VIEWPOINT

Why Must One 'Restart' a Method That Is Still Working? A Case for Redefining Injectable Discontinuation

By Linda S. Potter

Combined oral contraceptives and male condoms, which have typical pregnancy rates of 5% and 14%,[1] respectively, account for 27% and 20% of all U.S. contraceptive users, according to data from the 1995 National Survey of Family Growth.[2] In contrast, the three-month injectable contraceptive depot medroxyprogesterone acetate (DMPA, which is marketed under the name of Depo-Provera) is estimated to have a typical first-year pregnancy rate of 0.3%.[3] Yet in prevalence it is a distant third among reversible contraceptives, with only 3% of contraceptive users reporting its use nationally in 1994 (although this proportion is now much higher in some settings, especially in inner-city clinics).[4]

Despite DMPA's effectiveness and duration of protection, clinical records indicate that more than two-thirds of all new acceptors stop using the method within the first year: Four recent studies found first-year DMPA discontinuation rates ranging from 65% to 77%.[5] (In comparison, discontinuation rates for the condom and the pill have recently been estimated at 44% and 29%, respectively.[6]) Why would U.S. women so often discontinue using such an effective, long-term contraceptive?

When the criteria used to estimate discontinuation are examined, it becomes clear that DMPA must meet a higher standard than other methods. DMPA's apparently high discontinuation rates are artificially inflated compared with the rates of other methods, most notably condoms and oral contraceptives.[7] This inflation is the result of different criteria for continuation among methods. A DMPA user is counted by default as having discontinued use if she returns for a subsequent injection more than 14 weeks after the preceding injection—even if she receives her next injection only a few days late. She must then "restart" the method, even though her last DMPA injection may still be protecting her from pregnancy.

Moreover, if all contraceptive users were categorized according to what they report to be their current method, and according to their adherence to that method's regimen (and, thereby, their level of protection), criteria for discontinuation and discontinuation rates could be standardized across methods. This would make rates for DMPA comparable to those for condoms and pills. Such an approach would make it easier for users, providers and researchers to compare the acceptability and effectiveness of all contraceptive methods, to distinguish between poor adherence and discontinuation, and to evaluate the most useful interventions for each of them.

Injectable Discontinuation

As part of the product labeling produced by DMPA's manufacturer (Pharmacia-Upjohn), the information leaflet enclosed in each package specifies that injections should be given "every three months (13 weeks)." Virtually all clinical protocols allow a slightly more flexible interval of 12–14 weeks.

However, clinical trials have shown DMPA to be effective for at least 16 weeks.[8] Nevertheless, women who do not return for their next injection within 14 weeks are recorded as having discontinued the method. They must have a negative pregnancy test before they can "restart" DMPA—even when the method is still providing protection. Such is not the case with other contraceptives, most importantly the pill or the condom. The inconsistency between standards for discontinuation of DMPA and those for discontinuation of other methods implies inconsistencies in rates of continuation as well.

Four studies published in 1996 and 1997 retrospectively analyzed first-year discontinuation rates among women who initiated DMPA use during 1993 (the first year that DMPA was generally available as a contraceptive). Those studies involved chart reviews on 261 patients at two clinics in New York City,[9] on 510 clients who initiated use at an urban health department in North Carolina,[10] on 536 clients from 17 clinics in southeast Texas[11] and on 5,178 Planned Parenthood clients in Colorado.[12]

The results of the four studies are not directly comparable, due to differences in the sites and the participants' characteristics, in the length of the study period and the length of the follow-up period, and (most importantly) in the criteria for discontinuation. The New York and Texas sites used 14 weeks as their cut-off, the Colorado Planned Parenthood site allowed 15 weeks and the North Carolina county health department allowed an interval of 16 weeks.*

Yet, despite these differing criteria, the discontinuation rates across the four studies are remarkably consistent: 70% in New York, 65% in North Carolina, 71% in Texas and 77% in Colorado. It is also worth noting that the lowest discontinuation rate was found in the study with the 16-week interval.

All of these rates excluded clients lost to follow-up. However, the authors of the New York and North Carolina studies also calculated life-table rates that included those lost to follow-up, as if they had the same continuation rates as those continuing at the clinic (assuming that a proportion of them would have received subsequent injections elsewhere). Such reestimation reduced DMPA discontinuation rates from 70% to 58%[13] and from 65% to 51%.[14]

*The North Carolina county health department has since switched to the 14-week interval, to bring their standards into line with other provider agencies.

