

BULLETIN BOARD

UK judge confirms emergency hormonal contraception does not cause abortion

In a judgement following a 3-day judicial review hearing in February, Mr Justice Munby dismissed the Society for the Protection of Unborn Children (SPUC)'s claims that emergency hormonal contraception causes abortion under the 1861 Offences Against the Person Act. The judgement confirms that emergency hormonal contraception does not cause an abortion: 'the morning-after pill cannot as a matter of law bring about a 'miscarriage'.

Much of the argument focused on the legal meaning of the term miscarriage. The judge said: 'Whatever it may or may not have meant in 1861 the word miscarriage today means the termination of an established pregnancy and there is no established pregnancy prior to implantation'.

Emergency hormonal contraception has now been the subject of unprecedented legal, medical and political scrutiny. In all cases it has been found to be safe and effective and it is right that it should be made widely available to women.

Other comments made by Mr Justice Munby included the following: 'There would be in my judgement something very seriously wrong, indeed grievously wrong with our system, if a judge in 2002 were to be compelled by a statute 141 years old to hold that what thousands, hundreds of thousands, indeed millions, of ordinary honest, decent, law-abiding citizens have been doing day-in day-out for so many years is and always has been criminal.' 'It is, as it seems to me, for individual men and women, acting in what they believe to be good conscience, applying those standards which they think appropriate, and in consultation with appropriate professional (and, if they wish, spiritual) advisers, to decide whether or not to use IUDs, the pill, the mini-pill and the morning-after pill. It is no business of government, judges or the law.'

Source: *fpa Sexual Health Agenda 2002; 5(2): 3*

Consort reporting of randomised controlled trials

Although randomised controlled trials (RCTs) can offer a robust method of investigation, they are not without limitations. Poor reporting of RCTs has meant that readers are often unable to judge if the results are valid and applicable to their own clinical situation. In the early 1990s, an international group of clinicians, scientists and epidemiologists developed the Consolidated Standards of Reporting Trials statement. This is widely known as the CONSORT statement. It includes a 22-point checklist and a flow diagram. CONSORT is regularly reviewed and updated as necessary. The aim is to provide a guideline for authors reporting results of RCTs. However, they can also be invaluable for those researchers designing trials or those of us reading published trials. The CONSORT statement has been endorsed by a number of medical journals including our own *Journal of Family Planning and Reproductive Health Care*. The checklist and flow diagram are available online at www.consort.statement.org. They are also published in *The Lancet* (2001; 357: 1191-1194). The checklist covers details relating to the title, abstract, introduction, methodology,

results and discussion of the paper. Particular attention is given to the methodology specifically covering: eligibility criteria; details of interventions; the outcomes to be measured; sample size calculations; randomisation process; blinding of participants; and statistical analysis. Attention is also given to reporting of results including: the flow of participants through the study process which is highlighted in a flow diagram; periods of recruitment and follow-up; primary and secondary outcomes; adverse events reporting; and data analysis including subgroup analysis and analysis based on intention to treat. The flow diagram aims to summarise this information for the reader. The CONSORT statement therefore aims to improve the standard of reporting RCTs, thus allowing readers to understand how the trial was conducted and allowing the validity of the results to be interpreted.

Source: Moher D, Schultz KF, Altman DG, for the CONSORT Group, The CONSORT statement: revised recommendations for improving the quality of reports of parallel-group randomised trials, *Lancet* 2001; 357: 1191-1194

Data protection

All family planning clinics across the UK should now comply with the Data Protection Act (1998). Information is available on line at www.doh.gov.uk/dpa98/. This Act refers to any information held in paper record or computer files that contains personal identifiers: name, postcode, date of birth, or user record number. The Caldicott recommendations provided a statutory framework for the Data Protection Act. It is now mandatory to advise users as to what information is being held about them; what use is being made of their data; and that they have a right of access to information held about them. Therefore it is recommended that every person attending a health service is given a leaflet detailing their rights. They should also be made aware of other uses of their data, such as audit, research, investigation of critical incidents or complaints, administration and official returns to statutory bodies. Anyone employed within the health service who is handling such data must process it in accordance with the eight principles of the Act. These principles are as follows:

- fairly and lawfully
- only for *specified* purposes
- adequate, relevant and not *excessive*
- accurate and *kept up to date*
- kept for *no longer* than necessary
- *processed* in line with users' rights
- be subject to appropriate, technical and organisational measures to *protect against unauthorised*, unlawful processing and accidental loss
- not be transferred to countries without adequate data protection.

