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Differentiating between audit and research. Undue protection of patient confidentiality jeopardises both research and audit

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Managing self poisoning

Gastric lavage is perhaps more important in developing countries

EDITOR—In their clinical review of recent advances in the management of self poisoning, Jones and Volans briefly discuss gastric lavage and state: “many clinical toxicologists rarely use this method now.”¹ The impression given could support the abandonment of gastric lavage. This could be particularly deleterious in developing countries.

In developing countries, poisons consumed are commonly toxins such as organophosphorus compounds and aluminium phosphide, and thus mortality is high. The organophosphorus compounds are usually consumed in liquid form. In such cases of poisoning, prevention of absorption of even a small amount may make a considerable difference. Furthermore, antidotes to poisons and intensive care may not be available. Any intervention, such as gastric lavage, which can be carried out easily cannot be neglected. The value of gastric lavage depends on the amount, toxicity, and effect of the poison and the time since consumption. Its role in certain cases should have been highlighted.

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1 Jones AL, Volans G. Management of self poisoning. *BMJ* 1999;319:1414-7. (27 November.)

Common sense makes no sense

EDITOR—Although Jones and Volans’s article updating doctors on the management of poisoning is welcome and informative, I was a little bemused by the contradictions in it.¹

We are told that gastric lavage should not be used unless two criteria are met: it should be used within an hour of ingestion of the poison, and the amount of toxin should be substantial. Though these criteria are repeated often in the literature there is no evidence to support either of them. The literature indicates only that there is no difference in outcome when gastric lavage is used. But Jones and Volans—like the authors of the papers quoted—give way to that devil, common sense.

It makes sense to try to remove a toxin before it is absorbed; therefore, when the poisoning may be serious, scrap the evidence, go for common sense, and do a gastric lavage. How, in real life, we are accurately to determine the time of ingestion and

amount of toxin ingested in a group of patients who are notoriously unreliable is a moot point.

We see the same reversion to common sense in Jones and Volans’ update on carbon monoxide poisoning. The most rapid way to displace and eliminate carbon monoxide is to use hyperbaric oxygen—there is no doubt about this fact in the literature. But if we are informed that the usefulness of hyperbaric oxygen is far from proved then surely we must consider it seriously in all patients on the grounds of common sense, or we must not use it at all on the grounds of evidence. Incidentally, there is no evidence showing selective benefit in those patients who have been obtunded, and to preach such a qualification is unjustified.

I welcome evidence based medicine wholeheartedly but can’t help smiling when I encounter authorities making clearcut recommendations ... up to a point—the point after which they get cold feet.

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Guidelines for accident and emergency departments are needed

EDITOR—In their review on the management of self poisoning Jones and Volans suggest that decontaminating the gut by gastric lavage or administration of activated charcoal be carried out within one hour of ingestion of the toxin.¹ In practice, however, it is rare for such patients to present at an accident and emergency department and to be assessed within one hour of ingestion. There are many reasons for this, including patients’ delay in seeking help, transportation time to hospital, and triage category. The average time from receipt of an emergency call to arrival at hospital is 38 minutes for all patients in the West Midlands area (S Edwards, West Midlands Ambulance Service, personal communication). Additionally, the standard UK triage system assigns asymptomatic poisonings to category 3 (to be seen within one hour of arrival).²

As similar recommendations on time since ingestion have already been implemented in many accident and emergency

departments, gastric lavage is now seldom performed. With this loss of training opportunity for new staff, the skills needed to perform the procedure safely may be lost, with the result that it may not be performed in the few patients in whom it remains indicated.

Clearly, the sooner activated charcoal is given the better. It has been given successfully in the prehospital setting.³ This is probably the best way, and in many cases the only way, of administering it in the one hour time frame that clinical toxicologists recommend.

Although the authors suggest a carboxyhaemoglobin level of >40% as an indication for hyperbaric oxygen therapy, another recent review has suggested a much lower (>20%) level as an indication for this therapy.⁴

Unlike other authors,^{4,5} Jones and Volans do not include pregnancy as a special indication for hyperbaric oxygen therapy. The fact that two recent publications in journals from the BMJ Publishing Group should give different recommendations for managing important aspects of such a common problem illustrates the divergence of opinion in this area and the problems faced by accident and emergency staff while making decisions.^{1,4}

These issues need to be clarified, and consensus guidelines relevant to the realities

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in accident and emergency departments need to be drawn up. This should ideally be done by a joint working party of UK toxicologists, prehospital care providers, hyperbaric therapy clinicians, and accident and emergency clinicians.

