, and higher for patches and vaginal rings),[170,171] but the absolute risk is low, ranging from 2 events per 10,000 woman-years among those aged 15 to 19, to 7 events per 10,000 woman-years among those aged 45 to 49.[172,173]

Cancer

Many clients have concerns about the effect of hormonal contraception on cancer risk. COCs are the best studied, as they were the first hormonal method available in the United States. Given that cancer incidence increases with age, and clients potentially use hormonal contraception for several decades, methods must be available on the market for long periods of time before researchers can identify increases in risk, especially when those increases are small.

At the population level, the net effect of COC use across all cancers is neutral,[174-177] and ever-users of COCs have a significantly lower death rate from all cancers than do never-users.[158] Use of COCs (and presumably the patch and ring as well) protects users against cancers of the endometrium and ovary. Longer duration of use increases that protection. A comprehensive review concluded that use of COCs is associated with an increased risk of cancer of the cervix and liver, an increased risk of breast cancer in young women (equivalent to the risk with pregnancy), and a decreased risk of colorectal cancer.[174] The risk of death is lower among ever-users of COCs than never-users for colorectal,[158,176] uterine,[157,158] ovarian,[157,158] and lymphatic and hematopoietic[176] cancer. Moreover, COC use has neither a harmful nor a beneficial effect on breast cancer mortality.[157,158,178]

Fewer studies have evaluated cancer risk among users of progestin-only methods of contraception (including POPs, injectables, implants, and levonorgestrel-releasing IUDs). Use of injectable contraception, and likely other progestin-only methods, substantially reduces the risk of endometrial cancer.[179] Though some studies have identified an increased risk of breast cancer for some progestin-only methods,[180-184] a 2016 systematic review concluded that progestin-only methods of contraception do not appear to increase the risk of breast cancer.[185]

See individual method chapters for more information on method-specific health risks, and a summary of risks associated with each contraceptive method in **Table 5-3**.

Goals For Communicating About Safety

Providers should prioritize the following in communicating about the safety of contraceptive options:

1. **Users must be offered information on both the risks and benefits of contraceptive option(s) that align with their preferences**. It is essential to provide detailed information regarding any potential risks and contraceptive benefits as part of person-centered contraceptive counseling.
2. **Be clear about cancer risks and benefits.** While the risks of certain cancers may be increased with the use of hormonal contraception, recent large-scale

Table 5-3 Summary of Major Risks, Bleeding Pattern Changes, Side Effects/Noncontraceptive Benefits, and Return to Fecundity[a]

Method	Major Risks	Bleeding Pattern Changes	Selected Side Effects and Noncontraceptive Benefits	Return to Ability to Conceive
Permanent contraception (vas surgery, Fallopian tube surgery)	Anesthetic or surgical complications; if pregnancy occurs after tubal surgery, high risk of ectopic. Risk of regret.	None	Pain at surgical site. Tubal surgery reduces risk of ovarian cancer (particularly salpingectomy) and may protect against pelvic inflammatory disease (PID).	None
Progestin implant	Problems with removal if inserted too deeply. Extremely rare: migration, infection at implant site.	Irregular bleeding or spotting, may range from amenorrhea to frequent bleeding	Mood changes, increased acne. Decreases dysmenorrhea, can be used to treat endometriosis.	May be delayed by up to 2 cycles
Intrauterine devices	Expulsion (and subsequent risk of pregnancy), perforation, embedment, infection, anemia (with copper-bearing IUD). If pregnancy occurs, higher risk of ectopic.	Irregular bleeding or spotting, increased bleeding with copper-bearing IUD; less bleeding or amenorrhea with levonorgestrel-releasing IUD	Levonorgestrel-releasing IUD: Hormonal side effects. Decreased dysmenorrhea, decreased anemia, can be used to treat endometriosis, and can provide progestin for hormone therapy. Copper-bearing IUD: Increased dysmenorrhea, heavier menses.	May be delayed by up to 2 cycles
Injectable	Injection site reactions, decreased bone mineral density, cardiovascular complications.	Irregular bleeding or spotting, amenorrhea (increases over time)	Weight gain, adverse effects on lipids. Decreased anemia. May protect against ovarian and endometrial cancers.	Delayed up to 12 months (DMPA-SC); 5–8 cycles for DMPA-IM)

(continues)

Table 5-3 Summary of Major Risks, Bleeding Pattern Changes, Side Effects/Noncontraceptive Benefits, and Return to Fecundity[a]

(continued)

