

New *BMJ* policy on economic evaluations

Response of NHS Economic Evaluation Database Research Team

EDITOR—We, the NHS Economic Evaluation Database Research Team, agree with Smith that economic evaluations should contain comprehensive reporting of both clinical effectiveness and economic analysis and that the *BMJ* is right to implement this new policy.¹ How the clinical trial results (which inform the economic evaluation) are obtained is often paramount to the understanding and quality of the economic analysis conducted.²

Research reports are included and abstracted in full on the NHS Economic Evaluation Database (www.york.ac.uk/inst/crd)—if they explicitly report costs and clinical outcomes for an intervention and at least one comparator.³ However, to critique the method adopted in the effectiveness study underpinning the economic evaluation appropriately, our template requires information that is often omitted in the report of the economic evaluation. When the parent clinical study has been previously published elsewhere, we obtain the study and use that alongside the economic research when writing the abstract. The abstract on the database then provides information on sample selection, study design, method of analysis, and so on, with the fact that the relevant information is cited from the parent study.

Adhering to published guidelines, such as those provided by the *BMJ*,⁴ should produce publications of the highest quality, but authors are still likely to feel the need to be selective in their reporting, given word limits. If authors are required to report more effectiveness data other crucial aspects of the economic evaluation might receive less attention. The focus for *BMJ* editors should be to ensure that reporting of both important components of economic evaluations receives appropriate attention from the authors.

If the policy results in full reporting of both clinical and economic results in one place—for example, two papers in one issue

of the journal—this will constitute an improvement. If, however, the new policy results in the combination of clinical and economic results in one short paper, this may be a step backwards.

Dawn Craig *research fellow in health economics*
dc19@york.ac.uk

John Nixon *research fellow*
Nigel Armstrong *research fellow*
Julie Glanville *associate director*
Jos Kleijnen *director*

NHS Centre for Reviews and Dissemination,
University of York, York YO10 5DD

Michael Drummond *director*
Centre for Health Economics, University of York

1 Smith R. New *BMJ* policy on economic evaluations. *BMJ* 2002;325:1124. (16 November.)

2 Hoffmann C, Stoykova B, Nixon J, Glanville J, Misso K, Drummond M. Do health-care decision makers find economic evaluations useful? The findings of focus group research in UK health authorities. *Value Health* 2002;5:71-8.

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Will the *BMJ* return clinical trials if submitted without any economic results?

EDITOR—The implications of the *BMJ*'s new policy for economic evaluations are unclear.¹

Firstly, a lag often exists between the clinical and economic results, making simultaneous submission difficult. Typically, clinicians are eager to disseminate important clinical results immediately. For example, the extracorporeal membrane oxygenation (ECMO) trial was among the first research projects to incorporate economic evaluation in its design from the outset. But the preliminary clinical results were written up and fast tracked to the *Lancet* before I was even employed to continue the economic evaluation.² The economic evaluation was published in the *BMJ* years later, having required the clinical evidence in its analysis and appropriate sensitivity analyses and having undergone delay to publication.³

Would it have benefited anyone to withhold dramatic clinical results until the economic results were ready? Clinical results are often more generalisable to an international audience than the concurrent economic results. The limitations of any clinical information in the absence of economic evidence should be made explicit. The pertinent concern is surely to ensure

relevant policy makers exercise restraint until the full information is available.

Secondly, no incentive is given in the *BMJ* policy for clinicians to change their practice. Presumably clinicians send results to the *Lancet* for higher impact factors and wider dissemination. If economists cannot persuade colleagues to submit the clinical paper alongside the economic paper to the *BMJ*, they will resort to submitting results to economic journals for which a different style for different specialist audiences would be required, ensuring even poorer dissemination to clinical audiences and policy makers.

Finally, your editorial emphasised strong support for keeping clinical and economic results together, and Smith told us to send "somebody else your clinical results and us your economic results, and we will send them back, politely." May I therefore ask, politely, is the converse also true? Will you return clinical trials if submitted without any economic results?

