

Letters

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Medical errors See also p 1413

Analysis of adverse events must result in improvements in care

EDITOR—In his editorial on medical errors Alberti mentions studies of adverse events from Australia and the United States.¹ He then welcomes a paper by Vincent et al²: “Finally, we now have some British data from London based on retrospective record reviews” (of 1014 patients in two acute hospitals in London).

In 1980 colleagues and I published a detailed audit of adverse events occurring in 2607 inpatients treated by one surgical firm at the Radcliffe Infirmary in 1978.³ Major, moderate, and minor adverse events in adults and children were recorded prospectively, and we made suggestions (which we hoped would be noted by clinicians and administrators) that might encourage wider adoption of this type of investigation so that clinical care might be improved.

In 1990 I wrote an editorial in the *BMJ* on the findings of the 1989 national confidential enquiry into perioperative deaths (within 30 days of surgery) among children aged under 11.⁴ The editorial's concluding sentence was: “If clinical information services are improved ... then an

even more formidable task may lie ahead: the investigation of perioperative morbidity.”

In 2000, England's chief medical officer suggested that a national system for recording adverse events should be set up.⁵ This suggestion has Alberti's support, although he describes it as an enormous undertaking. I hope that we will not have to wait yet another decade before the analysis of data concerning adverse events leads to action being taken to improve care. Prompt action by the Department of Health to provide the resources necessary for this initiative would go some way to compensate for the previous delays.

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- 1 Alberti KGMM. Medical errors: a common problem. *BMJ* 2001;322:501-2. (3 March.)
- 2 Vincent C, Neale G, Woloshnowych M. Adverse events in British hospitals: preliminary retrospective record review. *BMJ* 2001;322:517-9. (3 March.)
- 3 Gough MH, Kettlewell MGW, Marks CG, Holmes SJK, Holderness J. Audit: An annual assessment of the work and performance of a surgical firm in a regional teaching hospital. *BMJ* 1980;281:913-8.
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- 5 Department of Health. An organisation with a memory: report of an expert group on learning from adverse events in the NHS. London: DoH, 2000.

Organisational ethos is important

EDITOR—Alberti highlights the possible magnitude of the problem facing the NHS with regard to medical error, but he makes little mention of clinical governance.¹ In its definition of governance the Department of Health includes the words “safeguarding of high standards of care by creating an environment in which excellence in clinical care will flourish.”² The organisational ethos is paramount.

Those responsible for clinical governance in trusts must ensure that it becomes the catalyst for improving standards (based on a system of praise and reward) and not a catalyst for a blame culture. A trust-wide audit of clinical notes or prescribing will almost certainly identify individual clinicians who seem to be risk takers with such fundamental aspects of clinical practice. These clinicians must be identified and educated in good practice; these are potential rather than fulfilled adverse events.

The Institute of Medicine's Committee on Quality of Health Care in America has identified why errors arise in clinical care in North America.³ The underlying message in the United Kingdom, however, is for organi-

sations, not individuals. Organisations must get the governance process and hence the ethos right.

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- 2 Department of Health. *A first class service*. London: DoH, 1998.
- 3 Institute of Medicine. *To err is human: building a safer health system*. Washington, DC: National Academy Press, 2000.

System for reporting errors is not highest priority to decrease errors

*Knowing is not enough; we must apply.
Willing is not enough; we must do.*

Goethe

EDITOR—I cannot agree with Alberti's conclusion that a reporting system is our main priority.¹ The report by the Institute of Medicine in the United States focused on the unacknowledged high level of medical errors and the need to transform the system to improve patient safety.² Only a small element was devoted to reporting systems; many of the contributors are alarmed at how this aspect of the system has been overemphasised.³

A reporting system would certainly allow research into errors, but medical errors are not fundamentally due to lack of knowledge—we already know far more than we put into practice. By talking to colleagues, Alberti could easily find two years' work to improve safety without such a database. Unfortunately, simple measures of known effectiveness are often ignored: changes to improve patient safety could begin at once on the basis of currently available knowledge.⁴

Organisations with successful reporting systems for errors are way in advance of health care in terms of safety.⁵ The airline industry has already sorted out the most pressing problems and is now looking for less obvious ones through reporting systems. Medicine has plenty to do now, and reporting systems are not the highest priority. The next step is for the medical establishment to agree what it can do to build a safer system and then do it.

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- 2 Institute of Medicine. *To err is human: building a safer health system*. Washington, DC: National Academy Press, 2000.
- 3 Leape LL. Reporting on medical errors: time for a reality check. *Qual Health Care* 2000;9:144.
- 4 Leape LL, Berwick DM. Safe health care: are we up to it? *BMJ* 2000;320:725-6.

Advice to authors

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Responses should be under 400 words and relate to articles published in the preceding month. They should include ≤ 5 references, in the Vancouver style, including one to the *BMJ* article to which they relate. We welcome illustrations.

Please supply each author's current appointment and full address, and a phone or fax number or email address for the corresponding author. We ask authors to declare any competing interest. Please send a stamped addressed envelope if you would like to know whether your letter has been accepted or rejected.

Letters will be edited and may be shortened.

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5 Barach P, Small S. Reporting and preventing medical mishaps: lessons from non-medical near miss reporting systems. *BMJ* 2000;320:759-63.

Media tend to link error with blame

EDITOR—The Editor's Choice of 3 March emphasises the importance of establishing the frequency of medical errors.¹ The greater goal, however, is to achieve the changes of culture that will enable us to learn more from errors and improve practice. That is not easy, particularly in the face of media attitudes linking error with blame.

Harper's one sided account of events in Brighton is regarded as unhelpful locally.² Brighton Health Care NHS Trust, like many trusts, receives a number of clinical incident reports each week. There is no dispute with Doctor A over that. He has spoken openly to me and several colleagues about his concerns.

All the cases that he refers to were the subject of clinical incident reports. In each case the error was discovered during routine checking procedures, and no patients were harmed. Practice has been changed as a result of those incident reports. Arguably this is an example of effective clinical governance processes rather than a failure of reporting procedures. I expect that there is underreporting, but Doctor A has not told me of any such instance.

