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Evaluation of palliative care

Recruitment figures may be low

EDITOR,—In response to the paper by Ian R McWhinney and colleagues[1] we wish to report our experience of recruitment into trials in the palliative care setting. The trials were not of a palliative care service but of palliative therapeutic interventions in a specialist cancer hospital. These included randomised studies of pharmacological and non-pharmacological strategies in the management of bowel obstruction, hypercalcaemia, nausea induced by opiates, anorexia, pain, and dyspnoea as well as non-randomised studies in patients in pain.

In the 12 months to October 1994, 344 patients were referred to one of two research sisters in palliative care as being suitable for entry to one of the above studies. Both inpatients and outpatients were referred by medical and nursing staff throughout the hospital. Of the 344 patients, 109 were not approached as they did not fulfil the criteria for inclusion in the studies. Thus after full discussion regarding the implications of entering the trial 235 patients were asked if they would agree to participate in one of the studies. Only 142 patients gave informed consent. The remainder were not entered into the studies because they were too unwell or their condition had deteriorated (27), they were eligible but declined to consent (38), they lived too far away from the hospital (16), or for unknown reasons (12). Thus 41% of the patients initially referred and 60% of the patients who were approached were entered into studies. These figures are low but are likely to be higher than those achieved in other palliative care settings since the patients were recruited in a specialist cancer hospital with a high research profile, where the role of the research sister is well established.

We agree with Henry McQuay and Andrew Moore that palliative care should not be excused from conducting randomised controlled trials simply because they are difficult to do,[2] but our recruitment data show several of the inherent difficulties.

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Patients should be randomised at time of diagnosis

EDITOR,—Ian R McWhinney and colleagues report the difficulties that they experienced in evaluating a palliative care service.[1] The underlying cause of the methodological difficulties was that patients were referred to the palliative care team late in the course of their illness.

Altogether 1268 residents of Warwickshire died between 1 July 1993 and 30 June 1994 and had a diagnosis of cancer recorded at some point on their death certificate. Record linkage showed that, before their death, 394 of these 1268 residents had been in contact with community Macmillan nurses based in Warwickshire. The first contact occurred less than four weeks before death in 159 cases and less than eight weeks before death in 241 cases.

The same problems would thus probably arise if a study similar to that attempted by McWhinney and colleagues in Canada was undertaken in Britain. It has been suggested that in an ideal future palliative care would start at the time of diagnosis and form a gradually increasing component of care between diagnosis and death.[2] Randomised controlled trials of palliative care should therefore recruit and randomise patients at the time of diagnosis, not during the terminal stage of illness.

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Important factors are hard to measure

EDITOR,—Ian R McWhinney and colleagues and Henry McQuay and Andrew Moore draw our attention to the problems in assessing palliative care, but their contributions also show the physical emphasis that preoccupies doctors, naturally enough, in the care of dying patients.[1,2] Of course control of symptoms must be audited and multicentre trials will help neutralise the overoptimistic prognosis routinely given by our profession. But what is not yet achievable, except in certain specific aspects of palliative care, and especially while the measurement of quality of life is still so crude, is any randomised trial of the fundamental problems of dying patients—loneliness and fear—and, for relatives, lack of commitment or of confidence. These require affection, understanding, and ungrudging availability as well as competence. These are so much more difficult to measure than the speed of throughput or equivalent data that are irrelevant yet close to the heart of NHS purchasers.

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Patients must be told that treatment will be randomised

EDITOR,—Henry McQuay and Andrew Moore refer to equipoise being the requirement for an ethically sound randomised controlled trial.[1] Although equipoise is a necessary condition, it is not sufficient. In addition, those whose participation is sought in a randomised controlled trial should be informed about all relevant features of that trial, an important one of which is the randomisation process. For an ethically sound trial of the sort reported by Ian R McWhinney and colleagues[2] it would be necessary to recruit only those patients who were genuinely ambivalent (or were prepared, knowingly, to forgo their choice) about whether to receive palliative care support immediately[1] or after a delay of one month. Although the figure is not explicitly stated in the report, it seems unlikely that fewer than 20 of the 166 eligible patients refused to participate in the trial on this basis.

The moral and practical difficulties of informed consent in medical research frequently hinge on disclosure of the fact of randomisation. When the interventions being compared are identical in form (such as active and placebo drugs presented as indistinguishable tablets) genuine ambivalence is much more likely.