Tracy Roberts *lecturer in health economics*
University of Birmingham, Health Economics
Facility, Birmingham B15 2RT
t.e.roberts@bham.ac.uk

1 Smith R. New *BMJ* policy on economic evaluations. *BMJ* 2002;325:1124. (16 November.)

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Economic evaluations should be judged on scientific merit

EDITOR—Health economists have been grateful for the *BMJ*'s hitherto supportive stance towards the publication of economic evaluations. The proposed new policy not to publish economic evaluations unless also offered the clinical results is disappointing and misjudged.¹

Firstly, this policy denies the fact that, although clinical and economic results from a trial are both components of an overall evaluation, they also have many differences, often including the funding agencies supporting them, the researchers, and the timescale over which they are performed and published. Perhaps most importantly, important trials are often prepared for an international audience, but economic evaluations usually relate to specific healthcare systems; large trials may generate the need for several country specific economic evaluations.

These differences justify researchers in choosing to submit clinical and economic

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results to different journals, and entitle journals to use different criteria when deciding whether to publish or reject. Consequently, as in other disciplines, research findings that are closely related and possibly interdependent often appear in different journals. That poses no great problem to readers, especially in the era of electronic publication championed by the *BMJ*.

Secondly, what is the likely effect of this policy? Researchers aim to publish where they judge they make most impact. Surely no one will forgo an opportunity to publish trial results in the *Lancet* simply because the *BMJ* will not then consider publishing an economic evaluation?

Smith's editorial included no positive proposals to make the *BMJ* a more attractive outlet for trial results. Instead, this policy will inevitably mean turning away well conducted empirical research—such as the economic analysis of the multicentre aneurysm screening study that occasioned this announcement²—on strictly non-scientific grounds. Arguably these are precisely the more scientifically important papers, leaving the *BMJ* with a greater preponderance of non-trial based economic analyses and data-free “think pieces.” This is hardly the route to improving the journal's impact on the adoption of new treatments or technologies.

Smith admits this new policy owes something to petulance but nevertheless defends it as reasonable. We think it is unreasonable and ask him to reconsider.

Alastair M Gray *professor of health economics*
alastair.gray@ihs.ox.ac.uk

Andrew Briggs *NHS public health career scientist*
Philip Clarke *research fellow*
University of Oxford, Oxford OX3 7LF

We are currently involved in economic analyses of several large trials whose clinical results have recently been published in other journals, including the *Lancet*. If adopted, this policy will deny us the opportunity to have our scientific research results considered for publication by the *BMJ*.

1 Smith R. New *BMJ* policy on economic evaluations. *BMJ* 2002;325:1124. (16 November.)

2 Multicentre Aneurysm Screening Study Group. Multicentre aneurysm screening study (MASS): cost effectiveness analysis of screening for abdominal aortic aneurysms based on four year results from randomised controlled trial. *BMJ* 2002;315:1135-41. (16 November.)

Economic evaluations are often based on many studies

EDITOR—I understand the reasons for the new policy on publishing economic evaluation studies,¹ but it is not clear how this will apply to many of the best evaluations that are based on reviews of many randomised controlled trials and other clinical studies, and use modelling to assess outcomes and cost effectiveness. There is no reason to exclude such studies.

If the new policy is to work it is important also for the *BMJ* to ensure that its processes of review and decision making are joined up in terms of the different components of studies. Too often in the past when pairs of papers were submitted or when a single paper reported the overall

results of a study the reviewing of the economics has been weak. Smith's editorial raises the point that publishing clinical outcomes without economic ones is really incomplete evaluation. I look forward to results of high quality clinical trials being rejected for want of a proper economic evaluation.

Charles Normand *professor of health economics*
London School of Hygiene and Tropical Medicine,
London WC1E 7HT
charles.normand@lshtm.ac.uk

1 Smith R. New *BMJ* policy on economic evaluations. *BMJ* 2002;325:1124. (16 November.)

Will the *Lancet* play ball?

EDITOR—The debate ensuing from the *BMJ*'s new policy on publication of economic evaluations is interesting.^{1 2} Smith made several important practical points, but we believe that some broader strategic issues still remain.

Thankfully, major research funders in the United Kingdom increasingly require that economic evaluation be an integral part of the design of a clinical trial. In many ways the *BMJ*'s decision is the natural extension of this philosophy. The risk is, however, that unless other major journals follow suit the policy will damage the dissemination of cost effectiveness information.

