Scare over oral contraceptives

Effect on behaviour of women attending a family planning clinic

EDITOR,—The Department of Health's recent press release concerning the safety of some third generation contraceptive pills has important consequences for women using oral contraception.¹ To document their views and any change in behaviour of women taking the contraceptive pill after this warning, a survey was carried out at a large family planning clinic.

After the announcement a telephone helpline was established at the clinic. This took 2348 calls on the first seven days, and the number of attendances rose from an expected 700 to 2029 in that week. One week later a piloted questionnaire was given to a representative sample of women before consultation over six days. A response rate of 71% was obtained (n=274). The age range was 14-54, with 50 women under 20 and 58 over 30. The table gives the women's views. Those who were and those who were not using oral contraception differed in terms of their awareness of the announcement (177 (99%) v 85 (89%) were aware of it) although not in the belief that the announcement was a reasonable method of informing women (97 (54%) v 50 (52%).)

The behaviour of the 178 women taking the pill was examined. Altogether 141 were taking a preparation implicated in the scare. Thirty seven

Women's views on announcement about risks associated with contraceptive pill. Figures are numbers (percentages)

	Women using pill (n=178)	Women not using pill (n=96)
Reason for visit		
Information about scare	77 (43)	1 (1)
Routine contraception	54 (30)	17 (18)
Emergency contraception	16 (9)	27 (28)
Pregnancy test	12 (7)	21 (22)
Other	19 (11)	30 (31)
Source of information		
Television or radio	124 (70)	67 (70)
Newspaper	23 (13)	10 (10)
Relative or friend	16 (9)	1 (1)
Other	15 (8)	18 (19)
Reaction		
Interested	48 (27)	37 (39)
Worried	72 (40)	11 (11)
Not bothered	5 (3)	9 (9)
Other	53 (30)	39 (41)
Action taken		
Appointment with general practitioner	4 (2)	2 (2)
Family planning appointment	65 (36)	1 (1)
Discussed with friend	24 (13)	19 (20)
Nothing	41 (23)	54 (56)
Other	44 (25)	20 (21)
Opinion		
Storm in a teacup	21 (12)	10 (10)
Much needed warning	43 (24)	46 (48)
Scare mongering	46 (26)	14 (15)
Other	68 (38)	26 (27)

Advice to authors

We prefer short letters that relate to a recently published article and we are unlikely to publish letters longer than 400 words and containing over five references. Letters may be shortened. Your letters should be typed with double spacing and include a word count. All authors need to sign the letter and provide one current appointment and address. We encourage you to declare any conflict of interest. If you wish to know whether your letter has been accepted or rejected please enclose a stamped addressed envelope.

either had already changed brands or commented that they intended to change. Sixteen had stopped taking the pill because of the announcement, of whom eight subsequently had intercourse without contraception. No one taking pills not mentioned in the scare stopped because of the announcement or intended to change.

It has been estimated that 1.5 million women were advised to change brands.² Although the findings of this survey cannot be generalised, we think it likely that many thousands of women may subsequently have had unprotected intercourse, which will have resulted in an increase in unwanted pregnancies.

The use of the mass media to disseminate information is well established and has led to a high level of awareness in the target group (pill users). Ways of using this resource that will also give women an accurate representation of the risks must be developed.

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1 Department of Health. *New advice on oral contraceptives*. London: DoH, 1995.

2 Carnall D. Controversy rages over new contraceptive data. *BMJ* 1995;311:1117. (28 October.)

Effect on women in a general practice in Devon ...

EDITOR,—On 19 October, while working on my thesis on teenage pregnancy, I was astonished to hear the news of the new "pill scare." This was broken to an unsuspecting public and profession through the media. My copy of the *British Journal of Family Planning* had arrived that morning but did not contain anything on the matter. I listened amazed as the plot thickened, and for once the media tried to unravel it in a constructive manner. I wondered whether to return to my practice the next day or leave the country.