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Indications for the use of whole bowel irrigation are weak

EDITOR—I was surprised to see in Jones and Volans' review of management of self poisoning the headline advice that when a potentially lethal amount of a drug is not adsorbed by activated charcoal, whole bowel irrigation with polyethylene glycol solution is recommended.¹

One of the references cited is the American Academy of Clinical Toxicologists/European Association of Poisons Centres and Clinical Toxicologists' position statement on whole bowel irrigation. The position statement represents a thorough review of the literature and appraisal of the data concerning whole bowel irrigation (WBI) and states: "There are no established indications for the use of WBI... The use of WBI for the removal of ingested packets of illicit drugs and in the management of patients who have ingested substantial amounts of poisons not adsorbed to activated charcoal is also of theoretical benefit."² This seems a weak foundation for such a strong recommendation of a procedure that is not without complications.

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- 2 American Academy of Clinical Toxicologists and European Association of Poisons Centres and Clinical Toxicologists. Position statement: whole bowel irrigation. *J Clin Toxicol* 1997;35:753-62.

Body packers need careful treatment

EDITOR—We support most of Jones and Volans' recommendations concerning the management of self poisoning, which have been reached using an evidence based approach.¹ However, we think that their suggestions for managing self poisoning among drug couriers who have ingested packets of drugs (body packers) are based on anecdotal case histories and contradict most of the published literature. Some of these suggestions may be dangerous.

Methods of drug smuggling are becoming increasingly sophisticated, which has led to the development of packaging that is more tolerant of gastrointestinal transit. Breakdown of packages is now thought to be relatively rare. Most authors therefore recommend a conservative approach to body packers who have no symptoms.²

Although there are reports of success, we do not recommend endoscopic removal of packages from the stomach or colon owing to the considerable danger of perforation on capture. With the average package of cocaine containing 10 times the median lethal dose, perforation is likely to be fatal.

The use of whole bowel irrigation and laxatives is more controversial and needs more controlled research. However, Caruana et al report a series of 50 patients treated with mineral oil without a single instance of a package degrading.³ Visser et al cast doubt on the use of mineral oil in their report of a single case, but their patient had shown signs of cocaine toxicity before the oil was given, which suggests that the packet was already starting to degrade.⁴

In conclusion, we recommend a conservative approach to treating body packers with no symptoms. Endoscopy is contraindicated and surgery should be reserved for those with delayed transit, bowel obstruction, or signs of toxicity or passage of damaged packages.

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Poisons database is still not on the NHS net

EDITOR—A couple of points about Jones and Volans' clinical review.¹ Firstly, ketamine is not just a veterinary anaesthetic but is still available in most operating theatres.

Secondly, it is appalling that a poisons database is still not on the NHS net (but then again, what is; not even the *British National Formulary*). Why is so much spent on setting up the NHS net and so little of practical value put on it?

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Authors' reply

EDITOR—We agree with Bhattarai that the evidence on which the European and American guidelines have been created is largely from more developed countries and

involves overdoses of pharmaceutical agents. However, it is probable, given the number of studies to date, that gastric lavage is unlikely to be of established value beyond one hour after ingestion of a variety of agents. When it is carried out too late, the stomach contents may have passed into the small bowel and gastric lavage would not be expected to retrieve such material, except if gastric emptying were in some way delayed. In addition, gastric lavage can actually push the gastric contents beyond the pylorus, which enhances absorption.¹ We must remain vigilant to the possibility of exceptions, but, from our experience in Nepal with the World Health Organization, we would not recommend using gastric lavage with water for aluminium or zinc phosphate poisoning, as contact with water liberates phosphine gas, which is a potent respiratory toxin. Gastric lavage with vegetable oil is preferred under such circumstances.

Chaudhry and Khanna make practical points about the implications of the new guidelines for decontamination in accident and emergency departments. As the evidence for the efficacy of gastric lavage and activated charcoal is only for its use within an hour, it is important that such patients are triaged rapidly. If a considerable delay in transit to hospital is anticipated, general practitioners may be best placed to give activated charcoal, providing the patient is not too drowsy or at risk of fits.²

Trimble shows that the evidence on which some recommendations have been made is a few case reports, and randomised controlled clinical trials are often not available. The guidelines are exactly that—guidelines and not protocols. The lack of an evidence base behind the bowel irrigation guidelines may reflect limited experience of the procedure, but it is a potentially important advance in treating patients with overdose of slow release formulations or substances that do not bind to charcoal. We wanted to raise awareness of whole bowel irrigation and to indicate when we, as clinicians, would consider using it in our patients, though clearly more data collection is needed to show efficacy.³ Whole bowel irrigation may offer a new conservative approach to treating body packers. Sadly, there are still sudden deaths from packages that rupture, and, as Hollingsworth and Jones point out, the need for removal must be judged by risk assessment. When signs of toxicity are developing, such as cocaine toxicity, the need for urgent removal is pressing and the risk assessment strongly favours removal of the packet.