The background to my press release was intense media interest in three incidents (two of which did not cause patient harm) and the suggestion following Doctor A's interview that medical errors were causing death on a daily basis in Sussex hospitals. Patients were losing confidence in our services, and staff morale was threatened.

I said that "clinical errors, like that currently being investigated, are not an everyday occurrence in Brighton." I was referring to the fatal incident in which, in the words of our press statement, "a drug, bupivacaine, which should have been delivered epidurally after the operation for pain control, was injected, in error, into the patient's vein." I do not understand how Doctor A's saying that bupivacaine was administered instead of a plasma expander contradicts our press statement.

Sensational reporting may make clinicians less likely to report clinical errors and lose us chances to learn. Perhaps it would have been less alarmist in the Editor's Choice to say that Vincent et al's paper showed that error may have contributed to death in 8% of cases³ rather than that "a third of [adverse] events lead to moderate or greater disability or death."

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- 1 Editor's choice. Medical error: creeping from words to action. *BMJ* 2001;322(7285). (3 March.)
- 2 Harper A. Blunders will never cease. A risky business. *BMJ* 2001;322:562. (3 March.)
- 3 Vincent C, Neale G, Woloshynowych M. Adverse events in British hospitals: preliminary retrospective record review. *BMJ* 2001;322:517-9. (3 March.)

Perhaps blame-free culture is needed in NHS to reduce errors

EDITOR—Johnson makes valid points about comparing safety systems in medicine and aviation, and some of his suggestions might be worthwhile pursuing.¹ I will continue his analogy between medicine and aviation.

There are some branches of medicine in which not only is the doctor the only pilot on the flight deck but he is flying in a converted second world war bomber with questionable reliability. I would dearly love to fly in such an aircraft, but whether I would choose to fly in one to the United States is another matter. The airlines (the NHS in this case) are unable to afford to replace the aircraft regularly. And who flies the plane when the pilot is away being updated? The passengers (patients) don't like being kept waiting, and often there are no spare pilots.

Johnson speaks of the data collected on adverse incidents in the aviation industry, but where are these data? An industry insider tells me that some airlines regularly fly with aircraft that are mechanically dangerous. Which airlines? Which is the world's worst airline or most dangerous airport? Can I find out? Is there an aviation or pilots' league table similar to the hospital league tables that we hear so much about? And just how much choice do I get over who flies me when I next board a plane? I rarely get a choice of seat or meal, let alone pilot.

In my field, histopathology, error rates are considerably lower than those in other branches of medicine, and systems have long been running to minimise these. Mistakes do, however, occur; when they do, consultants may be suspended or lose their jobs, and the media reaction is unforgiving and predictable. Disclosure of the mistake to the patient may cause legal proceedings to be started. There is not much incentive, then, to own up.

I look forward to the day when a blame-free culture exists in the health service, but—as events in the past couple of years have shown—that day seems a long way off.

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- 1 Johnson D. How the Atlantic barons learnt teamwork. *BMJ* 2001;322:563. (3 March.)

Terminology of "error" is important

EDITOR—At least some of the media's response to Alberti's editorial results from his failure to clearly define the terms "error" and "adverse event."¹ This illustrates the need for a clear and common understanding of the terminology of risk management.

Sheikh and Hurwitz have defined error as either the failure, for reasons that are preventable, of a planned action to be completed as intended (error of execution) or the use of a wrong plan to achieve an aim (error of planning).² An adverse event is an injury caused by medical management rather than the patient's underlying condition and may or may not be attributable to an error. The terms "significant event" and

"critical incident," though not used by Alberti, also have specific and different meanings.

Does it matter? The blame culture of the NHS still exists, and these terms each carry a different potential for blame. Healthcare professionals will be suspicious of any risk management initiative that confuses their use.

Errors are probably no less common in primary care than in secondary care, although the prevalence of adverse events in a primary care study in the United States was only 3.7/100 000 clinic visits.³ Relatively few errors in primary care lead to serious adverse events. When they do, practices are increasingly using significant event audit as a means of evaluation. By concentrating on the detection of errors we have the opportunity to identify and remedy system faults without evoking blame.

Just as the successful introduction of clinical governance depends on a peer led, supportive philosophy, so the process of learning from our mistakes will be most effective if it develops in a similar, non-threatening way.

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- 2 Sheikh A, Hurwitz B. Setting up a database of medical error in general practice: conceptual and methodological considerations. *Br J Gen Pract* 2001;51:57-60.
- 3 Fischer G, Fetters MD, Mumro A, Goldman EB. Adverse events in primary care identified from a risk management database. *J Fam Pract* 1997;45:40-6.

Errors can have their uses

EDITOR—Alberti reflects on why it is so hard to persuade people to report medical errors.¹ Since 1999 the *Lancet* has collected² (and it now publishes³) self declared errors to help doctors change the blame culture that Alberti rightly deplores. The journal has had a tremendous response from readers. There are clear signs that a cultural change is taking place, with openness being welcomed as both an educational and a liberating experience.

I look forward to Alberti's own contribution to this section as part of a wider effort to, in his words, "improve our practice to the ultimate benefit of the public."

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- 1 Alberti KGM. Medical errors: a common problem. *BMJ* 2001;322:501-2. (3 March.)
- 2 Horton R. The uses of error. *Lancet* 1999;353:422-3.
- 3 Horton R. We all make mistakes: tell us yours. *Lancet* 2001;357:88.

Courses on crisis avoidance and resource management are available

EDITOR—We are concerned that both Alberti and Johnson give the impression that crew resource management is not practised in medicine in the United Kingdom.^{1 2} All four simulation centres in the United Kingdom are currently running courses incorporating the principles of such man-

agement for anaesthetists. Indeed, over one third of trainee anaesthetists in the United Kingdom receive annual training in this; this figure does not take into account career grade anaesthetists or trainees from other specialties who have attended such courses.

The Scottish Clinical Simulation Centre has strong research links with the department of psychology at Aberdeen University. The industrial psychology group there has extensive experience of training in crew resource management in aviation and many other industries, including nuclear and offshore industries. Working in collaboration with this group, we have created a course for doctors, entitled crisis avoidance and resource management. The name highlights the emphasis that we place in the early part of the course on using the systems approach to identify and deal with latent errors.