The collaboration between clinicians and health economists is often delicate. The pressures that this new policy will place on this relationship will have implications for long term cooperation. Given the pressure to publish rapidly in high impact journals to secure long term funding, the interests of clinical and economic researchers will not always coincide.

An immediate effect of this policy for those of us participating in multidisciplinary research is the need to agree publication strategies at the outset of a project. It may be that a process similar to the *Lancet*'s protocol pre-approval could facilitate these discussions by providing confidence that high quality clinical trials including an economic evaluation will be acceptable to the major journals.

Unless all researchers accept the need for the simultaneous publication of clinical and economic results, cost effectiveness information may be confined to more specialist journals, which are rarely seen by the clinical community. The best solution would be for the major journals to agree that clinical trials designed to inform policy decisions must include a high quality economic evaluation. We would be interested to know the *Lancet*'s thoughts on this issue.

Christopher J McCabe *senior lecturer in health economics*
c.mccabe@sheffield.ac.uk

Jennifer Roberts *senior lecturer in health economics*
University of Sheffield, Sheffield S1 4DA

It is important for our research careers to be able to publish in high impact journals.

1 Smith R. New *BMJ* policy on economic evaluations. *BMJ* 2002;325:1124. (16 November.)

2 Electronic responses to: New *BMJ* policy on economic evaluations. bmj.com 2002. bmj.com/cgi/content/full/325/7373/1124#responses (accessed 14 Feb 2003.)

Editor's clarifications

EDITOR—We thank everybody who responded to our proposal to consider for publication economic evaluations that accompany clinical papers only if we are sent both the economic and the clinical papers. More respondents are in favour than against, but people have raised important questions that we must answer.

This is a further clarification of our policy.

(1) If both the clinical and the economic paper are submitted to us we might accept one and not the other.

(2) We will be willing to consider for publication economic papers that are submitted some time after the clinical paper if the clinical paper was also submitted to us. It will not matter if we decided not to publish the clinical paper. We might still be willing to publish the economic paper.

(3) We will not reject clinical papers if they are not accompanied by an economic evaluation. There would be a logic to such a policy, but we are first and foremost a clinical journal.

(4) We will be willing to consider either papers that combine clinical and economic results or pairs of papers. Pairs of papers will usually be better. Our ELPS (electronic long, paper short) policy means that we can publish long papers on bmj.com—longer than 2000 words.¹ We prepare the shorter version for the paper edition of the *BMJ*. Authors approve it before publication. If we take two papers then we will publish them together.

(5) We will continue to consider for publication economic papers—perhaps modelling papers—that are not related to particular clinical papers.

Richard Smith *editor*
BMJ, London WC1H 9JR

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Self help smoking cessation in pregnancy

Programmes for smoking cessation can work

EDITOR—Moore et al show that giving smoking cessation booklets to pregnant women does not help them stop smoking.¹ But the intervention offered to pregnant smokers in this study was not based on previously available evidence that adding booklets to face to face advice does not improve smoking cessation rates² and that more intensive interventions are needed to help pregnant smokers stop smoking.³

Nevertheless, a recent meta-analysis indicates that individually tailored materials produced by computers increase by 80% the odds of stopping smoking compared with receiving no materials.² Because computer tailored programmes are based on the relevant personal characteristics of each smoker, participants may be more interested in reading these documents and prepared to

apply the advice included.^{4,5} Consequently, individually tailored documents are 1.36 times more effective than booklets in helping smokers stop smoking.³ In addition, most available computer tailored programmes include a follow up, which is an essential element in the treatment of addictions.

Tobacco dependence is a chronic condition with relapses and often needs prolonged treatment. It is a serious condition that is unlikely to be treated with booklets alone. But computer tailored programmes can be a useful adjunct to pharmacotherapy and to advice given by doctors and midwives. By using new information technology (internet, text messages on cell phones, etc), these programmes can reach large numbers of smokers at a low cost. Because the prevalence of smoking among pregnant women has increased sharply in many European countries in recent years, and few doctors and midwives are trained in treating tobacco dependence, there is an urgent need to assess the efficacy of computer tailored smoking cessation programmes in pregnant smokers.

