Third generation oral contraceptives

CSM's advice will harm women's health worldwide

EDITOR,—The Committee on Safety of Medicines' recent advice that oral contraceptives containing gestodene or desogestrel should not be prescribed¹ has caused confusion and concern among family planning specialists and has major public health implications.

In 1977 the Royal College of General Practitioners concluded that women aged over 35 and heavy smokers aged over 30 should not use oral contraceptives because of an increased risk of cardiovascular disease.² These conclusions were highlighted in the Dutch media and caused a drop in the use of oral contraceptives from 34% to 27%, resulting in a sudden, 22% increase in induced abortions followed seven months later by a 6% increase in the birth rate. I calculated that this sensational media coverage caused some 13 000 extra unplanned pregnancies (40% ending in induced abortion) in the following year in the Netherlands. It took five years for the use of oral contraceptives and for the abortion rate to return to the rates that existed before the scare. Ironically, induced abortions increased more among younger women than older women (34% among those aged 20-24 v 9% among those aged 35-49). Hence those at increased risk were least affected, while those not at increased risk were disproportionately affected.³

Family planning specialists have learnt from such experiences, which is why the Committee on Safety of Medicines' advice causes such concern. It is based only on epidemiological surveys and does not take into account the negative public health impact of such advice. At best, the advice might prevent 1.5 cases of thromboembolism per 10 000 woman years, of which less than 1% are lethal (the thromboembolic risk of pregnancy is double this). Women often pick up the message that "there is something wrong with the pill" and that it is better to stop or not to start using it, with subsequent increases in the abortion and birth rates. Therefore some unofficial "rules" (which the committee ignored) should be adopted by anyone dealing with the outcome of epidemiological studies:

- Do not publicly highlight results until they have been confirmed in several studies
- Do not publicly highlight or draw practical conclusions from studies that focus only on a single risk or benefit. New information should be presented publicly only within the framework of both risks and benefits.

The British advice will undoubtedly influence public opinion and health policies abroad, particularly in developing countries. Recent estimates from the World Health Organisation indicate that 60 000-100 000 women die annually from the consequences of (illegal) abortion.⁴ This can be prevented by increasing the use of modern contraception. Ill judged messages like that issued by the Committee on Safety of Medicines impede the transition to modern contraception and increase reliance on abortion, causing unnecessary harm to women's health worldwide.

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1 Committee on Safety of Medicines. *Combined oral contraceptives and thromboembolism*. London: CSM, 1995.

2 Royal College of General Practitioners' Oral Contraception Study. Mortality among oral-contraceptive users. *Lancet* 1977;ii:727-31.

3 Ketting E. *De teloorgang van "de pil"*. Zeist: Netherlands Institute of Social Sexological Research, 1981.

4 World Health Organisation. *Abortion, a tabulation of available data on the frequency and mortality of unsafe abortion*. 2nd ed. Geneva: WHO, 1994.

CSM should rethink its approach for such announcements

EDITOR,—Klim McPherson estimates that in making its announcement when it did rather than waiting until all the relevant studies of third generation oral contraceptives had been published, the Committee on Safety of Medicines saved one life and prevented 80 cases of venous thromboembolism.¹ Our concern is not with the timing of the announcement in relation to the publication of peer reviewed papers or with the committee members' appraisal of the research evidence but with the manner in which the committee communicated the information to professionals and the public.

The announcement created much public anxiety and put great pressure on primary care services. Professionals working under pressure are less likely to be able to explain difficult concepts such as risk to their patients and more likely to make mistakes. Patients under stress are more likely to make the wrong decisions and less likely to be able to look after themselves. The public's health depends on individual people looking after themselves in a myriad of small ways every hour of every day. Anything that interferes with that process increases the risk of wrong decisions being made, resulting, for example, in an increase in unwanted pregnancies.