Other aspects of the course address the issues of situation awareness, communication, leadership, decision making, and team working skills—the human factors that can help reduce the incidence of human error and mitigate the consequences of any errors that do occur. The course has been piloted on trainee anaesthetists, with overwhelmingly positive feedback, and is now integrated into the five year specialist registrar training programme in anaesthesia in Scotland

Our centre is a national resource funded by the Scottish Council for Postgraduate Medical and Dental Education. We are now extending the availability of such training to all medical and dental trainees in Scotland—some 10% of trainees in the United Kingdom. It is important that everyone in medicine, and members of the public, are aware that the issue of medical error is being taken seriously in the United Kingdom and addressed in a positive manner.

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2 Johnson D. How the Atlantic barons learnt teamwork. *BMJ* 2001;322:563. (3 March.)

Different formulations of drugs often look confusingly similar

EDITOR—The Editor's Choice of 3 March highlights the articles in that issue of the *BMJ* that discuss medical errors.¹ Some common medical errors are routinely ignored despite frequent and serious adverse effects for the patient. Use of the antiepileptic carbamazepine is particularly problematic as the drug is often most effective when used at doses approaching the maximum tolerated, and a change from controlled release to standard formulation of the same tablet strength can precipitate intoxication.

Such inadvertent substitution of different formulations of carbamazepine is, in our experience, common in hospitals. It is also a problem in primary care. We recently solicited reports of problems with carbamazepine from readers of *Epilepsy Today*,

the magazine of the British Epilepsy Association.² We received 30 replies detailing episodes of overdosing and (less commonly) underdosing with carbamazepine, several with serious consequences to the patient. Sequelae included loss of control of diabetes, loss of driving licence, admission to hospital, and time off work.

Analysis of the errors showed that more than half were dispensing errors, some of which were attributable to the similarity of packaging between formulations of Tegretol of different tablet strengths and pharmacokinetic properties. Some of the reported problems could have been avoided by education of the prescribing medical practitioner. Patients have become so used to the supply of generic equivalent drugs which differ subtly in size, shape, or colour from what they expect that they cannot recognise dispensing errors themselves.

Pharmaceutical companies should consider the possibility of confusion between different formulations of a drug when designing packaging, and be aware that brand image can be at the expense of patient safety.

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2 Mack CJ, Kuc S, Grünewald RA. Errors in prescribing, dispensing and administration of carbamazepine: a case report and analysis. *Pharm J* 2000;265:756-9.

Appropriate training should avoid accidental intrathecal injection of vincristine

EDITOR—Various suggestions have been made about how systems of work, packaging, and labelling of drugs and equipment could be improved to decrease the risk of accidental intrathecal injection of vincristine.¹ Most of these suggestions have merit and if adopted as part of a multifactorial approach would undoubtedly help to reduce risk. Two points, however, deserve vigorous challenge.

The first is the suggested use of negative labelling on vincristine syringes or, indeed, any other drugs. Despite knowing that the Medicines Control Agency take a different view, we believe this is fundamentally wrong and as likely to cause an accident as prevent one. In the case of vincristine or any other vinca alkaloid, the safest label is one that clearly states "for intravenous use only" and on which the word intrathecal does not appear at all. To include phrases such as "not for intrathecal injection" or "fatal if given intrathecally" is courting disaster. It may create a subliminal association between the name of the drug and the routes of administration listed. Fail to read the word "not" in the first phrase or to note more than intrathecal in the second and yet another almost certain death is imminent. Furthermore, where should the list of prohibited routes of administration stop? An accidental intramuscular dose of vinca alkaloid may not be fatal but nevertheless causes serious harm.

Our second concern is that none of the measures suggested for improving ease of identification of otherwise similarly presented drugs mentions the single most critical variable that must be addressed as part of the safety equation: the absolute necessity of reading the label. We fully accept that, despite the prolonged and enthusiastic efforts of hospital pharmacists over many years, standards of manufacturers' labelling often leave much to be desired. Yes, of course, small print and similar or nearly identical packaging designs make the chance of confusion greater. There can only ever, however, be one genuinely unique identifier of the contents of a medicine package of any sort: the drug name. The central focus of our efforts must be to make sure that the approved name is as prominent and legible as possible. We should do nothing to detract from this and everything we can to facilitate it.

As far as haemato-oncology practice is concerned, there is one thought which should now give us some confidence. No appropriately trained doctor who has actually read vincristine on the label (which in this case is unlikely to be the manufacturer's but one generated locally by the hospital pharmacy) is likely to inject the contents intrathecally into his or her patient.

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1 Correspondence. Not again! *BMJ* 2001;322:548-9. (3 March.)

Dosage nomenclature of bleomycin needs to be standardised to avoid errors

EDITOR—The consequences of errors involving anticancer drugs can be devastating. As correctly detailed by Seale, errors arise not only from inadequate time and training and supervision of medical staff but also from poorly written or ambiguous protocols.¹ Such ambiguity is associated with the dosage nomenclature for bleomycin. Published protocols give bleomycin doses in milligrams (mg), international units (IU), or United States Pharmacopoeia units (USP units). This inconsistency in nomenclature seems to be universal and can lead to incorrect interpretation of medical literature.

Historically, bleomycin dosage has been described in terms of milligram potency (mg potency), in which 1 mg potency corresponded to 1 unit. In the original preparations 1 mg potency was also equivalent to 1 mg by weight (mg weight). Modifications and improvements in purification over time have meant that ampoules labelled as containing 15 mg—that is, 15 units—contained less than 15 mg weight of bleomycin.²

In 1995 labelling of bleomycin products in Australia changed from USP units to IU in line with changes in the *British Pharmacopoeia* and *European Pharmacopoeia*. The 10 mg vial, formerly labelled as containing 15 USP units, is now labelled as containing 15 000 IU. This

has resulted in considerable confusion when older protocols are used or when referring to literature from the United States. Currently, the *British Pharmacopoeia* and *European Pharmacopoeia* specify 1500 IU per mg, while the *United States Pharmacopoeia* specifies 1.5-2 USP units per mg.²⁻⁴ Protocols that give bleomycin in mg or mg/m² refer to mg potency, not mg weight. Therefore, 1.5-2 USP units is equivalent to 1500 IU, which is equivalent to 1 mg (by weight) or approximately 1.5 mg (by potency).