Jean-François Etter *lecturer*
Institute for Social and Preventive Medicine, Faculty of Medicine, University of Geneva, CH-1211 Geneva 4, Switzerland
Jean-Francois.Etter@imsp.unige.ch

Competing interests: J F Etter developed an effective computer tailored smoking cessation programme, available in four languages at no charge.

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What does work in Doncaster

EDITOR—Moore et al reported that self help strategies to give up smoking do not work with pregnant women.¹ This is certainly the case.

Pregnant women require sophisticated, tailored packages to meet their individual needs. The care they receive needs to be delivered by highly trained specialist midwives. The midwives who deliver antenatal and postnatal care to pregnant and postnatal women and their families need to be trained to raise the issue of smoking with them and refer to specialist services as necessary.

Doncaster has a history of working with pregnant women who want to give up smoking and it was part of the initial pilot study with QUIT to develop and implement

a smoking and pregnancy helpline. Building on the success from the pilot study, Doncaster launched its own service, "SmokeFree Pregnancy." This service encompasses all of the elements recommended for a successful service.

Two specially trained, highly motivated midwives have been employed to offer flexible support to women and their families before, during, and after pregnancy. They also negotiate the use of nicotine replacement with general practitioners.

All midwives in Doncaster are trained to raise the issue of smoking, and in the past year 150 pregnant women have successfully stopped smoking as a result of the interventions they have received. The success of this type of specifically tailored service in Doncaster is reflected in the percentage of women who give up smoking, which is one of the highest in England and is seen as an example of good practice.

Tracey A Battersby *midwife specialist*
tracey.battersby@doncastercentralpct.nhs.uk

Lisa Fendall *midwife specialist*
Doncaster SmokeFree Pregnancy, Health Promotion Development Centre, St Catherine's Hospital, Doncaster DN4 8QN

Carole Pougher *assistant director of public health*
White Rose House, Doncaster DN4 5DJ

Competing interests: None declared.

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WHO advocates investment in global infrastructure for outbreaks such as smallpox

EDITOR—In their editorial describing the interim smallpox guidelines for the United Kingdom Harling et al ask how countries lacking the public health infrastructure to respond to outbreaks and without vaccine supplies would be able to control an outbreak of smallpox.¹

Confronted with the threat of intentional release of biological agents, the World Health Organization advocates dual use investment in public health infrastructure to strengthen outbreak intelligence and verification, support the response to an outbreak, maintain an emergency vaccine reserve, and provide public health information.

In 2002 the World Health Assembly urged countries to share expertise, supplies, and resources, and asked WHO to develop collective mechanisms to contain or mitigate the impact of such a global health threat.² Since the successful eradication programme ended in 1979 WHO has managed an emergency stockpile of smallpox vaccine, which now consists of some 500 000 doses.³ Access to stockpiled vaccine is restricted to contain- ing epidemiologically and virologically con-

firmed outbreaks of smallpox. The organisation has built an adequate global reserve as a critical element of smallpox preparedness by engaging with a global health security initiative that has undertaken to support and increase WHO's existing global vaccine reserve and encourage others to do the same.

WHO has been working intensively to provide member states with technical guidance and help, improving preparedness for epidemics of natural or intentional origin. The organisation's global alert and response programme detects rumours of outbreaks, verifies or refutes such rumours with the affected countries, and rapidly offers technical and operational support through the global outbreak alert and response network.⁴ Since 2000, investigations by WHO have refuted 13 smallpox rumours.

Other support for preparedness is through training in collaboration with the US Centers for Disease Control and Prevention to recognise and respond to smallpox. Technical guidance on immunisation, diagnosis, and other information on smallpox for healthcare professionals and the public is available on the WHO website (www.who.int/csr/disease/smallpox/en/).

WHO recognises that countries may wish to identify key workers and immunise them to allow a rapid response to a smallpox outbreak. It is in keeping with WHO policy for countries to devise and implement such a plan in line with their own assessment of national infrastructure and needs.