When our article was submitted to the *BMJ*, TOXBASE was not available on the internet. It is now available at www.spib.axl.co.uk. We contribute to updating TOXBASE and strongly support its use as a first line in helping to answer poisons inquiries.

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- 1 Saetta JP, March S, Gaunt ME, Quinton DN. Gastric emptying procedures in the self-poisoned patient: are we forcing gastric content beyond the pylorus? *J R Soc Med* 1991;84:274-6.
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Health minister clarifies Care Standards Bill

EDITOR—I believe that your article on private health care was in places misleading and factually incorrect.¹ The article implies that the Care Standards Bill will only extend to standards of premises and equipment in independent health care, and that the bill will not address the core problem of the quality of clinical care. It also wrongly implies that the bill does not address issues about safety and quality in cosmetic surgery.

Current regulation of the private sector is undoubtedly inadequate and no longer appropriate for the range of treatment provided by private hospitals. The Care Standards Bill will address just this issue, setting up a new care standards commission, which will take on the role of regulating the private health sector. It will oversee the registration and inspection of private healthcare providers and carry out annual checks on all private facilities, including unannounced spot checks. Where necessary the commission will have the power to take enforcement action, including closing a hospital or a clinic down if patients are at risk.

Emphasis on quality and standards of care will be greater under the new system. Minimum care standards will be set that must be met by all private healthcare providers. In cases where things do go wrong patients will have redress through a proper complaints system. We will introduce arrangements for independent investigations where patients are not satisfied with how their complaint was handled. The registration, inspection and enforcement processes will help ensure that the organisations running independent hospitals and clinics will have to account for the care provided in them.

Although it is true that the Department of Health's main responsibility is to ensure that health care is managed effectively within the NHS, that does not mean that it is unconcerned about the safety and standards, and patients' rights of redress, in independent health care. This government is determined that there is proper protection for people who choose to use private health care—and the Care Standards Bill will address just this issue.

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- 1 Beecham L. BMA seeks clarification on Care Standards Bill. *BMJ* 2000;320:255. (22 January.)

Differentiating between audit and research

Undue protection of patient confidentiality jeopardises both research and audit

EDITOR—Wilson et al have highlighted an important double standard that distinguishes clinical research from audit.¹ While researchers are obliged to struggle for ethical approval to examine patient records,² auditors seldom have to, even though they may be temporary, non-medical staff without a long term professional commitment to respect patient confidentiality.

The protection of confidentiality is clearly essential in each activity, so we would expect both to be affected equally by the implementation of the Data Protection Act (1998) this month. Unfortunately, it seems that identifiable information about patients, and access to their records, can be obtained only with their explicit or implicit permission. The extent to which the act will require protection of both anonymised and patient identifiable data will affect, and even perhaps jeopardise, epidemiological research, audit, and therefore clinical governance. Even the BMA's stringent contemporary guidelines on this issue have been deemed insufficiently protective and therefore unlawful.³

Gone will be the days of carefully considered guidance from working parties with strong lay membership, which have advised that, "research involving access to medical records, registers, or existing biological samples only, without direct patient contact or involvement, is not considered to require individual patient consent or independent ethical approval provided explicit consent to access a patient's records is obtained either from the official custodian of those records or from the patient's clinician."⁴

This kind of well intentioned protection of patients will inevitably wreck epidemiological research. Furthermore, if the same rules are applied, we cannot see how meaningful audit or clinical governance can ever happen. For example, the interpretation of "league tables," or even early warning of another Bristol, would be impossible without ready access to routine patient records, both in primary and in secondary care. The cost to society of hampering timely medical research and audit must surely outweigh the risk of bona fide researchers and auditors endangering patient confidentiality. The uncertainty surrounding access to patient records is causing great confusion, contradictory guidelines, and fear of litigation and is making clinical research even more difficult than it already is.

