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Smeeth, L; Fletcher, AE; (2002) Improving the response rates to questionnaires - Several common sense strategies are effective. *BMJ*, 324 (7347). pp. 1168-9. ISSN 1468-5833 DOI: <https://doi.org/10.1136/bmj.324.7347.1168>

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## Improving the response rates to questionnaires

*Several common sense strategies are effective*

Most readers of the *BMJ* probably receive postal questionnaires from time to time. Whether such questionnaires are dutifully completed and returned, left to gather dust, or rapidly thrown away may seem like a random process of little importance. However, while response may be of little consequence at the individual level, for many research studies a high response rate to a postal questionnaire is critical. No matter how expensive, well designed, or important a study, a poor response rate can introduce such uncertainty—and worse still, bias—in the results as to make the study of little scientific value. However, postal questionnaires are attractive to researchers because they are likely to be substantially cheaper than data collection based on interviews. Postal questionnaires are increasingly used in other areas of health care, for example in screening programmes, to assess patient satisfaction, or to assess outcomes after treatments such as surgery. Methods to maximise response rates from postal questionnaires therefore have considerable relevance for medical researchers, practitioners, and policy makers alike.

In this issue Edwards and colleagues present a systematic review of interventions to improve response rates to postal questionnaires (p 1183).<sup>1</sup> The review included 292 randomised trials that evaluated 75 different strategies. The scale of the review indicates the need for high quality, rigorous systematic reviews—identifying, appraising, and collating such an enormous volume of research would clearly be beyond even the best intentioned researchers planning to post a questionnaire. The systematic review identified several factors that were associated with increased response rates including monetary incentives; sending the questionnaires by recorded delivery and by first class post; short questionnaires; coloured ink; personalised letters; and follow up contact and second copies. Questionnaires including questions of a sensitive nature and those from commercial as opposed to university sources were less likely to be returned. None of these factors are likely to surprise readers. However, even though the review by Edwards and colleagues serves to confirm many ideas that make sense, it is important because it provides a firm evidence base for researchers trying to improve response rates and therefore the quality of their research.

Some caution is required in interpreting the findings of the review. Many of the included trials had

nothing to do with health care. This meant that a lot more trials could be included in the review, allowing the reviewers to assess a wider range of possible interventions and greatly increasing the power and precision of the estimates of effect of these interventions. However, the extent to which findings from, for example, commercial fields such as marketing can safely be generalised to a healthcare setting is questionable. The intervention found to have the greatest effect on response rates—offering money—raises a number of ethical considerations and is a strategy that many people in health care would be reluctant to use, particularly with vulnerable groups. The current relevance of the findings is also important. Some of the trials were done some decades ago, when the public was relatively naive. Personalised letters, coloured inks, free pens, promises of free gifts, and even gold or silver envelopes are now routinely used by the commercial sector to attract the attention of potential customers. Many recipients may now be immune to such devices. One clear message that does emerge is the need for health researchers to make their letter different from that of commercial organisations.

Edwards and colleagues quite rightly focused on a single issue: response rates to postal questionnaires. Their review is the first Cochrane review focusing on research methodology.<sup>2</sup> Systematic reviews addressing a wide range of other methodology questions are clearly needed. For example, while postal questionnaires are relatively cheap and high response rates can be obtained, they are also associated with higher levels of missing or incomplete responses.<sup>3</sup> Choosing between postal questionnaires and other methods for collecting data is another important question where the evidence is unclear, indicating the need for a systematic review. Much of the research on postal questionnaires will be irrelevant in some developing countries, where strategies such as door to door surveys are more likely to be used. Again, the evidence about factors associated with higher response rates for door to door surveys is unclear and a systematic review would be of great value.

The evidence base for research methodology is growing fast. An early example was a study showing that in randomised trials, concealment of allocation (meaning no one can predict which group participants will be randomised to) and blinding of outcome assessments were associated with reduced bias.<sup>4</sup> Other areas

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such as methods for undertaking systematic reviews and health services research have substantial literature.<sup>5,6</sup> Such evidence matters because it can improve the quality of research and ultimately improve clinical care and health policy. As more is known about the factors associated with high quality research, it is up to investigators to make more use of research findings. The review by Edwards and colleagues is a valuable step towards making evidence based research a reality.

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LS and AF work in the same institution as some of the authors of the paper by Edwards and colleagues, but have no research

links with them. LS is an unpaid editor for the Cochrane Collaboration.

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## Implications of the EU directive on clinical trials for emergency medicine

*Many trials in emergency medicine will not be possible*

**A** laudable attempt by the European Union to implement good clinical practice in the conduct of clinical trials on drugs for human use will, unless amended, make impossible a range of potentially life saving studies after May 2004.

Directive 2001/20/EC, adopted in April last year, is an important and comprehensive document.<sup>1</sup> It is a cornerstone of a Europe-wide harmonisation of the provisions governing clinical trials and can be expected to foster and facilitate multinational clinical research. It will be adopted by member states before 1 May 2003, and its provisions will be applied from 1 May 2004 at the latest.

Several articles in the directive deal with the protection of clinical trial subjects. Article 5 outlines the conditions for research in incapacitated patients unable to give informed consent. The article, however, is framed to address the needs of individuals who are incapacitated for long periods, many even permanently. A clinical trial can only be done if "informed consent of the legal representative has been obtained." This will be difficult in many emergencies—when a patient is suddenly and perhaps temporarily incapacitated.

In some countries, such as the United Kingdom, there appears to be no provision for a legal representative for incapacitated patients. This means the doctor in charge takes responsibility for entering the patient into the trial. The situation appears to be similar in Spain and in Norway. In the Netherlands consent may be given by the life partner, at least in acute emergencies. In Germany patients may be enrolled if it can be assumed that the effectiveness of a treatment appears to be unclear. In other countries such as Ireland and Austria the situation may be more difficult. Legal representatives cannot be produced quickly and usually do not even exist, since a healthy adult person does not need a legal representative.

Therefore, many studies performed in emergency medicine will no longer be possible after May 2004.

Acute diseases such as cardiac arrest, major stroke, or severe trauma are major health burdens. How shall we assess the effectiveness of healthcare interventions in patients with such diseases in the future? The directive may not only affect unconscious people. Thousands of patients with acute myocardial infarction have been enrolled in clinical trials so far. Many of these have severe pain on admission and receive treatment with opiates: can they give informed consent, particularly those with cardiogenic shock? Research in the acute care setting is already difficult and this directive will make it even more difficult.

The provisions of article 5 draw a sorry parallel to current legislation in Austria regarding the clinical testing of medical devices. Article 49 of Austria's Medical Device Act (implemented in 1996) states that any clinical study on a medical device can be done only if the patient has given her or his informed consent. At first sight, this seems reasonable and clearly in the spirit of the Helsinki Declaration. No provision exists, however, for a patient who is temporarily unable to give consent. Consequently, any device designed for use in emergency situations, such as cardiopulmonary resuscitation, cannot be used in a clinical trial anywhere in Austria.

This legislation has created the absurd situation that a modern, industrialised country, loyal to the ethical principles of the Helsinki Declaration, leaves research and testing of medical devices to other countries. Austria is ready to use it only after clinicians and patients in other parts of the world have taken the risk of researching the intervention. Outside a clinical study, however, physicians are legally permitted to use any medical device if they think it is best for their patients. It seems barely credible that any legislation can create such an illogical situation for patients and their doctors.