DISCUSSION

Injectables as a choice – evidence-based lessons

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Newer, better contraceptive methods may not result in increased reproductive choice if health systems cannot ensure quality of contraceptive services.

Though extensively researched and used by over 16 million women in 130 countries DMPA's controversial history has restrained its use by national family planning programmes worldwide. Early clinical trials were abandoned due to the adverse US FDA ruling and opposition by health advocates in India. After US FDA approval DMPA was licensed for use in 1993 in India conditional on post-marketing surveillance by its manufacturer for side-effects. Since 1994, injectables are available through commercial and social marketing channels but not in the public sector. In 1995, a panel favoured the use of injectables rather than Norplant in India, because of the ease of dispensing injectables and the prohibitive expense of Norplant. A recommendation was made in 1998 to introduce injectables in suitably equipped centres in the public sector with appropriate screening, counseling and medical backup, and emphasis on good clinical practice and post-introduction surveillance for side effects and management. Women activists opposed its introduction in the national family welfare programme for reasons of safety and fundamental inadequacies in providing quality contraceptive care, ensuring informed choice and consent. The debate on injectables touches wider issues of gaps in existing population and drug policies, a lack of male responsibility and involvement in reproductive health, and vested interests of multinationals.

Injectables have the lowest failure rates among methods of contraception. This efficacy is dependent on appropriate timing of the first injection, and repeat injections. The typical acceptor is a woman in her early 30s, with two or three living children, who wants to limit rather than space her children. Women prefer injectables to pills or IUDs. Acceptors include first-time contraceptive users because of the convenience, effectiveness and perceived safety. They also include women who switch to injectables after experiencing side-effects with other contraceptives. An initial high acceptance of injectables is not sustained as most women experience menstrual disturbances resulting in one-year discontinuation rates of 15 to 50%. Menstrual disturbance as a reason for discontinuation is context- and culture-specific, with high discontinuation rates seen amongst women in Pakistan, where women are less likely to accept amenorrhoea; in contrast, infrequent bleeding was less likely to result in discontinuation than frequent heavy bleedings in Indian women. Tolerance thresholds and partner attitudes to menstrual disruption need to be studied. Protagonists of injectables seek to underplay the side-effect of menstrual disturbances as not being harmful or life-threatening. This is not to underplay the women's perception of side-effects as a reason for discontinuation. High discontinuation rates may be due to poor selection of method, poor attributes of the contraceptive or just the inability of the services to ensure continued use of the injectable. Alternately, it may be seen as a measure for the woman's freedom of choice to opt out of the method, if she dislikes it.

Another concern is the reversibility of injectables. The median delay to return to fertility (8-9 months after last injection), as expected, is higher than barrier methods, OCs, or IUDs. Large variations are seen amongst women from different populations, reflecting differences in the nutritional, metabolic and fertility status. Return to fertility is not affected by duration of injectable use or by parity, implying that women can safely use injectables for even delaying their first pregnancy.

How safe are injectables?

This is probably the most controversial and researched aspect. Studies of Chinese women show bone mineral loss to be much lower than previously projected (0.4-1% per annum) and unrelated to duration of DMPA use. Debates on DMPA-induced bone mineral loss and its effect on pubertal skeletal growth in adolescence, or the risk of aggravation or acceleration of osteoporosis in lactating women *vis a vis* the benefits of contraception, have been largely speculative. Though WHO recommends its use amongst adolescents and lactating women, India chose to play it safe by recommending that use of injectables be avoided in adolescents.

Adverse effect on blood pressure and thrombosis has not been reported. One study has shown glucose intolerance following long-term DMPA use. There is no link between breast cancer and long-term DMPA use. An increased risk was seen in recent users but not in long-term users suggesting that DMPA may trigger the growth of existing breast tumours rather than turn normal cells cancerous. Prolonged use of DMPA may cause *in situ* cervical carcinoma but not invasive cervical carcinoma; hence the need for periodic monitoring for cervical cancer.

