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The public health implications of the 1995 'pill scare'

Ann Furedi[1]

British Pregnancy Advisory Service, Solihull, UK

The warning issued by the UK Committee on Safety Medicines in October 1995, followed by their 'Dear Doctor' letter of October 18, 1995, that oral contraceptive pills containing gestodene or desogestrel were associated with a higher risk of venous thromboembolism has had a negative impact on public heath. A significant number of women either switched brands or ceased contraception altogether following the announcement. National data suggest a strong association between the pill scare and a substantial increase in the number of unintended pregnancies, particularly significant among younger women, with use of oral contraception falling from 40 to 27% of under 16s between 1995–1996 and 1996–1997. The resulting cost of the increase in births and abortions to the National Health Service has been estimated at about £21 milllion for maternity care and from £46 million for abortion provision. The level of risk should, in future, be more carefully assessed and advice more carefully presented in the interests of public health.

Keywords: oral contraception/public health/pill scare

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Introduction

In October 1995, the UK Committee on Safety of Medicines (CSM) issued a warning that oral contraceptive pills containing gestodene or desogestrel were associated with a higher risk of venous thromboembolism than pills containing other progestogens. The advice was based on the results of three—at that time unpublished—epidemiological studies submitted to the Medicines Control Agency (MCA) and a subcommittee of the CSM.

On October 18th, 1995, the CSM sent a 'Dear Doctor' letter to 190 000 general practitioners, pharmacists and directors of public health throughout the UK, alerting them to the research. This information to health professionals was supplemented by a statement to the press and broadcast media which explained that doctors and pharmacists were 'being informed of important new information'. The statement explained that: "It is well known that the pill may rarely produce thrombosis (blood clots) involving veins of the legs. New evidence has become available indicating that the chance of a thrombosis occurring in a vein increase around two-fold for some types of pills compared with others".

The statement went on to list the brands of pills associated with the increased risk and concluded with the following advice: "For the vast majority of women, the pill is a safe and highly effective form of contraception. Women taking one of the relevant pills should, if possible, see their doctor before their current cycle ends. No-one need stop taking the pill before obtaining medical advice".

Despite the reassurance of safety, the message conveyed was one of alarm at the increased risks. This is unsurprising as the release contained no numerical information on what the increased risk represented in real terms and the manner in which the information was conveyed to journalists—an emergency announcement at the end of a routine press briefing on another subject—emphasized its importance and urgency. Subsequently published papers showed that the risk of thromboembolism to women on the allegedly more risky pills was half that faced by a woman experiencing a normal pregnancy.

The actions of the CSM in issuing the 'Dear Doctor' letter and in alerting the media to this was strongly criticised by leading epidemiologists involved in the collection of data on which the CSM statement was based. Spitzer insisted that: "As a pharmacoepidemiologist and principal investigator of the study I believe that the associations shown do not justify haste

[1]Address for correspondence: British Pregnancy Advisory Service, Austy Manor, Wooten Wawen, Solihull, West Midlands B95 6BX, UK

in decision making". He explained that "Our results for venous thromboembolism are equivocal, being neither fully reassuring nor alarming. But I thought the absence of danger or imminent danger afforded the opportunity to evaluate the results carefully and deliberately, to present them for scientific feedback and to submit them to a peer-reviewed journal. The Medicines Control Agency and the Committee on Safety of Medicines chose to short-circuit the formal peer review process to make decisions about third generation oral contraceptives in the absence of a community health emergency" (Spitzer, 1995, 1997).

Those who supported the decision justified it as being in the interests of public health (Department of Health, 1995a,b). In a *British Medical Journal* editorial (McPherson, 1996), the actions of the CSM were defended with the claim that "delaying the announcement until all the studies had been published would have incurred a further 500 000 uninformed women years of use of third generation oral contraceptive pills, which might have resulted in 80 new cases of thromboembolism and possibly one death". This view was countered by Spitzer, who argued that: "Referring to absolute rates by speculating about one possible VTE (venous thromboembolism) death averted is an emotive way of invoking absolute rate differences. One death among 11 million women of child-bearing age is impressive to the public but meaningless in public health terms. Unless McPherson can show unambiguously and verifiably that there were no abortions due to unwanted pregnancies and not one single associated death in the same short span of time, the 'one death averted' argument is misleading at best" (Spitzer, 1996).