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- 1 Wilson A, Grimshaw G, Baker R, Thompson J. Differentiating between audit and research: postal survey of health authorities' views. *BMJ* 1999;319:1235. (6 November.)
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Clinical audit is research

EDITOR—In their paper Wilson et al write: "Our experience shows that consensus is lacking on the definition of research and audit."¹ They are right. A dictionary defines research as "a careful search; investigation; systematic investigation towards increasing the sum of knowledge."² The nearest it comes to a medical definition of audit is "a calling to account generally; a check or examination; a periodical settlement of accounts."³ The best current definition is probably Wilson et al's: "Perhaps the most helpful distinction (between research and audit) is about motivation and the objectives of the project: audit has the objective of directly improving services against a standard; research may include the objective of defining best practice."⁴

Not everyone may agree with Wilson et al, which is why we wrote to the *BMJ* in 1997.⁵ Our journal *Anaesthesia*, in its notice to contributors, had introduced a new hurdle: "Prospective ethics approval should be acquired for papers based on clinical audit data."⁶ Partly as a result of our letter, we believe, and partly from the subsequent correspondence in the columns of *BMJ*, *Anaesthesia* removed the hurdle. That does not mean that the journal was entirely convinced by the arguments. Nor does it mean, as is clear from Wilson et al's paper, that health authorities and ethics committees up and down the land are less confused now than they were then.

Taking the dictionary definitions of research, it is plain that clinical audit has to be, must be, research. The remaining question is whether an audit is ethical. Since the Clinical Audit Committee of the BMA seems to have taken upon itself responsibility for ethical issues in audit,⁵ perhaps it should look once again at the problem and find a definitive and non-politically correct solution which might satisfy scientists, writers, editors, and literary pedants.

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- 1 Wilson A, Grimshaw G, Baker R, Thompson J. Differentiating between audit and research: postal survey of health authorities' views. *BMJ* 1999;319:1235. (November 6.)
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Authors take issue with commentary on their paper

EDITOR—We commend the development of the *BMJ's* guidelines on educational interventions, which were used to assess our paper.¹ At several points in Ker's commen-

tary on our paper, however, she raises the need for further information. We recognised this need when we prepared the manuscript. We were also aware, though, of the constraints on space; articles in the *BMJ* should not exceed 2000 words, and providing the requisite information would have made our paper substantially longer. An alternative would have been to give the information on the journal's website; this has the disadvantage of increasing the demands on authors but should be considered if the guidelines are to be fully applied.

We had some difficulty in following the comments on the randomisation approach. Firstly, it is unclear why Ker thinks the term "controlled" should be dropped; this is the conventional term for a trial such as this one, entailing randomisation to two or more groups, one of which is a control or comparison group.

Secondly, Ker suggests that contamination threatens the status of the control group. Presumably she is referring to the control group experiencing the effects of the intervention. It is certainly true that contamination is a major consideration in a study of this kind. We recognised this before we started the study and chose the sampling design specifically to minimise its likelihood. We believe that contamination was minimal, but even if this was not so it should have reduced the chances of finding the differences that emerged. This does not represent an absence of control.

Thirdly, Ker suggests that imbalances in the demographic variables in the intervention and control groups threaten the study's internal validity. Such an imbalance can arise in randomised controlled trials, and steps were taken in the data analysis to adjust for baseline differences between intervention and control groups.

Fourthly, Ker comments on the randomisation process. We believe that randomisation took place at the highest level possible for this kind of community based intervention. The suggested purposive sampling method, with presumably some form of pairwise or stratified randomisation, may be the ideal but raises a further barrier to the recruitment of adequate numbers of general practitioners. By making recruitment more difficult it would probably reduce further the representativeness of those practitioners who eventually participate.

Lastly, Ker's final sentence is ambiguous. A simple adjustment to the wording, replacing "the study" with either "a study" or "this or any other study," would more adequately describe her meaning.

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Mortality prediction model is preferable to APACHE

EDITOR—In their article on scoring systems in intensive care, Gunning and Rowan provide a detailed description of the APACHE II mortality prediction model.¹ This model was developed with data collected between 1979 and 1982 and was replaced by APACHE III in 1991.² Unfortunately, there is a substantial charge for using APACHE III; thus many intensive care units continue using the outdated APACHE II, but do you really want to compare your standard of care with that delivered by North American units 20 years ago?

There are several other problems with APACHE II and APACHE III. Firstly, they use the worst value of several physiological variables (such as blood pressure and heart rate) in the first 24 hours in intensive care to calculate each patient's risk of dying. Any score that uses data collected over 24 hours is affected by the quality of care provided³—the very thing that units are trying to assess. Patients mismanaged in a bad unit will have higher APACHE scores than similar patients managed in a good unit, and the bad unit's high mortality will be incorrectly attributed to its having sicker patients.

Secondly, using the worst scores in 24 hours gives a spurious impression of accuracy⁴; many deaths occur during the first 24 hours in intensive care, and during this time the score is diagnosing death rather than predicting it (it is not difficult to detect that something is wrong with a dead patient).