On 20 October the letter from the Committee on Safety of Medicines at last arrived.¹ I designed a short handout for the receptionists and local pharmacists to use and discussed with my partners how we would manage the crisis. Each partner was given a list of his or her patients who were taking

the relevant pills. The first panicking patients telephoned and turned up in the surgery.

Now, five weeks later, what has happened? I am impressed by the common sense and intelligence displayed by my patients. I have had at least 44 extra consultations. So far no woman has stopped the pill precipitously (one missed one day). All the women were counselled about the content of the Committee on Safety of Medicines' letter and the articles in the *BMJ*,² as they became available.

Of the six women currently taking Mercilon (20 µg ethinylloestradiol and 150 µg desogestrel), all opted to continue to take it as they could tolerate only 20 µg ethinylloestradiol and thought it the best pill they had ever had. Of 42 prescribed Marvelon (30 µg ethinylloestradiol and 150 µg desogestrel) in the past six months, 10 chose to continue to take it, 11 to change to another pill, one to change to intramuscular injections of medroxyprogesterone acetate, and two (who were not using it for contraception) to stop; 18 have yet to contact the surgery, some of whom may have stopped the pill for other reasons (for example, short term control of their periods).

Of 15 women given Femodene (30 µg ethinylloestradiol and 75 µg gestodene) in the past six months, two decided to continue taking it, three to change to another pill, one to try intramuscular injections of medroxyprogesterone acetate, and one to try an intrauterine device (Mirena). Three women not using the drug for contraception stopped taking it. Five women have not yet contacted the surgery. Only one woman was taking Minulet (30 µg ethinylloestradiol and 75 µg gestodene), and she opted to continue it.

Initially women were scared, although few panicked. As they learnt more, many thought that the problem had been exaggerated and were keen to explain that they had known of the risk of thrombosis and were prepared to accept it. Overall, this pill scare has not caused as much trouble as I initially expected. It has given a few women the opportunity to review their contraceptive practice. Whether there will be the usual increase in unplanned pregnancies after a pill scare, only time will tell.

I am just sad at the way the scare was handled, as there can be no excuse for it. The message that should be given to women is how safe their pills are, particularly in a society that is seeking to reduce teenage pregnancy. I only wish that energy could be channelled into a new "tobacco scare"—then we might really see some lives saved.

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

2 Guillebaud J. Advising women on which pill to take. *BMJ* 1995;311:1111-2. (28 October.)

3 McRae K, Kay C. Third generation oral contraceptive pills. *BMJ* 1995;311:1112. (28 October.)

... and south Wales

EDITOR,—After the recent adverse publicity about some third generation contraceptive pills and changed guidelines¹ we analysed the number of consultations in which patients were advised about contraception. We practise in an urban area of

south Wales, and our list size is 5600. All consultations in this context were initiated by patients.

We routinely code clinical information during consultations on our computer database; this facilitates audit of clinical practice. When a patient is advised about contraception a Read code (6777: contraception counselling) is recorded. Over the 10 weeks before the "pill scare" on 19 October the code for contraception counselling was recorded 18 times (average 1.8 times a week). Over the three weeks after the announcement the code was recorded (week by week) 30, 28, and 27 times (average 28.3).

If it is assumed that these figures are reflected throughout England and Wales the effect on general practitioners' workload nationally can be estimated and perhaps costed.

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1 Health Commissioning Division. *Pharmaceutical hazard warning No 580*. Cardiff: Welsh Office, 1995.