Subsequent data have shown that there was a significant increase in conceptions and abortions and that the episode has undermined confidence in the pill as a safe method of contraception, creating on-going circumstances in which a greater number of women were placed at risk of unintended pregnancy (Furedi and Furedi, 1996). Misconceptions and exaggerated concerns about risks continue to dominate public perceptions of oral contraception.

It seems that the 1995 pill panic has had a significant, if unintended negative impact on public health.

The effect on contraceptive use

The most obvious effect of the 'pill scare' was that on the use of oral contraceptives. There is evidence to suggest that, following the alert, a significant number of concerned women contacted their doctors and either switched their brand of pill, changed to another method of contraception, or ceased contraception altogether. This is shown by the following studies. First, researchers at the University of Exeter questioned 1334 pill users in the 10 days following the CSM advice and found that 1% stopped using contraception after the scare, 58% switched to another pill brand, and 33% continued to use the brand that had previously been prescribed. A quarter of the women said they had telephoned a health professional for advice after seeing the media coverage of the issue (Allison and Roizen, 1996; Allison *et al.*, 1997). Second, 12% cent of pill users surveyed by an Oxford general practitioner stopped taking their pills on the day of the CSM announcement, despite clear publicity that they should not do this (Hope, 1996). Third, an analysis of prescription data in the Northern Yorkshire region suggested that up to 5% of oral contraceptive users may have stopped using effective contraception between October 18, 1995 and December, 1995 (Roberts, 1997).

Anecdotal reports from those providing family planning advice suggest that women still have exaggerated concerns about oral contraceptives, and that these are causing women, who would otherwise wish to use a hormonal contraceptive, to opt instead for a barrier method. Such women may be placed at continued increased risk of unwanted conception.

The importance of contraceptive choice based on accurate information has been widely discussed. Non-hormonal methods of contraception can be effective in preventing pregnancy if couples are highly motivated to use them, but failure is more likely if they are the 'second choice' of women who would prefer to use the pill. A study of contraceptive preferences, in which field work was conducted after the CSM announcement, found that of pill users who had switched to other methods of contraception, 66% did so because they were worried about health risks (Walsh *et al.*, 1996). As a result, a significant number of couples may be using barrier methods reluctantly and may be exposed to an increased risk of unintended pregnancy—both now and in the future.

Public concern about the safety of the pill has yet to be allayed. National Opinion Poll surveys commissioned by Schering Health Care Ltd found, in 1993, that 24% of women questioned said they would never consider the pill as a method of contraception, but in 1996 the comparable proportion had risen to 33% (Schering Health Care, Ltd, 1996).

The effect on unintended pregnancies and abortions

National data suggest a strong association between the pill panic resulting from the letter from the CSM and a substantial increase in the number of unintended pregnancies.

Between 1990 and 1994, there was a decrease in both the numbers and rates of conceptions and abortions in England and Wales. Quarterly conception figures recorded by the Office for National Statistics show that this downward trend continued for the first three quarters of 1995. But the conception rates increased by 1% in the last quarter of 1995 compared with last quarter of 1994, and by 5% and 3% respectively in the first three quarters of 1996, compared with the same quarters in 1995 (Table I) (Wood *et al.*, 1998a,b). In the fourth quarter of 1996, the conception rate fell by 1% compared with the fourth quarter in 1995. (Conception statistics include pregnancies that result in births and legal abortions, but not miscarriages.) Post-1995 abortion rates in the UK were assessed (Child *et al.*, 1996), and details of

pregnancies and terminations after the 1995 warnings about third-generation oral contraceptives have been provided (Jick *et al.*, 1998). These data are also discussed in this symposium (Mills, 1999). The implications were felt worldwide, demonstrated by the situation in Norway (Skjeldestad *et al.*, 1997).

This pattern supports the hypothesis that the increase was a result of a change in women's contraceptive behaviour. Relatively few women who stopped using the pill following the announcement would have become pregnant immediately. There may be a delay of two to four weeks before ovulation recommences, and the chance of a fertile couple conceiving in any one menstrual cycle is only about 30%. Also, women using third-generation pills were advised to complete their current pack. This could explain why conceptions increased more in 1996 than immediately after the pill scare.

