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(Title 17 U.S. Code).Commentary*Dual Protection Against Unintended Pregnancy and Sexually Transmitted Infections*

What Is the Best Contraceptive Approach?

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In the midst of the global epidemics of both unintended pregnancy and sexually transmitted infection, contraceptive options that provide dual protection are ideal. However, those contraceptives with the best record of preventing pregnancy under typical use conditions (sterilization, hormonal methods, intrauterine devices) provide little if any protection against sexually transmitted infection. Alternatively, barrier contraceptive methods (specifically, condoms), which can reduce risks of many sexually transmitted infections, are associated with relatively higher pregnancy rates for most users than other contraceptives. This situation has produced a dilemma for those wishing to promote dual protection: whether to advocate use of two methods (one primarily to prevent pregnancy and the other primarily to prevent infections) or whether to emphasize use of condoms for both purposes. Data comparing these two approaches are limited and often contradictory. We discuss the underlying concepts of exposure to both pregnancy and infection, provide a broad overview of the effectiveness of contraceptive methods against these two conditions, present approaches to optimize dual protection, and propose several new directions for necessary research. In the absence of evidence-based recommendations, we believe clinicians should assist clients in assessing their likelihood of exposure to infection, either by prevalence of sexually transmitted infection in the community or by the specific risk factors of the client. If exposure is likely, particularly to the more serious infections such as human immunodeficiency virus, the one-method approach should be given greater weight. However, in settings where unintended pregnancy is the greater concern, emphasizing the two-methods approach as a first option may be appropriate.

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DESPITE ALL OUR TECHNICAL ACHIEVEMENTS, the adverse consequences of sexual intercourse continue to haunt us. At least half of all pregnancies—an estimated 133 million annually worldwide—are unintended.^{1,2} Moreover, approximately 340 million curable sexually transmitted infections (STIs) occur each year.³ Another 5 million people acquire HIV annually, with 1.8 million of these new infections occurring among women and 800,000 among children younger than 15 years of age.⁴ At least 40 million persons are currently living with HIV/AIDS, of whom 17.6 million are women.⁴

In the midst of these continuing global epidemics of unintended pregnancy and STIs, policy-makers have been examining approaches to providing contraception that will have a simultaneous impact on the dual trends. Worldwide, patterns of contraceptive use have been encouraging. Between 1990 and 1995, overall contraceptive coverage increased approximately 6%,⁵ and fertility rates declined concomitantly. Likewise, in the United States, use of contraception has evolved in directions that have reduced unintended pregnancies.⁶ In 1995, effective methods such as sterilization and oral contraceptives were the predominant family planning approaches.⁷

However, the concept of providing dual protection against both unintended pregnancies and STIs has run into a complex roadblock.^{8,9} Those contraceptive methods with the best record of preventing pregnancy under typical use conditions (sterilization, hormonal methods, intrauterine devices) provide little if any protection against STI. Alterna-

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tively, barrier contraceptive methods (specifically condoms), which can effectively prevent both STI and pregnancy if used consistently, are associated with relatively higher pregnancy rates than other contraceptives for most users.⁸ This situation has produced a dilemma for those wishing to promote dual protection: whether to advocate use of two methods (one primarily to prevent pregnancy and the other primarily to prevent infections) or whether to emphasize use of condoms for both purposes.

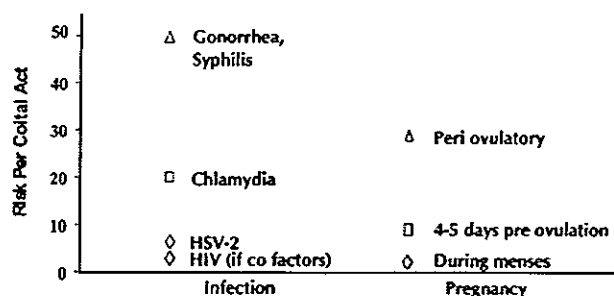
Our analysis below provides a current scientific framework upon which clients, clinicians, and policy-makers alike can make the decisions on how to achieve dual protection. We present broad themes in an attempt to clarify an issue that is exceedingly complex, whether applied to resource-rich or resource-poor settings. By design we have kept our text relatively short and simple, risking being viewed as simplistic rather than confusing. For more in-depth examination of specific topics, we refer readers to the overview references we have cited.

