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Midwifery and body fluid contamination

EDITOR,—The short report by Josaphat J Kabukoba and Pam Young highlighted a high incidence of skin contamination from patient's body fluids in obstetric and midwifery staff.¹ In their discussion they quoted observations of Braathen *et al* that suggested a possible role for epithelial Langerhans cells as vehicles for HIV infection across intact skin and mucous membranes.² This work was entirely experimental and there is no evidence that it has any clinical significance in the context of HIV transmission from patients to health care workers.

In a summation of prospective surveys documenting mucocutaneous exposure to blood infected with HIV, none of 453 health care workers became infected.³ In contrast, of 1177 episodes of percutaneous exposure, five resulted in infection. Three cases of infection after mucocutaneous exposure have occurred,⁴ and so a risk does exist—but, although no precise figure can be assigned to it, the risk must be very small indeed. A recent editorial in the *BMJ* reiterated the point that seroconversion after mucocutaneous exposure has not been reported in prospective studies.⁵ Furthermore, in specialties where mucocutaneous exposure to blood is common, such as orthopaedic surgery, the prevalence of HIV antibody is determined by non-occupational factors alone.⁶

Kabukoba and Young concluded that "current practices for preventing contamination are inadequate." However, their report does not mention what proportion of those studied were following local infection control guidelines or indeed what these guidelines were. In contrast to this, a study by Marcus *et al* suggested that 37% of exposures would have been avoided if recommended guidelines had been followed.⁷

We believe that appropriate barrier protection and precautions to avoid needlestick injuries should be used universally. However, the argument that non-parenteral contamination of skin and mucous membranes represents an important route of transmission of HIV infection to health care workers is at best speculative and at worst alarmist.

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EDITOR,—I was pleased that Josaphat Kabukoba and Pam Young recognised the high rate of contamination of the surgeon's forearms while performing caesarean section¹ but was surprised that they did not look at manual removal of the placenta.

The report on HIV infection in maternity care and gynaecology, published by the Royal College of Obstetricians and Gynaecologists recommended that elbow length gloves should be available if gowns with an impermeable sleeve were not available for the manual removal of the placenta.²

Over the past three years I have made numerous inquiries about these items at all the hospitals where I have worked. They are rumoured to exist, but no one has ever seen them or knows where to obtain them. In my present post I at last found an elbow length rubber gauntlet, but it had perished after many years of repeat autoclaving and was no longer of any use.

I have found the following method effective in eliminating the contamination of the forearm with blood while carrying out a manual removal of placenta in an ordinary "permeable" gown wearing an ordinary pair of "short" surgical gloves. After donning a gown in the usual manner, a pair of surgical gloves are taken and all the fingers cut off. Both of the remaining sleeve portions are then pulled all the way up the same arm to the elbow, with some overlap. A second pair of gloves is then worn in the normal manner. This effectively forms an elbow length rubber glove and stops contamination of the sleeve of the gown and forearm with blood.

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Contamination of skin and clothing of A and E staff

EDITOR,—Patricia Littlechild and colleagues found the personal clothing and uniforms worn by accident and emergency staff to be inappropriate.¹ We suggest that staff from all disciplines who are on call for emergencies anywhere in a hospital should wear the type of suits worn in hospital theatres. Such staff include members of cardiac arrest and trauma teams, all doctors with duties in accident and emergency departments, and the staff of intensive care, endoscopy, and maternity units. Staff can quickly discard soiled theatre clothes and maintain personal cleanliness and limit cross infection.

The Expert Advisory Group on AIDS recommended degrees of protection according to the risk category of tasks.² The full range of protective wear is recommended for category A(i) tasks, with potential for uncontrolled bleeding and spattering; gloves and possibly masks and protective eyewear are recommended for category A(ii) tasks, in which contact with blood is probable but spattering is unlikely; and gloves are recommended to be available for category A(iii) tasks, in which no contact with blood is likely. After many incidents of splashing we now take category A(i) precautions

for category A(ii) tasks and wear gloves for category A(iii) tasks in high risk patients.

