

interacting factors through clinical and epidemiological investigations.

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## Patient package inserts

To be successful, drug treatment needs co-operation from the patient, who must therefore have certain information about the drugs he is taking. The minimum information<sup>1</sup> includes dosage, frequency of dose, and duration of treatment; whether the drug or drugs should be taken before, during, or after meals; whether alcohol, driving, or operating heavy machinery should be avoided; and whether there are any adverse effects requiring prompt action. Moreover, in an age when unquestioning acceptance of professional advice is being eroded (and doctors who dispute—or deprecate—this tendency should recall their own attitudes to accountants, solicitors, and their children's teachers) younger patients in particular may wish to know how their drugs work, how they will help their disease, why it is necessary to take them, and what adverse reactions might occur.

Traditionally, responsibility for telling patients about their drugs has rested primarily with the prescribing doctor, who has given the patient a verbal explanation and instructed the dispensing pharmacist to label the medicine bottle appropriately. This system, however, has drawbacks. Consultation times in general practice are little enough for an adequate history and physical examination. Patients remember only about half the information they are given during a consultation,<sup>2,3</sup> and most of the forgetting takes place immediately. And, even if that unenlightening phrase "Take as directed" is excluded, patients' interpretations of apparently unambiguous labelling instructions (for example, "every six hours," "three times a day," "with meals") are erroneous in up to two-thirds of cases.<sup>4</sup>

In Britain patients receive written instructions about a few categories of drug. These include warning cards for those taking monoamine-oxidase inhibitors, systemic corticosteroids, and anticoagulants. Other cards have been produced by bodies such as the British Diabetic Association and the British Epileptic Association, and some drug manufacturers

supply leaflets for patients with their products. In the United States of America the Food and Drugs Administration (FDA) requires printed material ("patient package inserts" or PPIs) to be provided for patients receiving oral contraceptives, intrauterine contraceptive devices, and oestrogens. The FDA is now under pressure from professional<sup>5</sup> and consumer<sup>6</sup> organisations to extend PPIs to other (and ultimately nearly all) prescribed drugs. According to the present plan,<sup>7,8</sup> the FDA would draw up PPIs (after consultation with interested parties), which would be issued to patients by the dispensing pharmacist at the same time as the prescribed drug. Doctors would retain the right, however, to prevent the patient from receiving a PPI by annotating the prescription accordingly. The information contained in the PPI would answer questions about why the drug is used, how it can help the patient, why it should be taken as directed, what adverse effects may develop, and what to do if these occur.

Inevitably, the PPI proposals have met with resistance. Critics argue, for example, that they would interfere with doctor-patient relationships, increase the tendency towards malpractice suits, pose considerable problems of production and distribution,<sup>9,10</sup> and also possibly diminish, rather than enhance, patients' compliance by making them afraid of adverse reactions. Moreover, PPIs are likely to benefit a small minority of younger educated patients. Most of these doubts could be investigated by controlled trials, and the FDA is indeed conducting a study of PPIs for thiazides and methyldopa among hypertensive patients.<sup>7</sup>

In Britain there are no immediate plans for introducing PPIs, but the health professions are increasingly aware that patients need more information. Last month some 160 doctors, pharmacists, nurses, and health education officers took part in a symposium at Sheffield University on "Medicines, Information and the Patient"; and the DHSS and Medicines Commission are exploring ways of providing patients with information about drugs. These might include a more subtle approach to the medical consultation,<sup>11</sup> counselling by the dispensing pharmacist, and better labelling of medicine bottles. A British equivalent of the PPI might well supplement these more traditional approaches, but which individuals taking which drugs would benefit? This is a problem needing carefully constructed randomised trials.

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## The gate control theory of pain

The gate control theory of pain sounds complex, but its principle is simple and has had wide practical consequences. Its essence is that signals which reach the spinal cord and are transmitted upwards to conscious sensation are modulated by