Linda S. Potter is visiting research collaborator at the Office of Population Research, Princeton University, Princeton, NJ. The author thanks Barbara Cromer, Margaret Polaneczky and James Trussell for their comments on this article, as well as Deborah Oakley, Helen Koo and Barbara Dalberth for earlier discussions of the issue.

Defining Discontinuation

Discontinuation criteria for DMPA vary somewhat from study to study, but an examination of criteria across contraceptive methods reveals more important differences. Three questions can provide a standard for determining the comparability of discontinuation rates of different methods:

- Is each dose's length of effectiveness taken into account?
- Are the measures of compliance and continuation comparable?
- Is the client's report of her current use taken into account?

The responses to these three questions reveal important differences in the criteria for discontinuation among methods. When DMPA is compared with combined oral contraceptives and male condoms, cross-method discrepancies appear for all three criteria. For example, a condom provides protection for just one act of intercourse. Yet in most studies, a respondent is counted as a current or continuing condom user as long as she says that she is, even if she reports that she and her partner use them only "sometimes" or "rarely." These imprecise criteria strongly suggest that the 14% typical pregnancy rate for condoms is somewhat inflated when compared with rates for DMPA or oral contraceptives.

Unlike condoms, combined oral contraceptives are not coitus-dependent, and one pill can protect the user for at least 24 hours, regardless of the number of acts of intercourse during that 24-hour period. Most clinical protocols define a continuing pill user as one who refills her prescription regularly; exactly when she refills it or whether she takes the pills consistently are not considered. Therefore, as in the case of condoms, a continuing pill user is not necessarily the same as a fully protected user, and typical pregnancy rates for oral contraceptives are estimated to be 5% or higher.[15]

The criteria for DMPA continuation, on the other hand, are much stricter. DMPA is continuously, fully effective for 16 weeks, with nothing required of the user until the end of that period. Yet a DMPA acceptor must return for each injection before protection from the previous one has ended if she is to be counted as a continuing user, regardless of her actual or perceived level of contraceptive protection. Incomplete adherence to the regimen is recorded as discontinuation, requiring that she "restart" the method regardless of the reason for the delay or whether she is still protected.

Defining Protection

The disparities in the discontinuation criteria for condoms, pills and DMPA—and therefore in their discontinuation and pregnancy rates—suggest that using a single "yes/no" criterion for method discontinuation would be useful. That criterion should be the user's explicit declaration that she is no longer using her method of record, regardless of whether she is practicing contraception at all, has switched to another method, is pregnant or seeks to become pregnant. One possible construct would be to include three levels of protection for continuing users of a method and a fourth category of self-defined discontinuation.

Under this construct, *a fully protected user* of any method is one who defines herself as a current user and who protects herself from pregnancy by using that method consistently or who protects herself by temporarily but consistently using another method during occasional gaps in use (for example, by using a condom during gaps in protection by the pill or the injectable, or by abstaining from sex).

The second category is *the partially protected user*—a woman who defines herself as a current user but who uses her primary method (and any backup methods) inconsistently. This group would include a condom user who has even a single act of unprotected intercourse, a pill user who has unprotected intercourse after missing two or more pills in a row, or a lapsed injectable user who has otherwise unprotected intercourse more than 16 weeks after her last injection.

The third group consists of *unprotected users*. These are women who define themselves as users but who have not been protected by their method of record or by any other method for more than four weeks. This would include avowed condom users who had not used the condom in that time period, pill users who had missed a full cycle of pills and injectable users who had gone at least 20 weeks since their last injection (i.e., four weeks beyond the estimated 16-week period of effectiveness for the injectable). Such users might also be described as lapsed or "interrupted" users.

Finally, the *discontinuing user* is one who states that she has made a conscious choice to stop using the method, whether or not she is using another method, or is pregnant or seeking to become pregnant.

These categories can be applied to any reversible method of contraception. An additional differentiation for DMPA would be to categorize the level of compliance and protection by the number of weeks between injections: A fully protected consistent user is one who obtains each subsequent injection within the prescribed 14 weeks. A fully protected inconsistent user is one who receives her next injection in 14–16 weeks or who practices backup contraception consistently until she can.

Lapsed Use and Restarting

Three studies have specifically accounted for long lapses in use among continuing users. One recent analysis found that 31% of a sample of 400 injectable users in two South African family planning clinics had at least one "non-use segment"—i.e., "a temporary break from the method when no other contraceptive method [was] used before returning to the same method."[16] Other research found that 37% of discontinuing users restarted DMPA within three years, but there was no discussion of contraceptive status during that time.[17] Finally, the North Carolina study revealed that among 510 women who initiated use in 1993, 35% of those who followed up at the clinic received all injections for a full year within 16 weeks,[18] with another 8% who returned to the clinic for an injection between 16 and 20 weeks being classified as discontinuing by the clinic but being classifiable as poorly adherent users. An additional 17% returned to injectable use within a year. Finally, 20% of lapsed users were lost to follow-up (although they might have continued to receive injections from another provider).