Concepts of Exposure

Although transmitted by the same human behavior—penile–vaginal intercourse—the outcomes of pregnancy and genital infection have fundamentally different epidemiologic profiles.¹⁰ In brief, they differ in terms of (1) the percentage of the population at risk, (2) the rate of “transmission” per each coital episode, and (3) the foci for prevention that the first two variables create.

First, a much smaller percentage of the population is infected with an STI than is fertile. The prevalence of different STIs varies widely, depending on such factors as age, sex, and geographic region. For example, teenagers are more likely to be infected with chlamydia than older persons,¹¹ and the proportion infected with HIV ranges from a reported 0.1% in the general population of northern hemisphere countries to more than one third of individuals in Southern Africa.⁴ In most areas of the world, more than 9 in 10 persons between 18 years and 35 years of age are fertile.

Second, with exposure to an infected and/or fertile person, the risk of transmission per each unprotected coital episode differs—for infection, according to the particular organism, and for pregnancy, according to the timing of coitus during the menstrual cycle. In general, the risk of transmitting a bacterial cervical infection is higher than the chance of producing an unintended pregnancy during a random act of unprotected intercourse during a menstrual cycle (Figure 1). For example, the probability that an infected person will transmit gonorrhea or syphilis to a susceptible partner is approximately 50% for each coital act.¹² Other sexually transmitted bacterial organisms such as chlamydia may be associated with lower per-act risks of transmission.^{12,13} Viral STIs, including herpes simplex virus type 2 and HIV infection, are associated with even lower risks of



Sources: Anderson (1999); Wilcox (1995)

Fig. 1. Risk of events per single act of unprotected intercourse, by sexually transmitted condition.

transmission at each exposure.^{14–16} However, the rate of transmitting pregnancy depends on the timing of intercourse in the woman’s cycle. Coitus can lead to pregnancy on only about 6 days of the menstrual cycle, with the daily probabilities of conception rising gradually before the day of ovulation and then dropping sharply after ovulation.¹⁷ Even on the most fertile day, the woman’s risk of becoming pregnant from a single unprotected coital act is approximately one-half that of her becoming infected if her partner has gonorrhea.

Third, the two differences above combine to create theoretically different prevention foci, depending on whether the major concern is reducing STIs or reducing unplanned pregnancies. To prevent STIs, attention should be concentrated primarily on *with whom* intercourse occurs. i.e., how likely the partner is to be infected. For those STIs with high transmission rates, preventive measures must be used at essentially every coital act with an infected or potentially infected person. To reduce unintended pregnancy risk, by contrast, a more relevant issue is *when in the cycle* or *how often* a couple has intercourse. More frequent coitus increases the likelihood that a given couple will have intercourse during the relatively short fertile interval. In practice, these different foci may coincide if people have frequent intercourse with potentially infected partners. However, in most situations, clearly one or the other focus predominates: for example, mutually monogamous couples may not be concerned with STIs, and women who have infrequent sex with men who have other partners may be more at risk of infection than of pregnancy.

Effectiveness of Contraceptive Methods Against Pregnancy and STIs

Our currently available contraceptives have differing effects on pregnancy and STIs. With regard to pregnancy, different contraceptive methods can be viewed as having both a perfect-use effectiveness and a typical-use effectiveness.¹⁸ Contraceptive counseling messages often attempt to

convey precise point estimates of a method's effectiveness by presenting these two pregnancy rates. This precision may be misleading for particular individuals because these are average rates that do not pertain to any specific person but rather represent the mix of user behaviors influencing pregnancy in populations. A recently proposed alternative is to de-emphasize point estimates and instead group contraceptives into three categories.¹⁹ The first category includes methods that are highly effective and do not depend on user adherence (e.g., sterilization, implants, injectables, intrauterine devices). The second category contains only the oral contraceptive pill. The pill is highly effective if used correctly and consistently and still quite effective during typical use because it is relatively forgiving of imperfect use. The third category includes methods that are less effective than those in the first two categories. All barrier methods are included in this category, primarily because they require correct and consistent use during every act of intercourse, at least during the fertile period. These methods are quite unforgiving of imperfect use, as are withdrawal and natural family planning.