Cathy E Roth *medical officer, global alert and response*
rothc@who.int

Patrick Drury *project manager, global alert and response network, global alert and response*

Roberta Andraghetti *medical officer, global alert and response*

Ray R Arthur *project leader, viral haemorrhagic fevers, arbovirus and orthopoxvirus infections, global alert and response*

Michael J Ryan *team coordinator, global alert and response*

Guenael Rodier *director, department of communicable diseases surveillance and response*
Department of Communicable Diseases Surveillance and Response, Communicable Diseases Cluster, World Health Organization, 1211 Geneva, Switzerland

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Polyspecific snake antivenom may help in antivenom crisis

EDITOR—In Africa snakebites cause thousands of deaths annually and much permanent physical disability, but the supply of antivenom, the only specific treatment, is threatened by commercial pressures and privatisation. This has been caused over the

past few years by the cessation of antivenom manufacture by Behringwerke in Germany, greatly reduced production by Aventis Pasteur in France, and the threat to continued production by Africa's sole remaining producer, the African Health Laboratory Service in Johannesburg.

Without antivenom, human suffering and death from snake bite are increasing, especially in west Africa.¹ Only conservative treatment is possible, or the use of ineffective antivenoms manufactured in Asia or dangerous traditional remedies.

In February 2001 a workshop held by the World Health Organization identified interregional collaboration as the only short term solution.² Colombia's national institute for public health responded by offering to develop a prototype pan-African polyspecific antivenom.

Venoms from nine species of *Echis*, *Bitis*, and *Naja* were selected as being medically the most important in Africa (a mamba antivenom is being developed separately). Horses were hyperimmunised with 13 African venoms using the Colombian institute's standard protocol. The neutralising potency of the equine antiserum in WHO standard preclinical assays against five intravenous median lethal doses of the individual and pooled venoms was sufficiently high to justify the purification of the crude antiserum to produce a definitive antivenom.³

In preclinical tests this antivenom showed good neutralising potency against the venoms covered by the African Health Laboratory Service's polyspecific antivenom. The new antivenom also neutralised the venoms of saw scaled vipers (genus *Echis*) (ED₅₀ 14.3 µl/mouse) as effectively as both the African Health Laboratory Service's *Echis* antivenom (12.8 µl/mouse) and Micropharm's *Echis ocellatus* Fab fragment antivenom (13.0 µl/mouse).⁴ Unlike these two monospecific antivenoms, the pan-African antivenom powerfully neutralises the venom of *Bitis arietans* (1.3 µl/mouse) and has moderate activity against *Naja nigricollis* venom (73.0 µl/mouse). These species cause most serious snakebites in Africa.

Another polyspecific African antivenom (developed in Costa Rica) and a new Micropharm monospecific *E. ocellatus* F(ab')₂ fragment antivenom are undergoing pre-clinical testing. These three antivenoms will be compared by randomised controlled trials in Nigeria.

G D Laing research fellow
R A Harrison research fellow
R D G Theakston professor of medical biology
r.d.g.theakston@liverpool.ac.uk
Liverpool School of Tropical Medicine, Liverpool L3 5QA

J M Renjifo coordinator
Grupo Antivenenos, Instituto Nacional de Salud, Bogotá, Colombia

A Nasidi director, special projects
Federal Ministry of Health, Abuja, Nigeria

J M Gutierrez professor, research division
Instituto Clodomiro Picado, University of Costa Rica, San José, Costa Rica

D A Warrell professor of tropical medicine
Nuffield Department of Clinical Medicine, University of Oxford OX3 9DU

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Randomised controlled trial for twin delivery

EDITOR—The article by Smith et al is a timely retrospective cohort study, in which the possible benefit of planned caesarean section for twins is suggested.¹ A meta-analysis of available studies did not show any appreciable difference in neonatal outcomes, but pointed out that available data are mainly level 2, being based largely on retrospective cohort studies.²

On the basis of these data and data from the Alee Nova Scotia perinatal database we have estimated that planned vaginal delivery of twins at 32 weeks or older carries a risk of perinatal mortality or serious morbidity of about 4%. To show a reduction in this to 2% requires 2500 patients (power 80%, alpha error 0.05, two sided). On the basis of our experience with the term breech trial we believe that such a trial is possible, and with support from over 175 centres we have submitted such a proposal to the Canadian Institutes for Health Research. We caution against any radical change in practice without strong evidence from a well designed randomised controlled trial. Any centre that is interested should contact our group at jon.barrett@swchsc.on.ca

Jon F R Barrett associate professor
University of Toronto, SWCHSC and Maternal Infant Research Unit, 76 Grenville Street, Toronto, Canada M5S 1B6
jon.barrett@swchsc.on.ca
for The Twin Birth Study Collaborative Group

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Thrombolysis with recombinant streptokinase in Cuba

EDITOR—Analysis of the causes of the low rate (21%) of thrombolysis for acute myocardial infarction in England and Wales described by Mayor would be interesting.¹ In Cuba thrombolysis with home manufactured recombinant streptokinase has been widespread since 1993. When this procedure was introduced nationwide, the overall proportion of patients receiving treatment was a little above 30%.