The fact that these risks are not easy to quantify does not mean that they are less important than the risk of thromboembolism or that the committee can ignore its responsibility for creating them. A phrase in McPherson's editorial perhaps holds the clue to at least one of the motivating forces in the committee's decision: "disproportionate fear of litigation." The committee members would be more likely to be blamed in court for a thromboembolic event than for complications of a termination of pregnancy that occurred because of a panic decision to stop taking oral contraceptives. Thus the committee's decision was the public health equivalent of the practice of defensive clinical medicine. It was more comfortable for the professionals but more distressing for the public.

This is not the first time that such problems have arisen. Perhaps in future a more proactive approach should be considered. The Committee on Safety of Medicines could ensure that its announcements are preceded by the development of written material for the public, to be distributed alongside the usual professional communications. The information would need to be prepared by professionals used to developing health education material and would need to be easily reproducible locally. If the committee made future announcements in this way it would support health professionals and encourage informed decision making by the public rather than create panic and confusion.

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1 McPherson K. Third generation oral contraception and venous thromboembolism. *BMJ* 1996;312:67-8. (13 January.)

12% Of women stopped taking their pill immediately they heard CSM's warning

EDITOR,—In his editorial on third generation oral contraceptives and the Committee on Safety of Medicines' actions Klim McPherson states, "We have no clear idea how many women responded to the committee's advice and in what way." I recently undertook a postal survey of all the women aged over 18 who had been prescribed a third generation pill in the past year in my practice

(total population 9651). A total of 324 questionnaires were sent out, and 172 (53%) women replied. Twenty women (12%) said that they had stopped taking their pill on the day that the Committee on Safety of Medicines announced its warning, despite clear publicity that women should not do this.² My finding must have implications for the way in which messages are handled by the committee in the future.

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1 McPherson, K. Third generation oral contraception and venous thromboembolism. *BMJ* 1996;312:68-9. (13 January.)

2 Committee on Safety of Medicines. *Combined oral contraceptives and thromboembolism*. London: CSM, 1995.

How one clinic's practice conforms with CSM's advice

EDITOR,—In seeking to interpret for women the recent research showing an approximate doubling of the relative risk of venous thromboembolic disease in women taking oral contraceptives containing gestodene or desogestrel¹ we need ways in which to explain the complicated and subtle statistical evidence.

John Guillebaud contends that we can reassure a woman who has been taking combined oral contraceptives for a considerable time that "as she has not had a venous thrombosis in these years she is particularly unlikely to have one,"² but I do not believe that this view is evidence based. The World Health Organisation's recent study concludes that "duration of current episodes of use and lifetime duration of use did not effect the risk estimates of VTE [venous thromboembolic disease]."

It is important to get the risks into perspective. The combined oral contraceptives are safe and effective for many women. The recently published data confirm the low risk of venous thromboembolic disease associated with combined pills containing norethisterone or norgestrel, at 15/100 000 women per year. The risk for pills containing desogestrel or gestodene is reported as around 30/100 000 women per year.³

In the service in which I work we now reserve pills containing desogestrel or gestodene for those few women who, having had unacceptable side effects while taking other combined formulations, do not wish to consider an alternative contraceptive method and have discussed and understand the current estimation of risks. Women who have been happy with pills containing gestodene or desogestrel but have never tried any others are being offered the opportunity to change to a formulation that we now believe confers less risk. In our experience most women in this situation are pleased to be offered the opportunity of minimising their risks. We discuss with the women how to change between formulations without diminishing contraceptive cover, and we record careful notes of the clinical consultations. We do not prescribe pills containing desogestrel or gestodene as first line choices for women with no experience of oral contraception, except occasionally to women with severe acne. We believe that this practice is in line with the current research evidence and the Committee on Safety of Medicines' advice.⁴

In our attempts to interpret new research evidence to inform our clinical practice and to present clear information to those who seek our advice and treatment we must guard against stepping over the boundary into untested hypotheses or wishful conjecture.

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