Main public health issue is failure to use contraception

EDITOR,—The letter from the Committee on Safety of Medicines to all doctors about the increased risk of thromboembolism in women taking oral contraceptives containing desogestrel and gestodene,¹ and the manner in which it was released to the press, has caused predictable public panic. Surely the data should have been presented in the context of the wider issue of the provision of effective contraception. As has been pointed out, protective effects against other diseases must also be balanced, but most importantly the data must be viewed alongside figures for termination of pregnancy (which is only one of the possible outcomes of unwanted pregnancy caused by ineffective contraception).^{2,3}

In Scotland in 1993, 1% of women aged 15–44 had a termination of pregnancy, and the cumulative percentage of 25–44 year olds who had had a termination of pregnancy was 15%.⁴ The physical and psychological sequelae are well documented. Such figures suggest a much larger public health concern—namely, underuse of contraception.

I recently studied the provision of contraception at Springburn Health Centre, a general practice in inner city Glasgow run by Dr M R McLaughlin and partners. An initial audit showed that the practice was providing contraceptive services to 165 out of 770 women aged 16–45. The remaining 505 women were surveyed opportunistically over the next nine months (244 (48%) were seen). The women were asked whether they attended elsewhere for family planning (for example, a family planning clinic), whether they did not require contraception (for example, because they were sexually inactive or had had a hysterectomy), or whether they had an unmet need for contraceptive services. Only 15 attended elsewhere, 174 had no requirement for contraception, and 55 required contraception. Analysis by age group showed that 8 of the 24 women aged 16–20, 20 of the 41 aged 21–25, 20 of the 105 aged 26–35, and 7 of the 74 aged 36–45 required contraception.

Such figures support the view that the main public health issue is failure to use contraception at all, let alone effectively. While I agree that research on the safety of methods of contraception is essential, the Committee on Safety of Medicines must surely have realised that its letter would be sensationalised and should not be presented to the press in isolation.

Evidence already exists that fear about the safety of contraception prevents the public from seeking advice.⁵ Many doctors will share my fear that an

erroneous "take home message"—that the pill is dangerous—will be yet another barrier to overcome for those trying to promote and provide safe, effective advice on family planning.

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- 1 Committee on Safety of Medicines. *Combined oral contraceptives and thromboembolism*. London: CSM, 1995.
- 2 Guillebaud J. Advising women on which pill to take. *BMJ* 1995;311:1111–2. (28 October.)
- 3 MacRae K, Clifford K. Third generation oral contraceptive pills. *BMJ* 1995;311:1112. (28 October.)
- 4 Office of Population Censuses and Surveys. *Abortion statistics 1993*. London: HMSO, 1994. (Series AB No 20.)
- 5 Zabin LS, Stark HA, Emerson MR. Reasons for delay in contraceptive clinic utilization. Adolescent clinic and nonclinic populations compared. *J Adolesc Health* 1991;12:225–32.

New group will review evidence for effective care in family planning

EDITOR,—One of the problems in the provision of family planning is the dearth of useful, clinical randomised controlled trials on which to base our practice. For some rare events such as thrombosis, heart attacks, and stroke, randomised controlled trials are clearly not feasible and we rely on the epidemiological data from well conducted studies. Some factors, however, are readily amenable to randomisation. John Guillebaud suggests that it would be appropriate for a client to start taking a pill containing desogestrel or gestodene if the predictable incidence of breakthrough bleeding, acne, headache, and weight gain with alternative pills is higher.¹ It is extraordinary that, although three million women in Britain are using the pill for contraception, we have little evidence to support this advice.

I have performed a Medline search, from 1976 to the present, for randomised controlled trials comparing these minor side effects associated with second generation pills with those associated with the newer combined pills containing desogestrel or gestodene and found only one trial. In a randomised trial of 456 women Loudon *et al* found a reduced incidence of breakthrough bleeding with a pill containing gestodene compared with one containing levonorgestrel but no difference in weight gain.² There is no evidence on headache and acne.

The Cochrane Collaboration, which prepares, maintains, and disseminates systematic reviews of the effects of health care, will be organising an exploratory meeting early next year with a view to establishing a Fertility Control Cochrane Review Group. The aim of the group will be to review the evidence for effective care in family planning. This will involve an extensive search for published and unpublished trials and the preparation of systematic reviews for wide distribution. Anyone interested in this project can contact me for further details.