When dissimilar treatments—for instance, surgery and radiotherapy—are being compared many people will have an innate preference based on personal considerations rather than scientific evidence. In such circumstances there may be genuine clinical equipoise but the right of autonomous choice should not be removed by failure to disclose the fact of randomisation.

While many individual interventions in palliative care may feasibly be subject to randomised controlled trials, the assessment of a whole service by such means seems a tall order indeed.

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Randomised controlled trials and health services research

EDITOR,—Randomised controlled trials are viewed as the gold standard for medical research, and are advocated as an appropriate method for evaluating almost any medical intervention. However, they are neither universally applicable[1] nor, as Ian R McWhinney and colleagues show,[2] always realistically possible. Although they have been advocated as appropriate for use in health services research, serious problems can arise in practice that affect whether the data can be generalised.

Evaluation of programmes is a case in point. The simple act of defining the intervention to be tested can be problematic. During the development phase of a randomised controlled trial of a hospital at home scheme in Northamptonshire lengthy discussions took place between the providers, the clinicians, and the research team about the package of care to be evaluated. Agreement was finally reached, but not until the views of the provider unit, professional groups, the acute unit, general practitioners, secondary care clinicians, the primary health care team, the family health services authority, social services, the hospital pharmacy, the ambulance service, carers, the health authority, and the local research ethics committee had been taken into account. At every stage of the trial's development the views of each of these groups had to be considered. Although these problems can be resolved, the resources put into this process must not be underestimated.

Methodological problems are less easily resolved because of the lack of published material on the application of randomised controlled trials in health services research. This problem will continue with increasing use of subjective assessments of health as outcome measures in such research.[3] In many instances the data on which to base calculations of sample size for these measures do not exist, and their clinical relevance has yet to be determined.

It is unfashionable to publish results of unsuccessful studies. We urge, however, that research that highlights the difficulties in this area should be given space in journals. This would help to ensure that impractical projects were not funded and that

those attempting such projects could read about the experience of others.

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Identifying relevant studies for systematic reviews

EDITOR,—We agree with Kay Dickersin and colleagues' recommendations regarding the need for improved reporting of randomised controlled trials by authors and improved indexing of such trials in electronic databases.[1] We wish to make two additional points on the basis of our experience of searching for randomised controlled trials related to stroke.

Firstly, there is a need for improved indexing in Medline (and other databases) of the medical subjects as well as the terms used to identify trials. For example, the MeSH term that covers stroke is CEREBROVASCULAR-DISORDERS but this is imprecise as it also covers many conditions not related to stroke (such as vascular dementia and migraine). In addition, the term CEREBROVASCULAR-DISORDERS is not used consistently for all stroke trials, especially for trials relating to prevention and rehabilitation. After studying the text and MeSH headings of several hundred stroke trials, which we had identified using a variety of methods, we have had to add 13 further MeSH or free text terms to maximise the sensitivity of our search. This further reduced the precision: the search with maximal sensitivity (87% of the articles in Medline that related to stroke trials) had a precision of only 10%. When this search was applied to all journals in Medline over six years about 10 000 articles were retrieved, each of which had to be assessed.

Secondly, given the problems with electronic searching of Medline and the practical difficulties of organising hand searching of all journals likely to include relevant trials (we think that at least 300 journals have included stroke trials), we suggest that several overlapping search strategies should be used to ensure that as many as possible of the available randomised controlled trials are included in systematic reviews. The Cochrane Stroke Review Group uses several such strategies: hand searching 15 major journals and the proceedings of major meetings on stroke; electronic searching of Medline, Embase, the Index to Scientific and Technical Proceedings (a database of conference proceedings available through the Bath Information and Data Services), and two dissertation databases; searching of the Ottawa stroke trials registry; reviewing the bibliographies of trials and other relevant articles; and contacting drug companies and colleagues. Each of these methods has retrieved trials that would have been missed if a single search strategy had been used.

