



IPPF Medical Bulletin

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Routine breast and pelvic examinations before prescription of hormonal contraception

Alison Scott, Anna Glasier

In the USA and Japan and some European countries, it is common practice to examine a woman's breasts and pelvis before starting her on hormonal contraception, and to repeat the examinations annually. In its recent publication *Selected Practice Recommendations for Contraceptive Use*¹ the World Health Organization puts the question, "What examinations or tests should be done routinely before providing a method of contraception?" Breast examination, before provision of any method of contraception, is regarded as a procedure which 'does not contribute substantially to safe and effective use of the contraceptive method'. Pelvic examination is considered essential for safe and effective use of an intrauterine device, diaphragm, or cap or before a decision whether to sterilize a woman, but is judged unnecessary before provision of hormonal pills or injections. Why then are these intimate examinations routinely performed in so many countries?

Breast examination

In clinical medicine, some procedures become routine because of belief that they will lead to the early detection of important disease. These routine procedures are in fact a form of screening, and they should be judged by the criteria of screening tools – sensitivity, specificity, cost-effectiveness. The usual reason given for doing breast and pelvic examinations before prescription of the pill or injections is to exclude conditions that contraindicate hormonal contraception or would be worsened by it. In the *WHO Medical Eligibility Criteria for Contraceptive Use*,² current breast cancer is specified as a contraindication to all forms of hormonal contraception, the reason being that these agents can enhance progression of the disease. However, most women who use hormonal contraception are young and at extremely low risk of breast cancer. In the UK only 16 women in every 10 000 will have developed breast cancer by the age of 35 and the risk is probably lower in developing countries. Although it is good practice to ask about breast problems, breast examination by health professionals has been shown to be ineffective in reducing mortality from breast cancer.^{3,4} In a trial involving women aged 45–64 (considerably above the age of most hormonal contraceptive users) only 2% of woman referred to a specialist with abnormal findings on breast examination were found to have breast cancer; 98% did not.⁴ Together, the insensitivity of

breast examination as a screening tool and the rarity of the disease in young women mean that 175 000 women aged 20–24 would have to be screened by clinical examination in order to detect one case of breast cancer. As a public health measure routine breast examination cannot be justified on any grounds. Certain clinicians, however, will continue to argue that it should be done selectively – partly because, whatever the results of recent research, the pill is inextricably linked to breast cancer in the minds of some women, and regular breast examination can be reassuring. Against this, the insensitivity of the examination means that the reassurance may be false; moreover, an abnormal finding causes great anxiety. Screening of 175 000 women aged 20–24 would generate 10 500 false positives (abnormal examination with no underlying abnormality) for the sake of one woman who truly does have breast cancer. Finally, many women would wish to be spared breast examination, which is somewhat embarrassing, if it is not necessary. Breast examination should be targeted according to personal history. It is good clinical practice, however, to discuss breast awareness with all women – especially the over-40s.

Pelvic examination

What are the reasons for pelvic examination in women attending for hormonal contraception? Clinicians may justify it as a means of detecting pelvic disease, sexually transmitted infection, or pregnancy. In the section on reproductive tract infections and disorders in the *WHO Medical Eligibility Criteria*, the following conditions are category 1 for hormonal contraception (that is, can be used in any circumstances and provided by a person with limited clinical judgment): endometriosis; uterine fibroids; benign ovarian tumours; endometrial and ovarian cancer; cervical ectropion. Other conditions in which hormonal contraception is *not* contraindicated are sexually transmitted infections (including HIV) and pelvic inflammatory disease. Although none of these conditions – or even pregnancy – is adversely affected by hormonal contraception, diagnosis of those that are serious would unquestionably be in the best interests of the affected women. If present, many are associated with symptoms which can be elicited from a medical history, which *should* be routine before provision of hormonal contraception. But how common are these disorders in women of reproductive age, and is pelvic examination the most appropriate diagnostic tool? Pelvic examination may detect uterine or ovarian enlargement and cervical or vaginal lesions, but ovarian and endometrial cancer are diseases of postmenopausal women. Moreover, pelvic examination has a low specificity for detecting ovarian or endometrial enlargement when used without ultrasonography.⁵ Functional ovarian cysts can be intermittent and unless causing symptoms do not require treatment; nor does ectropion. Uterine fibroids are common in women of reproductive age but very seldom transform to become malignant.⁶ In a woman who has no symptoms, the finding of a fibroid on clinical examination is not relevant. Cervical cancer should be detected through routine screening programmes; visual examination will detect only cancers that are invasive. Cervical polyps need not be treated unless causing bleeding or malignant. Sexually transmitted

infections are common among young sexually active women but a careful sexual history will allow at-risk women to be targeted for screening. Symptomless infections such as *Chlamydia trachomatis* will be missed unless microbiological tests are also routinely performed. Pregnancy can usually be excluded by taking a menstrual history, and if earlier than six weeks gestation will not usually be detected on pelvic examination.

