Meanwhile, proposed changes in the organisation of another subspecialty, gynaecological oncology, cast further doubt on the appropriateness of the existing surgical bias in gynaecology. The Calman proposals for cancer centres in Britain highlight the need for highly trained surgeons with access to a large enough throughput of cases to maintain their surgical skills.[8] If the most difficult surgery is to be undertaken by a smaller number of expert surgeons, training the rest to such a high level will not be necessary.

Chemotherapy and radiotherapy (whose practitioners are medically trained) already take an appreciable share of the therapeutic load in gynaecological cancer. Developments in protein and gene therapies are likely to further erode the position of surgery, as is the increase in endoscopic procedures, which are no longer the sole domain of surgeons.

The process of subspecialisation is well advanced in most teaching hospitals where there are enough specialists, but it is likely to create immense organisational difficulties for district general hospitals. Where subspecialisation is feasible, hospitals should have at least one gynaecologist with a special interest in the medical aspects of gynaecology. As regards training, the question remains: should gynaecology be a medically based subject in which specialists learn specific operative procedures, or should it be a surgical speciality in which specialists learn some medicine? Implementation of the new structured training programme, which recognises the increasing importance of medicine to the specialty, provides the framework for the shift in basic training.[9]

There is no suggestion of abandoning the surgical skills that are needed to practice gynaecology. However, specialties must evolve to incorporate new developments and the changing needs and lifestyles of patients. Gynaecological training needs to accommodate medical aspects more fully. Such a change would have important consequences for women's health care and should be influenced not just by debate within the profession but by the informed opinions of women.

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Over the counter drugs

Changing the roles of doctors and pharmacists

See p617, 629, 644

People are buying more medications for themselves,[1] and increasingly powerful drugs are obtainable without prescription.[2] In view of these trends, it is timely to examine their implications for patients and health care professionals. A series of articles starting in this issue of the *BMJ* (p 629) examines the move towards greater over the counter access to drugs and its relation to increasing public awareness of health and medicines, the changing roles of doctors and pharmacists, pharmaceutical industry strategies, and the question of safety and abuse of drugs.[2]

Over the counter (OTC) drugs are available to the public without prescription. They include traditional pharmacy preparations and drugs that have more recently been deregulated from their previous status as "prescription only medicines." Policies on over the counter drugs vary around the world. In many European countries, over the counter drugs are available only through pharmacies,[3] but in the United States, all over the counter drugs can be sold in general retail outlets. In Australia, pharmacists are required to personally advise purchasers of specific over the counter drugs.

Britain and Ireland have two categories for over the counter drugs: drugs on the general sales list may be sold in general retail premises, while drugs in the pharmacy category are restricted to sale by registered pharmacies.[2] This is supposed to ensure that pharmacists monitor patients and give advice on correct usage. However, this responsibility is frequently devolved to pharmacy assistants, and a recent study has cast serious doubt on the accuracy and appropriateness of the advice offered.[4] Uncertainty remains as to whether pharmacists should be required to participate personally in every sale of a pharmacy category drug and whether they should have to adhere to agreed protocols on advice and treatment.[5]

Since January 1992, Britain has deregulated 27 drugs from prescription only to pharmacy status, more than in the previous decade.[1] In 1992 Britain's drug licensing body, the Medicines Control Agency, streamlined their procedures for deregulating drugs, and an amendment to the Medicines Act in the same year obliged the agency to reassess licensed drugs every five years and to justify their continued restriction to prescription only status.

In 1994, sales of over the counter drugs in Britain comprised 23% of total medication sales, compared to 28% in Switzerland, 23% in Belgium, 19% in Germany, 18% in France, 14% in Ireland, 13·5% in Italy, 12% in the Netherlands, and 9·4% in Sweden.[1] However, direct comparisons between countries are flawed because differences in health care funding, cultural health beliefs, and the range of drugs available all influence usage of over the counter medications.

Promoting greater direct access

Patients, pharmacists, governments, and drug companies have all helped to promote greater direct access to medication: patients find such greater access more convenient and economical[6]; governments want to transfer a share of the expanding health cost burden to consumers[3,5]; the pharmaceutical industry seeks new customers to maintain profitability

in leaner health care markets; and pharmacists want to extend their role by providing health and drug advice as the need for their traditional technical skills decreases.[7]

However, general practitioners have tended to remain sceptical about the value and safety of over the counter drugs. Many feel uneasy about devolving decisions about medication to patients, other members of the primary care team, or pharmacists.[7] Increased self treatment may relieve general practitioners' drug budgets and reduce their workload. However, the move may also decrease opportunities for monitoring patients' progress, screening, and education, and it may increase inappropriate use of drugs. Also, while general practitioners can recommend over the counter drugs to their patients, their knowledge of what drugs are available is often limited and patients may object if they will have to pay for what would otherwise be free on an NHS prescription.

Some of the doctors' concerns can be addressed. Firstly, deregulating drugs does not imply slackening legal constraints or manufacturing standards. Manufacturing regulations for over the counter and prescribed drugs are identical, and pharmacies must now establish protocols for sale of pharmacy category medicines.[7] The indications for use, dose, and duration of treatment are more restrictive for over the counter drugs than for prescription only versions of the same drug. Secondly, communication skills and rational drug use are emphasised in the new undergraduate curricula adopted by most schools of pharmacy, in the postgraduate programme of the College of Pharmacy Practice, and in training schemes for pharmacy assistants, practice nurses, and nurse practitioners. Thirdly, information on which drugs are available over the counter can be found in the OTC Directory, which is supplied to all doctors in Britain.

GPs' attitudes are changing

Other concerns relate to ensuring safety and recording side effects. The safety of any drug is determined by two attributes: the intrinsic capacity of the drug to do harm and the quality of the information provided to the public about its use. Good patient education and drug information can promote safer use. In Britain, the safety, appropriateness of use, and level of misuse of over the counter drugs are difficult to assess. The safety profiles of prescribed drugs, as determined by adverse drug reactions and post-marketing surveillance studies, are considered when assessing a drug's suitability for deregulation. However, the collection of data on the safety of over the counter drugs is hindered by community pharmacists being excluded from the Committee on Safety of Medicines' yellow card scheme for reporting adverse drug reactions.

A more recent survey of 1301 general practitioners published in this issue of the *BMJ* (p 617) suggests that attitudes are changing, with an increasing proportion of general practitioners being in favour of wider availability of certain drugs over the counter.[8]

Britain's more than 12 000 community pharmacies take up 2% of the NHS annual budget.[7] Using this resource effectively will mean developing the pharmacists' role from reactive dispenser of drugs to proactive adviser of patients and doctors. However, this development has raised some anxieties. Although a quarter of consultations between patients and community pharmacists conclude without the sale of a product, there is potential for commercial and ethical conflict: over the counter sales generate income for the pharmacists, whereas the provision of advice alone does not. Local health authorities could negotiate payment for pharmacists who provide advice and cooperate with general practitioners over developing formularies of over the counter drugs and protocols for referral and care.[5 7]

Greater availability of drugs over the counter could profoundly change the roles of doctors and pharmacists, turning them from paternalistic controllers of access to medicines into patients' advisers and collaborators. Greater ease of access to medicines carries benefits and risks, and we must ensure that full consideration is given to the implications for drug safety, health care costs, education, and rational drug use. The remuneration system for community pharmacists must be adapted to reward those who give accurate advice to patients and liaise with general practitioners; and it is essential for doctors to expand their knowledge of over the counter drugs, to record use of over the counter drugs in patients' notes, and to detect and report adverse drug reactions.

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