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- 1 Guillebaud J. Advising women on which pill to take. *BMJ* 1995;311:1111–2. (28 October.)
- 2 Loudon NB, Kirkman RJ, Dewsbury JA. A double-blind comparison of the efficacy and acceptability of Femodene and Microgynon-30. *Eur J Obstet Gynecol Reprod Biol* 1990;34:257–66.

Doctors should take warning seriously

EDITOR,—I wish to challenge John Guillebaud's editorial¹ on the recent warning by the Committee on Safety of Medicines about combined oral contraceptives containing gestodene and desogestrel.² Some family planning doctors will not agree with his views on a continued role for preparations that seem to double the risk of venous thrombo-

embolism for current users compared with users of low dose monophasic oral contraceptives containing levonorgestrel and norethisterone. There is no evidence from epidemiological studies that preparations containing levonorgestrel and norethisterone carry a comparatively greater risk of excess deaths from myocardial infarction or stroke. It is virtually impossible to show an increased risk of myocardial infarction in current or past users of any combined oral contraceptive formulation if they have avoided higher dose preparations, provided that they do not smoke.³ It hardly seems necessary, therefore, to make premature claims for formulations that may protect women from a barely identifiable risk.

Claims that the combined oral contraceptives containing gestodene and desogestrel may protect women from myocardial infarction are apparently based on the theory that a decreased high density lipoprotein cholesterol concentration is an appropriate single marker for the risk of myocardial infarction in premenopausal women. This is dubious because a reduction in high density lipoprotein cholesterol concentration in premenopausal women without a concomitant increase in total cholesterol or triglyceride concentration, or both, is unlikely to increase the risk of myocardial infarction.⁴ Moreover, metabolic studies tend to be conducted on small numbers of women for relatively short periods and to report mean changes that are still within normal limits. There is a considerable margin of error and interlaboratory disagreement. One reported study on which much reliance was placed is now known to have been fraudulent.⁵ There is probably considerable reporting bias, and the few published randomised comparative studies of older and newer pills containing progestogen offer conflicting results.

Doctors will be well advised to take seriously the letter from the Committee on Safety of Medicines about the risk of venous thromboembolism and to reserve their judgment on other possible cardiovascular risks of combined oral contraceptives until more definitive epidemiological evidence is published.

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- 1 Guillebaud J. Advising women on which pill to take. *BMJ* 1995;311:1111–2. (28 October.)
- 2 Committee on Safety of Medicines. *Combined oral contraceptives and thromboembolism*. London: CSM, 1995.
- 3 Thorogood M, Mann J, Murphy M, Vessey M. Is oral contraceptive use still associated with an increased risk of fatal myocardial infarction? Report of a case-control study. *Br J Obstet Gynaecol* 1991;98:1245–53.
- 4 Stampfer MJ, Sacks FM, Salvini S, Willett WC, Hennekens CH. A prospective study of cholesterol, apolipoproteins, and the risk of myocardial infarction. *N Engl J Med* 1991;325:373–81.
- 5 Briggs MH. Recent biological studies in relation to low dose hormonal contraceptives. *British Journal of Family Planning* 1979;5:25–8.

If a woman has not had a thrombotic event in years of use she is unlikely to have one now

EDITOR,—My editorial commenting on the letter from the Committee on Safety of Medicines and the three studies that gave rise to it had to be cut because of lack of space.¹ In the original version I argued that, in these trials, the proportion of women who had been exposed in the past to ethinylestradiol (in any combination) might be higher among current users of the third generation pills containing desogestrel and gestodene; ethinylestradiol is still recognised as the prime prothrombotic constituent of contraceptive pills. This difference would effectively mean that a smaller proportion of women taking the longer established pills had hereditary disorders of coagulation (since such women would have stopped