Two studies have found that patients who said they had not returned for an injection within 14 weeks because of side effects were the ones who were least likely to resume DMPA use at any time.[19] However, the North Carolina study found no such difference in rates of side effects between those who ultimately returned for an injection and those who stated that they were no longer using DMPA.[20] Some of those recorded as lost to follow-up in clinic records reported in telephone interviews that they had instead switched providers.

Thus, research on contraceptive users needs to differentiate those who are lost to follow-up from those who discontinue, because of the possibility that the former continued using the method (but obtained it elsewhere) or experienced a prolonged delay in returning. For example, reported continuation rates could be calculated both with and without those lost to follow-up.

Conclusion

At this time, the criteria for discontinuation of DMPA and for poor adherence to its 14-week regimen are one and the same. Therefore, discontinuation rates for DMPA are inadvertently but artificially inflated compared with rates for other methods.[21] The pregnancy rate for DMPA (0.3%) was calculated based on a 14-week

cutoff; extending that cutoff time to 16 or 20 weeks (a total of four or five months between injections) is unlikely to raise DMPA pregnancy rates above 1–2%. Instead, redefining some discontinuing users as partially protected or unprotected users would increase the pregnancy rates among continuing users, as it would with any method, but it would make rates of protection, compliance and discontinuation comparable with those of other methods and would allow those methods to be evaluated accordingly.

The behaviors involved in using a method continuously differ from those related to using it consistently. Therefore, interventions to increase consistency and continuation need to be directed to the user's own report of her contraceptive status. Put in the context of a behavioral stages of change model,[22] decreasing discontinuation requires helping the user to decide whether she wants to continue or restart that method or, if not, select another method she feels she can use more comfortably and effectively, then help her get started; increasing consistent use requires helping the continuing user maintain consistency over time.

Practice Implications

All four of the studies of injectable contraceptives discussed above followed women who initiated DMPA use during the first year in which the method was generally available. Neither these women nor their providers had any history with the method as a context for their own experiences. Now that DMPA has been widely available in the United States for six years, users and providers know more about it. The most frequent side effects—menstrual irregularities and weight gain, for example—are less often a surprise, and the counseling given before symptoms appear can cushion the experience.[23] Aggressive counseling for those who experience side effects before their first reinjection should help users feel more comfortable with the method or may help them make an active decision to change methods by the time DMPA's protection ends.[24]

Anecdotal data strongly suggest one important misconception based on a statement in the original product labeling for DMPA: The original labeling stated that it could take up to a year to conceive after discontinuing DMPA use. This language apparently led some users to believe that they were protected for up to a year by a single injection, making it unnecessary for them to obtain a reinjection promptly. That language has now been clarified, which may help increase consistent use.

The need for proactive counseling before the next injection is due is better recognized now, and raises the issue of the value of reminder cards or telephone calls. A reminder system was found to work in one descriptive study,[25] but not in another randomized, controlled trial.[26] Nevertheless, personal contact would seem to be essential as a reminder about the next appointment, about anticipating and dealing with side effects, and about any concerns or misconceptions about the method.

Research Implications

The bottom line, then, is that operational definitions of contraceptive compliance and continuation must be quantifiable, at least categorically, if accurate and comparable data on compliance and continuation rates, as well as on pregnancy rates, are to be determined for any contraceptive method. Only the New York study directly compared DMPA's discontinuation rate with that of another method: Among a subsample of postpartum teenagers, the first-year discontinuation rates were 66% for DMPA but 68% for the pill, and the mean duration of use was only 8.1 months for DMPA but just 5.4 months for the pill.[27] It is interesting to imagine how these highly similar rates might change if the categories of protection described in this article were used.

The construct proposed in this article would permit more accurate estimates of continuation and levels of protection, as well as better measurement of the effectiveness of programmatic interventions. However, the proposed construct represents only one set of options for defining and measuring contraceptive use more systematically. Other constructs may achieve the same end. Readers interested in suggesting alternatives or offering critiques of the construct presented here are encouraged to do so.

References

1. Trussell J, Contraceptive efficacy, in: Hatcher RA et al., eds., *Contraceptive Technology*, 18th ed., New York: Ardent Media, 1998.