With regard to STIs, our knowledge of the effect of contraceptives on the spread of different organisms is less certain.²⁰ Moreover, the various contraceptive methods have a wider range of both protective and harmful influences on STIs than on pregnancy. For example, male condoms have been shown to protect against several STIs, including HIV infection, but only if used consistently and correctly.²¹ Just as with pregnancy, they are unforgiving of imperfect use. Female condoms should have a similar protective spectrum with consistent and correct use. However, spermicides containing nonoxynol-9 have not been shown to prevent STI.²² Diaphragms (usually used with spermicides) and cervical caps provide a mechanical barrier against cervical infection, but they have been associated with vaginal and bladder infections.^{23,24} Oral contraceptives are associated with an increased detection of cervical chlamydial infection. They appear to protect against symptomatic pelvic inflammatory disease²⁵ but may simply mask symptoms, resulting in unrecognized endometritis.²⁶ The role of hormonal contraception in either potentiating or protecting against the transmission of HIV remains unclear.²⁷ Finally, intrauterine devices are associated with upper-genital-tract infection in the first month after insertion.²⁸ Thereafter, the device's association with pelvic inflammatory disease appears no higher than for other methods of contraception that provide no STI protection.^{29,30} Thus, we emphasize again that to achieve dual protection under typical circumstances, trade-offs must be made.

Motivations for Dual Protection

Whether the major goal is to prevent pregnancy, infection, or both undoubtedly influences the dual-protection approach. In all surveys to date, relatively few male condom

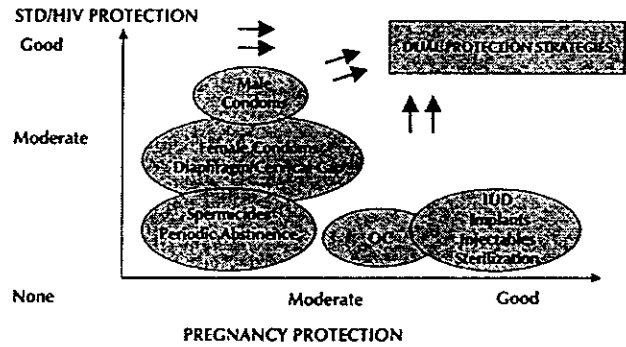


Fig. 2. Dual protection strategies eliminating the trade-off?

users—about 10%—report they use condoms primarily to prevent STIs.^{31–33} The rest are approximately equally split between those using condoms for pregnancy prevention only and those using them for dual protection. The most extensive examination of the motives for using condoms or other contraceptives was conducted among sexually active young adults in Buffalo, New York. Those who reported using condoms to prevent infections also reported more high-risk behaviors than those motivated by pregnancy-prevention goals.³³ In fact, those who used condoms to prevent pregnancy had more behavioral and psychological characteristics in common with those who were using other methods of contraception than with condom users seeking infection protection. This implies that persons in pursuit of the same goal (pregnancy protection) choosing different contraceptive methods (e.g., condoms and oral contraceptives) may resemble each other to a greater degree than those choosing the same method (condoms) but for different purposes.

Approaches to Optimize Dual Protection

To illustrate the two-dimensional trade-off, we have developed a simple graph, depicting the differential effectiveness of our main contraceptives against unintended pregnancy on the x axis and STI on the y axis (Figure 2). Our dual-protection goal is to promote those contraceptive options that move the user closer to the upper-right quadrant of the figure. With use of the current semantics, the two-methods approach would emphasize that methods in category 1 with the best pregnancy protection (sterilization, implants, injectables, intrauterine devices) be used in conjunction with condoms to create an additive effect. Alternatively, the one-method approach would emphasize more consistent use of condoms, so that they become more effective in preventing both pregnancy and STIs. These approaches would require different behavioral choices by individuals: the two-methods user needs motivation to use both methods (although condom use could be focused on

potentially infected partners), whereas the one-method user requires motivation to use condoms *consistently*, even during sex with uninfected partners.

Two Methods

Using two methods simultaneously should enhance the degree of protection against both unwanted pregnancy and STIs. However, arguments against this approach include the following. (1) Many people dislike using even one contraceptive method; motivating them to use two simultaneously may be unrealistic. (2) Adding a second method may impair consistency of use of the first. (3) Promoting condoms only for disease prevention may stigmatize the method and inhibit people at risk for STIs from using them. (4) Finally, using or promoting two methods may not be financially or logistically feasible, either for the client or for public health programs.

