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The importance of oral contraceptive compliance*

Introduction

More than 63 million women around the world currently use oral contraceptives (OCs). This corresponds to 8% of all married women of reproductive age. However, despite the extremely widespread use of the Pill since it was introduced 30 years ago, very little scientific attention has been devoted to the types of errors women make in taking OCs. To fill this gap, Family Health International, a USA-based family planning research organization, has begun collecting data available on usage practices, and is supporting new studies of OC compliance in several countries.

We have found that, although the Pill has the lowest failure rate of any reversible form of contraception when taken exactly as prescribed (0.1%–1% for the combined oestrogen-progestagen OCs), failure rates in the general population are often much higher. They range from at least 3% to as high as 16–20% in some studies. The primary cause of high failure rates appears to be incorrect use.

Compliance can be defined as the consistent and correct taking of OCs for the prevention of pregnancy. Poor compliance is not always the fault of the user, since users often do not receive complete or correct information from clinicians, pharmacists or manufacturers. Regardless of the reason for it, poor compliance can pose a real threat to the effectiveness of OCs as well as to women's overall satisfaction with the method.

Compliance and effectiveness

Effective use of OCs requires that women keep strictly to the recommended Pill-taking regimen. Correct OC use means that a healthy woman has to take a Pill daily for months or years at a time, whether her intent is to delay or prevent pregnancy, and whether she is consistently sexually active or not. She must know how long to wait between Pill packets, how to make up missed Pills, and when to use another method as a back-up (e.g. condoms or spermicides). She must have the back-up method available and actually use it. Finally, she must be confident about the Pill's effectiveness and safety, despite frequent rumours and negative reports in the press. *In short, the Pill is a more complex method to deliver and use than we previously thought.*

Poor compliance can lead directly to pregnancy. However, incorrect use can also contribute to discontinuation. Studies indicate that as many as 60% of new OC users discontinue use before the end of the first year, most within the first six months, and most of these because of menstrual irregularities and other side-effects. The side-effects may be either the cause or effect of incorrectly taken Pills, and may lead to either discontinuation or failure, making the relationship a complex one. For example, nausea in the first few months may lead to intermittent use, which in turn may provoke breakthrough bleeding, which in turn may lead to discontinuation.

Research indicates that many women are discontinuing this effective contraceptive method because they do not understand how to use Pills correctly and do not know enough to cope with potential side-effects. A smaller proportion are not following the correct instructions which they do receive.

Factors affecting compliance and effectiveness

Several OC compliance studies have examined user knowledge, pointing out serious gaps in information. For example, few users know that starting a Pill packet late in the cycle is the most likely cause of breakthrough ovulation. Some women take the Pill only when they have sexual relations; others skip Pills whenever they have physical ailments or when their husbands are away; and others run out of supplies or simply forget. Seaton's study¹ in Matlab, Bangladesh, followed 175 women for three to four months through home visits every two weeks. By counting Pills remaining in packets, trained health workers found the women had over- or under-taken an average of eight OCs per month, with 87% missing at least one or more per cycle.

The 28-day packets were designed to make compliance easier, since they require no waiting time between packets. But we have found that 28-day packets are often used as if they are 21-day packets. That is, women discard the seven iron pills or take them 'as needed', and then wait until the fifth day of withdrawal bleeding or until bleeding ends to start the next packet.

Our study of 500 OC users in Magdalena, Colombia,² found that fewer than 30% of the women knew the correct length of time to wait between their Pill packets. We also found that fewer than two-thirds of the OC providers knew how long to wait between Pill packets. The 1988 Demographic Health Survey in Egypt³ found that fewer than 12% of a national sample of 1,258 Pill users knew how long to wait between packets. A small qualitative study found that only three of 34 providers, representing more than 12 OC sources in Egypt, knew how long to wait between packets.⁴

In both Colombia and Egypt, the most common error of providers, like users, was the belief that the next packet of Pills should be started on the fifth day of withdrawal bleeding. In fact, there should be no waiting period between cycles for the 28-day packets, and a seven-day wait is recommended for the 21-day packets. Starting on the fifth day of bleeding may lead to too long a Pill-free time, since bleeding may not start immediately after the Pills are finished. Although some women may be starting the next cycle as early as 5–6 days after the last one, others may be starting 8–10 days after the last packet.

