legitimate goal of treatment: intermediate goals (such as stopping injecting) may be more realistic for some drug misusers. It may be a useful early step on the long journey of treatment.[1]

The first needle exchange scheme in the United Kingdom opened in 1987, and there are now more than 130 such schemes in England.[11] There are also extensive over the counter sales of needles in high street pharmacies.[12] Maintenance programmes using oral methadone, popular in other countries, may represent harm reduction in another guise. A prompt response to withdrawal crises—for example, when the normal illicit supply is interrupted or while the user is on remand or in custody[13 14]—may be particularly important in avoiding the transition from smoking to injecting a drug.[15]

Where does harm minimisation lead? Providing advice on safer injecting (and in some cases needles and syringes) fails to address the fundamental need for behavioural change. Alternative strategies are already being used, such as booklets giving advice on safer drug use[16 17] and the innovative comic for drug users, *Smack in the Eye*, which weaves health promotion into an alternative cartoon format.[18] But orthodox medicine must also take up the challenge and explore these new territories. Why don't we already offer injecting drug users testing and vaccination for hepatitis B infection?[19 20] Perhaps a case can be made for distributing ampoules of the opiate antagonist naloxone. Its potential for abuse is nil, the risks are probably minimal, and considerable benefit may accrue if drug users could give emergency doses of antagonist to fellow injectors who inadvertently overdose.

Finally, we need to know more about how risk behaviour is changing. If a prescribing programme is intended to reduce the frequency of injecting or a needle exchange scheme is intended to reduce the frequency of sharing then measures of these behaviours are needed to monitor progress over time. Harm minimisation must now move to a stage where the critical researcher is not outlawed as a heretic but welcomed as a scientist.

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NCEPOD: Revisiting perioperative mortality

Same lessons; same problems with compliance

The first *Report of the Confidential Enquiry Into Perioperative Deaths*[1] received a mixed reception. Some doctors hailed it as an outstanding example of self audit while others were critical, calling it politically naive and suggesting that its lack of scientific method would have prevented its publication by a refereed journal. But the climate for audit has changed since then: in 1987 the white paper *Working for Patients* had not been published and many doctors considered audit to be poor quality research of dubious value. Despite its critics the report remains the most ambitious audit undertaken in the United Kingdom, and the term "CEPOD" is now firmly established in the vocabulary of surgeons and anaesthetists.

The report's successor, the *Report of the National Confidential Enquiry Into Perioperative Deaths 1990*, doubles the dose rather than changing the treatment. Its methodology is similar, and the text states, "There are no new lessions." The report comprises 400 pages of tables, comments, and illustrative cases, leaving readers with a distinct feeling of déjà vu.

The same problems of deficient data from case notes and Hospital Activity Analysis, inadequate provision of emergency services, low necropsy rates, poor supervision of junior staff (particularly senior house officers in anaesthetics), and surgeons operating outside their specialty are highlighted in both studies. The new inquiry, however, examines additional topics such as the quality of locum cover, the isolation of doctors occupying staff grade posts, split site working, and deficiencies of operating department assistants and nurses.

On the negative side, the new inquiry is affected by underreporting: one fifth of requests for information were met with silence and a further fifth yielded incomplete data. Whether this represents simple apathy, active resistance, or an attempt to conceal is unknown. Detailed analyses of compliance show a variation from 64% to 82% in the return of completed surgical questionnaires from regions contributing more than 100 forms. Interestingly, the adjacent North East Thames and North West Thames regions are the worst and best respectively, with the independent sector occupying the middle ground at 74%. Northern Ireland is worthy of particular mention, returning 45 (88%) of its forms. The authors do not make any recommendations about how they intend to improve compliance in future or give any advice regarding an appropriate response from the sponsoring bodies. Interestingly, a "list of participants is not included." No reason is given, and readers are left to ponder whether this might be to prevent identification of the 313 non-participating consultants.