As with breast examinations, false-positive pelvic examinations cause needless anxiety and often lead to invasive and expensive investigations when the condition is benign and self-limiting. Despite reassurance, women worry if they know that something is 'abnormal' – even if it is only ectropion. Pelvic examinations are embarrassing and uncomfortable and may deter women – especially young women – from returning for more supplies of contraception.

Conclusion

Breast and pelvic examination have low detection rates for disease. They do, however, tend to pick up abnormalities that are not clinically relevant and in doing so generate anxiety and concern. Women would be more likely to attend for contraceptive advice if these examinations, which are of little clinical use, ceased to be routine and were prompted by the individual's medical history. Physicians who undertake these examinations routinely should ask themselves why they continue to do so. The current WHO recommendations for contraceptive use indicate that, in terms of medical examination, only blood pressure measurement is necessary before prescription of hormonal contraception.

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IMAP recommendations on nonoxynol-9

The statement below was produced by the IPPF Medical Advisory Panel (IMAP) at its meeting in May 2002.

Nonoxynol-9 is a spermicide widely available as an over-the-counter product. Several clinical trials have investigated whether nonoxynol-9 can be used as a microbicide for protection against HIV and sexually transmitted infections (STIs). A review of all the nonoxynol-9 clinical trials has shown that this agent does not protect against HIV. Furthermore, there is some evidence that frequent use of nonoxynol-9 (twice a day or more) actually increases the risk of acquiring HIV infection, perhaps by disrupting the vaginal

and cervical mucosa. The most recent randomized controlled trial also shows that use of spermicides containing nonoxynol-9 does not protect against cervical gonorrhoea or chlamydia infection. Therefore, spermicides should not be used for protection against HIV or other STIs. For this purpose, condoms are the method of choice.

Although the contraceptive effectiveness of nonoxynol-9 is low compared with other methods, this spermicide is generally easily available, can be obtained over the counter without requiring a medical consultation or prescription, and is a method under the control of the woman. Because of its low contraceptive effectiveness, IPPF recommends that nonoxynol-9 should be used only in combination with a female mechanical barrier method. Condoms prelubricated with nonoxynol-9 have no advantage in contraceptive efficacy and are not recommended. Women at high risk of HIV should not use nonoxynol-9 products.

Family planning associations that have in stock condoms with nonoxynol-9 in the lubricant should cease to obtain such condoms but can finish their existing supplies – especially if those condoms cannot be replaced in good time to prevent clients from running short. However, nonoxynol-9 condoms should not be distributed to women at high risk of HIV.

News

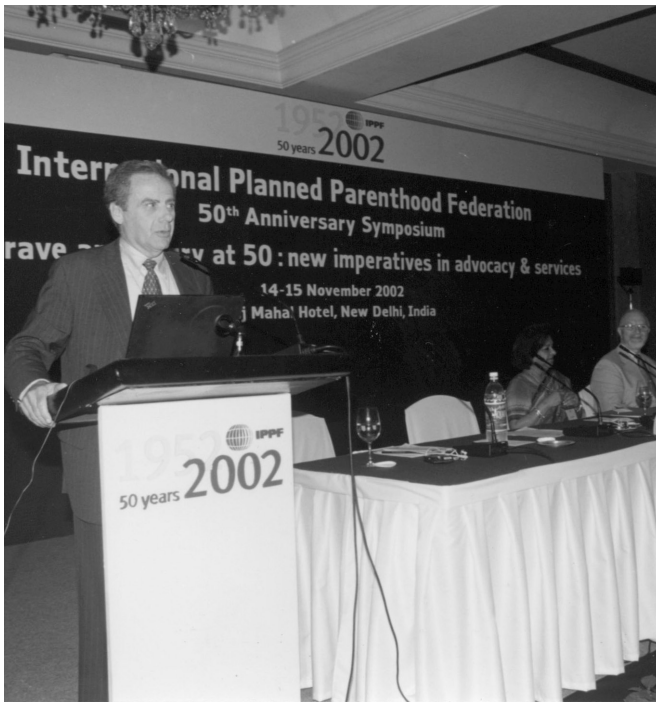
The scandal of maternal mortality and morbidity