Considerable problems arise when bleomycin nomenclature is stated as mg or mg/m². We have anecdotal evidence of patients prescribed bleomycin 30 mg as part of the bleomycin, etoposide, cisplatin protocol (BEP), erroneously receiving 45 000 IU. In the original protocol the total dose of bleomycin is specified as 30 units.⁵ This refers to 30 mg potency (not 30 mg weight), which is equivalent to 30 USP units or 30 000 IU.

This highlights the essential need for bleomycin dosages to be stated in terms of units (USP units in the United States or IU in Europe, the United Kingdom, and Australia), and not as mg or mg/m². Otherwise, the risk of misinterpretation, incorrect conversion, and potential overdose of bleomycin is considerable. Standardisation of dosage nomenclature is one way of minimising errors with cytotoxic chemotherapy.

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- 1 Seale JRC. Not again! *BMJ* 2001;322:548. (3 March.)
- 2 Parfitt K, ed. *Martindale. The complete drug reference*. 32nd ed. London: Pharmaceutical Press, 1999:507-9.
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Chemotherapy regimens have been formalised into protocols in British Columbia

EDITOR—Cancer chemotherapy is a discipline in which the risks of error need to be minimised.¹ Treatment regimens are often complex, involve very toxic agents, and require special precautions in preparation and administration to protect the health workers. In British Columbia we have formalised many chemotherapy regimens into protocols to ensure that adequate and appropriate information is readily accessible by those prescribing, preparing, and administering chemotherapy.

Each protocol is a concise but accurate summary of the treatment regimen and fol-

lows a standard format. Each has a unique protocol code (indicating tumour site and drugs used), eligibility and exclusion criteria for the treatment, baseline and ongoing clinical and laboratory tests, treatment regimen, dose modifications, premedications, precautions, the name and telephone number of the doctor responsible for the protocol, and revision date.

Each protocol is reviewed by an oncology doctor, pharmacist, and nurse for the adequacy, appropriateness, and potential misinterpretation of the information. To enable easy access, the protocols are available on our local area network and internet website (www.bccancer.bc.ca). To date, we have developed over 160 protocols, covering 13 major tumour groups and supportive care.

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1 Editor's choice. Medical error: creeping from words to action. *BMJ* 2001;322 (7285). (3 March.)

Medical schools can teach safe drug prescribing and administration

EDITOR—The medical world has been slow to realise the importance of drug errors as a cause of morbidity and mortality. The numerous instances in England where doctors have injected vincristine intrathecally, not intravenously, underline this.¹ Woods has now produced a report on intrathecal medication errors for the United Kingdom Department of Health.² It recommends that medical schools should ensure that their core curricula provide a thorough knowledge of safe drug prescribing and administration and that there should be proper assessment. We strongly endorse these recommendations.

In Birmingham we have for several years helped final year medical students learn practical therapeutics by interactive teaching based on clinical problems. We examine students' knowledge after a course of "therapeutics roadshows" by multiple choice questions. In addition, we and a clinical pharmacist lecture aspiring house officers on the sorts of errors in prescribing and giving medicines that are commonly encountered.

Students who are expected to transmute overnight into doctors often lack practical preparation. Teahon and Bateman found that many house officers felt unprepared to give intravenous treatment, and many admitted to making errors.³ Unfamiliarity greatly increases the chances of error.⁴ Nearly two years ago we introduced an objective structured clinical examination in therapeutics to test rudimentary skills, in addition to the test of knowledge. Part of the examination presents clinical vignettes of conditions such as myocardial infarction, asthma, and severe pain and asks students, for example, to write a suitable prescription or submit an adverse drug reaction report. Some questions have required the administration of

drugs by intravenous injection, nebuliser, or an automatic injector (as used at cardiac arrests). Others have asked students to give specific practical advice to a patient receiving, say, sublingual glyceryl trinitrate for angina or an inhaler for asthma.

In addition to small group teaching on writing prescriptions and giving intravenous injections, students are encouraged during their final medical attachments to write prescriptions to be countersigned by trained medical staff and to take a practical part in the administration of drugs. We suspect that our students are now better equipped to cope with the demands of practical therapeutics as house officers: the average percentage score in a test of reconstituting and administering an intravenous injection has risen steadily from 48% in 1999 to 72% in 2001.

A practical test of simple therapeutic skills such as writing prescriptions and giving injections ensures a minimal level of competence in junior doctors. Although changes to the systems of prescribing and giving drugs will also be needed, better practical training and assessment may help to protect patients from the tragic consequences of drug errors.

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- 1 Dyer C. Government to introduce safer administration of cancer drugs after fatal error. *BMJ* 2001;322:1013. (28 April.)
- 2 Woods K. *The prevention of intrathecal medication errors. A report to the chief medical officer*. London: Department of Health, 2001.
- 3 Teahon K, Bateman DN. A survey of intravenous drug administration by pre-registration house officers. *BMJ* 1993;307:605-6.
- 4 Ferner RE, Aronson JK. Medication errors, worse than a crime. *Lancet* 2000;355:947-8.

Medical profession must take drug errors seriously

EDITOR—Errors relating to drug treatments are common and can arise from various sources.¹ Ferner considered a selection of mistakes and slips that led to fatal outcomes,² but the vast majority of errors are less serious and may therefore remain undetected.

Correct patient identification and clear written prescriptions are important components of the safe administration of drugs in hospital. Few studies, however, have considered how frequently these basic requirements are adequately met. I performed an observational audit in a busy district general hospital in Essex, looking at all of the drug charts in the hospital on one defined day to ascertain whether the basic requirements for safe prescription had been fulfilled.

