Abstract

The current presentation of contraception pregnancy rates fails to address long-term planning or dual method use. This work fills that gap by creating a presentation that deals with both important issues. Framing pregnancy rates beyond one year is important because individuals intend to use contraception beyond just that one year. Including dual methods is also important because of its low theoretical pregnancy rate, and 15% of contraception users take this approach.

Further, future studies may benefit contraception users by including pregnancy rates for dual methods instead estimating them. This estimated calculation for the typical use of dual methods may violate assumptions within prediction models. Researchers should also gain accuracy by differentiating between simultaneous and alternating dual-method users because this classification yields different pregnancy rates. Finally, researchers should reconsider coding dual-method users as single method users. This practice artificially lowers the pregnancy rate for primary methods.

Reframing the Presentation of Contraception Pregnancy Rates: Integrating Long-Term Planning and Dual Methods

Prevalence of Unintended Pregnancy and Births

Eluding unintended pregnancy is a high stakes challenge that all sexually active, fertile women face. For the average woman this begins at first intercourse around age 17 (Alan Guttmacher Institute, 2002) and wanes off towards the onset of menopause near age 51 (Kato et al., 1998). Trussell and Vaughan (1999) calculated that the typical woman using contraception (including sterilization) would have 1.3 unintended pregnancies by age 45. This estimate rose to 1.8 when they excluded sterilization (Id). By age 40, 60% of women have faced an unintended pregnancy, not including unintended pregnancies ending in spontaneous loss (Henshaw, 1998). Half of the 6.4 million pregnancies in the US during 2001 were unintended. Roughly 1.4 million of these pregnancies eventually resulted in a birth (Finer & Henshaw, 2006).

Family planning involves the attempt to avoid unintended pregnancies. Unfortunately, unintended pregnancies become a reality for many women. About 44% of these unintended pregnancies conclude in a birth with the remainder ending in abortion or spontaneous loss (Finer & Henshaw, 2006). As a result, a woman often exceeds her desired number of children. Roughly 9% of women expect to avoid child bearing altogether (Chandra, Martinez, Mosher, Abma, & Jones, 2005). Among these women intending to avoid childbirth, 90% bear children anyway with the majority having two or more births. Of the 13% of women that expect to limit their children to one, 55% are not

successful (Chandra et al.). Even within women wanting to limit their number of children to two, 20% are unable (Chandra et al.).

Impact of Unintended Pregnancies

Unintended pregnancies also limit a mother's options to prevent birth defects (Brown & Eisenberg, Eds, 1995) because the embryo is most susceptible to teratogens early on in the pregnancy (weeks three through eight) (Sadler, 2004). In practice, it is difficult to detect pregnancy this early. The pregnancy may be dismissed as a late period or simply unnoticed entirely. And the embryo's vulnerability begins so early that by the time woman recognizes her pregnancy, the damage may have already occurred. The woman would have had no signal to avoid teratogenic substances, lose weight, develop proper nutrition, avoid alcohol, or cease smoking.

This ignorance of early pregnancy may explain why alcohol consumption during pregnancy is a leading cause of mental retardation (Sadler). A pregnant woman with a BMI over 29 kg/m^2 or has delayed in taking folic acid supplements also unknowingly jeapardizes the fetus to neural tube defects (Sadler). Smoking puts the embryo at risk for premature delivery and intrauterine growth deficiency (Sadler). This early risk period starting at day 21 is why precautions should be taken *before* pregnancy has occurred, because these options are not available to those with unintended pregnancies. This point supports the need to guard from of all unintended pregnancies, even mistimed.

Contraception Use in Practice

Understanding contraception use in practice permits us to evaluate whether current contraception use adequately meets family planning needs. Contraception use is extremely common. Among women who are fertile, sexually active, and not currently

wanting a pregnancy, nine in ten report currently using contraception (Mosher, Martinez, Chandra, Abma, & Willson, 2004). Among female contraception users, the most popular forms of current contraception in order of prevalence are:

- female or male partner sterilization (36%),
- oral contraceptive (31%), condom (primary[1] or secondary[2] method) (24%),
- Depo-Provera (5%),
- withdrawal (primary method) (4%),
- IUD (2%), and
- periodic abstinence (primary method) (1%) (Mosher et al.).

Of female contraception users under 25, more than 50% use the pill. Of female contraception users over 35, more than 40% use female sterilization and 14% rely on sterilization from their male partner (Mosher et al.). The proportion of female contraception users with condoms as their primary or secondary method is highest at 45% between ages 15-19 and makes a steady decline throughout the lifespan plummeting to 14% between ages 40-44 (Mosher et al.). Women over 35 that no longer desire children prefer sterilization. But younger women with many fertile years ahead are relying mostly on the pill and condom. The question becomes whether these younger women are correct to rely on the pill or condom alone to limit their pregnancies.