Breaches of these principles can lead to prosecution of senior individuals responsible for data control. It is recognised that it is impossible to guarantee against theft of data, but health service managers must have taken reasonable measures to protect against this.

Family planning clinics have a long history of good practice around confidentiality and protection of individual rights. This means that relatively little may need to be done to become fully compliant with the Data Protection Act. It

may be useful, however, for all units to review data handling, consider whether it is necessary to record personal identifiers, and be very cautious about releasing any data whatsoever from the immediate department. Individual clinicians should review their own practice also. It is no longer acceptable to keep a personal notebook with the names and addresses of patients whom you have carried out a clinical procedure or had a particular type of consultation, even if this is for training purposes. Individual clinicians would be fully responsible for the security of that data. It is therefore wise to remove personal identifiers from any audit data that you remove from the protection of the clinic environment. Online teaching packages are available to health care professionals to provide an update on data protection at www.show.scot.nhs.uk/elearning.

Source: Alison Bigrigg, FRCOG, FRCS, MRCP, President of the Faculty of Family Planning and Reproductive Health Care

The role of the nurse practitioner in delivering care

Recent policy changes within the National Health Service (NHS) have led to the role of the nurse being extended. Often nurses are the first point of contact for health service users, such as with NHS walk-in centres or the new NHS Direct service. Nurse-led care has been developed in general practice, accident and emergency medicine and in family planning and reproductive health care. For many years now nurses and doctors working in family planning and reproductive health care have worked as teams to provide effective health care to women and men accessing our service. A recent systematic review in the *British Medical Journal* (April 2002) has looked at nurse practitioners providing care in a primary health care setting. The authors reviewed 11 trials and 23 observational studies. When compared to consultations with doctors, consultations with a nurse practitioner led to greater patient satisfaction, longer consultations and more investigations. However, no differences were seen in terms of prescriptions, return consultations or referrals. The authors highlight the limitations of their review and the need for further study. The role of the nurse in family planning has expanded greatly in recent years. The prescribing of medication under the 1968 Medicines Act suggested that doctors, dentists and veterinary surgeons were the only professionals allowed to prescribe. Under Section 50 2b, nurses were enabled to administer medications if acting in accordance with the request of a practitioner. This would indeed hamper the extended role of nurse practitioners. In 1999, recommendations in the Crown Report, led by Dr June Crown, suggested two types of prescribers: independent nurse prescribing and supplementary prescribing. Nurses can prescribe named medicines, under an agreed protocol, in identified clinical situations. This has allowed nurse prescribing and has allowed the role of the family planning nurse to continue to expand. There is also, however, an important health promotion role for the family planning nurse in reproductive and sexual health from promoting healthy lifestyle to safe sex.

Source: Horrocks S, Anderson E, Salisbury C, Systematic review of whether nurse practitioners working in primary care can provide equivalent care to doctors, *BMJ* 2002; 324: 819-823

A new contraceptive patch

A new contraceptive patch, Ortho Evra®, has been approved in the US and should be ready for European approval later this year. The once-a-week transdermal patch should improve compliance. It adds to the selection of safe, effective and convenient contraceptives presently available. Transdermal hormonal delivery systems have been used effectively by women as hormone replacement therapy for many years. The patch may provide an alternative to contraceptive injections, implants and oral contraception, particularly in women who are unreliable pills users. Although cost may be an important issue in prescribing, if compliance is increased and unintended pregnancies reduced it may well be a cost-effective option.

Source: Datamonitor news release at www.datamonitor.com

Violence against women

A series of six articles were published recently in *The Lancet* (April–May 2002). This series provided an overview of health issues central to violence against women. A summary of each article is outlined here. Violence has been defined by the United Nations Declaration on the Elimination of Violence Against Women as 'any act of gender-based violence that results in, or is likely to result in, physical, sexual or psychological harm or suffering to women'. The reporting of violence is likely to be universally under-reported. Figures are often obtained via cross-sectional population surveys, either by face-to-face interviews or by structured questionnaires. Women may not feel able to report violence. These violent acts towards women are not a unique event but part of ongoing abuse and have been shown to have a major impact on general health.

I: Global scope and magnitude

This paper outlines the global problem of violence against women. Intimate partner violence: between 10% and 50% of women worldwide have been physically assaulted by a partner. Although sexual assault by a stranger is acknowledged as a crime in many countries, sexual assault within marriage is often tolerated. Prostitution and trafficking: 700 000 to 2 million women and girls are trafficked for prostitution, across international borders, every year. Rape in war: an estimated 20 000 to 50 000 women were raped in the conflict in Bosnia-Herzegovina between 1992 and 1995. Missing women: worldwide an estimated 60 to 100 million

women and girls are 'missing' through sex-selective abortion, female infanticide and deliberate neglect.

