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Because we receive many more letters than we have room to publish we may shorten those that we do publish to allow readers as wide a selection as possible. In particular, when we receive several letters on the same topic we reserve the right to abridge individual letters. Our usual policy is to reserve our correspondence columns for letters commenting on issues discussed recently (within six weeks) in the BMJ.

Letters critical of a paper may be sent to the authors of the paper so that their reply may appear in the same issue. We may also forward letters that we decide not to publish to the authors of the paper on which they comment.

Letters should not exceed 400 words and should be typed double spaced and signed by all authors, who should include their main degree.

Over the counter sale of topical corticosteroids: evidence versus anecdote

SIR,—At a recent dermatological debate I spoke in support of a motion that "1% hydrocortisone cream be available without prescription on a pharmacy only basis." Although the motion was lost by the narrowest of margins I was impressed by the number of colleagues, previously adverse to the motion, who changed their minds after hearing the arguments. Professor Sam Shuster, who took the opposite view, has reported his reactions to the proposal (6 July, p 38). "Over the counter" (OTC) sales of a drug are either "pharmacy only" or "general sales"—that is, available at any supermarket or general store that cares to stock the drug. I am in favour of the former but not the latter. Because the arguments Professor Shuster presents are unreferenced, I will review, as objectively as possible, the available evidence.

Sufferers from headache, soreness from mild injury, or joint pain can obtain effective analgesic and anti-inflammatory OTC agents. Those who develop trivial but irritant eruptions due to handling solvents, oils, detergents, or cosmetics are limited to preparations that rely on their physical properties for any modest benefit they confer. Self-medication with topical 1% hydrocortisone is justifiable in these circumstances. Professor Shuster rightly says that patients cannot be expected to diagnose the multiple causes of a rash, but neither can they identify the causes of a headache. Would Professor Shuster like to have aspirin, codeine, and paracetamol on prescription only?

Rashes which present in the skin clinic are often puzzling. But most patients with rashes do not get referred to a clinic since the relation between a rash and its cause (soaps, detergents, alkalis, oils, cosmetics) is often obvious. These patients should, but at present cannot, obtain without prescription a safe and effective topical preparation to provide rapid relief. Instead, 60% of patients who use a medication for a skin problem obtain it without seeking medical advice (Anders HJ, Köpl, I, paper at symposium on self medication, Stockholm, 1983), the probable sources including hoarded, potentially hazardous, drugs of their own or their friends.

No one can categorically state that repeated use of 1% hydrocortisone can do no harm. The same is true of mild analgesics, oral iron, vitamins, and many other non-prescription drugs. The central issue is whether the benefits outweigh the risks. Professor Shuster's arguments boil down to listing most of the complications of potent topical steroids and asserting that they "may" occur with 1% hydrocortisone. He has provided no substantiation apart from unreferenced figures on rat glucocorticoid receptors. The evidence does not support his contention that 1% hydrocortisone may produce iatrogenic Cushing's syndrome, perioral dermatitis and rosacea, an increase in colonisation by bacteria, fungi, and yeasts, corticosteroid habituation, and a deterioration of allergic contact dermatitis.

Side effects of topical steroids occur only when appreciable amounts are absorbed percutaneously. Negative results in intact skin are of doubtful relevance, but studies have been done of absorption through broken skin. Feldman and Maibach showed that if 1% hydrocortisone was applied to Sellotape stripped skin and occluded up to 20% of the dose might be absorbed.¹ Similar results were obtained when 1% hydrocortisone was applied to infant's skin. In a hypothetical worst possible case the contents of a 15 g tube of hydrocortisone could be applied under occlusion to abnormal skin; this amount would cover most of an adult body.² If 20% is absorbed percutaneously then up to 30 mg hydrocortisone might enter the circulation. This is about equal to the total daily output of cortisol from the adrenal cortex in a healthy adult. However, in contrast with more potent esterified or fluorinated steroids, topically applied hydrocortisone is rapidly metabolised to inactive 17-oxosteroid metabolites.³ Users of OTC hydrocortisone are also unlikely to apply it under occlusion. Thus, even under the worst possible conditions, pituitary adrenal function is unlikely to be influenced adversely. I have been unable to find any reports of systemic toxicity due to topical hydrocortisone. Fleischmajer applied 2.5% hydrocortisone (total dose 8750-9500 mg) to patients with various dermatoses for 3-20 months.⁴ Clinical and laboratory tests failed to detect evidence of systemic toxicity. In infancy, however, extreme caution is

prudent because of the high ratio between surface area and body mass.