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Pressure sores

Clinical trials best way of assessing different matresses

EDITOR,—R K Vohra and C N McCollum's review on pressure sores contains two misconceptions.[1] Firstly, the authors state that measurement of the interface pressure is the best method of comparing the efficacy of pressure relieving supports, whereas clinical trials have shown that it is a poor indicator.[2,3] Deep periosteal pressures are considerably higher than the interface pressure,[4] and animal studies have repeatedly shown that the initial ischaemic necrosis that causes deep sores occurs in subcutaneous tissues, not in the skin.[5]

Secondly, the authors share the common confusion concerning the different actions of low pressure and alternating pressure supports: "in a comparison of alternating air, static air, and water mattress overlays on sacral and heel pressures . . . mean pressures were significantly higher for the alternating air mattress than the other surfaces; they should therefore be avoided."

Low pressure mattresses are soft supports that aim at distributing the weight as widely as possible and thus at preventing high pressures over bony prominences, which cause distortion of tissue and ischaemia. In contrast, alternating pressure mattresses are designed to be sufficiently firm to lift the patient off the bed and to support him or her while adjacent cells inflate and deflate underneath the body, constantly changing the areas of high pressure. They mimic the alternate high and low pressures that occur in normal people as a result of changes of position in response to pain due to pressure, which permit reactive hyperaemia and reoxygenation of the tissues and thus prevent ischaemic necrosis. Averaging the pressures in alternating pressure mattresses to enable them to be compared with low pressure supports is therefore meaningless.

Only clinical trials can show which system works best for different types of patient. A recent randomised trial in a district general hospital comparing alternating pressure mattresses with similarly priced constant low pressure mattresses (for example, fibre fills, slit foam, static air, water, and low air loss overlays) showed the alternating pressure mattresses to be considerably more effective.[1]

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Carers should provide informed, cohesive approach

EDITOR,—I hope that R K Vohra and C N McCollum's review on pressure sores will be read by the people who chair curriculum committees of medical schools.[1] Pressure sores are seldom included as a specific topic for instruction to medical students. This accounts for widespread ignorance on the subject among doctors both in hospitals and in the community. It has always struck me as extraordinary that a condition that affects between 5% and 10% of all patients in hospital should not be a matter of top priority for teaching of medical students.

One point that the review fails to emphasise is the need to establish satisfactory preventive measures in the community before patients are discharged from hospital. One of the commonest causes of the high rate of recurrence of pressure sores is the failure of communication between carers in hospital and carers in the community.

As a surgeon with an interest in pressure sores, I seldom agree to close a pressure sore until I know that future prevention of the same sore is assured. This often means that special equipment has to be purchased and so proves expensive, but, in the long term, prevention of sores is much cheaper than treatment and the cost of providing the equipment for prevention is equivalent to that of only a two or three week stay in hospital. Demarcation disputes often delay the decision on who should fund the equipment: the hospital believes that the community should do so and the community believes that the hospital should. It would be in everybody's interest if each health authority set aside money for the provision of equipment for patients with pressure sores that could be called on by both hospitals and the community.

Finally, I agree with the authors that a wide range of topical dressings and applications is marketed with, usually, little evidence of efficacy. This can be summarised in the aphorism "it matters far more what you put a pressure sore on than what you put on a pressure sore."

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Assessing risk of suicide

Samaritans' scoring system helps develop judgment

EDITOR,—H G Morgan's article on the role of doctors in preventing suicide emphasises the need for training in assessing the risk of suicide and responding appropriately.[1] Samaritan volunteers in training are taught always to ask about suicidal feelings and to assess the risk in detail. A rough and ready scoring system is sometimes used to help develop sound judgment based on thorough inquiry; it is mainly useful for training purposes.

The scoring system was based partly on a booklet about assessing the risk of suicide published by the New York Suicide Prevention Center (which was much too detailed and elaborate for day to day use) and partly on advice from the Los Angeles Suicide Prevention Center, which emphasised the importance of whether there is a suicide plan and, if so, its nature and intended timing in the assessment of the immediate risk. Sudden deaths (by hanging, shooting, or jumping), which are final, are distinguished from slower deaths (by overdosing, for example), in which rescue is possible if the chosen place and time favour it. Other risk factors—historical, social, and medical—are then scored as features that increase the immediate risk or warn of longer term risk for those not in imminent danger (table). The table thus offers reminders about what to ask: Any plan? What? When? Where? Are the means available? Ever tried before? How seriously? Preparations (making a will, giving things away, etc)?

The score that results offers guidance for an appropriate response: a score of 7 or 8 in the first