

Use of Wau Wa in dermatitis patients

Sir—The parents of three different children with atopic eczema seen in our paediatric dermatology clinics informed us that they were applying a product called Wau Wa cream to their children's skin, with substantial benefit. In every case, the parents had presumed that this product was free from corticosteroids, which they believed to be harmful. One child had skin atrophy at several sites.

Wau Wa cream is widely available in the UK, especially in southeast England. Its label states that it contains extract of Wau Wa root and cream, and is made in Ghana.

Independent analysis shows that Wau Wa cream contains 0.013% clobetasol propionate.¹ This corticosteroid molecule is the same as that present in one of the most potent commercially available prescription topical corticosteroid treatments, although the concentration is about a quarter of that used in the commercial preparation, in which the concentration is 0.05%. The data sheet for the prescription cream states it must not be used long term in children.

The Wau Wa tree grows in Ghana and, paradoxically, causes severe dermatitis in timber workers; no therapeutic use for it is known.^{2,3} Clobetasol propionate is a synthetic steroid molecule and does not occur naturally; therefore, it is highly improbable that it is derived from the root of the tree.

Parents are using this Wau Wa cream as an alternative to steroid treatments, unaware that it is not purely a herbal product. Doctors, under the same misconception, have recommended it to patients. Anyone known to be applying it should be made aware that it contains a potent corticosteroid that could damage the skin under certain circumstances. The Department of Health has been informed of the illegal sale of this cream. There have been previous concerns about steroids in herbal creams from China and Ireland.^{4,5} The wide availability of this cream emphasises the need for improved quality control for all herbal products. Also, more effective controls of the entry into the UK of illegal drugs of all types is desirable.

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- 4 Keane FM, Munn SE, du Vivier AWP, Taylor NF, Higgins EM. Analysis of Chinese herbal creams prescribed for dermatological conditions. *BMJ* 1999; 318: 563–64.
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Supply of opiates from UK for children in African hospitals

Sir—When I started work in Cameroon for the humanitarian aid agency Child Advocacy International, as with so many hospitals in poor countries, no system to provide strong analgesics was in place in the two main hospitals. One hospital was a government institution, the other supported by a religious body. We describe the process by which we acquired supplies of opiates for children from a reputable UK source, on a sustainable basis.

We presented a report on the subject of pain control for children at a meeting of all senior staff in the mission hospital. Present were the director, the head of the nursing school, the chief medical officer, the chief pharmacist, senior nursing staff from the children's ward, and doctors. The thesis was well received and a decision was taken to act on its recommendations.

We contacted the Government's chief pharmacist, whom we met and told about the above meeting and requested his views on the supply of opiates for children in Cameroon. His advice was that if we could provide a good case for use of opiates in children, he would facilitate its passage through the customs service. He would recommend to the Ministry of Health that passage should be permitted; the Minister would sign and stamp the authority at once.

The chief pharmacist at the mission hospital started the necessary paperwork to be sent to Cameroon's Ministry of Health. At the same time we sent requests for quotes for oral morphine to various reputable suppliers in the UK and elsewhere in Europe. To avoid duplication of requests, the mission hospital sought supplies sufficient for both hospitals; it would purchase the total order and would sell the required proportion to the other hospital at cost.

Once the best deal was identified, 50 bottles of 100 mL (10 mg/5 mL) morphine were purchased by the

mission hospital. 30 were retained by the mission hospital, the other 20 were purchased by Child Advocacy International for the government hospital. There were no governmental or customs service hitches in the transport of the drug. The whole process took 7 months.

The government departments of sub-Saharan Africa can be expected to listen to closely argued requests for opiates for children. Institutions in which the opiates are to be used should hear the reasoning for purchasing the drugs from the doctor in charge. Personal contact with all officials, locally and at government level, is better than by letter or email. The administrative mechanisms for the acquisition of opiates are in existence, can be used, and should be workable. The cost of the world's best analgesic is trifling, even by African standards. The recipients must respect the strict rules in force in the country, as to the care and use of the opiates in their institution.

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How many committees does it take to make a project ethical?

Sir—Appropriate concern about the protection of research participants in low-income countries has led to changes in the ethics review process that have created a crisis for international medical research. The process of protocol approval may now be deemed an unethical barrier to international health research.

Research projects increasingly benefit from multiple international partners that are frequently required by funding bodies. Internal review boards (IRBs) or ethics committees oversee only their own faculty members and the modifications required by each must be resubmitted to the others. Modifications are frequently required at annual reviews that must again be reconsidered by all.

For example, a 4-year study involving a centre in a low-income country, two in the USA, and two in Europe, would require five initial applications, perhaps two revisions with subsequent resubmissions, and three annual reviews with perhaps two of these requiring modifications resubmitted to all. The result is 15 initial submissions and then, after approval, a further 25 applications in five formats.