Research on the success of the two-methods approach is limited and often contradictory. A nationally representative survey in France showed that condom use among single women was not influenced by the use of hormonal methods.³⁴ Similarly, a longitudinal study evaluating the influence of an HIV intervention to promote condom use showed no adverse effect on continued use of hormonal methods.³⁵ Conversely, multiple observational studies have found, in general, that the more effective the contraceptive method, the lower the level of consistent condom use.⁸ For example, nationally representative surveys in the United States²⁷ and a large survey of Canadian college students³⁶ both showed consistency of condom use to be lower among oral contraceptive users than among women using condoms alone for dual purposes. Moreover, the adoption of methods such as tubal sterilization,³⁷ injectables,³⁸ and implants³⁹ reduces subsequent condom use. A recent study⁴⁰ compared the consistency of condom use in three groups of urban teens choosing contraception (implants, oral contraceptives, or condoms). Self-reported condom use over a 2-year period was lowest in the implant group. However, similar and fairly high STI rates were observed in all three groups, a circumstance implying the teens did not use condoms consistently enough in any of the groups to prevent STIs. Since none of these studies were randomized and many lacked statistical power, no definitive conclusions can be drawn about the appropriateness of promoting use of two methods.

One Method

The one-method approach encourages the sole use of condoms for its dual goals, namely, to protect against both pregnancy and STI. The main argument against this approach is that condoms used under typical conditions (e.g., inconsistently) provide less effective protection against pregnancy than hormonal methods or intrauterine devices. Thus, many fear that although emphasizing one method for

dual purposes will provide some STI protection, it will do so at the cost of reduced pregnancy protection. This trade-off may be prudent in countries facing high prevalence of STIs and HIV, especially if safe pregnancy termination is accessible and affordable, but might be ill advised in low-prevalence settings where unplanned pregnancy and unsafe abortion are more important public health concerns.

Proponents of the one-method approach point to the example of Japan, where, until recently, condoms were the main available contraceptive method. The low unintended pregnancy and abortion rates in Japan show that it is possible for a population to rely successfully on condoms for pregnancy prevention. However, Japan was able to achieve this high level of condom use and effectiveness, primarily by limiting access to hormonal contraceptives.⁴¹ Whether restricting overall contraceptive choices is an acceptable way to achieve this end is questionable.

The recently expanded selection of barrier methods (e.g., female condom, polyurethane male condom) increases the likelihood that couples will find one they can use correctly and consistently. Although some studies have shown offering a choice of barrier methods may reduce use of the male condom,^{42,43} this substitution may not be a drawback if the alternative methods are also effective for STI and pregnancy prevention. For example, in Thailand, women given both female and male condoms had a slightly lower incidence of STIs than the women given only male condoms.⁴³ Other studies have found interventions at both individual and community levels that offered female condoms plus male condoms increased overall use of the latter, perhaps because of a heightened ability to negotiate with the male partner for use of either barrier method.⁴⁴⁻⁴⁷

Having emergency contraception as a back-up to barrier methods also may make the one-method approach more acceptable by increasing its effectiveness in preventing pregnancy.^{48,49} However, some of the arguments outlined above against the two-method approach (adherence, substitution effect, and cost) might apply to use of emergency contraception as a supplement to condoms. Again, data are inconsistent on whether making emergency contraception more widely available has a positive or negative impact on use of other methods.⁴⁹

Two mathematical models have been used to estimate the effects on pregnancy and STD/HIV transmission of different dual-protection approaches (Schwingl PJ, Visness CN, Welsh M, et al. TRADE-OFF: a tool for modeling the outcomes and costs of reproductive health interventions. Unpublished manuscript shared August 26, 1999. Kahn JG. Promoting dual contraception: a model to estimate pregnancy and STD effects. Unpublished manuscript shared January 6, 2000). The results of the hypothetical exercises were similar and not surprising. Regardless of the assumptions used, consistent use of two methods resulted in the lowest level of pregnancies and infections—but at the high-

est financial cost. Use of hormonal contraception alone protected against pregnancies but not infection. Use of condoms alone produced more pregnancies than hormonal methods but fewer infections. Both research groups acknowledged the uncertainties inherent in their assumptions and called for empirical research.

Next Steps

Unfortunately, the above data provide no easy answers. The data from investigations to date remain inconclusive about the best approach to achieving dual protection. The research hypotheses are complex, the study designs have been observational, and the exposure-outcome variables have been inadequately measured. This has led to a variety of inherent methodologic weaknesses in the studies of dual protection. These include self-selected populations of contraceptive users that may be fundamentally different from each other (selection bias); an inability to accurately measure either the consistency of method use or exposure to infection; and the absence of biologic outcomes leading to reliance on self-reported data subject to social desirability bias.

