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Identifying reports of controlled trials in the *BMJ* and the *Lancet*

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In 1994 the European Union BIOMED programme awarded £330 000 to a project, coordinated by the UK Cochrane Centre, to identify reports of randomised controlled trials in general health care journals in Europe. The rationale is that reports of randomised controlled trials are difficult to identify through sources such as Medline.[1] For example, a study of the first six months of Medline for 1993 identified over 400 reports of randomised controlled trials which were not coded as such, despite having the word random or randomised in the title or abstract.[2] A systematic review in 1993 indicated that, on average, searches of Medline identify only 50% of trials.[3] We present here the results of handsearching the *BMJ* and the *Lancet* from 1948 onwards to identify reports of trials.

Methods and results

Twenty handsearchers were trained to identify reports of clinical trials where random allocation, or some quasirandom method of allocation, such as alternation or date of birth, was definitely or possibly used to assign individuals (or other units) prospectively to one of two (or more) alternative forms of health care. Handsearchers coded these reports as randomized-controlled-trial (RCT) or controlled-clinical-trial (CCT), the Medline publication type terms introduced in 1991 and 1995 respectively. They also noted any reports about which they were uncertain. All articles, editorials, letters, and news items in the *BMJ* and the *Lancet* were examined from 1948 to 1994. The most experienced handsearchers were assigned to the period 1948-65, when the quality of methodological reporting made identifying trials more difficult.

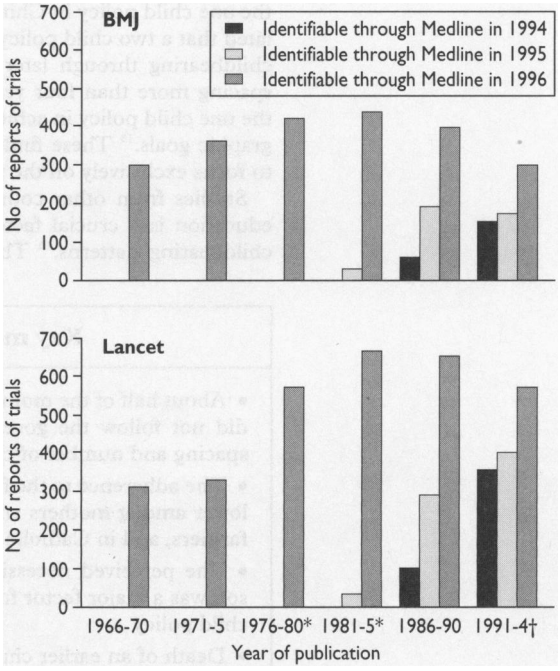
All identified reports were verified and recoded where necessary by an experienced clinical trialist (MC). The relevant electronic records for 1966-94 were taken from Medline and submitted to the US National Library of Medicine through the Baltimore Cochrane Center, which coordinates this activity on behalf of the Cochrane Collaboration. They were retagged with the correct publication type terms and have been available in Medline since January 1996 (fig 1). For those reports not on Medline (missed issues, pre-1966 reports, etc) electronic records have been generated.

For the period 1948-65, 1916 reports were identified, 956 (255 RCTs; 701 CCTs) in the *BMJ* and 960 (214 RCTs; 746 CCTs) in the *Lancet*. These 1916 reports, for which no Medline records exist, are now available in *The Cochrane Library*[4] and will also be included in an ancillary database of the National Library of Medicine, currently under development. For 1966-94, 5347 reports of trials were identified, 2153 (1451 RCTs; 702 CCTs) in the *BMJ* and 3194 (2074 RCTs; 1120 CCTs) in the *Lancet*. Of these, 4093 reports are now identifiable in Medline using the publication type terms randomized-controlled-trial or controlled-clinical-trial. These are in addition to the 1050 which were previously identifiable. A further 204 reports with no Medline records have been added to *The Cochrane Library*.

Comment

This project builds on work undertaken at the UK Cochrane Centre in 1994, when about 100 000 Medline abstracts from 1985 to 1993 were read to identify reports of trials: as a result roughly 19 000 additional reports of randomised controlled trials were retagged in Medline for 1995. Of these, 185 were in the *BMJ* and 282 in the *Lancet*.