One way to investigate whether the pill or condom's appropriateness is to assess their use. Unfortunately, half of women report missing one or more contraceptive pills per cycle (Rosenberg & Waugh, 1999). Results from the National AIDS Behavioral Survey stated that just 19% of condom users were perfect[3] users while the majority, 61%, used condoms less than half the time (Catania, Canchola, Binson, Dolcini, Paul, & Fisher,

2001). It may be that condom use as a secondary alternative method can partially explain this high rate of inconsistent use. The survey, however, failed to investigate this possibility.

Dual Method Contraception Use

Researchers often overlook dual-method users despite 15% of contraception users take this approach (Mosher et al., 2004). Among female contraception users, 4.1% use the condom and the pill, 2.7% use condom and withdrawal, 2.7% use a condom and another method, and 5.4% use other forms of dual methods not including the condom (Mosher et al., 2004). There is little information on dual-method use despite its theoretically high effectiveness.

One set of researchers highlighted a consistently ignored aspect of dual users when they differentiated dual users into two classes: simultaneous and alternating (Wilson, Koenig, Walter, Fernandez, & Ethier, 2003). Simultaneous dual users utilized multiple forms of contraception during the same act of intercourse (Id). Perfect simultaneous use would mean using both forms of contraception concurrently at every act of intercourse (Id). Typical[4] simultaneous use would include imperfect[5] primary, imperfect secondary, imperfect primary and secondary, or total absence of contraception use while generally using methods concurrently (Id). Alternating dual users employ just one form of contraception per act of intercourse, but the contraception method may change (Id).

This may mean that another form of contraception is used when the primary method is not available (ex// condom alternating with withdrawal) or has been used incorrectly (ex// missed pill alternating with condom) (Id). Perfect alternating use would

mean that during every act of intercourse one of the utilized forms of contraception is used (Id). Typical alternating use includes imperfect primary or total absence of contraception use while generally using a primary method with an alternate available (Id). As is obvious, perfect simultaneous dual use is much more effective at preventing pregnancy than perfect alternating dual use when dealing with the same forms of contraception. For clarification, remember that perfect users are included in typical-use rates but imperfect users among typical users are not included in perfect-use rates.

There is some concern over dual-method users, however. That's because condom-use consistency may actually be lower in dual-method users than in those using the condom as their sole means of contraception (Cates, 1996; Cates & Steiner, 2002; Cushman, Romero, Kalmuss, Davidson, Heartwell, & Rulin, 1998). This lower condom use may be more pronounced when the primary form of contraception affords an exceptionally low risk of pregnancy.

There's a problem with this interpretation, however. The studies analyzing this trend did not differentiate between simultaneous and alternating use among those using dual methods. Now, differentiating between these two uses would have been beneficial since we would actually expect a lower rate of condom use among alternating dual method users. But since there is no differentiation between these dual users, the study *does not* actually answer whether there is less consistent condom use among simultaneous dual users.

Failure to consider dual users also produces some minimal (but avoidable) error in contraception pregnancy rates. Researchers frequently--and erroneously--code dual-users as single-method contraception users in their methodology (Ranjit, Bankole, Darroch, &

Singh, 2001; Trussell & Vaughan, 1999). This coding procedure treats dual-users as having used only the more effective contraception method of the two being utilized. Instead, users should have been coded as utilizing both methods. Because of this coding, these "single-method" data points get the unwarranted benefit of dual-method protection pregnancy rate. And it's this benefit that artificially lowers the pregnancy rate—albeit not by much.

Current Contraception Pregnancy Rate Tables

By now we see that at least among typical users that the most common forms of contraception are among the least effective (relative to family planning goals). Given this disconnect, it is appropriate to look at how prospective contraception users choose their methods. Traditionally, prospective users access pregnancy-rate tables via contraceptive products or health professionals.

The purpose of contraception-pregnancy-rate tables is to give prospective contraception users a tool to pick contraception with an acceptable pregnancy risk. Current tables, such as that provided by the FDA (1998), allow prospective users to see pregnancy rates for one year (See Figure 1). But is it appropriate for tables to restrict themselves to one year? Realistically, prospective users will be using this information for multiple years. These women, after all, do not become indifferent to unintended pregnancies after one year. And even if a prospective contraception user intends to become pregnant at some point, there is still the matter of the remainder years where the user intends to prevent pregnancy. For younger users, this means limiting pregnancy risk for decades.

So it is essential to remember that it is not the prospective contraception user's intent to avoid unplanned pregnancy for merely one year. Users want to prevent *all unplanned pregnancies* in their fertile lifetimes. Now those users not familiar with probability theory (as we should not require them to be) may be comfortable with the seemingly low contraceptive pregnancy rates. But there are numerous cognitive errors a layperson can make when they extrapolate yearly pregnancy rates to longer periods. These may include errors such as assuming rates are additive for each year, or that the probability of pregnancy for one year is similar to the probability of pregnancy over some 15 or 20 years. Indeed, these types of cognitive errors may contribute to the popularity of less effective methods.