Local toxicity from prolonged application of 1% hydrocortisone to the eyelids can occur.⁶ In two cases skin atrophy occurred after several months' application and in one after several years. I have found no other convincing reports of atrophy despite years of widespread use. I have also uncovered no evidence that topical hydrocortisone causes or exacerbates perioral dermatitis or rosacea. Professor Shuster says it may, but Cotterill and Sneddon in their reviews of many cases did not implicate hydrocortisone.^{7,9} Guin described three patients who developed a rosacea like eruption after using hydrocortisone for one to three months, but he was unsure of the relevance of hydrocortisone.⁵

Professor Shuster predicts dire consequences on bacterial, fungal, and yeast flora. No published data support his view. None of the patients with "tinea incognito" reported on by Ive and Marks had received hydrocortisone.¹⁰ In Carpenter's study topical hydrocortisone was applied to patients with secondary bacterial or fungal infection, and after 10 days' use there was no higher incidence of deterioration in the hydrocortisone treated group than in control groups using base alone or hydroxyquinoline antimicrobial preparations.¹¹ Surprisingly, Professor Shuster does not mention virus infection. Hydrocortisone is contraindicated in herpes infections affecting the eye. For this reason I do not support its indiscriminate OTC sale and would prefer to see it available from pharmacies only.

Finally, topical hydrocortisone 0.5% was released in the USA by the Food and Drug Administration for OTC use in 1979; 35.9 million units were sold OTC in 1980 and 1981. During this period the FDA received seven adverse reaction reports, none serious. In Britain we also have nearly 30 years' experience of the agent's safety on a prescription only basis. With this record the onus is clearly on opponents of its OTC use to produce concrete evidence why 1% hydrocortisone should not be available on a pharmacy only non-prescription basis provided appropriate warning and advice are included in the package.

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SIR,—Professor Sam Shuster has pointed out many of the dangers of indiscriminate use of hydrocortisone on undiagnosed skin conditions. Whereas 1% hydrocortisone is the correct treatment for mild eczema, it is not appropriate for tinea, acne, impetigo, or most other skin conditions. The application of "over the fence" (OTF)

Betnovate from well meaning neighbours is already a hazard to dermatological diagnosis; over the counter (OTC) hydrocortisone will only compound the problem.

Professor Shuster correctly states that the comparison with self administration of aspirin for a headache is invalid, but this comparison highlights an important practical point about public attitudes to drugs. The general public regards non-prescription preparations as being unscientific or ineffective or both, even when this view is not justified. The newer, prescription only, non-steroidal anti-inflammatory drugs are held in higher public esteem than aspirin. We foresee that OTC sale of 1% hydrocortisone will devalue this preparation in public regard and undermine its prescription use by general practitioners and dermatologists alike. It is difficult to imagine any mother accepting gracefully 1% hydrocortisone cream for her child's eczema from a doctor if this cream has already been bought over the counter and failed to "cure." Unfortunately there is no effective and totally safe substitute for hydrocortisone in these circumstances. Subtle pressure will then lead to demands for more potent, possibly fluorinated, and certainly medically less appropriate topical steroids for mild eczema.

Experience in the United States with OTC hydrocortisone may be reassuring, but it is totally irrelevant to Britain. In the United States it is expensive to consult a physician about a skin complaint and pay for the treatment, whereas in Britain free consultation and diagnosis are fundamental principles on which the National Health Service is based. There is no economic necessity for patients to use non-prescription blunderbuss therapy. To suggest that OTC hydrocortisone will relieve pressure on busy general practitioners and dermatologists is as fallacious as recommending free availability of handguns to beat the current crime wave.