Although Pill instructions often mention using a back-up method (condoms, diaphragms, spermicides) in case of missed Pills, providers rarely give women a back-up method either when Pills are initially provided or are re-supplied, nor do they women how to use the back-up methods. Several studies indicate that in many cases neither users nor providers know to use back-up methods.

OC compliance problems are not restricted to developing countries. Emans and colleagues⁵ reported non-compliance with the prescribed OC regimen by 16% of 49 adolescents in a Boston (USA) private practice, and by 52% of 61 users at an inner-city adolescent clinic during a three-month investigation. The number of users making errors increased to 45% of the adolescents from the private practice clinic, and 76% of the adolescents from the inner-city clinic by the end of a year. Of the 61 inner-city adolescents, 16% became pregnant during that year.

Variations in oral contraceptives

The original OC formulations contained up to three times the level of oestrogen and more than five times the progestagen of the new lower-dose Pills. Although the higher doses of hormones in the early versions caused more side-effects, they also provided more protection if a woman forgot to take the Pill for one or two days. The smaller margin of error with the newer lower-dose OCs requires more careful compliance to avoid breakthrough bleeding and ovulation.

Careful compliance is essential, yet the diversity of Pills has led to increased confusion for the user. There are three different types of OCs (combined, progestagen-only and bi- or triphasic) and many dozens of brands (more than 40 in the USA alone) packaged in different configurations. However, the instructions for use are not consistent from source to source. For example, package inserts (when available), provider instructions and various OC experts disagree on the use of a back-up method when even a single Pill is missed. Some say no back-up is needed; others recommend use of an additional method for one week; others say two weeks; and still others say for the rest of the cycle. Some materials provide no instructions on how to make up for more than one missed Pill.

What to do about poor compliance

The small body of literature suggests that Pill compliance is a problem wherever OCs are used. Based on limited research about users' incorrect knowledge and their use of OCs, the first step to improve OC compliance is to be sure providers give correct information and that users do in fact understand how to take their Pills in the proper manner. This means providing new OC users with easily understandable instructions, including clearly labelled Pill packets. Illiterate or semi-literate users should be given pictorial information to take home with them. All instructions should be explained by the provider.

Twenty-eight day packets should help reduce errors in changing to a new packet. However, if 28-day packets are used, providers and users must clearly understand that Pills must be taken continuously with no break between packets, and that the seven placebo/iron Pills must be taken at the end of the cycle. Women who use packets with 21 Pills may need to start their

first Pill packet on day 1 or 2 of menstruation so that there is no confusion later as to when to start the next pack.

Pill users should also be provided with a back-up method (such as condoms) along with their Pill packets, and taught when and how to use them. They should know that the most hazardous times to miss Pills are at the very beginning and end of a cycle.⁶ Users need to establish a regular time to take their OCs each day. Providers must repeatedly monitor users' knowledge and Pill-taking until their clients become correct, consistent, and satisfied users. Women who continue to have trouble taking the Pill correctly should be advised to switch to another less user-dependent contraceptive method.

Conclusion

Most OC failures are due to incorrect or inconsistent use, not to a failure of the Pill itself. Modern low-dose OCs require even stricter compliance than the older high-dose Pills. If we could reduce the failure rate of the Pill by even 1% by improving Pill taking, at least 630,000 fewer women would have accidental pregnancies each year.

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1. Seaton, B. (1985) Noncompliance among oral contraceptive acceptors in rural Bangladesh. *Studies in Family Planning*, 16, 52-59.
2. Potter, L. et al. (1988) Oral contraceptive compliance in rural Colombia: knowledge of users and providers. *International Family Planning Perspectives*, 14, 27-31.
3. Sayed, H.A.A.H. et al. (1989) *Egypt Demographic Health Survey 1988*. Cairo: Egypt National Population Council.
4. Leza, S. & Potter, L. (1990) A Qualitative Study of OC Use in Egypt (draft report). Cairo.
5. Emans, S.J. et al. (1987) Adolescents' compliance with the use of oral contraceptives. *Journal of the American Medical Association*, 257, 3377-3381.
6. Fraser, I. & Jansen, R. (1983) Why do inadvertent pregnancies occur in oral contraceptive users? Effectiveness of oral contraceptive regimens and interfering factors. *Contraception*, 27, 531-551.