Rates framed in terms of one year are misleading for the same reason rates framed in terms of single use or one month would be misleading. For example, yearly typical pregnancy rates for the condom and pill are 17.4% and 8.7%, respectively (Kost, Singh, Vaughan, Trussell, & Bankole, 2008). If we mathematically translated these to monthly pregnancy rates, they would be 1.6% and .8% for the condom and pill, respectively[6]. The estimated monthly pregnancy rate illustrated here gives the illusion that both the pill and condom are highly effective. Indeed, these methods would mostly likely be suitable for those who actually intend to be at risk for an unplanned pregnancy for only a month out of their lives. But for those intending one year of risk, the pill then shows to be a clear winner over the condom.

This example shows that even the pill may cease to be appropriate for longer spans of time. This example demonstrates why it is important to match intended length of use to the appropriate time scale. Yet, time scales do not match to intent within current

tables. After this example, one also wonders if less effective methods are more popular because users mistakenly dismiss highly effective methods as overcautious.

Current tables offer little useful information to prospective contraception users. These tables contrast between perfect and typical use rates and note the presence of STI protection. But this does little more than communicate a limited perspective of relative contraception effectiveness.

We must keep in mind the users' needs when we create these tables. This means providing information in an accessible way so that an informed decision is possible. The use of contraception tables should be one of the first steps for prospective contraception users as they decide which method to use. Contraception users utilize these tables by matching the risk of pregnancy they are willing to accept to a corresponding set of contraception options. The users' next step is to assess the acceptability of these methods' potential side effects, noncontraceptive benefits, cost, accessibility, and adequacy in practice.

Looking beyond a clinical setting, companies use pregnancy tables with yearly rates in the packaging of contraceptives such as condoms and the pill. Durex condoms (Durex, 2008) also include the standard-format pregnancy rate table provided by the FDA (See Figure 1). Lybrel birth control pill inserts display pregnancy rates framed in one-year terms while also referencing other forms of contraception (Wyeth Pharmaceuticals, 2007). Using a package of Trojan condoms as an example, consumers are left with only "TROJAN Brand Latex Condoms, when used properly, are highly effective against pregnancy – although no contraceptive can guarantee 100% effectiveness" (Church & Dwight, 2008). The general advisement within the Trojan packaging is not surprising

considering the phrase “highly effective” is exactly what the FDA recommends (FDA, 1998). Consider also that the FDA has outdated pregnancy rates and outdated forms of contraception in its table (Id). The World Health Organization does better in this respect in its contraception pregnancy rate table. But it still suffers from many of the other mentioned drawbacks since it uses the same standard one-year formatting, and it omits dual-methods (WHO, 2004).

Insert Figure 1.

Proposed Long-Term Pregnancy Rate Table

Design

As discussed, it is appropriate for tables to contain longer time scales and include figures for dual-method use. But other factors must be considered. In a randomized controlled trial comparing comprehension of contraception-pregnancy-risk tables, researchers determined that a category approach was best, but the table should also offer a general numerical range of risk (Steiner, Dalebout, Condon, Dominik, & Trussell, 2003). Participants found specific numbers distracting even when general categories were included (Id). Therefore, using categories and general numerical ranges should allow for increased readability. General numerical ranges will also offer increased forgiveness to inherent random error. Consequently, these features were utilized in the proposed long-term table (see Figure 2).

Insert Figure 2.

Recall from previous discussion that the proportion of people that are perfect users is not trivial (Catania et al., 2001). This thereby demonstrates the necessity for two

sections: perfect- and typical-use. The proposed table presents these rates side by side for contrast and readability. This inclusion of both rates is also consistent with most current tables.

The main feature in the proposed table is the inclusion of long-term pregnancy risk while also including simultaneous-dual-method rates. As mentioned, a pregnancy mistimed by even one month can have harmful consequences (Brown & Eisenberg, Eds, 1995; Sadler, 2004). This is why the proposed table stresses the risk of at least one unintended pregnancy. Many methods provided in the proposed table quickly reach the highest category of risk (>50%). Further, the proposed table offers information on the expected number of pregnancies in a lifetime. The expected number of pregnancies column helps to differentiate these high-risk methods while also offering information that is meaningful to the reader. STI protection details are also included as an essential piece of information.

Naturally, there are subgroups of users that are more and less susceptible to unintended pregnancies while using contraception. Subgroups such as race, poverty, and marital status are important to health professionals for identifying high-risk groups. But they are less important to prospective contraception users for their method choice. These subgroups' inclusion would also make any table unreadable with complexity. Regardless, the varying level of risk within these subgroups is completely moderated by other variables directly influencing pregnancy rates within each contraception method. These direct variables--coital frequency, fertility, instructional compliance, and consistency of use--are all more proximal. And as such, they will act as a much better guide for prospective contraception users. These variables are also included in the footnotes of the

long-term table. Further, table's rates describe a large distribution of users—not individuals.

Technically, readers abuse all pregnancy-rate tables in practice by extrapolating them to the individual level. Such statistics are for describing a population, not any one person. But, of course, if no one used tables for individuals, then all tables would be useless to the general public.