Thirdly, the worst scores in 24 hours depend on the method of data collection, being about 25% higher with continuous computer monitoring than with manual recording.⁴

Fourthly, collecting the worst value of 15 variables over 24 hours is difficult; either a disproportionate amount of work goes into collecting the information (which reduces the resources available for more creative research) or, as often happens, it is collected inaccurately or is not collected at all.

The mortality prediction model uses data collected during the first hour after admission to intensive care.² It was developed by Stanley Lemeshow, professor of biostatistics at the University of Massachusetts, who coauthored one of the standard texts on logistic regression. The model has been derived and tested on over 19 000 patients in Europe and North America and is free.⁵ For children, the paediatric index of mortality model uses data obtained at the time that a child is admitted to intensive care,³ and it too is free (<http://pedsccm.wustl.edu/clinical/pim-readme.html>).

The mortality prediction model has substantial theoretical, practical, and financial advantages over the APACHE model for use in adults in intensive care.

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Development and evaluation committees' methods for appraising new drugs

Committee failed to meet aims in producing report on low molecular weight heparins

EDITOR—We agree with Freemantle and Mason's view that the methods used by development and evaluation committees may be inadequate for appraising new drugs.¹ The InterDEC, a collaboration between Wessex and three other organisations, contends that none of the 100 reports produced so far has been significantly contradicted by later evidence.² From personal experience we would beg to differ.

In March 1999 the Wessex Development and Evaluation Committee published a report on the use of low molecular weight heparins compared with unfractionated heparins for use in unstable angina and non-Q wave myocardial infarction.³ The committee claims to use a thorough system of information search to ensure that any relevant information is taken into account when the reports are produced. Furthermore, its aim is to provide updates of reports within a short time when information becomes available that might alter the conclusion of the original report. In the above case it has failed to deliver on either of these counts.

Firstly, the report failed to identify a key paper by Fox showing the extended benefit to one year of treatment with enoxaparin versus unfractionated heparins in the treatment of unstable angina and non-Q wave myocardial infarction.⁴ This omission was further compounded by its failure to acknowledge several abstracts presenting these data at international meetings. As a result of this, the worst case scenarios were chosen for modelling to determine cost utility of the treatment, resulting in a conclusion of "no proved benefit." If the omitted data showing a sustained reduction of 13% at one year in death, myocardial infarction, and recurrent angina with enoxaparin compared with unfractionated heparins had been included in the assessment, the conclusion would probably have been "proved benefit" on grounds of both clinical and cost efficacy.

Secondly, this error was brought to the authors' attention in June 1999, and we have been informed that a review is scheduled for March this year. In our view, incorrect conclusions and misinformation should be dealt with expediently to ensure that patients benefit from optimum treatment.

Reports by development and evaluation committees are undoubtedly a valuable contribution to the evaluation of available treatments and the rational provision of health-care resources. The quality of the report from which the conclusions are drawn must be scientifically sound. Using the development and evaluation committees' own criteria for scientific validity of data, is it time that the committees' reports are peer reviewed before publication?

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- 3 Nicholson T, Stein K. *Low molecular weight heparins (dalteparin and enoxaparin) compared with unfractionated heparin for unstable angina and non-Q-wave myocardial infarction*. Southampton: Wessex Institute for Health Research and Development; 1999. (Report No 93.)
- 4 Fox K. The role of antithrombins in improving outcome in unstable angina. *Br J Cardiol* 1998;5(suppl 2):S7-9.

Reply by members of committee

EDITOR—Bosanquet and Fox's criticisms of the development and evaluation committee's conclusions¹ and report² on low molecular weight heparins are without foundation.

The authors make much of the omission from the report of the one year follow up data from the ESSENCE trial.³ True, electronic searching failed to identify Fox's paper, published with an uninformative title and after we had searched the relevant database. But we also had contact with enoxaparin's manufacturers and with experts in the field, none of whom mentioned the paper. It is unlikely that its inclusion would have made a material difference: the report already indicated that enoxaparin was probably less costly and more effective than unfractionated heparin, even if its benefits lasted for only 30 days and not one year. Furthermore, it is incorrect to say that no abstracts of Fox's paper were included: one was (reference 24), but because of past criticism this committee has decided to use data from abstracts only in sensitivity analyses. We make no apology for this caution.

The committee's discussion of the report in March 1999 was animated. The final "not proved" conclusion took account of the whole range of evidence presented in the report and was not formulaically derived from the committee's decision grid.⁴ The committee recognised that important new evidence was expected soon and so earmarked the report for early review.