The main reason why thrombolysis was not given was largely because patients arrived at hospital more than 12 hours after

the onset of symptoms. Other causes were non-ST elevation and contraindications for thrombolysis, such as possible causes of bleeding.² The management system for patients has, however, become more efficient, with patients arriving earlier. Also doctors in emergency departments are more acquainted with the product, so currently the rate of thrombolysis is around 50% nationwide and even 70% in some units.

The report also says that streptokinase should not be given twice because of the formation of anti-streptokinase antibodies. We found that almost all patients had low titres of anti-streptokinase antibodies before thrombolysis; they increased rapidly after treatment but then started to fall.³ After six months the average anti-streptokinase titre was roughly still enough to neutralise the thrombolytic activity in plasma achieved with the 1.5 million unit dose. After one year the titres had almost returned to pre-treatment values. Given these data, we think that streptokinase can be given again after a case by case analysis of risks and benefits six months after the first administration and surely after one year.

Pedro A Lopez-Saura head of clinical trials
Centre for Biological Research, PO Box 6162,
CP 10600, Havana, Cuba
lopez.saura@cigb.edu.cu

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Checklists for myocardial infarction should be precise

EDITOR—Savage and Channer highlight a serious problem in their editorial on managing acute myocardial infarction.¹ Doctors are under increasing pressure to reduce door to needle times to below 30 (possibly 20) minutes and often now delegate this task to thrombolysis nurses. Such nurses are accountable for the door to needle time and are often blamed if the targets of national service frameworks are not met. Often delay occurs in calling a thrombolysis nurse, such that the nurse has very little thinking time if he or she is to stay within the target.

Everyone involved should know that statistics on door to needle times should apply only to those patients in whom the diagnosis is definite and no possible contraindication exists. If potential problems are identified with either the diagnosis or a potential contraindication the clock should stop ticking. The thrombolysis nurse should then have ready access to someone with the experience and knowledge to weigh the risks and benefits in an individual patient. Although any decision should be made as

quickly as possible, sufficient time should be allowed to avoid hasty or ill considered decisions. Delays in calling the thrombolysis nurse or junior doctor should be minimised.

Every hospital in the United Kingdom has a different checklist for assessing patients. Is it not time for a nationally agreed list of relative and absolute contraindications to thrombolysis? Such a list should be precise and specific in its statements, not simply say uncontrolled hypertension. In addition, in some groups of patients the benefits of thrombolysis are higher and the complications are worth risking. Other groups of patients may have less potential benefit and therefore need a more cautious strategy. Thus users of the checklist require easy access to expert opinion.

G Alastair Cooke *consultant cardiologist*
King's Mill Hospital, Sutton in Ashfield,
Nottinghamshire NG17 4JL
alastaircooke@doctors.org.uk

1 Savage MW, Channer KS. Improving the management of acute myocardial infarction. *BMJ* 2002;325:1185-6. (23 November.)

Copying letters to patients

Psychiatrists omit information from letters when they know patients will be sent copies

EDITOR—From April 2004 patients will receive copies of all correspondence between clinicians working in the NHS as a matter of course.^{1,2} Previous research supports the view reported in Eaton's news item that patients appreciate this practice³⁻⁵; however, the way its national introduction will affect doctors' work is much less clear. We audited how psychiatrists' practice is affected when letters are to be copied to patients.

All 76 new patients who attended two general psychiatry outpatient clinics (one rural, one inner city) from January 2002 to July 2002 were included in the pilot study, as were all eight psychiatrists who worked in these clinics during this time. After the assessment patients were sent a copy of the psychiatrist's letter to the general practitioner and asked to complete a short questionnaire on their evaluation of the letter. Psychiatrists were asked whether anything of importance had been omitted from the letter that they would usually have included, and if so, the reason and how the omitted information would be communicated to general practitioners.