Table I. Conceptions in England and Wales (numbers per 1000 and rates)[a]

Year	March quarter	June quarter	September quarter	December quarter	Total for year
1993	199.8 (74.0)	202.5 (75.2)	209.7 (78.0)	207.0 (77.0)	819.0 (76.1)
1994	196.5 (73.2)	197.6 (73.6)	202.0 (75.3)	205.4 (76.6)	801.6 (74.7)
1995	193.2 (72.0)	194.1 (72.4)	195.2 (72.8)	207.8 (77.4)	790.3 (73.7)
1996	206.3 (77.3)	200.7 (75.2)	202.3 (74.9)	206.6 (76.5)	816.0 (76.0)

[a]Conception rates given in brackets refer to conceptions per thousand women aged 15–44 years. 1996 figures are provisional. Data from Wood *et al.* (1998a).

Table II. Annual numbers and rates of abortion to women resident in England and Wales

Year	No. of abortions	Rate per 1000 women aged 14–49 years
1990	173 900	13.61
1991	167 376	13.06
1992	160 501	12.51
1993	157 846	12.30
1994	156 539	12.18
1995	154 315	11.99
1996	167 916	13.03

Data derived from *Abortion Statistics* (1996).

The total number of abortions notified in England and Wales in 1996 was 8% higher than in 1995, and reversed the progressive decrease in the annual numbers that began in 1991. The number of abortions performed for women with addresses in England and Wales (resident women) rose by 13 601 to 167 916 (9%) (Table II). Abortions for women from the countries that make up the British Isles (Scotland, Northern Ireland, the Irish Republic, the Channel Isles and the Isle of Man)—who were exposed to the media reporting of the announcement by the CSM—increased by 478 (7%). The number of abortions for women resident in countries outside the British Isles fell.

Official conception data for the whole of 1996 show there were 816 000 conceptions in England and Wales—26 000 more than in 1995 (*Conceptions in England and Wales*, 1996). The proportion of these additional conceptions that ended in abortion cannot be determined precisely. Not all will have been unwanted—the debate about the pill may have encouraged some women to 'bring forward' their intention to have a child or to add to their family, and some will have been opposed to abortion on principle. However, the fact that 13 601 additional abortions were notified in 1996 suggests strongly that at least a half of the additional conceptions did not result in a birth. Abortion statistics are based on the date of the abortion, but conception statistics on an estimation of the date of conception and, as they are approximately three months out-of-phase, cannot be compared directly. Allowing for this, it is reasonable to assume that there were about 12 400 additional births and about 13 600 additional abortions in 1996 (birth statistics are based on the date of birth and are nine months out-of-phase with conception statistics).

The commentary to the volume of 1996 Abortion Statistics provided by the Office for National Statistics accepts that "there is evidence that reaction to publicity arising from the (CSM) announcement contributed to an increase in the number of conceptions and consequently an increase in the number of abortions in 1996" (*Abortion Statistics*, 1996).

The number and rate of abortions has remained at an elevated level. Provisional figures for the first two quarters of 1997 show that the total number of abortions for women resident in England and Wales fell by just 1.2% (*Legal Abortions, March Quarter*, 1997) and 0.7% (*Legal Abortions, June Quarter*, 1997) compared with the first and second quarters of 1996 respectively. In the third quarter, abortions for resident women increased by 2.6% compared with the same period in 1996 (*Legal Abortions, September Quarter*, 1997), and in the fourth quarter the number increased by 3% (*Legal Abortions, December Quarter*, 1997).

It is not yet clear why the abortion rate has remained elevated, and it is unlikely to be attributable solely to the 'pill scare'. In the UK during 1997 there was considerable publicity about abortion resulting from the 30th anniversary of the 1967 Abortion Act which legalized abortion. It has been suggested that discussion about the grounds on which pregnancies may be terminated, along with extensive media reporting of the number of unwanted pregnancies terminated as a result of the pill scare, may have increased knowledge and awareness of abortion, thus increasing its legitimacy among women who

would not otherwise have considered it as an option (Birth Control Trust, 1997–1998).