Skin contamination continues, often because recommendations are not followed and sometimes despite them being followed.³ Inappropriate fabric and design of current wear are often to blame. Cotton gowns are not protective. We have not seen anyone use elbow length gloves for manual removal of placentas. In our survey of one major teaching hospital with eight operating theatres only the orthopaedic theatre stocked water repellent gowns. One anaesthetic room had only a box of disposable latex gloves. One of 12 consultant anaesthetists wore gloves routinely. None of 15 junior colleagues interviewed had read the documents of the Expert Advisory Group on AIDS² or the BMA's *A Code of Practice for the Safe Use and Disposal of Sharps*.⁴

We are convinced that most incidents of splashing are preventable by better instruction and changes in attitudes and practice. This is important because the present suits do not provide overall protection. More long sleeved and high neck (Indian style) protective shirts would help. Junior members of teams are reluctant to adopt protective measures that make them stand out. Consultants or senior registrars can help by good example.

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Personal protective equipment for employees

EDITOR,—In their short report on contamination of skin and clothing Patricia Littlechild and colleagues refer mainly to clothing worn by accident and emergency staff.¹ The discussion of adequate personal protective equipment, which includes "all equipment designed to be worn or held by a person at work to protect him against one or more risks,"² needs to be widened to include that used in all areas where employees of health care organisations may be exposed to any risk while at work.

One of the aspects of the European single market is the implementation of numerous pieces of legislation drawn up by the European Community as health and safety directives. These directives have to be implemented by the member states by 1 January next year. The framework for these new regulations is provided by the proposed Health and Safety (General Provisions) Regulations, which, among many other things, require all employers to assess work practices in which their employees' health and safety may be at risk.³ The proposed Personal Protective Equipment at Work Regulations will require every employer to provide suitable protective equipment to all employees when risks cannot be adequately controlled by other means. When such equipment is deemed necessary the employer must ensure that it is appropriate for the risks entailed. The employer must also take into account ergonomic requirements—that the equipment will fit the wearer and, so far as is practicable, prevent or adequately control the risk without leading to any increased

risk. In many cases the equipment, if issued after certain dates, must comply with agreed European or national standards.

These new regulations will operate alongside some of the existing legislation, such as the Control of Substances Hazardous to Health Regulations, which already require employers to protect employees from such hazardous substances as glutaraldehyde, anaesthetic gases, infected blood, and other body tissues.¹ Accident and emergency staff who do not wear suitable personal protective equipment may therefore be in breach of new health and safety legislation, specifically the Personal Protective Equipment at Work Regulations and, generally, the Health and Safety at Work, etc, Act 1974 and the proposed "general provisions" regulations. It is rumoured that when the general provisions regulations are finally agreed they will be renamed the Management of Health and Safety at Work Regulations, which would put the onus of compliance for health and safety on management.

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When to stop a clinical trial

EDITOR,—Stuart Pocock's article on when to stop a clinical trial should be essential reading for anyone embarking on a large clinical trial.¹ Pocock asks many of the most important questions regarding the size and need for regular review of a trial and supplies many of the answers.

I am surprised, however, by the cursory manner in which he deals with smaller trials. Even in these days of multicentre "megatrials" only a select few workers have the facilities to organise and run such studies. Many new forms of management are first assessed in a small study, which may be ethically more controversial than the subsequent larger study based on it. In such circumstances the closed paired sequential design of trial described by Armitage,² to which Pocock barely refers, can be most useful.

Briefly, this is a graphical representation of the study as it progresses, the x axis representing the number of experiments and the y axis depicting whether the "new" (positive) or "old" (negative) treatment shows an improvement in outcome. Initially the statistical power required for the study is estimated and the borders plotted according to Armitage's calculations.² The observers performing the study can be blind to both the treatments and the results, depending on the study's design. One person, however, must have immediate access to all results, which are plotted according to the results of each individual experiment. The experimental plot starts at the origin of the graph, and the study ends when the plot crosses one of the predetermined borders. If the medial border is crossed first a significant difference is unlikely to be found between the two treatments, no matter how long the study continues. On the other hand, if the upper (lower) border is crossed first the new (old) treatment is likely to be significantly better.

