The hospital pharmacist

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Summary

In hospitals, the use of approved names for prescribing and labelling is an essential requirement for precision and safety in giving medicines. Substitution is an unavoidable consequence of using approved names which brings benefits, but creates problems that demand more widespread recognition and urgent attention. In particular, dangerous variations in response following brand changes can occur in patients stabilized on certain products. The Licensing Authority and the Pharmaceutical Industry have a responsibility to eliminate brand bio-availability differences. But there is an immediate need; firstly, to identify the small number of products where brand changes in patients stabilized on them can result in potentially dangerous variations in response; and secondly, to safeguard patients being treated with these products, by avoiding substitution and preventing inadvertent brand changes by including brand or manufacturer's names on labels and in all communications between hospital doctors and general practitioners. The complete elimination of substitution is not feasible and the indiscriminate use of brand names in hospitals causes confusion and increases risks of error in giving medicines.

As long as nurses have to select and give medicines for hospital in-patients from containers not dispensed for individual patients, two things are essential: firstly, uniformity of drug nomenclature on prescriptions and labels and secondly, substitution by nurses (i.e. the administration of the brand of product available as ward stock, irrespective of the brand prescribed). In the ward situation, the superficial attraction of proprietary names (they are often shorter and easier to remember) is outweighed by their disadvantages and approved names are generally preferred for prescribing and labelling as they are meaningful, each drug has only one, and the chances of treatment being inadvertently duplicated are reduced. The uniform use of brand names would be impracticable as many products are only available under approved names whilst many others are marketed under several brand names. The indiscriminate use of brand and approved names for

prescribing and labelling spells chaos for the nurse and a higher incidence of error in giving medicines.

Hospital pharmacists usually buy only one brand of each product: this is supplied and dispensed by pharmacists, and given by nurses to patients from ward stock, irrespective of the brand prescribed. Substitution helps to reduce the number of products stocked, the space required to store them, the work involved in distributing them and losses from unused or outdated stock. The success of regional drug contracting schemes has largely depended upon the practice of substitution, and contracts for one brand of each product for all the hospitals of a region have achieved considerable economies.

The use of approved names for prescribing and labelling medicines can create a variety of problems: most, however, can be prevented by sensible organization. Appropriate steps must be taken to ensure that drug names on prescriptions and labels are the same to minimize errors by nurses selecting and giving medicines. Endorsing brand name prescriptions with approved names and adding approved name labels to original packs labelled only with brand names are helpful. Co-operation is needed from manufacturers who exclude approved names from the labels of their products or assume that nurses always carry magnifying glasses when looking for approved names on labels.

Dispensing medicines prescribed and labelled with approved names, from packs labelled primarily or only with brand names, inevitably causes some practical difficulties in the pharmacy. Products are sometimes transferred from original packs to uniform containers labelled with approved names to help identification: but without appropriate safeguards, this results in loss of the manufacturer's identity and batch number: and where products that have not been used on the wards are returned to the pharmacy, different brands or batches of the same brand can more easily be mixed in stock containers used for dispensing.

Approved names are descriptive of drugs but not of products and are therefore unsuitable for describing medicines containing mixtures of drugs, controlled-release preparations and products exhibiting

brand bio-availability differences. The use of approved names for labelling discharge and out-patient medicines, without indicating the brand or manufacturer, can cause problems where another brand of dissimilar appearance or bio-availability characteristics is subsequently supplied to the same patient. Similarly, the use of brand names for labelling un-branded products containing the same ingredients is indefensible.

The main objection to the use of approved names for prescribing, is that this allows substitution by authorizing pharmacists to dispense any brand: and the case against substitution is primarily based on the risk of variation in patient response due to brand bio-availability differences. But the number of products available in Britain that have been shown to cause significant variations in response as a direct result of brand differences is very small: and bio-availability is only one of many potential variables that may affect patient response to drug therapy. In addition, for the majority of products, measurement of response and control of dosage are largely subjective, margins of safety are wide and small bio-availability differences would in most cases be of little significance.

The resolution of this problem by eliminating substitution is not a realistic proposal as this would involve: firstly, abolishing approved names, designating a unique brand name to each approved name product and requiring that brand names only were used for prescribing; and secondly, individual dispensing of all in-patient medicines to eliminate substitution by nurses; this would necessitate a 24-hr pharmacy service in every hospital and a very substantial increase in pharmacy manpower.

The cost and complexity of such changes and their inevitable consequences would be enormous and could not be justified by the significance of the problem they would seek to resolve. I can therefore see no practical alternative to the use of approved names in hospital for prescribing and labelling medicines. Variations in patient response occurring as a direct result of substitution must, however, be prevented and this can only be achieved by either eliminating brand bio-availability differences, or avoiding brand changes where these could give rise to unacceptable variations in response.

The former is the only satisfactory long-term solution and is primarily the responsibility of the licensing authority and manufacturers. The formulation of policies concerning the latter would help in the short-term to minimize the problem and could

be the responsibility of a representative committee of doctors and pharmacists within each hospital group or area. Such a committee might usefully concern itself with:

- (1) compiling a short list of products known to exhibit bio-availability differences, and others where the existence of differences could produce unacceptable variations in patient response;

- (2) agreeing the brand to be used;

- (3) considering ways in which brand changes for listed products could be avoided in patients taking them over a long period, particularly where supplies are obtained from more than one source. The latter is more likely to occur where patients obtain supplies both through the hospital and the general practitioner and communications between them should, therefore, indicate the brand or manufacturer. This could be achieved by appropriate labelling of discharge and out-patient medicines, by using carbon copies of discharge prescriptions endorsed at the time of dispensing or by issuing record cards to patients on long-term therapy.

I look forward to the day when all medicines are presented to their users in manufacturer's packs incorporating both brand and approved names as well as the manufacturer's identity and batch number.

Regional drug contracting and hospital purchasing arrangements would have to be slightly modified to conform with these policies. For many products a large number of alternative manufacturers is available and this is reflected in the number of tenders received by regional drug contracting committees for some products. The interpreted results of *in vitro* and *in vivo* bio-availability studies, although of limited value as indicators of patient response, would in certain cases help contracting committees to make decisions more rationally and not solely on the basis of price or the reputation of the manufacturer. Hospital pharmacists should be more actively involved in investigating the bio-availability characteristics of certain products.

Finally, although I accept that there are strong arguments in favour of promoting patented drug products under trade names, I am doubtful whether the same case is valid for products first marketed after expiry of the drug patent. Sales of such products are surely largely dependent on approved name prescribing and hospital contracts: the designation of proprietary names is therefore superfluous and adds unnecessarily to the plethora of trade names.