

# Pill scare: communication conundrum

Lindsay Edouard

## Summary

Adverse publicity for combined oral contraceptives (COCs) has led to pill scares on numerous occasions such as reproductive cancers in 1983 and venous thromboembolism (VTE) in 1995. Misinformation should be avoided, especially through the correct interpretation of relative risk to avoid confusion and decrease unnecessary anxiety. Reassurance is usually important, as the absolute risk is infinitely small. The popular media are very effective for the prompt dissemination of information, and authoritative statements are useful for improving communications with providers, patients and public.

## Symposium

Adverse effects of oral contraceptives were at the forefront of well-women services in 1984: the April issue of the Journal included a supplement entitled 'Recent Advances in Oral Contraception', comprising the proceedings of a symposium that had been held 11 months earlier in May 1983. The editors expressed regret for the late publication of the supplement.

In the absence of randomised controlled clinical trials on COCs, findings from epidemiological studies were challenged, as exemplified by the risk for VTE.<sup>1</sup> It is difficult for statistical analyses to correct for the careful selection of individuals for the prescription of COCs. With the "infinitesimally small" risk of mortality in women younger than 35 years old, analyses of vital statistics were not very valuable for determining trends.<sup>1</sup> Epidemiological evidence for a negative association of COCs with benign breast lumps, both fibroadenoma and chronic cystic disease, combined with the recognised association between chronic cystic disease with breast cancer, led to some speculation of protection by COCs against malignant breast disease.<sup>2</sup>

## Scare

On 22 October 1983, 5 months after the above symposium, *The Lancet* published two original research articles on the association of COCs with reproductive cancers.<sup>3</sup> The finding of an increased risk for breast cancer from COC use in young women was heavily criticised, not only from an epidemiological perspective but also for its estimation of hormonal load: ignoring both type and dose of estrogen besides using an obsolete test for the determination of progestogen potency.

An increased risk for both cervical intraepithelial neoplasia and invasive cancer was linked to the duration of use of COCs. However, those findings failed to take into account the role of sexual activity, which was then perceived as being the most important risk factor in the aetiology of cervical cancer.<sup>4</sup>

The importance of those two articles was reflected by an accompanying editorial that unfortunately stressed the association with cancer, as opposed to the limitations of the

studies. Furthermore, the related press release failed to place the studies in an appropriate perspective for the general public, especially with regard to the interpretation of risk level and potential role of cancer screening.<sup>4-6</sup> Wide coverage of those two articles in the media led to a pill scare.

To avoid further pill scares, it was recommended to have the prepublication review of contentious articles by an independent panel consisting of individuals who are active in research and clinical services, as opposed to "senior administrative figures who may be out of touch with recent advances in contraception".<sup>4</sup> Coping measures were also considered: aware that "through the technology of broadcasting, patients can now hear about medical advances before their doctors do", it was suggested that "the medical profession must use twentieth century methods of communication" such as "computer linkage schemes, with terminals in medical libraries" and health facilities.<sup>4</sup>

## Saga

The pill scare of October 1983 was neither the first nor the last. Earlier important scares had occurred in 1969 and 1977 but the worst case occurred in October 1995: an association of third-generation COCs with VTE was featured in the mass media before the receipt by providers of a 'Dear Doctor' letter from the Committee on Safety of Medicines which was based on different studies.<sup>7</sup>

One team of investigators had shared their tentative findings, in confidence, with the regulatory authority during a meeting that was surprisingly followed by the prompt release of the above letter, although that meeting had led to the setting-up of an independent *ad hoc* panel to oversee the final data analysis. The ensuing results were not released in a journal article until more than 2 months after the pill scare.<sup>8</sup> With further data analyses demonstrating that the actual risk was much less than originally estimated and, ironically enough, of a magnitude that had been well accepted previously, third-generation COCs returned to the front line of contraception prescribing in 1999.

## Service implications

A pill scare often leads to an immediate change in contraceptive practice with either discontinuation or switch to a less desirable method. As a result, an increase in unintended pregnancies usually occurs over the next 18 months with a rise in induced abortions.<sup>7</sup> The guidelines resulting from the 1983 pill scare strongly recommended that users should not immediately change their chosen COCs.<sup>3</sup>

Whereas epidemiological studies of contraceptive methods can estimate the relative risk for associations, the level of risk needs to be interpreted correctly for users by considering absolute risk, which is more appropriate and well understood.<sup>9</sup> Furthermore, those risks should be perceived in the much broader context of benefits, especially through the avoidance of the risk of pregnancy: prevailing levels of maternal mortality and morbidity as well as patterns of service provision, including screening for reproductive cancers, must be taken into account. Therefore, guidelines for contraceptive care should adapt international recommendations to fit country-specific situations.

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Algiers, Algeria

Lindsay Edouard, FRCOG, FFSRH, Member of the Editorial Advisory Board

Correspondence to: Professor Lindsay Edouard.