Clinical/Programmatic Recommendations

Notwithstanding the paucity of data upon which to make evidence-based recommendations, clinicians and policy-makers need to move forward to help achieve dual protection. Should a two-method or one-method approach be emphasized? One key factor affecting this decision is the client's likelihood of exposure to infection, which may be assessed either by the prevalence of STI in the community or by the specific risk behaviors of the client. If exposure is likely, particularly to the more serious infections such as HIV, the one-method approach should be given greater weight. Conversely, in settings where unintended pregnancy is the greater concern, such as in many family planning clinics in developed countries, emphasizing the two-method approach as a first option may be appropriate. Women using a hormonal contraceptive method could be counseled on when (or, more specifically, with whom) concurrent barrier use is most important—with new partners, with partners who have other partners, and with partners who have not been tested for STIs.

The relative consequences of either unintended pregnancy or infection are crucial factors. Women who wish to delay childbearing may choose the one-method approach, even if they are not at especially high risk of infection; for them, the importance of preserving fertility by reducing even a low infection risk may outweigh the importance of preventing an early but ultimately wanted pregnancy. In contrast, women for whom abortion is unacceptable or for whom having a child is medically dangerous may choose

the two-method approach because of its theoretically greater effectiveness in pregnancy prevention.⁵⁰

As with any contraceptive choice, clinicians should tailor their counseling messages to the individual client's desires and motivations. With either dual-protection approach, however, clinicians must provide directive counseling messages about the need for and correct use of condoms and other barrier contraceptives for protection from STI and pregnancy. This requires their commitment to deliver positive and reinforcing messages about the condom's dual-purpose effectiveness if used consistently. Moreover, making barrier methods physically available in the clinic setting should be an important component of all dual-protection programs.

Research Needs

Because of the increasing public health problems posed by both unintended pregnancies and the STI epidemic, we have a pressing need for accurate data to allow informed policy decisions about how best to promote dual protection. Three important testable hypotheses follow.

Promoting condoms for prevention of pregnancy, rather than (or in addition to) STIs, will result in greater condom use and, consequently, lower infection rates at the population level. The current practice of promoting condoms primarily to protect against STIs may stigmatize the method by raising the issue of trust. This in turn may make condoms unacceptable to persons who do not wish to acknowledge their STI risk. It may also undermine perceptions of the condom's effectiveness in preventing pregnancy. Delivering counseling messages that clarify the contraceptive effectiveness of condoms when used consistently, particularly if backed up by emergency contraception, may make people feel more comfortable about using them as a dual-purpose approach.

In a two-method strategy, advising use of condoms in situations of high STI risk will result in better adherence and fewer infections than advising use at all coital acts. The notion of using condoms at every sexual encounter may seem so unrealistic or unacceptable that couples will not initiate use or will fail to use them when they are most needed. More targeted approaches may be more effective. Such focused counseling messages could suggest that clients always use condoms outside of a stable relationship or always use condoms at the beginning of a new relationship, until both partners have demonstrated (e.g., by time or by testing) that they not to be infected. However, the use of condoms only with sex partners deemed at high risk of STI may stigmatize the method.

Providing an array of contraceptive choices will increase adherence (for barrier methods, the proportion of sex acts in which the method is used) and consequently decrease both pregnancy and STI rates. Offering clients a choice of

methods has been shown to increase the proportion of couples using any contraceptive method.⁴³⁻⁴⁷ Studies in different settings and with different alternative method combinations, as part of both one- and two-method approaches, would be extremely useful.

We need to rely on formative, qualitative research to further refine these questions and to develop our interventions. However, to test these (or other) hypotheses empirically, we need large, randomized controlled trials of services delivered at both the community level and the individual level. Rigorous measurement of key variables, including consistency of contraceptive use and prevalence of infection and pregnancy, is critical. Use of biologic outcomes (pregnancy and STIs) as primary study outcomes rather than self-reported behaviors will help prevent some of the measurement errors that have plagued previous research. We realize that stronger study designs require trade-offs in other areas, because they are costly, may affect generalizability of the results, may slow accrual to the study, and may make follow-up more difficult. Nevertheless, we believe these trade-offs are necessary to provide the most accurate, useful information.

Given the global importance of both unintended pregnancy and STIs, we must determine the best approaches to achieving dual protection. Unfortunately, at the present time, we are unable to make an evidence-based recommendation, save to call for well-designed intervention studies. It is hoped that in the near future, we will have enough data to resolve the dual-protection question.

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