Method	Major Risks	Bleeding Pattern Changes	Selected Side Effects and Noncontraceptive Benefits	Return to Ability to Conceive
Combined hormonal contraception (pill, patch, and vaginal ring)	Cardiovascular complications (stroke, heart attack, blood clots); hepatic adenomas; increased risk of breast, cervical, and liver cancer diagnosis	Reduces menstrual bleeding; irregular bleeding and spotting especially with extended or continuous use	Nausea, headaches, breast tenderness, melasma; decreases dysmenorrhea, decreases anemia and cyclic mood problems (PMS or PMDD); reduces acne, and protects against ovarian, endometrial, and colorectal cancer. Can be used to treat endometriosis. Ability to schedule bleeding.	May be delayed 3–4 cycles
Progestin-only pill	None known	Irregular bleeding or spotting	Increased acne.	
External condom	Anaphylactic reaction to latex	None	Protects against STIs, including HIV. May reduce sexual pleasure, delays premature ejaculation.	Immediate
Internal condom	None known	None	Protects against STIs, including HIV. May affect sexual pleasure.	Immediate
Abstinence	None known	None	Prevents STIs, including HIV, if anal and oral intercourse are avoided as well	Immediate

Method				
Diaphragm, sponge	Vaginal and urinary tract infections, toxic shock syndrome	None	Vaginal discomfort, vaginal irritation, vaginal discharge if left in too long, allergy to spermicides.	Immediate
Spermicides	Vaginal and urinary tract infections; possible increase in susceptibility to HIV/AIDS acquisition if exposed to positive partner. N-9 can denude vaginal epithelium	None	N-9 can denude vaginal epithelium and cause vaginal irritation, allergy.	Immediate
Phexxi	Urinary tract, bladder, or kidney infections; yeast infection, bacterial vaginosis	None	Vaginal itching, burning, pain. Painful urination. May positively affect sexual pleasure.	Immediate
Fertility awareness–based methods	None known	None	Users have knowledge about the functioning of their body; adaptability of the method to trying to conceive if reproductive desires change.	Immediate
Lactational Amenorrhea Method (LAM)	None known	None	Breast/chestfeeding provides excellent nutrition for infants.	May be delayed for duration of breast/chestfeeding
Withdrawal	None known	None	None known	Immediate

[a] Among healthy women with no concurrent medical condition.

analyses have found no increase in the short-term or long-term in all-cause mortality associated with contraceptive use. Hormonal contraception can reduce risk of endometrial and other cancers.

3. **Compare risks of using contraception with pregnancy risks**. In general, the potential health risks inherent in pregnancy, abortion, and delivery are far greater than those for using a contraceptive method, including hormonal methods. Poor access to maternity and abortion care may increase the health risks associated with pregnancy occurring during contraceptive use.

Comparative Side Effects

Side effects are the most frequent reason for method discontinuation or switching.[186-190] Often, the possibility of side effects influences whether an individual selects a certain method. Do not dismiss the important role that concerns about side effects play for an individual assessing whether to initiate or continue using a method. See Table 5-3 for a summary of side effects for each contraceptive method.

The vast majority of contraceptive studies are not placebo-controlled, and many do not have an appropriate comparison group to determine rates of various side effects attributable to a method. Placebo-controlled studies of COCs have shown no significant difference in the frequency of most nonspecific side effects,[191] but it should be noted that these studies are not large enough to encompass the full range of variations in patients' lived experiences. Patients reporting side effects that are not typically associated with their contraceptive method may want to explore whether the symptom(s) may be caused by factors other than the contraceptive method—for instance, other medications, health conditions, or social factors. However, it is not effective to attempt to talk someone out of symptoms that they have experienced first-hand, and it is coercive to try to convince them to continue a method with which they are not satisfied.

There are some side effects, such as bleeding and skin changes, that should be proactively brought up with the potential user. Offering anticipatory guidance about side effects and potential management options gives users the information they need, were they to experience side effects. Some researchers have argued (based on three randomized controlled trials that found similar levels of reported side effects between oral contraceptives and placebo pills) that anticipatory counseling about side effects may increase the probability that they will experience that side effect.[191] However, people who wish to discontinue using a method due to side effects must be supported in doing so, even if the clinician does not believe that the side effect is harmful or related to the method. Clinicians have an important role to play in respecting patient autonomy, helping clients feel heard, and helping them choose another method, if desired.

Bleeding Pattern Changes With Hormonal Methods and the Copper IUD

All hormonal methods, and the copper-bearing IUD, are associated with menstrual changes. Substantial variability exists in terms of how users respond to such changes, and they play a substantial role in patient satisfaction, contraceptive discontinuation, and unmet need.[192] Some of these changes, such as lighter or no periods associated with levonorgestrel-releasing IUDs, injectables, and continuous use of CHCs and POPs, may be considered "side benefits" and are desired by some patients.

Those who want regular periods may not appreciate these changes and may prefer methods like CHCs with hormone-free intervals that enable one to schedule bleeding to resemble regular periods. Some will prefer to maintain their natural menstrual pattern with a copper IUD, a method associated with heavier periods.