The effect of the increase in unintended pregnancies on the health of women and their families

The additional conceptions that followed the pill panic will have had serious effects on the health of women and their families. Health is defined by the World Health Organization as 'a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity' (World Health Organization, 1948). An unwanted pregnancy can threaten the physical and mental health of the woman and can result in long-term harm to her social well-being. Women do not expect to conceive an unwanted pregnancy, and the experience is frequently a cause of immediate and long-term anxiety and distress (Furedi, 1996). The woman may lose opportunities for career development that may permanently reduce her earning capacity and her standard of living. Continuing the pregnancy can lead to the child being reared in difficult circumstances, especially if the woman resents her situation and blames the child for the constraints placed on her. Women who already have children may be acutely aware that they will be unable to cope financially or emotionally with a larger family.

A woman choosing to continue her pregnancy has to accept a significant level of physical risk. A recent study reported an ante-natal admission rate of 25%. One-third of complications relate to the management of pre-term labour. Other complications are pre-eclampsia, pregnancy hypertension, antepartum haemorrhage, genitourinary infections and gestational diabetes (Scott *et al.*, 1997). Between 5% and 8% of pregnancies are complicated by hypertension; of these, pre-eclampsia accounts for 80% (Llewellyn-Jones, 1990). At least 25% of women will need an operative delivery (forceps or Caesarean section) and will face complications of anaesthesia and an increased risk of thromboembolic complications. The most recent report on Maternal Deaths in the United Kingdom documents 140 maternal deaths in the 1991–1993 period (maternal death rate: 6.0 per 100 000 maternities) (Department of Health, 1996).

Abortion is not risk-free, although the associated death rate is no greater than 1 per 100 000 abortions. A major study by the Royal College of Obstetricians and Gynaecologists (RCOG) and the Royal College of General Practitioners (RCGP) found that in the first 21 days following an abortion, 10% of patients reported problems directly related to the procedure of which 2% were considered to be major. Complications included: haemorrhage of >500 ml (1.3%); postoperative infection (3.6%); operative trauma such as lacerations to the cervix or uterine perforation (0.6%); thromboembolic disease (0.5%); and psychiatric morbidity (2.4%) (Joint Study of the RCGP and RCOG, 1985). Other studies have shown the total complication rate associated with early abortion to vary from 6% (Heisterberg and Kringelbach, 1987) to 15.7% (Henshaw *et al.*, 1994).

It is notable that pregnancy is associated with twice the risk of thrombosis that is estimated with use of the third-generation progestogen contraceptive pills that prompted the CSM announcement (Table III).

The effect on teenage pregnancy

The increase in conceptions and abortions was particularly significant among younger women. There were 8800 conceptions to girls under 16 in 1996 compared with 8000 in 1995. The 'under-age' conception rate rose by 1%, from 8.5% to 9.4% per 1000 girls under 16 (*Conceptions in England and Wales*, 1996). The number of abortions increased by 16% to girls of 15 and under, and by 15% in the 15- to 19-year age groups.

Table III. Comparative risks of non-fatal venous thromboembolism (VTE)

Risk of non-fatal VTE per 100 000 women per year[a]	
Women not using combined oral contraceptives	5–11
Women using combined oral contraceptives containing desogestrel or gestodene	30
Women using combined oral contraceptives containing levonorgestrel or norethisterone	15
Pregnant women and women post partum	60

[a]Data from Mills *et al.* (1996).

Table IV. Pill use among clients of Brook Advisory Centres[a]

Year	Under-16s (%)	16–19s (%)
1993–1994	47	59
1994–1995	44	56
1995–1996	40	51
1996–1997	27	38

[a]Values are percentage of clients choosing the pill. (Data from Brook Advisory Centres, 1996–1997).

There are specific public health concerns about unintended pregnancy when teenagers are affected. They are particularly likely to find themselves deprived of educational opportunities and subsequent employment possibilities. Young women who already live in socially and economically deprived environments may already be lacking in motivation to use contraception effectively, as they may have mothers, sisters, aunts and friends who became pregnant in their teens (Hudson and Ineichen, 1991). This may mean that any adverse publicity about contraception may cause a particularly demotivating effect. Also, younger women may lack skills to interpret the sensationalized reporting of 'health scares' and so are more

likely to be alarmed by reports which exaggerate the 'dangers' of the pill or fail to explain them in a balanced context.