Altogether I examined 317 (85%) of the drug charts in the hospital. A medication error was noted if the relevant information was missing, unclear, illegible, or incorrect. Only 51 of the charts were completely correctly filled in. The number of correctly

Most common types of errors overall. Data are missing unless stated otherwise

Type of error	No (%) of charts with error
Frequency in "as required" section	59 (19)
Prescription changed, entry not clear	40 (13)
Doctor's signature	39 (12)
Date of birth	37 (12)
Hospital number	37 (12)
Consultant's name	37 (12)
Dose of drug	29 (9)
Name of drug	25 (8)
Reason why prescribed drug not given	22 (7)
Date of prescription	20 (6)
Time of administration	11 (3)
Route of administration	10 (3)
Not clear why drug discontinued	3 (1)
Other	27 (9)

completed charts by subsection was: demographics subsection, 138; allergy box, 154; once only drugs, 182; regular drugs, 192; and as required drugs, 205. The most common error was an empty or illegible allergy box, in 51% of the charts. The table shows the next most common errors. Altogether 689 individual errors were noted (an average of 2.2 per chart). If even 1% of the errors found on the day of this study had led to a serious error seven adverse events might have occurred.

Many strategies to improve safety in the prescription and administration of drugs have been described and validated in clinical practice.³ Both low and high technology measures exist. It is time for the medical profession to take drug errors seriously and push forwards urgently with a multifaceted approach to improve safety.

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- 2 Ferner RE. Medication errors that have led to manslaughter charges. *BMJ* 2000;321:1212-6. (11 November.)
- 3 Bates DW, Leape LL, Cullen DJ, Laird N, Petersen LA, Teich JM, et al. Effect of computerised physician order entry and a team intervention on prevention of serious medication errors. *JAMA* 1998;280:1311-6.

Consent is outdated concept

EDITOR—Medical errors will always occur,¹ and inevitably debate will focus on whether truly informed consent was obtained from the patient. Much of the confusion surrounding this stems from the concept of consent itself.

In the past decade the doctor-patient relationship has changed radically. Unfortunately, the concept of consent has not. The doctor should not now decide the patient's treatment but should act as an adviser, explaining and giving the patient all the information necessary so that he or she can make the decision. This position is made clear by the General Medical Council, which states: "The patient [that is, not the doctor] makes an informed decision on treatment."²

For doctors still to seek consent from patients—seeking permission to perform a treatment or an investigation—directly contradicts this aim. Today the opposite applies: the patient seeks information and advice and then decides on the treatment he or she would like. The only way to "ensure voluntary decision making"² is not for patients to give consent to a treatment but for them to request a treatment.

The process of gaining consent from a patient is an outdated concept. Consent does not allow the patient to make it clear that he or she has decided on a particular treatment, and this lack of clarity will always act as a potential area of confusion, especially with regard to responsibility. It is the role of the doctor to advise, explain, and inform the patient and, if appropriate, perform the treatment that the patient has chosen.

The term "informed consent" for treatment should be replaced by "informed request" for treatment. Only then can patients be fully empowered, and with that power comes self responsibility.

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Adverse events in British hospitals

Preventive strategies, not epidemiological studies, are needed

EDITOR—Vincent et al estimated that about 11% of hospital admissions in two hospitals were associated with an adverse event and argue for a larger study to document the prevalence of such adverse events in the United Kingdom.¹ Their estimate of adverse events occurring in hospital is well within the statistical boundary of previous estimates obtained by much larger studies in the United States² and Australia³; their argument for yet another large study therefore seems weak. Sufficient evidence already exists; there is an urgent need now for strategies to prevent or reduce the error, not for another descriptive epidemiological study.

Death, cardiac arrest, and unplanned admissions to an intensive care unit are probably the most serious among the adverse events. Most of these events have their genesis in general wards; they are not sudden or unpredictable, because they are usually preceded by signs of clinical instability. Because of this, medical emergency teams have been developed and tested.⁴

The system has three components: identifying high risk patients at an early stage; providing a rapid response; and providing feedback data on the effectiveness of the medical emergency team. Under this system,

when a patient's clinical condition is unstable (as judged by specific criteria) a call is immediately made to the team for intervention. We postulate that the system is an effective strategy to reduce adverse events occurring in hospital.

In a prospective study conducted in a 300 bed tertiary referral teaching hospital in Melbourne, after the medical emergency team system was implemented the incidence of cardiac arrest was halved (unpublished data). Moreover, in a six month prospective study the incidence of cardiac arrest, deaths, and unplanned admissions to the intensive care unit in one hospital with a medical emergency team was lower than the incidence in two hospitals without this system; after adjustment for case mix, however, a significant difference was observed only in the rate of unplanned admissions to the intensive care unit.⁵

Further randomised controlled studies of several hospitals are required for systematic evaluation of the effectiveness of having a medical emergency team. Such a study is under way in Australia and New Zealand, and we suggest that a similar strategy and study should be considered by the NHS.

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"Errors meetings" in radiology did not identify errors leading to complaints and litigation

EDITOR—Vincent et al report that 10.8% of patients experienced an adverse event in hospital.¹ The importance of medical errors and what can be learnt from them is being increasingly recognised.² Rather than undertake yet further research to describe the scale of the problem we need to design and evaluate interventions to reduce these errors.

Errors in diagnostic radiology have been recognised and analysed for many years.^{3,4} The Royal College of Radiologists has recommended "errors meetings" for radiologists, at which mistakes can be discussed and learnt from. We reviewed the results of two years of self reporting of radiological errors in Bradford to determine how many of these errors resulted in litigation or adverse clinical outcomes.

Roughly 200 000 examinations were reported annually by nine radiologists. During 1998 and 1999 all the reported errors that were identified from repeat examinations or by clinicians were reviewed by one of us (SC). Minor errors were discarded. The remainder were reviewed anonymously in errors meetings and the lessons discussed. Complaints and litigation cases in the department were also reviewed for the years 1998-2000.

Altogether 35 major errors were reviewed by all radiologists; most were reported by the person who made the error. None resulted in complaint or litigation, and none of the complaints or legal cases that were reviewed could be traced back to reported errors.

One of the main justifications for risk reporting and management strategies is to reduce complaints and malpractice claims. We found no evidence that a self reporting system achieved this. The number of identified errors reported was small in comparison with the number of examinations carried out. Experience of errors meetings at other hospitals suggests that this number is typical. It is inevitable that many other errors occurred that were not identified or not reported.