Bosanquet and Fox have oversimplified the correspondence since June 1999. Once the ESSENCE follow up data³ were identified and their implications agreed, an addendum was prepared (published on the committee's website (www.hta.nhsweb.nhs).

uk/rapidhta/) and circulated with new copies of the report) and a full update was scheduled. After discussion with the NHS Executive it has now been decided to withdraw the original report. The committee will consider the update in the next few months, as originally planned. We reject the assertion that this dialogue has not been handled appropriately.

With regard to the final suggestion about peer review, all of the committee's reports are shown to several (named) experts in the field for their guidance and comments before being finalised and presented to the committee.

Bosanquet and Fox comment on the value of development and evaluation committee reports in providing decision makers in the health service with rapid but systematic reviews on the effectiveness and cost effectiveness of treatments. The handling of this report and of its criticisms show not the weaknesses but the strengths of the system.

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Osteoporosis and coeliac disease

Screening all patients with osteoporosis would be inappropriate

EDITOR—In his review of coeliac disease Feighery comments on the high incidence of osteoporosis in coeliac patients and says that this may be a presenting feature.¹ He goes further to recommend, however, that all patients with osteoporosis should be screened for coeliac disease by measurement of endomysial antibodies.¹ Most patients with osteoporosis do not have coeliac disease, and it is our experience that it is unusual for such patients to present without some other feature of coeliac disease. In their survey of 92 patients with osteoporosis Lindh et al comment that none of those patients found to have coeliac disease had intestinal symptoms, but no mention was made of anaemia.² Such a proposal would have considerable implications for resources, both in the cost of the assays and in the substantial number of

patients that would require referral to the gastroenterologists for intestinal biopsy. We suggest that screening for coeliac disease be reserved for when unexplained osteoporosis presents in association with anaemia or low serum concentrations of calcium in permanently tired premenopausal women and men aged 60 years who have a family history of coeliac disease or any gastrointestinal symptoms.

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Author's reply

EDITOR—I agree with Fickling and Bhalla that it would be inappropriate to screen all patients with osteoporosis for coeliac disease. The statement in the review that "all patients" should be screened is overenthusiastic and should be amended to read "all patients with unexplained osteoporosis." Because of the high prevalence of coeliac disease, in particular clinically silent disease, I believe that patients with unexplained osteoporosis should be screened for coeliac disease even when there are no additional clinical clues pointing towards coeliac disease. We screened 371 female patients with suspected, but unexplained, osteoporosis and confirmed coeliac disease in five patients; two further patients were persistently positive for endomysial antibody but refused small intestinal biopsy. The findings have been submitted for publication.

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Hospital of the future

Health economics may be misleading

EDITOR—Posnett in his article asserts that "a close observer of the NHS ... might be forgiven for thinking that the debate about the concentration of acute hospital services has been driven more by the needs of NHS managers and the medical professions than by the needs of the local populations that they are supposed to serve."¹ As director of the York Health Economics Consortium, he explains that the apparent logic of rationalisation and mergers is not supported by the evidence. He argues that service planners would do well to give more prominence to the importance of ensuring that hospital services are local and easily accessible.

Fine words, but what about the rationalisation in Liverpool that followed the consortium's recommendations in 1992? In their review of accident and emergency and related acute services for Liverpool Health Authority, the economists confidently pre-

dicted that efficiencies in health care would reduce the number of beds needed by 500.

Moreover, by combining these efficiencies with predictions of diminishing health needs in a dwindling population, they concluded that, by 2001, Liverpool and its neighbouring districts would require up to 1000 fewer beds.²

Their case was supported by speculation that comprehensive care in the future would be more often delivered by general practitioners and—despite fierce opposition by local people and their doctors—it was accepted. The consequences have been dire. For want of beds anywhere in Liverpool, patients in the new “super” emergency department now routinely wait for 24 hours or more in conditions that make everyone miserable and angry. Even heroic efforts by the staff have not prevented care for many being seriously compromised.

The crisis here—as in so many other parts of the NHS—results primarily from undue reliance on untested health economic theories and prompts a number of questions. If transparent, evidence based practice and accountability are required of clinicians, should they not apply to health economists? The answer would matter little if this government—like its predecessors—did not so clearly depend on health economists to justify its policies. Indeed, much of the hostility towards doctors originates with the privileged health economists of York.³ Doctors’ requests for a cautious approach to NHS reforms are treated with scorn,⁴ but when will health economists render themselves accountable for the effects of their prescriptions?