Calculation

Long-term cumulative pregnancy rates have been estimated by the formula: $1-(1-F_i)^T$ where F_i is the pregnancy rate of a contraceptive method (generally given in years) and T is the number of time units, generally years as well (Ross, 1989; Trussell, 2007, pp. 28-29). Long-term pregnancy rates tend to taper off at the group level as the more fecund become pregnant early on (Ranjit et al., 2001). Trussell (2007, pp. 28-29) observes in *Contraceptive Technology*, however, that this risk of at least one pregnancy is constant over time at the individual level. As such, this formula is appropriate since it makes the static pregnancy rate assumption for each given form of contraception. All pregnancy rates use this formula except for typical-use within vasectomy. The vasectomy cumulative pregnancy rate formula applied the typical-use rate to just the first year with the perfect use rate applying thereafter. Trussell (2007, chap. 27) cautions, however, that the pregnancy rates for vasectomy are most likely underestimates since there is a serious concern of sampling bias.

Lifetime years of risk for unintended pregnancy was estimated by taking difference between the median age of first intercourse at 17 (The Alan Guttmacher Institute, 2002) and the median age of menopause at 51 (Kato et al., 1998). This

difference was then multiplied by the proportion of women 15-44 who are at risk for an unplanned pregnancy (70%) (Mosher et al., 2004). This results in 24 lifetime years of risk. Those between 44 and 51 are not included in contraception pregnancy rates, may have a lower proportion at risk for unplanned pregnancy, and are much less fecund (Nelson & Marshall, 2007, p. 675). Thus, this figure of 24 years is likely to be an overestimate. As a result, the best guess for typical lifetime years of risk for an unintended pregnancy is lowered to 20.

To determine the expected frequency of an event, the number of trials is multiplied by the probability of that event occurring. This same idea was used to determine the expected number of unintended pregnancies over a lifetime. The pregnancy rate was standardized from one year to 40 weeks to show the unavailability of concurrent pregnancies and yet make pregnancies available after a birth. Then, the pregnancy rate for a given contraception method was multiplied against the number of 40 week blocks in 20 years (estimated lifetime years at risk for an unintended pregnancy). Therefore, the expected number of unintended pregnancies over a lifetime while using a given method is: $(1-(1-F_i)^{40/52})(20)(52/40)$.

The formula is slightly adapted for the vasectomy method. The vasectomy calculation method for expected number of unintended pregnancies over a lifetime is also consistent with its calculation of long-term risk of at least one pregnancy. To estimate expected unintended pregnancies for vasectomy, the first time interval uses the typical-use rate with the remainder intervals using the perfect use rate. Again, this adjustment only applies to the typical-use section for vasectomies.

Unfortunately, pregnancy rates for dual-method users (simultaneous and alternating) are unavailable. And only the pregnancy rates of simultaneous-dual-method users were estimated due to the pragmatics of estimating the rates for alternating-dual-method users. Also, pregnancy rates for simultaneous-dual-method users could only be estimated for methods that act independently of one another in order to satisfy basic assumptions. It is tempting to use the following formula to estimate pregnancy rates for simultaneous-dual-method users: $(F_{ij}) = (F_i)(F_j)$, but this has been shown as incorrect (Kestelman & Trussell, 1991). Kestelman and Trussell pointed out that there is a hidden variable in both F_i and F_j—the probability of conception without using contraception, noted as C. Thus, F_i is really the effectiveness of method i, noted as E_i, multiplied by C: $F_i = (E_i)(C)$. This means that: $(F_i)(F_j) = (E_i)(C)(E_j)(C)$. Thus, one "C" needs to be factored out: $F_{ij} = (F_i)(F_j/C)$. Since "C" must be a number between zero and one, we know that by factoring out one "C" that the result will be greater than the incorrect approach of $(F_i)(F_j)$. Strangely, Kestelman and Trussell reached the opposite conclusion (1991). In the proposed table, the formula $F_{ij} = (F_i)(F_j/C)$ was used to calculate the pregnancy rates for simultaneous-dual-method users. The annual rate of pregnancy with no method (85%) was assigned to the constant value "C" in calculations (Trussell, 2007, chap. 27). This method for calculating simultaneous-dual-method pregnancy rates is also more conservative than the one used by Kestelman and Trussell (1991).

The yearly contraception pregnancy rates used for calculations and information on emergency contraception and lactational amenorrhea were referenced from *Contraceptive Technology* (Trussell, 2007, chap. 27). Updated rates since the referenced edition of *Contraceptive Technology* were included to reflect more recent typical-use rates for the

pill, condom, withdrawal, and periodic abstinence (Kost et al., 2008). The median number of acts of intercourse per month typically found in contraception studies is 11 (Steiner, Hertz-Piccoiotto, Raymond, Trussell, Wheeless, & Schoenbach, 1999; Steiner, Hertz-Piccoiotto, Taylor, Schoenbach, & Wheeless, 2001). This number was provided in the footnotes of the long-term table so that readers may generally assess their relative pregnancy risk by evaluating their deviation from the coital frequency median.