In utero exposure to DMPA shows equivocal findings of its effect on birth weight and birth defects. DMPA and NETEN are secreted in breast milk in lactating women. There is no effect,

or insignificant effect, on breast milk or subsequently on infant development. Pubic hair development was delayed significantly in girls. Increased aggression responses in adolescents and an enhancing effect on female sexuality have been seen.

Service delivery issues

Screening, counselling on mode of action, side effects and their management are crucial. Poor follow-up of clients, lack of motivation, and lack of knowledge on side effects management are programme weaknesses. Standardised protocols for counselling and better provider skills are needed. Women attending FP clinics in the Philippines were not well informed about the range of services available. Studies amongst private providers in India showed that they did not promote indiscriminate use of DMPA. However, there was a need to develop standardised protocols for counselling and improve provider skills. Medical procedures were not explained while 16% of clients reported that providers did not inform them about side-effects resulting in most women with side-effects not returning to the clinic for assistance. Many DMPA programme dropouts reported that clinic staff were not caring or courteous. Findings indicate poor counselling of women by providers in terms of content and quality. Periodic orientation for providers on issues related to medical eligibility, side-effects management and counselling and skills to counter rumours were some strategies suggested by providers to improve quality of care.

Preference for a female provider and supply shortage often turned away would-be DMPA acceptors or resulted in method switching. Distance and inconvenience of clinic timings sometimes resulted in clinic switching or DMPA discontinuation. Client costs can adversely affect DMPA use. Acceptance is highest when DMPA is offered free. However, free services cannot sustain continued acceptance.

Though DMPA and NETEN may have similar effectiveness, continuation rates and side-effects, the service delivery implications are very different. To avoid field worker confusion, error, disruption of field worker routines, simplify managerial and supply logistics, it is recommended to use either DMPA or NETEN (not both) in the same geographical area as there are significant differences (different dosage regimes, needles etc.) that affect service delivery.

The Thailand experiences highlight the need for diligent follow-up, surveillance for side-effects, and accurate records. The Sri Lanka experience illustrates the need for transparency and flexibility of the health system to respond to concerns voiced by the community. The initial uptake of injectables is usually high; sustaining it is difficult because of inadequate preparation, poor training and poor logistics management. This resulted in poor counselling, lack of informed choice, poor selection of women and other concerns. Injectables were prematurely withdrawn from the national programme in the Philippines, to be re-introduced more successfully later.

Ethical concerns

Whether injectables undermine or further a woman's reproductive rights needs to be examined in the context of policy and practice. An injectable has to be evaluated from a rights perspective in terms of who controls it, its purpose, safety, effectiveness, risks and benefits, reversibility, and equally important concerns of availability, accessibility, affordability and quality of service delivery. Since its inception, India's FP programme has been driven by demographic goals of population control resulting in promotion of provider-controlled contraceptives. Recently we have a policy environment which reflects a commitment to widening contraceptive choice in the broader framework of reproductive health and reproductive rights. The National Population Policy 2000 seeks to provide gender-sensitive quality services and supplies, information and counselling and widening contraceptive choice to enable women and couples to make informed choices and access quality health care services.

Women's groups have opposed injectables because of the potential for violation of reproductive rights as well as of informed consent, autonomy and safety. Addressing resource constraints, removing informational, physical and economic barriers and strengthening the quality of reproductive health care delivery – putting a reproductive rights framework into practice – presents a challenge and an opportunity to offer injectables and widen contraceptive choices for women. It is time to ensure a health system which is sensitive to social and gender inequalities, one that respects women's dignity and autonomy.

This paper derives from a scientific literature review, by the author, on the use of long-acting, progestin-only contraceptives in the South Asian context. The review was commissioned by the UNFPA. A report of the review, Progestin-only Injectable Contraceptives Facts File, *was published by UNFPA India on October 15, 2004, and was available at* www.unfa.org.in/reports/17_Facts_File.pdf *when accessed on December 18, 2004.*

A complete list of references for this paper can be obtained from the author. It will also be available on the internet version of the IJME, at www.issuesinmedicalethics.org .