This method of review does not facilitate a high ethical standard. Rather, it represents a distortion of ethical review from a cooperative process to ensure high ethical standards into an unwieldy administrative task, which delays and discourages medical research in the areas of greatest need.

We have several proposals that might resolve this crisis. The only effective manner for their enactment would be through the insistence of funding agencies.

First, ethics review of multicentre international studies should be structured so that only one IRB in each participating country reviews the protocol. This should include the IRB at the principal investigator's institution.

Second, the documentation required for protocol review should be standardised, including a uniform format to eliminate needless reformatting.

Finally, the informed consent process is best reviewed locally. Consent forms should be written in simple language to achieve maximum comprehension. However, distinctions between simple and complex terms do not correspond between languages and the local IRB has a better knowledge of the study site and population than does an IRB abroad. The local IRB should, therefore, have sole responsibility for the vocabulary of the consent documents, whereas the primary international IRB limits its review of the consent forms to issues of content.

As researchers we share responsibility for the predictable consequences of our actions and inactions. Research addressing multidrug resistant tuberculosis, trypanosomiasis, malaria, and other diseases of poverty is needed. We are obliged to advance alternative solutions that ensure the protection of study participants without impeding research targeted at improving health in developing regions. We are not suggesting a process of ethical review that is any less stringent; only one that is

less redundant and more appropriate to research in international settings.

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Risk assessment for Creutzfeldt-Jakob disease

Sir—In 1998, the Spongiform Encephalopathy Advisory Committee (SEAC) defined patients' risk groups as known, suspect, and at risk of Creutzfeldt-Jakob disease (CJD) and related disorders.¹ Our Trust is a regional neurosurgery referral centre, and we have dealt with several situations that clearly identified the need for a robust risk assessment system.

To alert all people involved at the earliest opportunity before any invasive procedure was undertaken, we developed a risk assessment document (panel). The Infection Control Committee recommended the document to the Trust board, and it has now become part of the consent form for surgery. Its use has raised awareness in the Trust and precipitated circumstances that may not otherwise have arisen.

For example, a patient about to undergo endoscopy revealed that they had received blood products from a pool that included a donor who subsequently died of variant CJD (vCJD). Such information raised difficult management issues for this patient, since appropriate practical guidelines do not exist.

The CJD Incidents Panel held a useful meeting in April, 2002, to debate

its consultation document, produced in October, 2001, on the management of possible exposure to CJD through medical procedures.² The document contains information on the infectivity of CJD and vCJD in various tissues, the effectiveness of instrument decontamination procedures, and models of the probability of contaminated instruments transmitting CJD and vCJD. It also discusses the infectivity of blood components and plasma derivatives.

We find the document unclear on how to manage a situation such as that with the above patient. Although the patient had been informed of the situation, the implications for any future invasive procedures had not been explained.

Clear guidance and information is needed for health care professionals dealing with such patients and for the patients concerned.

In addition to clarifying their document, the CJD Incidents Panel must see their hard work translated into updateable guidelines produced by the Department of Health. These guidelines must enable Infection Control Teams to make prompt and practical assessments of all situations involving CJD and vCJD and reusable equipment. Advice for endoscopy and haemodialysis units must also be included.

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- 2 CJD Incidents Panel. Management of possible exposure to CJD through medical procedures: a consultation paper. London: Department of Health Publications, 2002: 1–62.

Risk assessment document for CJD and related disorders in consent form for surgery

The following document has been included in the consent form in order to identify patients who may fall into the "risk categories" for the transmissible spongiform encephalopathies such as Creutzfeldt-Jakob disease (CJD),* as defined by the Spongiform Encephalopathy Advisory Committee of the DoH.

The Health Care Worker completing the consent form should go through questions (a)–(d) below with the patient. If the answer is YES to any of the questions, all invasive procedures must be delayed and a member of the Infection Control Team must be contacted immediately.

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| (a) Has the patient ever received natural human growth hormone?† | Y | N |
| (b) Has the patient received any other natural human pituitary hormone?† | Y | N |
| (c) Is there a family history of CJD or a related condition (includes parent, grandparent, grandchild, brother, sister) | Y | N |
| (d) Has the patient had any neurosurgical or ENT procedure before 1993, where a human dura mater graft was used? | Y | N |

The clinical team must provide the answer to the following question:

Is CJD or a related condition part of the differential diagnosis in this patient? Y N

*In addition to CJD, variant CJD, Gertsman-Straussler Syndrome, and Fatal Familial Insomnia are related conditions. †This relates only to hormones that were harvested from the pituitary gland of human cadavers, a practice that was discontinued by 1985.