Discussion

Most women experience at least one unintended pregnancy in their lifetime (Henshaw, 1998). Whether in or outside of marriage, unintended pregnancies bear a high cost to society, the parents, and to the children that result (Brown & Eisenberg, Eds, chap. 3., 1995). This cost is even present for pregnancies that are only slightly mistimed because women then lose the ability to address birth defects proactively (Sadler, 2004). It is because of this frequency and high cost that we should be especially concerned with chosen forms of contraception. Unfortunately, the most commonly chosen contraception methods by those most fertile are the methods that are least reliable over time (Mosher et al., 2004). Also, male methods of contraception beyond the condom, withdrawal, and vasectomy are still in the future (Blithe, 2008). Those potential forms of male contraception may also open up the door for more combinations of simultaneous and alternating use. This is especially important because they act to prevent pregnancy by independent means other than focusing on ovulation prevention or barrier methods.

Perhaps the most promising future male contraceptive is RISUG. This reversible, nonhormonal, low-cost, and highly effective method has completed stage I and II clinical trials (Male Contraceptives.org; Male Contraception Information Project). Because user error is impossible with this method, its perfect-use rate is equal to its typical-use rate. Should RISUG reach the market, this would make it competitive with other long-term, reversible methods, but without any user concerns over using hormones.

Since the selection of contraception is so paramount, the responsibility of the public health field to provide clear and valuable guidance becomes all the more apparent. This responsibility includes providing accurate contraception pregnancy rates. It appears

current coding errors only minimally distort pregnancy rates. Even so, it is possible that the error may accumulate to meaningful values when used to estimate long-term pregnancy risk. This minimal error is also completely avoidable through coding correction.

There is also reason to directly measure pregnancy rates for dual-method contraception users because even indirect estimates of pregnancy rates for simultaneous dual method users may contain extra error. As discussed earlier, it is possible that typical-simultaneous-dual-method users will have higher pregnancy rates than estimated because they use their secondary contraception method less consistently (Cates, 1996; Cates & Steiner, 2002; Cushman et al., 1998). Recall, however, that there were serious concerns with the coding methodology that led to this conclusion. Therefore, it is unclear whether simultaneous-dual-method users are using their secondary contraception method consistently.

This ambiguity gives reason to empirically derive annual pregnancy rates for dual-method users rather than to indirectly estimate them by extrapolating data from respective primary and secondary pregnancy rates. It is necessary to indirectly calculate long-term pregnancy rates by extrapolating from annual pregnancy rates since it would be too impractical to obtain direct measurements for all birth control methods. However, it is clearly feasible and even preferred to directly measure annual pregnancy rates from various dual-method users.

Health professionals should frame contraceptive pregnancy rates for the convenience of the prospective contraception user. This means providing a functional

reference tool that shows rates over more useful time periods than a single year. This also means offering rates for dual-method use.

In light of long-term pregnancy rates, those in the public health field may consider reevaluating the discussion of certain contraceptive methods. For instance, as relationships become more established, partners may discourage the inclusion of condoms due to issues of trust (Woodsong & Koo, 1999). But from the data presented in this article, sexual couples may now sidestep those issues by touting the increased long-term pregnancy prevention of pairing the condom with other contraception. This argument for couples has promise because studies have repeatedly shown that protection against pregnancy garners much more influence than protection against STIs/HIV when choosing contraception (Crosby, DiClemente, Wingood, Sionean, Cobb, Harrington et al., 2001; Steiner, et al., 2003; Wilson et al., 2003; Woodsong & Koo, 1999).

The long-term table reveals the inadequacy of current tables by highlighting the similarity of various methods in their pregnancy risk over time. Within the typical users section of the long-term table, the pill and male condom fall in the same category of "very high risk" after just ten years. In contrast, two of the three tables used in Steiner et al. (2003) differentiate the pill and condom into two separate classes of effectiveness: "effective" and "less effective," respectively. Another disadvantage with current tables is that readers may misguidedly find the pregnancy rates of some contraceptives satisfactory and then respond by not investigating methods that are more effective. This reinforces the need to remember how contraception is used in practice (e.g. over a longer period of time) and that avoiding all unintended pregnancies is the primary goal of using

contraception. This focus on long-term pregnancy prevention should be one of the concentrations within sex education and family planning clinics—especially for youth.

The high pregnancy rates demonstrated in the long-term table should lead contraception users to question the role of certain popular forms of contraception, such as the pill and condom. The long-term table makes it clear that the typical use of these methods reduces the total expected number of unintended pregnancies. But it is dubious that these methods reduce the risk of at least one pregnancy to acceptable levels when used on their own. In perfect use, the pill does a sensible job of impeding the risk of unintended pregnancy over time. Alternatively, long-term use of the condom fails to keep this pregnancy risk in check for typical-use and is only able to hold pregnancy at "moderate" to "high risk" with perfect-use. This is in clear contrast to the FDA recommended label, "highly effective against pregnancy" that Trojan uses for its condoms (FDA, 1998; Trojan, 2008).

