admission and the presence of gastrointestinal bleeding or haematuria. Mild drug reactions were well recognised by these patients, but not severe ones.

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Conflict of interest: None.

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Breast examinations in older women: questionnaire survey of attitudes of patients and doctors

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Breast examination is important in older women, in whom the incidence of breast cancer is higher.[1] It is, however, an intimate examination, and older patients and doctors may be deterred for several reasons. The attitudes of older women to this procedure have not previously been established. Both this and the attitudes of doctors may determine whether the procedure remains part of the routine physical examination.

Subjects, methods, and results

The study was approved by the Wirral district's ethics committee. One hundred elderly (mean (range) age 83 (71-94) years) female inpatients (abbreviated mental test score 8/10 or more) were interviewed by a doctor not involved in their medical care. All patients were fully recovered from their acute illness. A questionnaire (available from us) was administered and the responses recorded. The case notes of the same 100 patients were audited by using a standardised proforma.

One hundred hospital doctors working in two hospitals were given a questionnaire (available from us); 75 responded. Replies were anonymous so non-responders could not be recontacted.

Review of 100 case notes showed only 11 of the patients had had a breast examination documented (two of which yielded abnormal results). Of 10 patients with a history of bone pain, only one had a breast examination, while four with weight loss had no breast examination documented. Liver function tests gave abnormal results in 15 women, only two of whom had a breast examination. There were five patients with a history of breast cancer, none of whom had a breast examination documented.

None of the patients said they would be offended if they were asked to undergo a breast examination. Fifty four patients felt neutral about it, 32 would be pleased to be asked, 10 would be reluctant about being examined, two would be upset, and two would be embarassed. Most patients (86) thought a breast examination was important and would give permission for this examination. Most (88) also had not had mammography or a breast examination previously. A few patients (12) said that they would always want a chaperone, while 18 wanted a chaperone only when a male doctor was examining. Most (70) were not concerned whether a chaperone was present or not. Only a few patients (13) thought a breast examination would worry them, while 45 thought it would reassure them. None of the patients had refused to undergo a breast examination. Some (25) would prefer a female doctor to examine them, but most (70) had no preference.

Of the hospital doctors interviewed, only five said that they would routinely do a breast examination on every woman over the age of 50 years, though 43 thought breast examinations should be a routine part of the physical examination. Some doctors (15) felt uncomfortable in performing breast examinations, and 34 (all men) would insist on a chaperone. Only 12 would be deterred because of the possibility of being accused of assault. Most hospital doctors (56) did not think women were offended by breast examinations. A small number of doctors (11) did not feel confident in detecting breast lumps because of inadequate training.

Comment

The treatment women of all ages should be getting for breast cancer has been outlined.[2] About 40% of women with breast cancer are aged over 70.[3] Giving women of 70 or over "adequate" treatment can enable them to reach a five year survival rate similar to that for younger women.[4]

Few women in this study had had a breast examination or undergone mammography. As most of our patients regarded a breast examination as important and would give permission, omission must be due to failure by medical staff to do this examination. Few doctors would routinely do a breast examination on women over the age of 50, although over half thought it should be done as part of the physical examination. Most doctors thought women were not offended so omission is not because of fear of offending patients. There are probably multifactorial reasons why doctors do not routinely perform breast examinations: some feel uncomfortable, a few lack confidence, and some are deterred by claims of assault. Requirement of a chaperone may make examination difficult as nursing staff may not be available. It may not be a priority in the assessment of an acute medical emergency and subse-

quently overlooked. Some doctors may also have misconceptions that breast cancer in elderly women is less aggressive than in younger women and that older women cannot endure aggressive treatment.

This study suggests that older female patients have a positive attitude towards breast examinations which is not reflected by the attitudes and practice of hospital doctors. There needs to be a change in attitudes and training so that older women do not miss out on diagnosis and treatment.

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Conflict of interest: None.

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Exclusion of elderly people from clinical research: a descriptive study of published reports

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See editorial by Avorn

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Conclusions reached in studies of young people cannot be extrapolated to elderly people.[1] It is thus essential that elderly people are included in clinical studies. We set out to discover whether and to what extent studies published in medical journals exclude this section of the population.

Methods and results

We examined all the original research papers in all the issues of the *BMJ*, *Gut*, the *Lancet*, and *Thorax* between 1 June 1996 and 1 June 1997. We excluded case studies and meta-analyses. We looked for a mention of age limit first in the abstract or the methods section of the papers, but we sometimes found it mentioned in other parts of the papers instead. We then categorised the papers as studies (*a*) specifically of elderly people (aged 75 years or more); (*b*) excluding elderly people for justifiable reasons (where long follow up was planned); (*c*) excluding elderly people with no justifiable reasons; and (*d*) not setting an age limit. We excluded papers that were concerned with children and adolescents; pregnancy and reproduction; sexually transmitted diseases; animal work; cell and tissue studies; or employment related research.

The results are given in the table. We found 1012 papers and excluded 522. Of the remaining 490 papers, 18 were specifically about elderly people, 37 excluded the elderly for justifiable reasons, 170 excluded them unjustifiably, and in 265 no age limit was set.

Comment

A third of the original research papers in major medical journals excluded elderly people without justification. Although the journals were not selected randomly and we included a small number of papers published within a short period of time, we believe that our findings are important and relevant to current practice and behaviour in clinical research.

Elderly people may be excluded from clinical research for many reasons. Often the decision to participate in research cannot be taken by the elderly person alone. Family members and caregivers take part in the decision to participate in the study, and the investigator has to establish rapport with both the patient and family members. This is usually a time consuming and complicated task. Many investigators may avoid these problems by excluding elderly people from their study.[2] Or they may exclude them because they fear that frailty and comorbid conditions may put elderly people at increased risk from the study, but we believe that such risks are best investigated in the rigorous setting of a clinical trial. Selected elderly patients can enter trials without being put at an increased risk of more severe or frequent side effects.[3]

Applying the results of research that excluded elderly people to the management of elderly people is, we believe, inappropriate and possibly dangerous. More elderly people should be included in clinical trials. Study populations should be stratified to include a sufficient number of elderly people to permit valid conclusions on effects on elderly people. If elderly people are excluded from any research work then this must be made clear to readers of the paper and the reasons for such exclusion justified.

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Conflicts of interest: None.

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Number (percentages) of original research papers (n=1012) in all issues of *BMJ*, *Gut*, *Lancet*, and *Thorax* between 1 June 1996 and 1 June 1997, by category of study

Study	*BMJ*	*Lancet*	*Thorax*	*Gut*	Total
Specific to elderly people*	11 (9)	6 (4)	0	1 (1)	18 (4)
Excluding elderly people justifiably	10 (8)	14 (10)	7 (8)	6 (4)	37 (8)
Excluding elderly people unjustifiably	44 (35)	37 (27)	39 (45)	50 (35)	170 (35)
No age limit set	60 (48)	79 (58)	41 (47)	85 (60)	265 (54)
Total	125	136	87	142	490
Excluded†	202	135	85	100	522

*Aged 75 years or more.
†Papers that were concerned with children and adolescents; pregnancy and reproduction; sexually transmitted diseases; animal work; cell and tissue studies; or employment related research.