Fifty six of the 76 letters (74%) were sent to the patient in an unaltered form (table). In three cases the psychiatrists thought it inappropriate for the patient to receive a copy of the letter, citing concerns over patients' distress. In 17 cases clinicians made omissions, mainly of parts of the history. Sixteen of these 17 patients were treated by just two of the eight doctors.

Reasons cited for omission were fear of distressing the patient (14 instances), concern about people other than the patient having access to information (four instances), and protection of information

Results of audit of psychiatrists' practice when copying letters to patients

	No of cases
Letter sent to patient	
Copy of general practitioner's letter	73
None	3
General practitioner's letter with at least one omission	17
Parts omitted	
History or examination details	14
Diagnosis	3
Prognosis	6
Reason for omission	
Fear of distressing patient	14
Other concerns	6

supplied by third parties (two instances). General practitioners were informed of the omitted information, either by letter or in person.

Forty patients (55%) responded to the questionnaires. Most patients (33 out of 40) wished to continue receiving copies of correspondence.

Sending patients a copy of the letter to the general practitioner after a psychiatric consultation is valued and appreciated by patients; some doctors are, however, worried about distressing patients by what they write and consequently tend to omit information. Some training and reassurance about this practice may be needed before implementation.

Graham K Murray *research associate*
Department of Psychiatry, University of Cambridge,
Box 189, Addenbrooke's Hospital, Cambridge CB2 2QQ
gm285@cam.ac.uk

Harpal Nandhra *specialist registrar, psychiatry*
Fair Mile Hospital, Wallingford, Oxon OX10 9HH

Nigel Hymas *consultant psychiatrist*
Box 179, Addenbrooke's Hospital

Neil Hunt *consultant psychiatrist*
Fulbourn Hospital, Cambridge CB1 5EF

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Copying letters can help avoid communications nightmare

EDITOR—As the parents of a young person with myalgic encephalomyelitis/chronic fatigue syndrome who has regular appointments at paediatric outpatient clinics, we have received copies of all follow up letters to our son's general practitioner for over three years now.¹

These have been provided as a matter of course, but we would have otherwise requested them. Copies of follow up letters are also copied to my son's educational welfare officer, school heads, and special educational needs coordinator, as appropriate.

We have also received copies of referral letters from his paediatric doctor to consultants and heads of other hospital departments, the local education authority in support of continuing provision of home tuition, and examination boards in support of "special arrangements" for GCSE examinations.

Occasionally, errors in letters have occurred, but we are in a position to pick up on these and have them corrected. Administrative errors have also occurred—I am told, through the use of temporary secretarial staff. This has resulted in follow up letters being sent to the wrong general practitioner at the wrong surgery and to an unnamed special educational needs coordinator at the wrong school, evidenced by the list of copied recipients at the foot of our copies of these letters.

For parents of young people who are unable to access mainstream education because of long term illnesses such as myalgic encephalomyelitis/chronic fatigue syndrome the difficulties in maintaining effective liaison between school, special educational needs coordinator, educational welfare officer, home tuition coordinator, general practitioner, hospital consultant, community paediatrician, and local education authority can be serious. In addition, some families also deal with social services and child and adolescent mental health services, as well as having input from the connections service.

For many it can be a communications nightmare on top of an already challenging situation. Anything that helps to improve liaison, such as receiving copies of hospital letters, is to be welcomed, and I would advise all parents to ask for copies of these letters if they do not already receive them.

Suzy Chapman *carer of young person with myalgic encephalomyelitis*
Lytchett Matravers, Poole, Dorset BH16 6BG
suzychapman@greywood.freemove.co.uk

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Employing users who turn back into patients is difficult

EDITOR—Simpson and House conducted a systematic review of involving users in the delivery and evaluation of mental health services.¹

I have certainly found employing users to be a positive experience. However, one difficulty not mentioned in the paper is that of subsequently treating these people as patients again when they relapse.

The move from patient to colleague is comparatively easy compared with the transition back to that of patient, particularly if the Mental Health Act is needed.

Anna Knight *consultant psychiatrist*
Yeovil, Somerset BA20 2BX
anna.knight@sompar.nhs.uk

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