The errors meetings did lead to the implementation of two changes in practice, which were minor issues of protocol. They also provided a forum for education and debate. But whether they resulted in better practice or reduced subsequent errors is unclear, and claims to the contrary should be evidence based. It may be that the wrong errors continue to be reported.

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Hospital acquired infections consume bed days and resources

EDITOR—Vincent et al commented that the epidemiology of adverse events has not been studied in Britain.¹ Neither their paper nor the additional information on the *BMJ* website provides detailed information on what constitutes an adverse event. From the example given, however, it seems that hospital acquired infections were included in this category.

It would have been interesting to know whether all hospital acquired infections were classified as adverse events or whether some were excluded because they were viewed as unfortunate consequences of the disease process. Information exists on both the epidemiology of hospital acquired infections² and the economic burden imposed.³

The paper reports that 46% of the adverse events identified were judged preventable and that preventable events cost the NHS around £1bn a year in terms of additional bed days. It would be interesting to know what proportion of these preventable events were hospital acquired infections and how this judgment was made.

Recent subjective estimates suggest that 15% of hospital acquired infections could be prevented through improvements in infection control,⁴ but more objective data suggest that it might be twice this figure.⁵ If 15% were prevented then, on the basis of recent estimates of the economic burden of hospital acquired infections, the prevention of this type of adverse event alone would result in the release of at least 546 000 bed days and resources valued at £150m.

These estimates are limited to hospital acquired infections occurring in adults admitted to selected specialties of NHS hospitals in England for non-day case procedures (roughly 70% of adult non-day case admissions).³ The overall number of bed days and resources released from the prevention of this adverse event are therefore probably considerably higher.

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Threshold used for determining adverse events is important

EDITOR—At first sight the results of Vincent et al's study are alarming: the rate of adverse events reported is 16.6% for Australia, 10.8% for the United Kingdom, and 3.7% for the United States.¹ Measuring the extent of adverse events and taking action to reduce them are certainly important, but the measures used should be reliable and reproducible.

It should be noted that the death rates are in the reverse order, being highest in the United States; they are 13.6% there, 8% in

the United Kingdom, and 4.9% in Australia. When plotted in a graph these figures provide an almost straight line.

The most likely methodological problem is the determination of the threshold for adverse events, with a high threshold providing small numbers of serious events and a low threshold providing large numbers of minor events. The general population, particularly in Australia and the United Kingdom, needs to be reassured that the healthcare standards in these two countries are unlikely to be inferior to those in the United States to the extent suggested by the studies used for comparison. The thresholds that the authors used for each study were different.

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Adverse events may occur whatever course of action is pursued

EDITOR—Vincent et al's paper draws attention to possible ways of improving practice.¹ No mention is made, however, of what might be called "no win" situations—those in which there is a high chance of an adverse event occurring whichever course of action is pursued. As far as we can ascertain from the criteria for adverse events given on the *BMJ*'s website, no allowance was made for this. However, it is important to acknowledge such a problem when commenting on the findings.

Even in the example of an adverse event given in the paper there is an element of this dilemma. Osteomyelitis as a complication of leg ulceration is probably quite rare, whereas the apparently preferred option of more aggressive management with antibiotics could have resulted in considerable complications.

Older people often have multiple diseases and are therefore particularly prone to develop adverse events. Should you increase treatment for cardiac failure in someone with renal impairment and risk precipitating frank renal failure (adverse event of commission) or risk the patient dying from undertreated cardiac failure (adverse event of omission)? Comparisons with civil aviation procedures seem popular in relation to adverse events and risk reduction. Perhaps we could suggest to patients: "We are flying a rather old and unreliable aircraft. Would you rather crash here or there?"

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Authors' reply

EDITOR—Our study was always intended to be a preliminary study to establish the feasibility of the method in a British context; we could not present a full rationale for the current methodology or a national study in a short paper.

Several authors suggest that a national study is unnecessary; this is a view clearly shared by the Department of Health. The argument is that we should get on with reducing errors rather than worry about describing the problem. It is hard to think of any other major public health problem for which this argument would be taken seriously. In the case of heart disease or road accidents no one would argue that we did not need to know the incidence, the major causes, and the costs to individuals and society. Such information is seen as essential for clinical and policymaking purposes. As Chakraverty et al point out, it will never be reliably obtained from incident reporting systems, which have a different purpose.

We agree that simply assessing the incidence of adverse events on a larger scale would not be worthwhile. Our full proposal set out a clear rationale for establishing the incidence of adverse events, establishing the causes and costs of different types of adverse event, developing a stronger causal analysis, and costing methods of prevention. Although it now looks unlikely that a national study will be funded, we are continuing to work on the review process to enable a stronger analysis of causes and costs of adverse events to be used at local level.

Several of the letters describe innovative methods of prevention. A national study would greatly help a sustained attack on these problems, but there is no need to wait for such a study if problems have already been clearly identified. As with all major health problems, many different types of studies are required, together with action at both a local and a national level.

One methodological improvement that we intended for a later study was to include a classification of the main types of adverse events, to improve reliability and enable more precise assessment of costs. We hoped that this would address the problem identified by Collopy and McDonald, which is that the Australian reviewers included many more minor events than the American reviewers. We agree that comparisons between the adverse event rates in different countries are premature until a more robust methodology is developed.

One important type of adverse event is hospital acquired infections; we identified 35 of sufficient severity to meet the criteria for adverse events, of which 12 were regarded as preventable. We are aware that there are epidemiological data on some adverse events, but no previous study has addressed the overall scale of the problem.

Griffith et al point out that there is often a high chance of an adverse event no matter what course is pursued. We addressed this in our study by specifying whether an adverse event was considered preventable, though

these authors' example is particularly helpful. They liken the NHS to an old and unreliable aircraft; this nicely captures the nature of the fundamental problems and the need to examine the wider systemic problems rather than the NHS's committed and over-worked aircrew.

