

mance.<sup>13</sup> In Maastricht, a similar programme runs throughout the curriculum.<sup>10</sup> The objective is to provide students with interpersonal skills which will allow them to cope with insecurity and the emotional burden of caring for real patients, attempting to forestall the emotional 'rigor mortis' that seems to result inevitably from traditional medical education.<sup>3</sup>

A further development in teaching is related to the need to provide more cost effective care, treating as many patients as possible in the community, with the use of expensive hospital facilities restricted to selected cases. Community care, prevention, early detection, selection of high risk patients, long term care and continuity of care must feature more prominently in medical training. At Nijmegen University the general practice clerkship has recently been transformed into a clerkship addressing medical practice outside the hospital.<sup>14</sup> In addition to general practice the clerkship includes social medicine (public health and occupational health) and community geriatrics. It is important that this part of the curriculum is compulsory for all medical students, particularly those who will later choose a career outside primary care. For these students it will be their only experience of functioning as a doctor in primary care, a field of practice of ever increasing importance for all doctors, irrespective of their specialty

These developments provide an exciting challenge for disciplines with a general responsibility in patient care, including general practice. Practical experience is the alpha and omega of successful medical education, but this success depends upon two pre-conditions: medical problems that represent the state of health and disease in the population must be included, and the supervision of teaching needs must be provided by practitioners with sufficient educational skills. By definition, general practice meets the first precondition,<sup>7,15</sup> and with its expertise development in undergraduate and vocational training, provides a model regarded as a 'standard' by other medical teaching disciplines. This should fill us with pride, but also with resolve to contribute to the important task of improving the teaching of future doctors. As Fraser has stated: 'Many of the current problems of undergraduate education could be solved, or at least substantially reduced, by correcting the current imbalance between hospital based and community based teaching and learning.'<sup>16</sup>

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# Prescribing topical corticosteroids

IN 1985 the government restricted the prescription of certain drugs to curtail expenditure in the National Health Service. In 1992 it announced that a further 10 categories were to be considered, including every drug which acts on the skin. A whole specialty is therefore under review. In order to illustrate some of the problems the government may face, it is worth examining topical corticosteroids which constitute a considerable proportion of those drugs acting on the skin and which are arguably the most important class of compound in dermatological therapeutics.

There are a large number of topical corticosteroids on the market. If restriction to generic products and substitution of generic for brand named products appear to be attractive options, then the following questions need to be answered: is there any justification for the number of corticosteroids on the market, are gener-

ic topical steroids equivalent to the brand name drugs, and will limitations on the freedom to prescribe be cost effective?

Dermatologists require a range of topical steroids for several reasons. First, there is a need for different strengths or classes of steroids<sup>1</sup> because of the diverse nature of steroid responsive skin disorders and the variation in the thickness of the skin in different parts of the body. Thus, lichen planus only responds to very potent steroids whereas atopic eczema may respond to weaker ones, although this depends on the site involved. Hydrocortisone is effective for eczema on the thin skin of the face, but more powerful steroids are required to penetrate the skin elsewhere including the most potent for the thick skin on the palms and soles. Increase in potency is achieved not by increasing the concentration of hydrocortisone but by modifications to the mole-

cule such as esterification and halogenation to increase lipophilicity. It might seem that a representative from each of the four potency classes would therefore suffice. Regrettably this is not so, because resistance to a particular steroid may develop and this is overcome by substituting an alternative steroid of the same class. The reason for this is not known although the phenomenon of acute tolerance (tachyphylaxis) has been well documented.<sup>2</sup>

Secondly, the drug delivery system has to be taken into consideration. The corticosteroid is added to a vehicle which may be a lotion, cream, ointment or gel to cater for the different characteristics of the skin in various parts of the body and in certain diseases. Thus, lotions and gels are appropriate for hair bearing areas, ointments for dry conditions, such as eczema, and creams have the greatest patient acceptability for the face. The choice of the vehicle is critical to optimize absorption of the steroid. The vehicle has a thermodynamic effect on the steroid<sup>3</sup> and this effect may interfere with the stability of the steroid or modify its release from the vehicle. In addition, preservatives have to be added, particularly to creams, in order to prevent bacterial contamination. Some patients become sensitive to these preservatives and develop contact dermatitis. Patients can also develop a sensitivity to the vehicle itself, for example, lanolin, and unfortunately even to the steroid,<sup>4</sup> particularly hydrocortisone, hydrocortisone butyrate and budesonide. Alternative preparations must therefore be available.