If audit works we might expect an improvement when comparing 1990 with the 1987 report. Direct comparison is often difficult and infrequently made by the authors. Necropsy rates have risen from 35% to 47%, although necropsy reports were considered to be poor in 25% of cases and reached the right doctors in only 75%. The proportion of patients examined by a consultant surgeon before operation did not change while consultant participation in the actual operation rose slightly from 47% to 52%. The presence of a consultant anaesthetist rose from 41% to 52%, although in a comparison with control cases a consultant was less likely to be present at emergency operations carrying a high risk of death than at elective, low risk operations. The report concludes that staff should be better matched to the patient's condition. Overall, CEPOD does not seem to have stimulated a radical change in operative practice, but where movement has occurred it has been in the right direction.

The report recognises the lack of data on denominators as a serious defect. There were 58 wound dehiscences and 54 anastomotic failures associated with perioperative death—but in how many wounds and anastomoses? How many patients survived these complications? Discussion is often limited, avoiding contentious topics; regional variations are not discussed. Patients and purchasers will obtain no useful information on which to base decisions. Perhaps rightly, the authors are satisfied to present the facts, leaving others to analyse the data more critically, quantify avoidability, apportion blame, and identify solutions.

For the individual doctors the messages are clear: better audit; clearer documentation; more consultant involvement; increased supervision of juniors, staff grade posts, and locums; and better liaison between surgeons, anaesthetists, and pathologists.

Colleges and other professional bodies must now respond to the non-compliance rate of 20%: audit is a fundamental component of professional activity and not an optional extra. The report's plea for more high dependency and intensive care units is directed at management and government, adding further to the demands on their budgets. In the short term clinicians should use these precious and expensive facilities to maximum effect. To maintain the interest and compliance of doctors the next inquiry should further sharpen its focus, giving priority to "unsatisfactory features" that lie within the province of the medical profession rather than those outside it.

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The role of local research ethics committees

Maintaining the pressure for improvement

At a time when many district health authorities and local research ethics committees are probably still digesting the significance of the new guidelines from the Department of Health[1] a report for the King's Fund Institute by Julia Neuberger has reopened many issues in the debate on the ethics of medical research.[2] In some senses the report tells us little that was not already known: the wide disparity in membership and working arrangements, the concern about obtaining consent, and the anxiety that not all research is submitted to a committee.[3-5] But the fact that it is based not only on a postal questionnaire to members of local research ethics committees but also on observation of committees at work and interviews with members in a sample of 25 districts should lend weight to some of its conclusions.

Many ethical aspects of research have improved over the past decade. The quality of patient information sheets is better. Fewer ethics committees conduct their business solely by post. Will the report contribute to a continuation of this improvement? Many of Neuberger's recommendations have already been adopted. For example, the keeping of records, the publication of an annual report, the need to inform subjects of arrangements for compensation, and the requirement to disclose financial considerations to the ethics committee are all dealt with in the government's guidelines.

Neuberger's report, however, makes some significant recommendations on matters of general principle that those guidelines steadfastly avoided. The report recognises the importance of someone other than the researcher being present when consent is sought, raises the question of sex bias in research design, and calls for fresh debate on research on children and mentally disordered people (to which an impetus has recently been given by working parties of the Medical Research Council[6,7]). On the vexed question of multicentre trials Neuberger proposes a national committee to give conditional approval, leaving local ethics committees free to accept or reject each study but without power to modify the proposal other than by amending the information sheet or consent form. This would be preferable to the vague proposal involving networks of neighbouring ethics committees contained in the Department of Health's guidelines.

Underlying the report's detailed recommendations is an insistence that the only effective way to strengthen the role of local ethics committees is through legislation. Others have pointed to the flaws that follow from the absence of legal status for ethics committees—notably, that there is no absolute requirement that all research should be approved by an ethics committee.[8] Neuberger suggests that legislation would make it likely that funding would be found for "proper monitoring" and "some form of policing." The inclusion of active monitoring would be at once a dramatic yet natural extension of the ethics committees' role. Dramatic, in the sense that doctors are unfamiliar with direct inspection of their work by an independent agency; natural, in that regulation without some means of enforcement (the present position of ethical review) is difficult to defend if any degree of public accountability is to be sustained.

In one respect the report overstates the benefits of legislation. It seems unlikely that, as a matter of simple cause and effect, "with legislation . . . RECs [research ethics committees] would be perceived as an essential part of the research machine, rather than, as in some cases, an irritating barrier which has to be overcome." Neuberger does not consider how legislation should be framed, and basic issues of definition are