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Maybe hospitals are not needed at all

EDITOR—With reference to Posnett’s article on concentration in the provision of hospital care,¹ outside operating theatres and intensive care units, the case for having hospitals rests on two assumptions: firstly, that there are advantages (either in terms of reduced costs or improved outcomes) to providing 24 hour care in a setting that encourages bed rest; and, secondly, that there are advantages (either in terms of reduced costs or improved outcomes) to having easy access to a range of other specialist staff. Our best estimate of the case for bed rest is that it is at best ineffective and at worst makes the outcome worse.² We all know how disorientating and incapacitating admission to hospital is for elderly people (and most patients are elderly). We also all know that social networks break down if admission is prolonged.

What is the case for economies of scope? There may be advantages in having a range of specialist services, but do these outweigh the disadvantages of cross infection and overinvestigation?

Emergency abdominal surgery is carried out in the same theatres as elective procedures. In other settings where sterility is important (such as the food industry), it would be unthinkable to allow faeces to be processed in the same building.

We are also all familiar with the way in which patients have unrelated and often quiescent problems “worked up” by specialists while they are in hospital. In the community, the general practitioner would deal with these problems, avoiding a great deal of unnecessary referral. Surely, with advances in technology making changes possible, it is time for us to rethink the settings in which care is provided? Or are we simply wedded to hospitals because they are the familiar institutions in which we were trained?

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Seasonality of birth in children with diabetes

Results of various studies differ

EDITOR—Rothwell et al have found evidence for seasonality of birth in children with diabetes from Great Britain but not elsewhere.¹ They do not, however, give ascertainment estimates for the centres participating in the study. Consequently, selection bias may play a part in their results, particularly in those centres with low case ascertainment.

Although this is a large multicentre study, the authors have not analysed the pooled data. They point out that sample sizes from many centres were too small to provide enough power for the seasonality of birth in these children to be assessed. It would be interesting to know if the analysis of the pooled data still showed a significant pattern.

The authors have previously shown evidence of seasonality of birth in children with diabetes in Scotland, Yorkshire, and England and Wales.² In contrast, the current report shows no evidence for this effect in children born in England and Wales, although the χ^2 value is greater than the one quoted in their previous paper. It is difficult to reconcile these two sets of data.

Rothwell et al also state that a similar pattern has been found in the Netherlands.³ The authors who reported the study there found that more boys with diabetes were born in April, May, and November but did not find an effect either for girls or for boys and girls combined.³ In contrast, Rothwell et al report a significant seasonal pattern of birth, with a peak in early summer and a trough in

winter.^{1,2} The pattern in Britain is clearly different from that in the Netherlands.

We have examined this phenomenon by the same methodology in our local register, the Cornwall and Plymouth children’s diabetes register.⁴ Children diagnosed with type 1 diabetes under the age of 16 were enrolled in our register, with 94.4% ascertainment. The analysis was of 417 children with diabetes born between 1970 and 1995. Our results showed that no significant seasonality of birth exists in the south west of England ($\chi^2 = 4.05$, $df = 2$, $P = 0.13$). This result is in line with results from Sardinia⁵ and some other European countries¹ but is contrary to the results presented by Rothwell et al. In our opinion, the evidence derived from such registers and its support for the environmental cause of childhood diabetes need to be assessed further.

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Maternally transmitted infection might increase risk of diabetes

EDITOR—Rothwell et al write that further studies are required to determine whether abnormal seasonality of birth exists in childhood diabetes.¹ Studies have been done in Israel,² China,³ and Japan⁴ of which the authors seem not to be aware. These studies support the hypothesis that in populations with a higher incidence of type 1 diabetes a maternally transmitted infection to the fetus or newborn infant increases the risk of their developing diabetes.

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Rationing certainly exists in treatment for cancer

EDITOR—I sympathise with the views given in the news item by Woodman about the report by the Campaign for Effective and Rational Treatment¹ and the letter by de Takats²: funding for both supportive treatment in cancer and cancer chemotherapy is inadequate in the NHS. In my own field of haematological oncology, decisions are made daily that deny either the most effective agents or those with fewest side effects solely on grounds of cost. It is no longer true (if it ever was) that the patient in front of me will receive the best care that I am capable of delivering; rather, he or she will receive the highest quality of care that is possible given what is affordable within the directorate.

Bisphosphonates to prevent bone disease in myeloma are a case in point. Two studies have shown their clinical efficacy.^{3,4} Their widespread use in my unit will cost an additional £75 000 a year. This has been identified as a substantial cost to our principal purchasers, who, while agreeing to their use, cannot provide additional funding. This results in the absurd situation where we ask sympathetic general practitioner colleagues to prescribe bisphosphonates, although the NHS financial burden would probably be less if they were prescribed by the hospital.