E-mail: [soranae@gmail.com](mailto:soranae@gmail.com)

The crucial flow of unbiased information, to providers and the public, can be hampered by individuals who seek unwarranted attention for their reports, whether in the media or scientific journals. Conversely, accurate reporting by the media on an excellent article can be misleading through misunderstanding and misinterpretation of its contents due to the different readerships.<sup>9</sup> A scare can result from inappropriate statistics causing confusion, fear, anxiety, negative emotions and feelings of terror<sup>10</sup> among the public, which can then blame the scientific community with loss of trust in providers. General practitioners can then be more concerned by legal,<sup>7</sup> as opposed to medical, aspects.

Conflicting advice from different sources is to be avoided and a pill scare can be mitigated through reassurance from both scientific experts and celebrity personalities in the popular media.<sup>11</sup> Authoritative statements and editorial commentaries are valuable for synthesising research findings so as to facilitate the tasks of providers and the media for communicating with patients and the public. The Internet has great potential for the prompt and wide dissemination of information but it has unfortunately also opened the door for unregulated websites to do much damage through the posting of inappropriate contents.

With both contraception and hormone replacement therapy involving large numbers of healthy women, reports of adverse effects can easily create huge interest thereby

becoming a public health issue. Despite well-intentioned measures for their prevention, scares are likely to recur. Efforts should then be deployed to minimise their impact through the prompt dissemination of objective and practical information.

#### Statements on funding and competing interests

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## NEWS ROUNDUP

### Free online postal chlamydia testing kits for young people

All young people aged between 16 and 24 years will be able to order free chlamydia testing kits online as part of a time-limited pilot project between Brook, the young people's sexual health charity, and Preventx.

Through the freetest.me website young people can enter their postcode and order a free chlamydia test. For about half of the country this will be through their local PCT and Brook is then supporting areas where there is no free National Health Service option so that all young people have access to free online chlamydia tests as part of the pilot.

Young people can choose how they would like to receive their results; via SMS to their mobile phone, e-mail or online results tracking, all in complete confidence. Chlamydia is easily diagnosed and treated although often has no symptoms and if left untreated can lead to fertility problems.

Patients who are outside the age range for free kits can order the test kit online for £25.00.

Source: <http://freetest.me.uk/>

### Older couples "use condoms less"

A recent study suggests that the use of condoms in a new relationship decreases with age.<sup>1</sup> While two-thirds of men and women in their late teens use a condom with a new partner, for men and women aged 35–44 years the rate was only one-third. This correlates with an increase in the diagnosis of sexually transmitted infections in the older age group. Men had sex sooner after first meeting a partner than women, with one in five men reporting sex within 24 hours of meeting their partner, compared with one in 10 women. Overall, half of all new partnerships involved condom use at first sex, but this declined with age. With 45% of marriages ending in divorce, the cohort of men and women forming new relationships later in life is increasing.

Researchers say that interventions that promote consistent condom use with new partners are urgently required, not just for young people as has been the focus recently, but for people in their 30s and 40s and older who are increasingly forming new partnerships.

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### COC provision by pharmacists

Pharmacists in south London look set to become the first in the country to provide the contraceptive pill to women without a prescription. Pilot schemes in Lambeth and Southwark are due to begin in mid-2009 and pharmacists involved will take an accredited training course. Dr Jane Fryer, Medical Director at Southwark PCT, said: "Women have told us that they want to access sexual health services that open for longer hours and in more convenient locations. The services we have developed in pharmacies reflect their demands". Lewisham PCT also said it planned to provide the pill from pharmacies, but was unable to confirm when the scheme would start.

Source: [www.chemistanddruggist.co.uk](http://www.chemistanddruggist.co.uk)

### PCTs plan to offer terminations in surgeries

Last year, a Department of Health pilot study found that women could safely receive early medical abortions (EMAs) in community settings, paving the way for PCTs to develop abortion services, as reported in *GP Newspaper*. Under the 1967 Abortion Act, an abortion can only be performed in a hospital or approved private sector clinic, however, Section 1(3a) of the Act gives the Health Secretary powers to approve abortions in primary care. The British

Pregnancy Advisory Service (BPAS) now has five GP-practice based locations providing pregnancy consultation (pregnancy testing and non-directive pregnancy counselling, ultrasound scanning and referral for abortion treatment, plus other family planning services). One of these locations has also been providing EMA treatment from a GP premises since mid 2008. PCTs across England have expressed interest in providing abortions in primary care. Ann Furedi, Chief Executive of BPAS, said: "It is about time this happened. EMAs are in great demand and are the method women want to use. It's about making access to abortions easier and more convenient, not increasing the number of abortions."

Source: *GP Newspaper*, 22 January 2009

### Abortion in South Dakota

The laws surrounding abortion in the state of South Dakota are some of the most restrictive in the USA. The 2005 'informed consent' law, which came into effect in June 2008, has been denounced in two leading medical journals.<sup>1,2</sup> This argues that the law "constitutes an affront to the First Amendment rights of physicians" as the physicians' words are mandated by the state. In effect, the law states that pregnant women must be told that the abortion will terminate a human life and that the constitutional rights with regard to her relationship with the fetus will be terminated. The woman is also advised of the gestational age and likely development of the fetus, and all known risks associated with termination of pregnancy.

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Reviewed by **Henrietta Hughes**, MRCGP, DFRH General Practitioner, London, UK