

to a clearing house for guidelines.<sup>7</sup> Thus the NHS and private sector have an opportunity to cooperate by sharing information to see if guidelines can not only change practice but also realise better outcomes for less cost: in other words, to determine if all the current activity on guidelines is justified. The opportunities should not be missed.

Managed care is in its infancy in the private sector, and its evolution could go several ways. Disease management could become a reality with clinician-manager relationships becoming cooperative rather than adversarial and clinical practice guidelines resulting in high quality, cost effective care. Alternatively, managed care systems might set medical fees, decide budgets for hospitals, and set standards of practice: use of services might be controlled but clinicians and patients could be left dissatisfied. The costs of administration could outweigh any savings, and quality might not be guaranteed. As the American experience tells us, the reality is likely to be somewhere in the middle, with insurers striving to get the best from managed care while eliminating the worst.

By whatever path managed care evolves, one thing is certain: unless the independent sector, like the NHS, can deliver high quality care at an acceptable cost it will not survive in its present form. Guidelines implemented through managed care

may be one answer. Whether the private sector has lessons for the NHS depends on its future development, its willingness to collaborate, and the willingness of those in the NHS to seize the opportunities. Whatever the outcome, we have an opportunity to observe managed care at work in a British setting.

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## Contraceptive implants

### *Users lose out when misleading information limits choice*

No single contraceptive method exists that meets all preferences, and a wide choice is therefore important in maintaining contraceptive cover and continuation.<sup>1</sup> This is reflected in NHS advice that family planning outlets should provide all methods,<sup>2</sup> as well as in public interest in research leading to new methods.<sup>3</sup> Unfortunately, incomplete or inaccurate information from any source may contribute to negative impressions of a method and thereby limit choices further. Norplant, a slow release progestogen implant that offers many advantages to users, is one method of contraception currently at risk of such treatment.

Norplant contains levonorgestrel, a synthetic progestogen prescribed to millions of women over two decades; 15 preparations are currently licensed for contraception and hormone replacement in Britain. Daily dosages of 75-250 µg occur in combined oral contraceptive pills and 30-75 µg in progestogen only pills. Users achieve peak blood concentrations in excess of 2.5 nmol/l.<sup>4</sup> If there were major problems with this compound they would have become apparent by now, but none have been reported. Indeed, a recent letter to prescribers from the Committee on Safety of Medicines (18 October 1995) encouraged greater utilisation of combined pills containing levonorgestrel because of apparently lower risks of venous thromboembolism.

None the less, within three weeks of that letter being sent, the television programme *Horizon* reported that undisclosed risks were associated with the newer levonorgestrel contraceptive, Norplant. This product releases approximately 30 µg of the drug daily, maintaining blood concentrations around 1.0 nmol/l.<sup>4</sup> It therefore seems biologically implausible that significant new systemic effects would come to light with this delivery system.

Norplant is, of course, not free from problems; problems already familiar to most prescribers and users (up to 95% of the 50 000 British women currently using Norplant have previously used other hormonal methods).<sup>5</sup> Norplant has, like all progestogen only contraceptives, a variable impact on the menstrual pattern, particularly in the first months of use, when irregular bleeding may occur. Interventions to improve this

pattern have been suggested. These include oestrogens or non-steroidal anti-inflammatory drugs, and where needed, these are preferable to premature discontinuation.<sup>6</sup> As with all hormonal methods, including combined pills, 5-10% of users report changes, sometimes in a beneficial direction, in their weight, hair and skin consistency, headaches, and mood.<sup>4</sup>

Another problem relates to reported difficulties in removing the subdermal capsules. Experience in other countries has shown that correct subdermal placement of the Norplant capsules is vital.<sup>7</sup> Because of this, the British distributors established a free training programme for doctors before the product was launched,<sup>8</sup> and its impact is reflected in the generally positive experience of British women and their doctors with regard to removal.<sup>9</sup> In our clinic, average removal time, including removal by trainees under supervision, is now less than eight minutes.

The overall success of Norplant in Britain is apparent from high one year continuation rates—85% from one study of patients treated predominantly by trained general practitioners,<sup>9</sup> and more than 90% in some larger centres (L. Mascarenhas; J Davie, personal communications). Where direct comparisons have been completed, Norplant continuation rates exceed those for the combined pill.<sup>10</sup> Users report that ease of complying with this “fit and forget” contraceptive method is one of its attractions.<sup>5 10</sup> From the providers’ point of view, long acting methods are recognisably more cost effective,<sup>11</sup> especially when providers are also responsible for the cost of unplanned pregnancies. This is likely to become increasingly important with the extension of general practitioner fundholding.