2. Abma JA et al., Fertility, family planning and women's health: new data from the 1995 National Survey of Family Growth, *Vital and Health Statistics*, 1997, Vol. 23, No. 19.

3. Trussell J, 1998, op. cit. (see reference 1).

4. Abma JA et al., 1997, op. cit. (see reference 2).

5. Polaneczky M et al., Early experience with the contraceptive use of depot medroxyprogesterone acetate in an inner-city clinic population, *Family Planning Perspectives*, 1996, 28(4):174–178; Potter LS et al., Depot medroxyprogesterone acetate "pioneers": a retrospective study at a North Carolina health department, *Contraception*, 1997, 56(5):305–312; Sangi-Haghpeykar H, Poindexter AN and Bateman L, Consistency of condom use among users of injectable contraception, *Family Planning Perspectives*, 1997, 29(2):67–69 & 75; and Westfall JM, Main DS and Barnard L, Continuation rates among injectable contraceptive users, *Family Planning Perspectives,* 1996, 28(6):275–277.

6. Trussell J and Vaughan B, Contraceptive failure, contraceptive discontinuation, and resumption of contraceptive use: results from the 1995 National Survey of Family Growth, *Family Planning Perspectives,* 1999, 31(2): 64–72 & 93.

7. Ibid.; and Potter LS et al., 1997, op. cit. (see reference 5).

8. Speroff L and Darney PD, Oral contraception, in: Speroff L and Darney PD, *A Clinical Guide for Contraception*, Baltimore, MD: Williams & Wilkins, 1992.

9. Polaneczky M et al., 1996, op. cit. (see reference 5).

10. Potter LS et al., 1997, op. cit. (see reference 5).

11. Sangi-Haghpeykar H, Poindexter AN and Bateman L, 1997, op. cit. (see reference 5).

12. Westfall JM, Main DS and Barnard L, 1996, op. cit. (see reference 5).

13. Polaneczky M et al., 1996, op. cit. (see reference 5).

14. Potter LS et al., 1997, op. cit. (see reference 5).

15. Trussell J, 1998, op. cit. (see reference 1); and Jones EF and Forrest JD, Contraceptive failure rates based on the 1988 NSFG, *Family Planning Perspectives*, 1992, 24(1):12–19.

16. Beksinksa ME et al., Compliance and use behaviour, an issue in injectable as well as oral contraceptive use? A study of injectable and oral contraceptive use in Johannesburg, *British Journal of Family Planning*, 1998, 24(1):21–23, 1998.

17. Polaneczky M and Liblanc M, Long-term depot medroxyprogesterone acetate (Depo-Provera) use in inner-city adolescents, *Journal of Adolescent Health*, 1998, 23(2):81–88.

18. Potter LS et al., 1997, op. cit. (see reference 5).

19. Polaneczky M and Liblanc M, 1998, op. cit. (see reference 17); and Sangi-Haghpeykar H, Poindexter AN and Bateman L, 1997, op. cit. (see reference 5).

20. Krueger S, An evaluation of 12 months of follow-up of Depo-Provera "pioneers" at a North Carolina Health Department, unpublished master's in public health thesis, University of North Carolina–Chapel Hill, 1996.

21. Potter LS et al., 1997, op. cit. (see reference 5); and Trussell J and Vaughan B, 1999, op. cit. (see reference 6).

22. Grimley DM et al., Assessing the stages of change and decision-making for contraceptive use for the prevention of pregnancy, sexually transmitted diseases, and acquired immunodeficiency syndrome, *Health Education Quarterly*, 1993, 20(4):455–470.

23. Cromer BA et al., A prospective study of adolescents who choose the levonorgestrel implant (Norplant), depot medroxyprogesterone acetate (Depo-Provera), or the combined oral contraceptive pill as contraception, *Pediatrics*, 1994, 94(5):687–694.

24. Polaneczky M and Liblanc M, 1998, op. cit. (see reference 17).

25. Madlon-Kay DJ, The effectiveness of a mail reminder system for depot medroxyprogesterone injections, *Archives of Family Medicine,* 1996, 5(4):234–236.

26. Keder LM, Rulin MC and Gruss J, Compliance with depot medroxyprogesterone acetate: a randomized, controlled trial of intensive reminders, *American Journal of Obstetrics and Gynecology,* 1998, 179(3, Part 1):583–585.

27. O'Dell CM et al., Depot medroxyprogesterone acetate or oral contraception in postpartum adolescents, *Obstetrics and Gynecology*, 1998, 91(4):609–614.