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Retrospective case record analysis has been superseded

EDITOR—Vincent et al's study shows that adverse events are probably frequent in British hospitals, but the authors fail to make a persuasive case for extending their study.¹ A larger study of the same design could give only an imperfect estimate of the true incidence of adverse events: case notes are an incomplete record of events and are difficult to interpret in retrospect, and other valuable data are often lost.²

The worth of a single clinician's analysis of the impact and preventability of adverse events was not assessed, but, by analogy with adverse drug reactions, such an analysis is likely to be fallible.^{2,3} For instance, the authors quote an example of a man who developed osteomyelitis as a consequence of failure to manage the leg ulcers aggressively. We are given no further details, so we do not know whether the authors are suggesting that different antibiotic drugs, higher doses, or a longer duration of treatment might have been beneficial.

We cannot judge how likely it is that aggressive treatment would have succeeded. Infected leg ulcers are difficult to treat, and osteomyelitis might have occurred anyway. Nor do the authors say whether the subsequent amputation was a consequence of osteomyelitis or of another factor such as vascular disease. It is not clear that it was reasonable to label this event an adverse event.

Retrospective case record analysis may have provided the foundation and driving force for initiatives in the United States, as Vincent et al say, but it has been superseded by prospective study,² systems analysis,⁴ and the assessment of interventions.⁵

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Expanded definition of adverse events is needed

EDITOR—The studies on adverse events associated with medical care such as that by Vincent et al¹ deal only with those events noted in a hospital record. We have no data on other events, yet a substantial portion of these may result in death. Hospital deaths may be only a part of a larger problem.

We need to expand the definition of an adverse event. This can include the financial effect on a family of having to pay a medical bill. In Nepal, where I have worked, private practice tends to be cost intensive and many expensive tests of dubious need are ordered. The patient and his or her family have no way of deciding whether the expense is justified. Families will borrow money to pay for the care and then limit spending on basic needs such as food, with resulting harm. The same happens to families in the United States who incur huge medical costs.

The United States spends 42% of the world's health budget² and ranks behind all other rich countries in what I call the health Olympics (ranking of countries by life expectancy). We should seriously question what we buy with health care.

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Cycle injury trends: helmets are most likely explanation

EDITOR—We studied national trends in hospital admissions among English cyclists during 1991-5 and found significant reductions in admissions of cyclists with head injury.¹ Data from annual surveys of cycle helmet usage during this period indicate that the proportion of children always wearing a helmet increased from 3% in 1991 to 20% in 1995,² this last figure corresponding well with the 16% of cyclists observed wearing a helmet in a separate large survey in 1994.³ The total number of non-fatal serious cycling injuries, however, remained constant during this time, leading us to conclude that the most plausible explanation for the decline in serious head injuries was an increase in use of cycle helmets.

In response to our paper both Adams and Hillman and Wardlaw refer to data on fatalities among cyclists⁴; helmets are, however, less likely to be beneficial in the very serious injuries that are potentially fatal since the protective effect of helmets is more likely to be exceeded. The two issues should therefore not be confused. That point aside, we have concerns about the validity of the (unreferenced) mortality statistics cited. Cycling fatalities fell each year from 242 in 1991 to 172 in 1994; they then rose to 213

in 1995 before falling again each year to 158 in 1998.⁵ This is not a simple trend and comparing the figures from any two years is misleading, witness the 25% increase in fatality reported by Wardlaw and the 8.6% increase in fatality and serious injury of Adams and Hillman.

We understand Godefrooij's concern that continuing debate on the question of helmet effectiveness could be counterproductive by increasing the perception of cycling as a risky activity,⁴ but we are not aware of any evidence to suggest that this is the case. Rather, what has been achieved is clarification of the benefits conferred by a safe and inexpensive health promotional intervention, one clear example that the message is getting through being the recent decision by the chancellor of the exchequer to abolish value added tax on helmets. It is surely high time that those who continue to express doubt on the question of helmet effectiveness strengthen their arguments, which have changed little over the years and remain as unsubstantiated as ever.

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Computer assisted learning aids management of course information

EDITOR—Greenhalgh summarises the key issues in the development and delivery of online teaching material in her paper on computer assisted learning in undergraduate medical education.¹ It is essential that online materials are well designed and structured, with a clearly defined learning pathway. The need to employ adequately trained tutoring staff is paramount, but the accessibility of the internet enables expert tutors to contribute where this would not have been possible previously because of geographical constraints. We would like to draw on our own experiences with the delivery of a web based distance learning course in medical informatics (available at www.bpdiploa.rcsed.ac.uk)—with 160 students in 19 countries.

The availability of a number of course delivery software packages facilitates the setting up of an online course, but we have rapidly outgrown those and are developing

our own system, an option that will not be available to all. Any course requires continual evaluation and modification, and the online nature facilitates this process, and allows for free asynchronous interaction between tutor and student. We have found that the accessibility of message boards and discussion areas can reduce the feeling of isolation that is common among distance learning students.

Although Greenhalgh has drawn attention to the need for multidisciplinary working, she has mentioned little of the information management advantages that the electronic environment brings. Awareness is increasing of the need to record accurately the training that has been given to individual medical students for future validation. The ability to track and monitor students as they progress through their course is a major advantage of an electronic course and will become an essential part of the seamless integration of undergraduate and postgraduate training.

The Royal College of Surgeons in Edinburgh is implementing an information management and educational delivery system that will escort the surgeon of the future from medical school to retirement. At the heart of this is the electronic delivery of educational material and support.