The advantage of a statistical tool such as this is that it allows for continuous monitoring of the trial, which then ends as soon as a likelihood of a significant result is achieved. This can be helpful when seeking ethical approval as a minimum

number of patients are exposed to the less advantageous form of management. The method would have been ideally suited to the randomised trial comparing extracorporeal membrane oxygenation with conventional medical treatment in newborns with persistent pulmonary hypertension cited by Pocock.

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EDITOR,—Properly designed and executed randomised controlled clinical trials are the most powerful tool we have to establish the effectiveness of a new treatment and to persuade doctors to adopt that treatment. A meta-analysis of several trials is even more persuasive. Lau *et al* estimated that cumulative meta-analyses would have allowed the efficacy of intravenous thrombolytic treatment in myocardial infarction to be accepted by 1973, after only eight trials.¹ The results of the next 25 trials, which enrolled an additional 34 542 patients, had no effect on the odds ratio establishing efficacy but merely narrowed the confidence interval.

Patients must not, however, be recruited into a clinical trial unless both they and their doctors are honestly ignorant of the relative merits of the two or more arms of the trial. Stuart J Pocock acknowledges the ethical dilemmas of communicating interim results of a trial to the doctors who are participating (and, of course, to the general public).² He recommends, however, either the O'Brien-Fleming rule that up to five analyses should be made at yearly intervals, the p values ranging from <0.0000001 for the first to the <0.009 for the last, or the Peto-Haybittle rule that a flexible number of interim analyses should be made, the p value being fixed at <0.001. If the first analysis shows p=0.01 the trial should continue. I doubt, however, whether doctors and patients can maintain their ignorance of the relative merits of the treatment regimens if they are told that there is a 99% chance that regimen A is better than regimen B.

Perhaps the rule should be that the trial co-ordinating committee should keep the results of interim analyses secret.

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Exposure to radon

EDITOR,—D P B Miles discusses whether radon causes lung cancer.¹ I am writing to identify some of the key documents on the subject.

There is conclusive evidence, from epidemiological studies of miners and experimental studies on animals, that products of radioactive decay of radon induce lung cancer,^{2,3} and there is a clear indication that the doses of radiation to the lung in miners and other groups are comparable.⁴ The collective results of epidemiological studies of lung cancer and domestic exposure to radon being conducted in Europe and the United States may eventually lead to refinements in the present coefficients of risk.

Against this background, international authorities have developed recommendations for protection against radon at work and in the home,^{5,6} which are reflected in developments in the United

Kingdom.^{7,8} What informs these moves is the desire to prevent high exposures to radon and keep the risk of lung cancer within reasonable bounds in various circumstances.

Government policy on radon in the home is strongly focused on the most affected areas in the United Kingdom^{9,10}: new houses are required to have preventive measures, measurements are made free for householders, technical advice is given on remedial measures when the radon concentration exceeds the action level of 200 Bq/m³; and grants for necessary work are available in cases of need.

Unlike employers, householders are not obliged to take action. Rather, they must be persuaded that the risk is real but easy to reduce.

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Poliomyelitis in developing countries

EDITOR,—The World Health Organisation's commitment to eradicating poliomyelitis from the world by 2000 is based on the assumption that the disease is a serious problem in developing countries.¹ We have challenged this assumption because the paralysis described as poliomyelitis in the tropics differs fundamentally from the classic disease and the diagnosis is retrospective, based on surveys of lameness rather than on observation of the children in the acute phase of the disease.^{2,3} Furthermore, estimated incidences derived from these surveys of lameness are 30 times greater than recorded incidences in Malawi and South Africa before vaccination was introduced.³

Recently there have been reports from China of an acute paralytic disease that differs from poliomyelitis⁴ and may be similar to a syndrome described in Mexican children.⁵ In the Mexican children postmortem examination showed a neuropathy that was not poliomyelitis despite isolation of the virus; this led to the comment that "the mere presence of poliovirus in the intestinal tract is no proof that the paralytic disease was caused by the virus."⁶ This statement supports our conclusion that isolation of the virus on its own is not diagnostic and that an accurate history must be taken, a clinical examination performed, and the cerebrospinal fluid examined before a definitive diagnosis can be made.³ In a report on a child in Bangladesh who developed an illness similar to that reported in China the authors suggested that "Asian paralytic syndrome" may be a more appropriate name for these diseases, implying that