Among those who gathered in New Delhi last November to celebrate IPPF's 50th anniversary was Dr Allan Rosenfield, a member of the UN Millennium Project's task force on child health and maternal health. One element that has been removed from the Millennium Development Group programmes is sexual and reproductive health, for which goals were set at the Cairo and Beijing meetings. "Our task", he said, "is to put it back in", and the Secretary General's office has agreed it can be reintroduced under maternal health. The principal goal of the task force is to reduce the maternal mortality ratio in resource-poor settings by three-quarters, from 1990 to 2015. Mortality is closely related to morbidity, and a decline in mortality can be expected also to reduce the numbers whose lives are ruined by long-term complications of pregnancy. Dr Rosenfield focused on Bangladesh and Afghanistan. For Bangladesh he gave the following figures:

- 11% of 10–15 year olds are married with a child
- 95% of births take place in the home, and only 13% are attended by trained personnel
- 3 maternal deaths every hour
- 14% of maternal deaths are due to violence or suicide
- 9 million women suffer pregnancy complications such as fistula, prolapse, incontinence, or dyspareunia
- 60% of the life of a woman is spent in coping with pregnancy and breastfeeding.

In Afghanistan the plight of women is even worse. That country has the world's highest maternal mortality ratio, at 1600 maternal deaths per 100 000 live births. For comparison the figure in Europe or North America is 8. The main causes of these deaths are obstructed labour, postpartum haemorrhage, complications of abortion, eclampsia, and postpartum infection.

Clearly, part of the solution is an expansion of family planning services. Dr Rosenfield focused on obstetric care. In many rural areas, women still give birth at home, often with the aid of a traditional birth attendant or relative. In the view of his task force, the essential needs for maternal mortality



DR ROSENFELD IN NEW DELHI

reduction are access to emergency obstetric care, with caesarean sections, fluid replacement, completion of incomplete or infected abortion, and management of other life-threatening complications. How can this be provided 24 hours a day 7 days a week? "If we stick to the current medical view that certain things can be done only by obstetricians or anaesthetists, we will never achieve it." An alternative model is offered by Mozambique, where surgical technicians are being trained to do caesarean sections, to complete abortions, and to provide other essential techniques – "and they do it as well and effectively and safely as physicians". That, he said, is a model that could be tried in many other countries, if we want to get rural coverage now and not in ten or twenty years.

Hormone replacement therapy and heart disease

Until quite recently, the medical consensus was that hormone replacement therapy (HRT) for postmenopausal women offered health benefits including some protection against coronary heart disease. In observational studies, HRT-users had better outcomes than non-users. However, randomised controlled studies have led to different conclusions. The most important of these is the Women's Health Initiative trial¹ in over 16 000 postmenopausal women who were randomised to receive either conjugated equine oestrogens plus medroxyprogesterone acetate or placebo. The trial was stopped prematurely when the data and safety monitoring board noted an excess of invasive breast cancer in the HRT group and global risks exceeding benefits. In the HRT group there were increased hazard ratios for breast cancer and cardiovascular disease, though hazard ratios for colorectal cancer and osteoporotic fractures were decreased. Absolute excess risks per 10 000 woman-years attributable to HRT were an additional 7 coronary events, 8 strokes, 8 pulmonary embolisms, and 8 breast cancers. On the benefit side, there were 6 fewer colorectal cancers and 5 fewer hip fractures.

This trial has generated huge debate. The reason why early observational studies were misleading seems to be that women with a healthy lifestyle were those most likely to opt for HRT. A particularly useful discussion is by Grimes and Lobo.² Although the trial results apply to only one regimen, these commentators recommend a more cautious approach to HRT in general. It remains the best treatment for menopausal

symptoms, but low doses are advisable, with reassessment at least once a year. For prevention of osteoporosis there are alternatives such as raloxifene, alendronate, and risendronate. For women who now wish to stop HRT, tapered withdrawal is likely to be less troublesome than sudden withdrawal.

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Mifepristone compared with levonorgestrel for emergency contraception

A World Health Organization research group¹ has provided important new information on emergency contraception. In 1998 a two-dose schedule of levonorgestrel was reported superior to the Yuzpe regimen (ethinylestradiol/levonorgestrel) and this has become the standard in many countries. However, a single dose of norgestrel would be preferable if equally effective. Moreover, there is another candidate agent for emergency contraception, oral mifepristone, which seems to work in a low dose that has few side-effects. The WHO group compared three regimens in a randomised trial – 10 mg single-dose mifepristone; 1.5 mg single-dose norgestrel; and two doses of 0.75 mg norgestrel 12 hours apart. The participants were just over 4000 women requesting emergency contraception within 120 hours after one unprotected intercourse.

The primary outcome of the study was unintended pregnancy, and the results were as follows:

	<i>N</i>	<i>Pregnancies</i>	<i>Expected pregnancies</i>	<i>Prevented fraction</i>
Mifepristone	1359	21 (1.55%)	108	81%
Single-dose norgestrel	1356	20 (1.47%)	111	82%
Two-dose norgestrel	1356	24 (1.77%)	106	77%

Side-effects were mild and differed little between the groups. Women who took levonorgestrel had earlier menses than did those who took mifepristone.