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Patients with depression can be taught how to improve recovery

EDITOR—Andrews has emphasised the chronic nature of depression and the need for endorsing treatment protocols such as those used for diabetes.¹ He has also raised the issue of being more honest with people about their prognosis and the need for prolonged treatment, particularly pharmacotherapy. But duration of treatment does not seem to affect long term prognosis once the drug is stopped.²

Whether you treat a depressed patient for three months or three years, it does not matter when you stop the drug. Indeed, a non-significant trend suggests that the longer the drug treatment is, the higher the likelihood of relapse.² Despite treating depression effectively in the short term, antidepressant drugs may worsen its course through a sensitisation process.³ Several clinical findings point to this possibility: paradoxical (depression-inducing) effects of switching antidepressants and cycle acceleration in bipolar disorder; tolerance to the effects of antidepressants during long term treatment; the onset of resistance on rechallenge with the same antidepressant in

some patients; and withdrawal syndromes after drugs that elevate mood are stopped.³

The pharmaceutical industry may not like this hypothesis, but a promising alternative exists. Treatment of depression by pharmacological means is likely to leave residual symptoms in most patients.⁴ Such symptoms hinder lasting recovery and are one of the strongest risk factors for relapse. In two randomised controlled studies cognitive behavioural treatment of residual symptoms significantly improved long term outcome of recurrent depression.^{4,5} In our affective disorders programme we tell our depressed patients that depression is likely to recur. But we also teach them that if they can change their lifestyle (with its maladaptive consequences), decrease their residual symptoms (particularly anxiety and irritability), and improve their psychological wellbeing the chances of a lasting recovery are far better.⁴

Rather than look to diabetologists, psychiatrists should be more inclined to look to cardiologists when they encourage their patients to reduce their risk factors (including type A behaviour) after a myocardial infarction. In our experience, patients in remission generally like the open and challenging nature of this type of communication. If people have a right to the truth, as Andrews says, they are entitled to the full story.

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Prevalence of type 2 diabetes in children in Birmingham

EDITOR—In their editorial on type 2 diabetes in children Fagot-Campagna et al have described the American experience of this emerging condition.¹ We represent the Paediatric Diabetes Subgroup of the Pan-Birmingham Diabetes Advisory Group and wish to describe our experience of type 2 diabetes in children in Birmingham.

We are responsible for 506 children with diabetes mellitus in Birmingham Health Authority; together our hospitals serve a paediatric population of 261 811.² The first case of childhood type 2 diabetes in Birmingham was diagnosed in 1993, and since then we have seen 17 children with the disease, of whom 10 remain in the paediatric clinics. Of these 17 children, 15 are female and 15 are South Asian. Three have type 2 diabetes after bone marrow transplantation.

In the 12 months to December 2000, 67 children presented with diabetes, of whom four were new presentations of type 2 diabetes. From this we can estimate that in our population the crude prevalence of type 2 diabetes in those aged under 18 is 0.038 per 1000, with an annual incidence of 1.52 per 100 000. This compares with a crude prevalence of type 1 diabetes in our population of 1.818 per 1000 and an incidence of 23.30 per 100 000.

We recently reported on eight British children aged 9-16 with type 2 diabetes, who were all female and overweight with a family history of diabetes.³ In contrast to the American experience of this condition in Native American, black, and Hispanic children,⁴ these children were all of South Asian or Arab origin. The condition presented insidiously without ketosis, and most of the children were asymptomatic at the time of diagnosis. All had features of insulin resistance (acanthosis nigricans or high plasma insulin or C peptide concentrations), and the high frequency of associated hypertension, dyslipidaemia, and features of polycystic ovarian syndrome in this cohort suggests underlying metabolic syndrome.⁵

Whether the emergence of type 2 diabetes in children from ethnic minorities has implications for the wider paediatric population is unclear, as is the part that obesity may play in its development. Not all of our children with type 2 diabetes are overweight, and this is clearly a heterogeneous condition in children. A national survey is under way under the auspices of the British Society of Paediatric Endocrinology and Diabetes to ascertain how many children are affected in the United Kingdom.

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Conclusions about type 1 diabetes and hygiene hypothesis are premature

EDITOR—Johnston and Openshaw state that children are born with strong interleukin 4 based (type 2) immune responses and mature to interferon γ based (type 1) responses, and that this process is under genetic and environmental influence.¹ They go on to state that asthma and atopy are rising in prevalence and that having older siblings and being exposed to infections promotes the normal maturation of the immune system towards a type 1 response.

This argument fails to take account of the evidence from type 1 diabetes, which is an interferon γ based disease. Type 1 diabetes is rising in incidence in children from Western societies and is commoner in first born children and in the children of the well off.²⁻⁴ Infection may have a role in the changing epidemiology of disease, but the evidence contradicts the suggestion that this is due to a failure of normal immune development towards a type 1 response.

Though consistent with current dogma, the conclusion that we should attempt to mimic the effect of childhood infection on the immune system is premature, if not totally flawed, on two counts. Firstly, association, not causation, has been shown,⁵ and, secondly, the proposed mechanism of action is inconsistent with available evidence.

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What author really said about malaria and climate change

EDITOR—I am writing to correct an error in a quotation attributed to me in a News article and to clarify my remarks.¹ Malaria is of course a vector-borne disease, not an airborne disease. Vector-borne diseases are sensitive to climatic factors such as temperature and precipitation. The distribution of a particular vector-borne disease, however, depends on a range of factors, including the biology of the local vector species, the local environment, and the effectiveness of vector control programmes.

In many countries that are free of malaria and have a well developed public

health infrastructure, the risk of sustained transmission of malaria with the reintroduction of the disease is low. Where malaria control programmes are ineffective, however, the spread of malaria may occur at the latitudinal or altitudinal edge of distribution (for example, in mountainous regions in Africa).

In the United Kingdom malaria seems to have been an important cause of death between the 16th and 19th centuries in communities living close to brackish marshes (for example, in the fens or the Thames estuary). It declined progressively from the 1820s onwards because of several factors, including improved housing, drainage of marshes, and wider availability of quinine.² Cooler summers in the 1800s may also have played a part.³

Climate change is unlikely to result in malaria becoming a substantial health problem in the United Kingdom, although the possibility of small outbreaks cannot be excluded. Travellers' malaria might pose an increased threat if British residents were to visit areas of the world affected by a changing distribution of malaria owing to climate change. Effective treatment of such cases, however, should ensure that a reservoir of parasites able to infect mosquitoes is not left in the community.

The potentially wide ranging health impacts and methodological difficulties in developing quantitative estimates will be described in some detail in the forthcoming report by Working Group II of the Intergovernmental Panel on Climate Change. Given the potentially substantial increases in global mean temperature over the next century,⁴ uncertainties about the magnitude of health impacts should not be used as a reason for inaction. Major reductions in use of fossil fuels and increases in energy derived from renewable sources will be needed to reduce the rate and magnitude of the increase in temperature and improve the opportunities for populations to adapt to changes in climate.

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Rapid responses

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