Obviously, using the condom or pill alone, even with typical-use, is still much better than using nothing. The pill, with typical use, is estimated to limit women to just one to two unintended pregnancies over 20 years. The condom, again with just typical-use, limits the expected unintended pregnancies to just three to four over a 20-year span as well.

The condom models itself best suited for protecting against STIs, as a complement form of contraception, and for those having infrequent intercourse. For example, typical simultaneous-dual pill/condom use keeps the risk of at least one pregnancy to a more reasonable level than the pill alone. And, in perfect-use, the pair does superbly. Allowing for a contrast of typical- and perfect-use rates over time (by

providing the proposed table) may also act to persuade prospective contraception users to spend more energy focusing on perfect-use.

This focus on perfect use is especially relevant to methods like the pill, condom, withdrawal, and the rhythm method, which are all highly sensitive to user error. As mentioned earlier, perfect-use of the pill, even by itself, contains a reasonable risk level across a user's lifetime. This method selection just reaches the "moderate risk" category of the long-term table with a pregnancy risk of about 5% after 20 years. Naturally, near-perfect use of any method would put a user closer to the perfect-use side of the table than the typical-use side. Of course, showing such permutations of use would render the table unusable. Current tables face this same obstacle.

The low, long-term pregnancy rates for typical-use of Implanon and Mirena make these methods particularly outstanding as candidates for reversible contraception. Importantly, these rates stay low across a lifetime ("very low risk" for Implanon and "low risk" for Mirena) and both keep to "very low risk" levels when simultaneously used with a condom. This is largely because their perfect-use rates and typical-use rates are functionally equivalent.

Unfortunately, with pregnancy rates framed annually, the comparative effectiveness of these long-term contraception methods just isn't clear. Some researchers have taken the idea of using category labels of effectiveness in their contraception tables to clarify differences between methods (Steiner et al., 2003). Still, even when yearly rates use categories, readers may not be able to fully appreciate the comparative effectiveness of these methods. In this traditional presentation, pregnancy rates for most contraception methods continue to appear reasonably low. The pregnancy rates of especially effective

methods only become meaningful when longer periods are considered. Adding category labels alone does not accomplish the same kind of contrast between highly effective and moderately effective methods. This contrast can only be achieved by displaying long-term pregnancy rates.

Implanon and Mirena have rates of at least 80% continuance over the course of one year, higher than any other form of reversible birth control (Trussell, 2007, chap. 27). Amenorrhea and oligomenorrhea are some of the main reasons women discontinued these methods (Bitzer, Tschudin, Alder, & The Swiss Implanon Study Group, 2004; Hidalgo, Bahamondes, Perrotti, Diaz, Dantas-Monteiro, & Petta, 2002). These menstrual changes may be especially startling to users uninformed of their likelihood or benign nature. Speroff and Darney (2005, p. 94) reaffirm the professional consensus against the myth that a woman "needs" to have a period when using continuous hormonal birth control.

Contraception users need to receive full disclosure of all the side effects for candidate methods and the seriousness of those effects. Further, health care providers should provide this information with clarity and without prompting from patient inquiry. It would also be worthwhile to weigh the side effects of a candidate method in comparison to the risks of an unintended pregnancy. As noted earlier, a long-term, nonhormonal method such as RISUG would sidestep these concerns.

The proposed table can easily be adapted for use as inserts in all contraception packaging to assure that consumers have a better understanding of the pregnancy rates for their method. And inserts may be especially suitable for groups without easy access to this information. Such groups may be those at high-risk for an unintended pregnancy

such as those experiencing poverty. Those at or below 150% poverty, for example, are over three times more likely to have an unwanted birth, and are over two times as likely to have a mistimed birth than those at or above 300% poverty (Chandra et al., 2005). Expanded contraception information may be particularly valuable for this group, but only if access to more effective forms of contraception is available as well.

Offering longer time frames and simultaneous-dual-method-use rates within tables may provide advantages not only in the medium of contraception packaging, but also within school- and counselor-based family planning/ sex education. It is especially critical to provide this information to those early in their fertility because this is when long-term planning of contraception is most appropriate. Finally, researchers should investigate the readability and usefulness of the presentation in the proposed table.

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Figures

Figure 1. FDA Contraception Pregnancy Rate Table.

The following table provides estimates of the percent of women likely to become pregnant while using a particular contraceptive method for one year. These estimates are based on a variety of studies.

"Typical Use" rates mean that the method either was *not always used correctly* or was *not used with every act of sexual intercourse* (e.g., sometimes forgot to take a birth control pill as directed and became pregnant), or was *used correctly* but *failed anyway*.

"Lowest Expected" rates mean that the method was *always used correctly* with *every act of sexual intercourse* but *failed anyway* (e.g., always took a birth control pill as directed but still became pregnant).