There are numerous other areas where we as doctors ration access to optimum treatment on grounds of affordability and conspire not to tell patients. In my own field the other drugs most frequently withheld are serotonin antagonists (for emesis), haematopoietic growth factors, purine analogues, rituximab, and liposomal amphotericin. I do not agree with Glynn-Jones that it is not “primarily a question of money”⁵; in my directorate it most certainly is. Despite constant vigilance our pharmacy budget has a projected overspend of £60 000 (annual budget £670 000) and there is considerable pressure within the trust to contain expenditure.

Those of us working in oncology have recognised for years that rationing exists in the NHS. I hope that some of these contentious areas may be resolved by definitive guidance from the National Institute for Clinical Excellence, although I doubt that such guidance will result in the release of additional funds. In the meantime should we not be more honest with our patients?

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Distress symptoms may be easy to miss

EDITOR—MacCorquodale's young woman with a wart on her nose was trying to transmit a distress signal on an unusual wavelength.¹ Whenever I hear of a suicide, especially an unexpected one, I wonder whether one of us in our profession failed to receive, or recognise, such a signal.

The suicide I have had on my conscience for 45 years was of a young man, an immigrant to Australia from central Europe. I had taken out his acutely inflamed appendix a few months before and had got to know him a little during his convalescence, so my failure to recognise his problem was all the more inexcusable.

He wanted to see me on a day when I was frantically busy. Everything seemed to be happening at once—two women in labour; an accident at a nearby factory, with several men needing stitches; and a waiting room full of patients. His complaint was that he couldn't get a date with a girl he was attracted to and thought he must smell. I saw him in the hall, not my office, and was brusque, telling him not to bother me with such a trivial problem when he could see how busy I was. He turned and walked quietly away.

Next morning I was called by the police, wanting to know what he had seen me about. He had a receipt from the receptionist for an office visit on the previous afternoon, and that night he had put the barrel of a rifle in his mouth and pulled the trigger. I knew instantly what a terrible wrong I had done him, but no amount of lamentation could restore him to life.

I hope I never again failed to recognise distress signals transmitted on unusual wavelengths. In my teaching of medical students I have often told this story of his needlessly wasted life—not to atone for my missed diagnosis but in the hope that others may learn from my terrible mistake.

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Centralisation of cancer services in rural areas has disadvantages

EDITOR—Smith describes “disproportionate time and energy” being spent in “a battle over surgical services” in Dumfries and Galloway.¹

In our rural practice of 2700 patients 32 cases of cancer were identified over 2.5 years. When travel to local services was excluded the 32 patients travelled on average 1479 km—over 20 hours by private car. Eleven died of their disease over that period and travelled an average of 1880 km, taking nearly 30 hours. No one chose ambulance transport, but six had to rely on it as their sole method of transport and three used a mixture of

ambulance transport and private car. One 84 year old patient who was receiving radiotherapy described a 7.5 hour one way journey by the patient transport service from Edinburgh to Stranraer. Even by car this would have taken over three hours.

Patients who died survived an average 165 days, of which 22 days (13% of their remaining life) was spent travelling to or in remote (by rural perspective) hospitals.

One third of Scotland is regarded as rural. Proposed centralisation of cancer services² places an extra burden on patients already frail from cancer or the effects of treatment. Will they benefit? Extrapolating our figures to the Wigtownshire district suggests that 482 800 km of patient travel occurs a year and 5800 inpatient days are spent in a cancer hospital more than three hours' travel from home. Four people from Stranraer have been killed in traffic accidents while visiting relatives in the past 15 years.

Solutions include developing and improving use of community resources; better personal communication and cooperation between specialists and general practitioners; block clinic bookings, allowing transport to be shared; and mobile facilities for imaging, investigations, or treatment. Patients travelled to Edinburgh rather than Glasgow for treatment (an extra 113 km) for reasons that did not seem to be patient centred. Telemedicine seems to have made little impact on travelling.³

Rural patients suffer the financial penalty of having to travel large distances. This is compounded by social and emotional deprivation caused by separation from home and friends. They have to balance spending 13% of their remaining life in a distant and lonely hospital against benefit from unpleasant and painful treatment. Visitors find the travel expensive and inconvenient.

Where cancer services are provided locally the uptake of treatment increases.⁴ If equity of access is important⁵ then where such barriers to treatment exist and services are made less, not more accessible, we have to strain to be optimistic.

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Rapid responses



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