Delayed Ability to Conceive

Desiring pregnancy is an often-cited reason for discontinuing contraception and delayed ability to conceive may be considered a serious side effect by some people. A recent prospective cohort study of 17,954 women trying to conceive suggested that people discontinuing injectables had the longest delay in return of normal fecundity (five to eight menstrual cycles), followed by patch users (four cycles), oral contraceptive pills (OCPs) and ring users (four cycles), and IUD and implant users (two cycles), with little to no long-term effects on fecundity.[193] Delayed conception is most likely to occur with DMPA (IM and SC). DMPA-SC prescribing information advises that the delay may be 1 year or longer based on internal data from 15 study participants.[194] More recent data support this substantial delay when discontinuing DMPA-SC.[195] DMPA-IM prescribing information provides a median time-to-pregnancy of 10 months after discontinuation.[196] A secondary metabolite of DMPA is stored in the adipose tissue and is biologically active; users with more adipose tissue have longer time to return of fertility. Delayed return to conception after contraceptive discontinuation may be greater among some individuals, including those living with HIV.[197] On the other hand, some individuals will experience immediate return to their normal fecundity patterns. People discontinuing a method who want to maintain protection against pregnancy should be reminded to begin another method immediately.

Changes in Sexual Desire and Function

Clients commonly express concern about sexual side effects. Potential effects on sexuality can include changes in desire, vaginal lubrication, pleasure, and orgasm. Physical sensations such as decreased penile sensitivity, pressure on vaginal walls, or uterine cramping may be caused by mechanical methods such as condoms, the diaphragm, or IUDs.[198-200] (See Chapter 6, Sexuality and Contraception.) DMPA can create a hypoestrogenic milieu that can cause the user to experience dryness in their vagina, especially when used by those who are chestfeeding.

Noncontraceptive Benefits

When a contraceptive side effect is considered positive, it is referred to as a "noncontraceptive benefit" or "something your birth control can do for you in addition to preventing pregnancy." Reduction in endometrial cancer risk is a noncontraceptive benefit of hormonal contraceptives, for instance. In some cases, whether a particular side effect is positive or negative depends on the user.

Noncontraceptive benefits can be major considerations when an individual selects a contraceptive method (see Table 5-3). Adolescents may opt for a CHC to help improve their acne or reduce dysmenorrhea, and an increasing proportion of people opt for a levonorgestrel-releasing IUD to reduce or eliminate menstrual blood loss. In many cases, noncontraceptive benefits can help patients decide between two or more suitable methods. Awareness that a method of contraception has noncontraceptive benefits may also increase the likelihood of satisfaction with continued use of

that method. In addition to counseling on risks, make it a practice to tell your clients about the potential noncontraceptive benefits of the various methods:

- **Reducing the risk of STIs** may be an important factor as an individual selects a contraceptive method. Any person who may be at risk of acquiring STIs has the contraceptive benefit of STI prevention with external or internal condoms, either alone or with another method. Because condoms reduce the risk of STIs that cause pelvic inflammatory disease, which can lead to infertility, they protect future fertility.
- Fertility awareness methods help users **learn about their menstrual physiology**. This knowledge can also help someone achieve a pregnancy.
- Several contraceptive methods treat **heavy menstrual bleeding**. They also decrease dysmenorrhea and are first-line treatments for endometriosis. Hormonal methods all contain a progestin and so can be used to protect the endometrium for individuals who are anovulatory, have polycystic ovarian syndrome, or are on hormone therapy.
- COCs, and presumably the patch and vaginal ring, can **improve acne and premenstrual dysphoric disorder (PMDD) and premenstrual syndrome (PMS)**. These CHC methods may improve bone health in women with low estrogen levels related to premature ovarian insufficiency. Higher-dose pills (those with 30–35 mcg ethinyl estradiol), DMPA injection, and implants may protect against functional ovarian cysts.

Table 5-3 summarizes major risks, bleeding pattern changes, selected side effects/contraceptive benefits, and return to fecundity for each contraceptive method.

Goals For Communicating About Side Effects

Side effects, particularly changes in bleeding pattern, are a major cause of method discontinuation. Some clients wish to hear about treatment options or the likelihood of the side effect improving over time. When management options are available, providing a treatment someone can try on their own in advance can reduce dissatisfaction with their method. Providers should prioritize the following in communicating about side effects:

1. Support individuals who report that they are experiencing side effects in learning about management options and in choosing whether to continue their method or select a new method.
2. Discuss noncontraceptive benefits when counseling about side effects. Noncontraceptive benefits may help individuals decide to use a particular method and increase patient satisfaction with their method choice.
3. Support a client's decision to discontinue a method for any reason (particularly a method that a user is unable to remove without assistance from a health care provider, such as an implant or IUD).

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