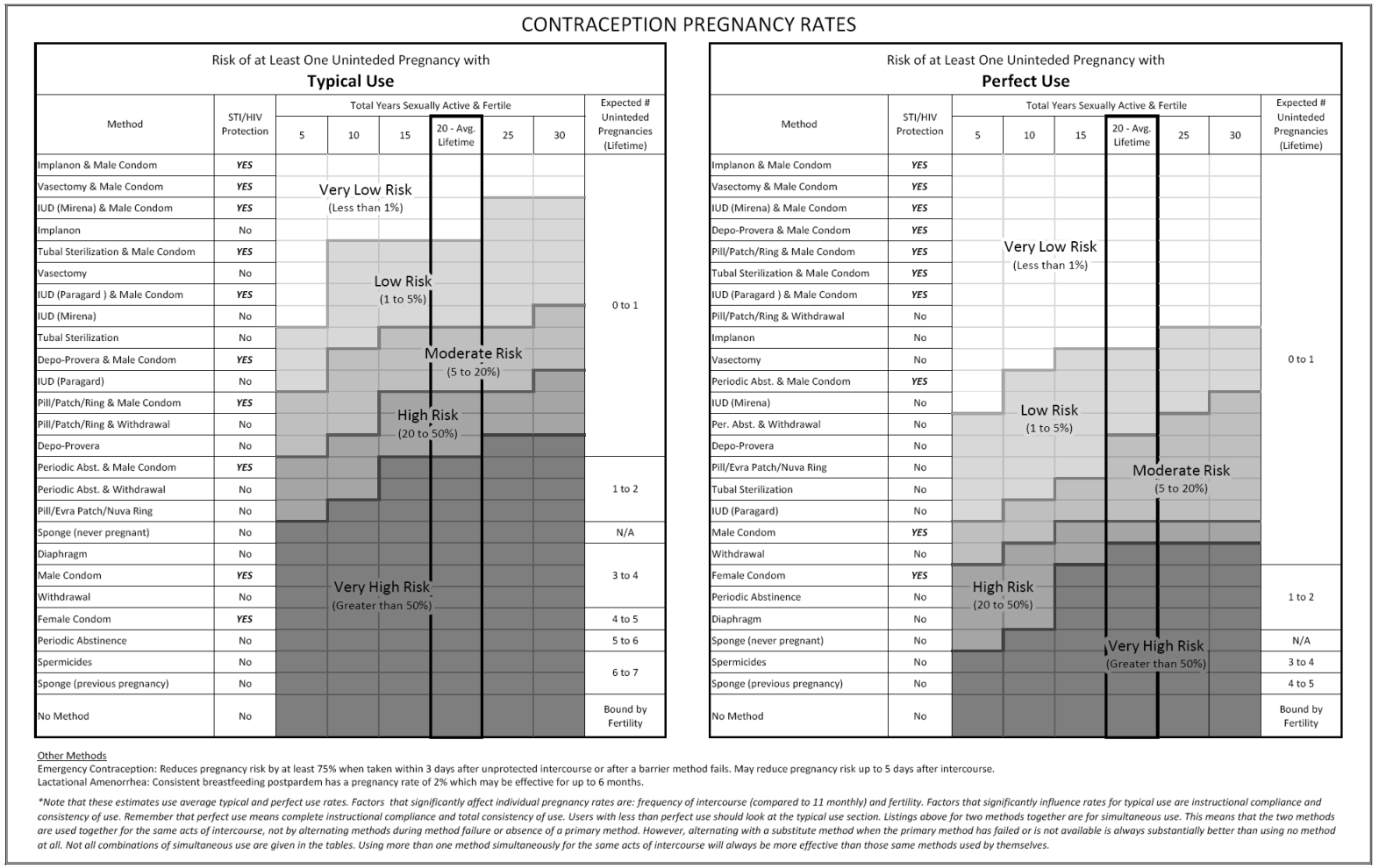
Method	*Typical Use Rate of Pregnancy*	*Lowest Expected Rate of Pregnancy*
Sterilization:		
Male Sterilization	0.15%	0.1%
Female Sterilization	0.5%	0.5%
Hormonal Methods:		
Implant *(Norplant™ and Norplant™-2)*	0.05%	0.05%
Hormone Shot *(Depo-Provera™)*	0.3%	0.3%
Combined Pill *(Estrogen/Progestin)*	5%	0.1%
Minipill *(Progestin only)*	5%	0.5%
Intrauterine Devices (IUDs):		
Copper T	0.8%	0.6%
Progesterone T	2%	1.5%
Barrier Methods:		
Male Latex Condom [1]	14%	3%
Diaphragm [2]	20%	6%
Vaginal Sponge *(no previous births)* [3]	20%	9%
Vaginal Sponge *(previous births)* [3]	40%	20%
Cervical Cap *(no previous births)* [2]	20%	9%
Cervical Cap *(previous births)* [2]	40%	26%
Female Condom	21%	5%
Spermicide: *(gel, foam, suppository, film)*	26%	6%
Natural Methods:		
Withdrawal	19%	4%
Natural Family Planning *(calendar, temperature, cervical mucus)*	25%	1-9%
No Method:	85%	85%

[1] Used Without Spermicide

[2] Used With Spermicide

[3] Contains Spermicide

Figure 2. Proposed Long-term Contraception Pregnancy Rate Table.