The WHO group concludes that mifepristone and levonorgestrel do not differ in efficacy, and that a single 1.5 mg dose of levonorgestrel can be used instead of the customary two doses of 0.75 mg 12 hours apart. Mifepristone delays ovulation, and women who use this agent, especially, need to be warned that they are still at risk of pregnancy after taking it.

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Low-dose nonoxynol-9 and HIV

The IMAP statement on nonoxynol-9 (p 2) refers to a randomised controlled trial that is reported in *The Lancet* of Sept 28, 2002. Van Damme and others¹ explored the effectiveness of COL-1492 in preventing transmission of HIV-1 in female sex workers. Nonoxynol-9 has microbicidal as well as spermicidal properties, and at one time there were great hopes that, when used in vaginal gels or on condoms, it

would offer some protection against HIV. Unfortunately, the evidence points to an increase rather than a decrease in HIV transmission, perhaps by irritating vaginal epithelium and reducing its integrity. The new gel formulation COL-1492 was chosen for study because it provides a much lower dose of nonoxynol-9 than usual spermicides and preliminary work suggested freedom from local toxic effects. 892 sex workers from Benin, Côte d'Ivoire, South Africa, and Thailand were randomly allocated COL-1492 or a placebo gel not containing nonoxynol-9, together with male condoms, for use with every sexual act. The primary endpoint was incident HIV-1 infection; secondary endpoints included infection with *Neisseria gonorrhoeae* and *Chlamydia trachomatis*.

HIV-1 incidence was 14.7 per 100 woman-years in the group using nonoxynol-9 compared with 10.3 in the group using placebo ($p=0.047$). The risk associated with nonoxynol-9 was especially high (almost double that of placebo users) in women who used the study gel more than 3.5 times a day, who also had a high incidence of lesions with epithelial disruption. At low-frequency use, nonoxynol-9 had no effect on incidence of HIV-1 infection. The nonoxynol-9 preparation had no apparent effect on the incidence of either gonorrhoea or chlamydia infection.

Despite the low dose in COL-1492, the results are consistent with previous disappointing data. Nine randomised trials have now been conducted in a total of over 5000 women, and a systematic review² of these shows the following relative risks (with 95% confidence intervals): for HIV infection 1.12 (0.88–1.42); for chlamydia 0.91 (0.67–1.24); for genital lesions 1.18 (1.02–1.36). This study spells the end of hopes that nonoxynol-9 will be useful in the battle against HIV and other sexually transmitted infections.

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Fertility after the pill

Women sometimes express concern that hormonal contraception will adversely affect their fertility when they eventually wish to become pregnant. The phenomenon of

post-pill amenorrhoea is well known (though infrequent), and temporary delays in conception have been reported, compared with other methods. But the question is difficult to answer because so many other factors affect fertility – age (both partners), body size, exercise, alcohol consumption, and so on. What is needed is a large prospective study of couples who are trying to conceive. Some useful information has been reported by Farrow and others, from the Avon Longitudinal Study of Parents and Children.¹ It was not strictly prospective, since the women were already pregnant when recruited, but at 18 weeks' gestation they were asked for information on specific fertility factors including obstetric and gynaecological history, use and total duration of oral contraception, time to achieve conception, and duration of current cohabitation. The data were collected in the early 1990s, when nearly all the pills would have been combined oestrogen/progestogen. By definition the study excluded infertile women. Data were collected on 14 893 pregnancies which resulted in 14 210 live births – representing about 85% of those in the local population. Logistic regression was used to identify factors independently related to conception within 12 months.

All the data suggested a positive rather than negative effect of the pill on subsequent fertility. Duration of oral contraceptive use was significantly related to the proportion of conceptions within 12 months.

How should this result be interpreted? Selection bias, whereby the most fertile women chose oral contraception, does not seem to be the explanation, since the positive effect was seen also in previously nulligravid women. One factor not recorded, and therefore not adjusted for in the analysis, was coital frequency. Couples who wish to start a baby after a long time on the pill may increase their frequency of coitus or time it more appropriately. The authors speculate interestingly on how oral contraception might improve subsequent fertility, if it does. For instance, it might halt progressive endometrial dysfunction; it might improve iron stores; it might lessen the spontaneous abortion rate; and it might protect against effects of age by preserving follicles. Their cautious overall conclusion, however, is that "Women who have prolonged use of oral contraceptives might be reassured that they will not be disadvantaged in terms of time taken to achieve conception".

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