Having identified reports of trials in the two richest UK sources, other UK general health care journals are now being handsearched. This activity is part of an international exercise to identify all reports of trials in health care journals and databases; over 600 journals are being handsearched within the Cochrane Collabo-



* Includes 258 reports from the *Lancet* to be retagged in Medline for 1997 (1976-80 = 118, 1981-5 = 140)
† Full data for 1995 publications not yet available in Medline

Fig 1—*Number of reports of trials in BMJ and Lancet (1966-94) which were identifiable as such in Medline in 1994, 1995, and 1996*

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ration. This exercise will help identify randomised controlled trials for health care decision making, and in particular will help the Cochrane Collaboration to prepare, maintain, and disseminate systematic reviews.

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Conflict of interest: None.

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Informed consent in biomedical studies on aging: survey of four journals

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International legislation requires that human subjects must give truly informed and free consent before participating in medical research. To achieve this, researchers must pay careful attention to the procedure for obtaining consent, especially in elderly subjects because of their high prevalence of impaired cognition, hearing, speech, and vision. Firstly, subjects judged incapable of giving consent must be excluded or consent by proxy obtained. There are, however, no well accepted standards for determining capacity to consent.[1] Secondly, the information given should be matched to the reading ability and comprehension of the subjects studied.[2] This requires a prior assessment of vision, hearing, and mental status. The approval of a study by the responsible ethics committee should, among other things, provide quality control of the consent procedure. We report here the first study to question how often approval of an ethics committee and obtaining consent were described in biomedical articles on aging.

Methods and results

Issues for 1993 and 1994 of the four journals with the highest impact factor in the category "geriatrics and gerontology" of the 1993 *Science Citation Index* were examined[3]: *Journal of the American Geriatrics Society*, *Journal of Gerontology: Medical Section*, *Mechanisms of Ageing and Development* and *Age and Ageing*. We found 586 articles reporting research in humans; case studies were excluded. We recorded the type of subjects, the study design, and whether informed consent procedures and approval of an ethics committee were mentioned. We also asked the editors of the four journals about their policies on these issues.

Most studies (316) included elderly patients who were recruited from geriatric departments (76), nursing homes (82), or other hospital departments (158). The remaining studies included healthy elderly (170) and young or middle aged subjects (100). Data on consent procedures and ethics committee approval were present in only a minority of the studies (table 1). Obtaining consent was mentioned more often than approval, and both were most common in clinical trials. Eighteen studies used age or clinical diagnoses—for example, dementia, confusion, frailty—as criteria for incapacity to consent. Only two articles described the assessment of capacity to consent in more detail. The two editors who responded agreed that consent and approval of ethical committees should be published, but they considered that peer reviewers were primarily responsible for ensuring that this information was present. One editor stated that guidelines to referees would be changed because of our findings.

Table 1—*Frequency of publication of informed consent and approval of an ethics committee according to study design in 586 biomedical studies on aging. Results are numbers of articles (and percentages)*

Design	No of studies	Informed consent	Approval
All studies	586	172 (29)	120 (21)
Prospective	448	169 (38)	118 (26)
Interventional	127	68 (54)	51 (40)
Clinical trial	37	23 (62)	18 (49)

Comment

Overall the frequency with which information on informed consent and approval by an ethics committee were given was low. This does not necessarily imply that the required preconditions for ethically justified research were not met, simply that readers were not informed. None of the four journals required in their instructions for authors that this information should be given. However, three journals implicitly required information on approval by referring to the "Uniform requirements for manuscripts submitted to biomedical journals."[4]

We advocate that editors should explicitly state to authors and referees that approval of an ethics committee and obtaining subjects' informed consent are absolute preconditions for publication and should be mentioned in all papers reporting prospective research on human subjects. Additionally, authors should be more aware of their responsibility to publish relevant details of the assessment of capacity to consent and of special measures applied in informing elderly subjects. Articles should present more details about essential ethical issues to fulfil legal requirements, to ensure public accountability, to help spread the practice of new consent procedures, and to stimulate ethical and scientific debate.

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Conflict of interest: None.

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