CONTRACEPTION PREGNANCY RATES

Risk of at Least One Uninteded Pregnancy with **Typical Use**

Method	STI/HIV Protection	Total Years Sexually Active & Fertile: 5	10	15	20 - Avg. Lifetime	25	30	Expected # Uninteded Pregnancies (Lifetime)
Implanon & Male Condom	***YES***							0 to 1
Vasectomy & Male Condom	***YES***							
IUD (Mirena) & Male Condom	***YES***							
Implanon	No							
Tubal Sterilization & Male Condom	***YES***							
Vasectomy	No							
IUD (Paragard) & Male Condom	***YES***							
IUD (Mirena)	No							
Tubal Sterilization	No							
Depo-Provera & Male Condom	***YES***							
IUD (Paragard)	No							
Pill/Patch/Ring & Male Condom	***YES***							
Pill/Patch/Ring & Withdrawal	No							
Depo-Provera	No							
Periodic Abst. & Male Condom	***YES***							1 to 2
Periodic Abst. & Withdrawal	No							
Pill/Evra Patch/Nuva Ring	No							
Sponge (never pregnant)	No							N/A
Diaphragm	No							3 to 4
Male Condom	***YES***							
Withdrawal	No							
Female Condom	***YES***							4 to 5
Periodic Abstinence	No							5 to 6
Spermicides	No							6 to 7
Sponge (previous pregnancy)	No							
No Method	No							Bound by Fertility

Very Low Risk (Less than 1%)
Low Risk (1 to 5%)
Moderate Risk (5 to 20%)
High Risk (20 to 50%)
Very High Risk (Greater than 50%)

Risk of at Least One Uninteded Pregnancy with **Perfect Use**

Method	STI/HIV Protection	Total Years Sexually Active & Fertile: 5	10	15	20 - Avg. Lifetime	25	30	Expected # Uninteded Pregnancies (Lifetime)
Implanon & Male Condom	***YES***							0 to 1
Vasectomy & Male Condom	***YES***							
IUD (Mirena) & Male Condom	***YES***							
Depo-Provera & Male Condom	***YES***							
Pill/Patch/Ring & Male Condom	***YES***							
Tubal Sterilization & Male Condom	***YES***							
IUD (Paragard) & Male Condom	***YES***							
Pill/Patch/Ring & Withdrawal	No							
Implanon	No							
Vasectomy	No							
Periodic Abst. & Male Condom	***YES***							
IUD (Mirena)	No							
Per. Abst. & Withdrawal	No							
Depo-Provera	No							
Pill/Evra Patch/Nuva Ring	No							
Tubal Sterilization	No							
IUD (Paragard)	No							
Male Condom	***YES***							
Withdrawal	No							
Female Condom	***YES***							1 to 2
Periodic Abstinence	No							
Diaphragm	No							
Sponge (never pregnant)	No							N/A
Spermicides	No							3 to 4
Sponge (previous pregnancy)	No							4 to 5
No Method	No							Bound by Fertility

Very Low Risk (Less than 1%)
Low Risk (1 to 5%)
Moderate Risk (5 to 20%)
High Risk (20 to 50%)
Very High Risk (Greater than 50%)

Other Methods
Emergency Contraception: Reduces pregnancy risk by at least 75% when taken within 3 days after unprotected intercourse or after a barrier method fails. May reduce pregnancy risk up to 5 days after intercourse.
Lactational Amenorrhea: Consistent breastfeeding postpardem has a pregnancy rate of 2% which may be effective for up to 6 months.

**Note that these estimates use average typical and perfect use rates. Factors that significantly affect individual pregnancy rates are: frequency of intercourse (compared to 11 monthly) and fertility. Factors that significantly influence rates for typical use are instructional compliance and consistency of use. Remember that perfect use means complete instructional compliance and total consistency of use. Users with less than perfect use should look at the typical use section. Listings above for two methods together are for simultaneous use. This means that the two methods are used together for the same acts of intercourse, not by alternating methods during method failure or absence of a primary method. However, alternating with a substitute method when the primary method has failed or is not available is always substantially better than using no method at all. Not all combinations of simultaneous use are given in the tables. Using more than one method simultaneously for the same acts of intercourse will always be more effective than those same methods used by themselves.*

Footnotes

[1]Primary method refers to the most effective method used when a contraception user utilizes multiple forms of contraception.

[2]Secondary method refers to the second most effective method used when a contraception user utilizes multiple forms of contraception.

[3]Perfect contraception use refers to utilizing a contraceptive device with complete instructional compliance and 100% consistency in use.

[4]Typical contraception use refers to average use. This includes all possible uses of the contraceptive (i.e. all levels of directional compliance and all levels of consistency).

[5]Imperfect contraception use refers to less than perfect instructional compliance or consistency.

[6]The translation used to estimate monthly pregnancy rates from the yearly rates uses the following formula: $1-(1-F_i)^{1/12}$