Although the “medicalisation” of removal is a disadvantage of Norplant use, it helps avoid the situation where users discontinue contraception without arranging an alternative method, a risk common in women using the pill at the time of “scares.” When scares about newer methods proliferate, in the face of objective evidence and biological plausibility, it is reasonable to ask whose advantage is served.<sup>12</sup> Certainly not that of the vast majority of users. “Trial by media” has major disadvantages for them—encouraging discontinuation, discouraging provision and uptake,

jeopardising continuing research into new methods, and potentially halting further expansion of the contraceptive "menu." It is hoped that newer implants such as Norplant 2 and Implanon will soon become available. These are suitable for further groups of users and their progression from research, through development and licensing, to general availability has been painstakingly and carefully overseen. It would be a pity if misleading information prevented appropriate uptake and further expansion of user choice.

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David Bromham receives fees from Norplant as a trainer.

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## Health workers and the baby food industry

### *World Health Organisation acts to end conflict of interest and promote breast feeding*

Recent reports about phthalates in infant formulas in Britain have revived interest in the possible dangers of breast milk substitutes and the need to promote breast feeding.<sup>1</sup> While the British government tried to calm public fears, the World Health Organisation's governing body, the World Health Assembly, passed a resolution urging health institutions, professionals, and ministries in all member states to prevent the baby food industry from providing financial or other support for health workers.<sup>2</sup> This resolution is likely to provide added strength to those committed to protecting, promoting, and supporting breast feeding. But what does it mean for the funding of health care and training; will it remove conflicts of interest; and can it be implemented?

Breast feeding is important for infant health—for rich people as well as poor people.<sup>3 4</sup> But poor people are especially at risk from inappropriate marketing of breast milk substitutes; as well as adding to infant mortality and morbidity, these products add further strain to the economy of already marginalised families and resource poor nations.

Breast milk substitutes are big business. The global market in 1983 was estimated to be \$3.3bn (£2200m)<sup>5</sup> and in 1991 over \$6bn (A Chetley, personal communication). For India, Prakash quoted a figure of £180m, growing at 6% per year.<sup>6</sup>

That companies strive to use health professionals to promote their product is no secret. Describing *Abbott Topics*, a medical magazine sent to health workers, the company says "As the voice of Abbott, *Abbott Topics* can be a positive force in moulding the physician's opinion of Abbott. In effect we are striving to make the physician a low-pressure salesman of Abbott."<sup>7</sup> Jelliffe wrote, "The medical and nursing profession can sometimes be very naive in their interactions with commercial companies, so that mixtures of 'manipulation by assistance' (free samples; assistance with research funds; hospitality at meetings) and 'endorsement by association' (advertisements in newsletters and journals of professional associations; sponsorships of conferences) are very frequently and successfully used promotional methods, usually unperceived, minimised, or tolerated as such by the physicians, nurses, and nutritionists concerned."<sup>8</sup>

Some professional bodies have already taken action. Since 1980, despite opposition from some quarters,<sup>9</sup> the Indian Academy of Pediatrics has been moving towards independence from the baby food industry. The government set up a committee to draft a code for marketing of baby foods. Nestlé offered a donation to an academy official on the committee. The academy saw conflict of interest and voted overwhelm-

ingly to refuse the donation.<sup>5</sup> Since then, the academy has held workshops on consumer protection and lactation management with support from Unicef and without aid from the baby food industry.

For several years Nestlé, followed by Wipro, had conducted a paediatric quiz for undergraduate medical students along with the academy. The academy decided to end that association and will now run the quiz independently. In 1994 a brand leader among multinational formula companies in India offered to pay all the expenses for the academy's sponsored 8th Asian congress of paediatrics, estimated by its president at about 10-15m rupees (\$0.5 million) (R D Potdar, personal communication). The academy refused the offer.

The Indian Medical Association (with 100 000 members) has also decided not to take any support from the baby food industry. The Pakistan Paediatric Association did not allow formula companies to participate in its recent 13th international conference. Such examples from resource poor countries, along with the World Health Association's resolution, may act as a shot in the arm for those paediatricians in Britain who have been pressing for the British Paediatric Association to refuse industry funding.

In its provision for monitoring the marketing practices of baby food manufacturers, India's law is unique;<sup>10</sup> as well as authorising government inspectors to take baby food companies to court if they violate the ban on promotion of bottle feeding and advertising of breast milk substitutes and feeding bottles, it has also given similar authority to selected voluntary organisations engaged in child welfare and nutrition. Four such organisations have now been given this power, and the Association for Consumers Action on Safety and Health has brought criminal charges against Johnson and Johnson and Nestlé. Johnson and Johnson is charged with promoting bottle feeding. According to the association, the company was selling feeding bottles to the public at a discount and giving retailers one bottle free for every dozen sold. Nestlé is charged with encouraging too early use of complementary foods. Since 1994, the World Health Organisation advises that these foods should be introduced from about six months of age, not four to six months as was previously recommended. Indian law clearly advises that they be started after the age of four months. Nestlé's promotional slogan in Hindi, "Chouthé Mahine Se," literally means "from the beginning of the fourth month." The association also says that Nestlé was failing to place the words, "mother's milk is best for your baby" in Hindi as well as English on the front of baby food packaging. The charges are still pending, but Johnson and Johnson has now decided to