Source: Watts C, Zimmerman C, *Violence against women: global scope and magnitude*, *Lancet* 2002; **359**: 1232–1237

II: Health consequences

This paper outlines how women who are victims of abuse may present to health care professionals. Although many abused women never attend hospital for treatment of acute injury, many are treated within the health care system. It is recognised that intimate partner violence results in long-term negative health consequences. Battered women can present with gynaecological symptoms, gastrointestinal symptom or stress-related disorders. Abuse may also occur during pregnancy. In the last year, 2.5% of women in the UK reported abuse during pregnancy. Figures for other countries varied from almost 6% in Canada, 7% in South Africa to 11% in Sweden. An awareness of, and an ability to assess, intimate partner violence should be within the remit of all health care professionals.

Source: Campbell JC, *Health consequences of intimate partner violence*, *Lancet* 2002; **359**: 1331–1336

III: Cause and prevention

This paper outlines some of the causes and strategies for prevention of domestic violence. Understanding the causes of intimate partner violence is more complex than understanding a disease. With the exception of poverty, most demographic and social characteristics of men and women are not associated with an increased risk of partner violence. The challenges for the health sector are to recognise that addressing intimate partner violence should be part of the public health agenda. Prevention strategies to tackle violence include: creating a climate of non-tolerance within society; reducing unemployment; addressing alcohol consumption; empowering women to control their fertility through accessible contraceptive and abortion services; continuing to research and monitor violence; and legislation on sex equality.

Source: Jewkes R, *Intimate partner violence: causes and prevention*, *Lancet* 2002; **359**: 1423–1429

IV: Health service response

This paper describes selective screening for

intimate partner violence by health care professionals. Recent initiatives in developing countries to raise awareness of violence against women are outlined. Dilemmas and challenges posed by current approaches to intimate partner violence are also discussed. Selective screening involves asking questions of women in whom one has reason to suspect violence is occurring. An awareness of the problem and adequate training of health care workers in asking such questions is essential. Providing a safe environment and assurances of confidentiality may increase the number of women disclosing intimate partner violence. Health care professionals may also have a role to play in identifying and helping men who abuse women.

Source: Garcia-Moreno C, *Dilemmas and opportunities for an appropriate health service response to violence against women*, *Lancet* 2002; **359**: 1509–1514

V: Ethics in domestic violence research

This paper reports on findings from the World Health Organization (WHO) Multi-Country Study on Women's Health and Domestic Violence Against Women. Guidelines exist for the ethical review of epidemiological studies, which outline basic principles of research including respect, minimising harm, maximising benefits and justice. How these principles can be adhered to when researching issues such as domestic violence are outlined.

Source: Ellsberg M, Heise L, *Bearing witness: ethics in domestic violence research*, *Lancet* 2002; **359**: 1599–1604

VI: Violence against women in health care institutions

This paper describes research carried out over the last 10 years on violence committed by health care professionals. Violent acts include: neglect during childbirth; verbal violence such as threats, shouting and intentional humiliation; physical violence including rough treatment or denial of pain relief; and sexual violence. Many of these research studies have been carried out in the developing world, but violence by health care professionals may also occur in developed countries. This form of abuse is a serious violation of human rights and this type of abuse must be minimised by adequate training of staff and resources.

Source: d'Oliveira A, Diniz S, Schraiber L, *Violence against women in health-care institutions: an emerging problem*, *Lancet* 2002; **359**: 1681–1685

BOOK REVIEW

Management of the Menopause (3rd edn) (The Handbook of the British Menopause Society). Margaret Rees and David W Purdie. Marlow: British Menopause Society Publications Ltd, 2002. ISBN: 0-9536288-1-9. Cost: £15.00 (plus P+P). Pages: 127.

The substantially revised version of this book, released recently by the British Menopause Society (BMS), provides an up-to-date review of the current knowledge on various subjects relevant to the menopause and its practical management. The editors acknowledge the help of 27 experts to make available an unbiased, comprehensive but compact practical guide. There is a clear emphasis on clinical aspects and, where evidence exists, the text is evidence-based. Besides covering symptoms and the long-term consequences of the menopause,

the book focuses on the numerous hormone replacement options and objectively assesses their therapeutic benefits and risks. This edition has two added chapters: the first deals with women with specific medical conditions and the second with complementary and alternative therapies. The next edition will hopefully include an index for rapid retrieval from a ready source of largely evidence-based information. The broad objective laid out by the BMS, to promote optimal management of the menopausal woman, is well attended to in this handbook.

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