There is evidence to suggest that young women's confidence in hormonal contraception has been significantly undermined by the pill scare. Brook Advisory Centres (1996; 1998, personal communication) have reported that the proportion of their clients requesting oral contraceptives fell sharply after the pill alert. The proportion of their clients aged under 16 using the pill fell by 13% between 1995–6 and 1996–7. The proportion of their clients aged 16–19 years using the pill also fell by 13% in the same period (see Table IV).

It should be noted that the above figures relate to clinic attendees. Evidence already exists that fears about the safety of contraception prevents young people from seeking advice (Zabin *et al.*, 1991).

The effect on service providers

The unanticipated increase in births and abortions led to increased expenditure on maternity and abortion services. Answers to Parliamentary Questions have recently confirmed the cost to the National Health Service (NHS) of a first-trimester abortion to be between £289 and £443 (Hansard, vol. 301, 1997) and the average cost of childbirth to be £1698 (Hansard, vol. 299, 1997). If, as suggested in para. 3.4 of the Hansard document, there were about 12 400 additional births and 13 600 additional abortions (70% paid for by the NHS) in 1996, the cost to the NHS would have been about £21 million for maternity care and from £4–6 million for abortion provision. In the long term there will be continuing costs to the Government from social security payments and from the provision of extra school places.

It is arguable that the most destructive effect of the pill panic on service providers has been the trend towards defensive prescribing practices. Family planning organizations are concerned that worries about medicolegal issues may cause doctors to avoid prescribing third-generation contraceptive pills, even when they believe such formulations to be clinically appropriate for specific women. Anecdotal accounts of such 'defensive' prescribing are supported by research commissioned by Organon Laboratories. When a sample of 355 GPs was asked: "What concerns, if any, do you have regarding prescribing third-generation pills?", 234 replied that they had medicolegal concerns compared with 184 who were concerned about the "perceived difference on the risk of side-effects such as DVT (deep vein thrombosis)" (Organon Laboratories, 1997).

Lessons to be learned from the pill panic

The confusion and conflicting expert opinions that followed the CSM letter has led to considerable discussion in the media about health panics, and public awareness of 'defensive decision making' (Furedi, 1997). This may have increased public cynicism in 'health alerts'. However, it may also have made the public more aware of how public health information is 'managed' leading to increased distrust of 'official' statements. Parental resistance to reassurance about the safety of the mumps–measles–rubella (MMR) vaccine—the subject of recent controversy in the UK—may be an example of this.

However, it is noticeable that the communication of issues relating to health risks has considerably improved, possibly as a direct result of conscious appraisal of the problems caused by the events of 1995.

The Chief Medical Officer (CMO), Kenneth Callman devoted a section of his annual report, *On the State of the Public Health*, to the communication of risk, using the October pill scare as an example of the problems faced by the medical profession (Callman, 1996). He observed: "It is true that the relative risk of venous thrombosis (defined as venous thromboembotic episodes, VTEs) is doubled by the combined oral contraceptives containing gestodene or desogestrel compared with the second-generation combined oral contraceptives. However, the absolute risk is very small in all types of oral contraceptives, and much smaller than the risk of pregnancy. The public presentation of these figures caused great anxiety; although the increased risk was small, women did need to be informed that there was a difference in risk between the oral contraceptives available to them. The message to continue to take the oral contraceptive pill, seemed to be ignored in the pressure for action".

This carefully worded statement implicitly recognizes that the announcement had an unintended, unwanted outcome. An accompanying discussion as to how risk issues could better be communicated in future implicitly accepts that mistakes were made in relation to this event and outlines a new procedure for classifying risks.

It would be of great benefit to public health if the advice on third-generation oral contraceptives were represented in the context of the advice on presentation of risk outlined in the CMO's annual report. The CMO suggests that risk estimates between 1:1000 and 1:10 000 are described as low and that "other words which might be used include 'reasonable', 'tolerable' and 'small'". This would, we believe adequately and accurately describe the risk of non-fatal VTE associated with third-generation oral contraceptives. We further believe that such a level of risk did not, and does not, justify the advice contained in the 'Dear Doctor' letter, and that this should be withdrawn in the interests of public health.

On 7th April, the 1995 regulatory decision was overturned on appeal (Department of Health, 1999).

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