Thirdly, topical corticosteroids are marketed in combination with antibacterials or antifungal agents or both. Secondary bacterial infection is commonplace in disorders such as eczema because the stratum corneum (the skin's barrier against infection) is disrupted. Fungal colonization, particularly with candida, occurs in warm and moist intertriginous areas (where there are two apposing skin surfaces). There is evidence to show that these combination preparations are more effective than the steroid on its own<sup>5,6</sup> and reduce the need for expensive and potentially toxic systemic antimicrobial agents. Occasionally, contact sensitization may occur to these combination preparations, particularly in varicose eczema, otitis externa and perianal dermatitis, and alternative antimicrobial combinations are then required.

Fourthly, there is the problem of side effects. The most successful bioassay for assessing the potency of a topical corticosteroid is the vasoconstriction test,<sup>7</sup> in which a topical steroid is applied to the skin of the forearm and observed for a blanching effect some hours later. It holds true that the greater the degree of blanching the more potent the steroid is clinically<sup>8</sup> and also the more likely it is to have side effects<sup>9</sup> if the steroid is wrongly prescribed or misused. At present it has not been possible to dissociate local side effects from the potency of the steroid, but it has been possible to separate systemic side effects from potency to some extent – the steroid clobetasone butyrate is moderately potent topically, but has not been shown to have any systemic effect.<sup>10</sup> This drug is particularly useful in children where there is an increased risk of systemic absorption and toxicity because of the greater surface area to size of the patient. More potent steroids are being developed and in particular fluticasone which is de-esterified by the liver and metabolized quickly and has no systemic side effects. Clearly there will be more steroids in the future as new less toxic compounds are developed.

Are generic steroids equivalent to the brand name products and are they cheaper? Topical corticosteroids are cheap but their generic equivalents are no cheaper. The drug tariff price for 1993 of a 30 g tube of Betnovate® (Glaxo) is £1.40 which is the same as generic betamethasone valerate, and 30 g of 0.5% Efcortelan® (Glaxo) costs £0.60 which is the same price as generic 0.5% hydrocortisone. Only 30 g of 1% hydrocortisone is £0.06 cheaper than 1% Efcortelan®. It would hardly seem worthwhile substituting generic compounds on grounds of cost. More importantly

there is considerable work from the United States of America using the vasoconstrictor bioassay to show that generic topical corticosteroids are by no means equivalent to the brand name drugs. Thus, five generic creams containing 0.1% betamethasone valerate were compared with Valisone® (the brand name for Betnovate® in the USA). In every instance the generic creams were less potent than the brand name product.<sup>11,12</sup> Similarly five generic creams containing 0.1% triamcinolone acetonide were compared with Kenalog® (the brand name for Adcortyl® (Squibb) in the USA), and in every instance they were weaker. This means that if a physician determines that a certain disease requires a certain potency of steroid and prescribes it and then a generic substitution is made by the pharmacist the patient may not respond as well. Further work has been done on dilutions of topical steroids.<sup>13</sup> Generic equivalents are not yet available in this area, but 0.1% betamethasone valerate is marketed in a quarter strength dilution (Betnovate-RD®). Vasoconstrictor studies do substantiate that this is an accurate dilution<sup>13</sup> but studies on other brand dilutions for example of triamcinolone acetonide have shown that they are not bio-equivalent.<sup>13</sup> This is almost certainly because the choice of the vehicle is incorrectly altering the release of the steroid from the vehicle.

Finally, although topical corticosteroids have fundamentally changed the therapeutic aspect of dermatology, there is still further progress to be made. The need for separation of potency from local side effects is the most pressing problem to be solved. The introduction of a limited list in a group of drugs which are already cheap is not economically necessary.

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