We hope that readers will value the concept of diagnosis before treatment and oppose the OTC sale of topical steroids.

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MRC trial of treatment of mild hypertension

SIR,—Our practice participated in the MRC trial (13 July, p 97). I note that the outcome is essentially negative and I wish to comment on the entry procedure.

Most patients reached the major admission examination after two screening attendances to a nurse and one later attendance to a partner. A minority (4 out of 21 of my patients) attended the doctor twice. Few doctors would start a patient on treatment on the basis of blood pressure readings taken at one attendance only. Implicit in this admission procedure, therefore, is the use of the nurses' readings, not only for screening but also as a contribution to subsequent decision making. I would question the wisdom of this for three reasons: firstly, the screening caravan was probably for some patients a strange and threatening environment; secondly, the random zero sphygmomanometer can achieve very high cuff pressures (up to 280 mm Hg) and induce pain and a startle effect—two of my patients had bruised upper arms; thirdly, I suspect that nurses, even with training for the occasion, often confuse the fourth Korotkoff sound with the fifth and some of their diastolic pressure readings are too high. Thus after serving their purpose of defining a potential study population, the nurses' readings should have

been discarded and played no further part in decision making.

In accordance with the study protocol I did not take the blood pressure of the first three patients who attended for the major medical examination on entry, but then I became uneasy and during this examination I took the pressures of the remaining 18 as if they were attending for a normal consultation. I used my own mercury sphygmomanometer and the same conventions as the study. I then compared these results taken on my own initiative with my own previous readings taken at the official screening examinations and using the random zero instrument. Usually my unofficial readings were much lower, particularly the diastolic readings. The difference between the means of my 18 screening and 18 unofficial readings was 13.0 mm Hg systolic and 12.8 mm Hg diastolic (table). The finding that 11 out of the 18 patients now had a diastolic pressure of less than 90

Mean (and SD) screening and unofficial blood pressures (mm Hg) in 18 patients

	Mean	(SD)	Statistical value
Systolic:			
Screening	165.2	(15.5)	$t = 2.5$
Unofficial	152.2	(15.8)	$p = 0.02$
Diastolic:			
Screening	100.6	(6.6)	$t = 5.2$
Unofficial	87.8	(8.0)	$p < 0.01$

mm Hg was emphatic and disturbing. I felt obliged to reassure and discharge four patients from the study (with pressures of 140/80, 140/78, 118/82, and 150/82 mm Hg). These blood pressures were checked and agreed by the trial nurse at the time. My orthodoxy as a recorder of blood pressures was confirmed later by an exercise involving 25 doctors during a course on epidemiology for clinicians. We watched a film and were asked to record the systolic and diastolic pressures for eight pairs of readings. The mean deviations of my figures from the class mean were: systolic -1.0 mm Hg (range -3.6 to $+0.8$); diastolic 0.0 mm Hg (range -3.5 to $+2.3$).

The tendency for blood pressure to fall with repeated attendances is well known and was shown in the MRC study. The percentages of patients regressing to normal after initially raised readings had been recorded elsewhere as 13¹ and 35.² My figure of 11 out of 18 (61%) is therefore high and may partially be due to chance or artefact. Gordon *et al* have argued from the Framingham data that "a single casual measurement of a group of people predicts which individuals are more likely to develop cardiovascular disease,"³ and this conclusion has been quoted to me as a justification for the entry procedure for the MRC study. But suppose the Framingham sample contained two subgroups: the first with blood pressures which subside rapidly to normal over a few attendances and the second with blood pressures which either do not subside or do so only over months—the "subsiders" and "sustainers." It is possible, indeed likely, that the subsiders have no increased risk for cardiovascular complications, while the sustainers are at risk. The Framingham data are too crude to distinguish between such groups and the generalised conclusion may well be misleading. The MRC may not, therefore, have undertaken a study into "borderline hypertensive" patients but into a mixed population of conventionally normal and borderline. The failure to show an advantage for treatment in respect of overall mortality could therefore be due to a type II error.

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