Letters

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Monitoring clinical trials

Dissemination of decisions on interim analyses needs wider debate

Editor—Lilford et al make a case that interim analyses from randomised trials should be shared with participants and doctors and patients.[1] These analyses should be shared for the sake of freedom of information and properly informed consent, as a counterweight to paternalism, for the better public understanding of uncertainty, and regardless of drug regulatory or financial considerations.[1] But the authors stop short of suggesting how to evolve the design of randomised controlled trials so that future patients and their doctors, in the light of emerging information, might have more choice than between 50:50 randomisation to treatments A and B versus self determination to receive treatment A or B.

The consumer principle of randomisation, which to my knowledge has not been implemented since its enunciation in 1994,[2] offers doctors and patients the option of choosing one of three randomisation ratios, such as 30:70 (uncertain or idiosyncratic preference for B, yet willing to be randomised if allocation is weighted in favour of B), 50:50 (absolute uncertainty or complete altruism), or 70:30 (uncertain or idiosyncratic preference for A, yet willing to be randomised if allocation is weighted in favour of A).

Importantly, the choice of randomisation strata is an additional patient covariate that was not previously available; comparison between treatments is unbiased within the chosen randomisation stratum; and how the choice of randomisation stratum drifts after disclosure of interim data is a measure of how those data were assimilated by future patients and their doctors. Data monitoring committees might even decide to close one of the randomisation strata, such as closing down 30:70 randomisation if the interim data pointed moderately convincingly in favour of A.

Not only should there be wider debate about the dissemination to doctors and patients of data monitoring committees' decisions on interim analyses but there should be wider debate about how those decisions might affect both patient information sheets and randomisation ratios.

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1 Lilford RJ, Braunholtz D, Edwards S, Stevens A. Monitoring clinical trials—interim data should be publicly available. *BMJ* 2001;323:441-2. (25 August.)
2 Gore SM. The consumer principle of randomisation. *Lancet* 1994;343:58.

Interim data should not be publicly available

Editor—Lilford et al show little understanding of the uncertainties involved in the assessments of treatment effects.[1] Few people are aware of how much point estimates wander about as both more patients and longer follow up accrue in a randomised clinical trial. This means that choices made by patients on the basis of interim analyses are unlikely to be "rational." The trouble is that when results go in a particular direction, the natural instinct is to assume that they will continue that way. This is why phrases appear in papers such as, "there was a trend of 5% in favour of treatment A, but this is not yet significant," implying that with more data it will become so. Of course, it is just as likely that future data will add up in the other direction so that the final result may be against treatment A.

Data monitoring committees have been implemented for good reasons that have been well discussed in the past. The issues involved in assessing results are not simple, and involve not only statistical uncertainty but issues such as length of follow up, internal consistency, baseline comparability, compliance, adjustment for repeated tests, etc.[2] The publication of interim results of ISIS-2 was for a particular subgroup where benefit was clear.[3] There are obviously circumstances where reporting certain results will increase recruitment (for example, where sceptical clinicians may decide to start entering patients because of apparently positive effect), and others where they will reduce it (for example, a slightly positive result might make clinicians stop recruiting, with the sceptical ones all stopping use of the treatment and optimistic ones all deciding to use it).

Rather than going backwards and repeating the mistakes of the past, when almost all trials were too small to give definite answers—and even some of those that apparently did, later turned out to be misleading[4]—we should be concentrating on the problem of lack of reporting of final results for all randomised trials done. At present the information available on a question is often a biased subset owing to this lack of publication.[5]

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2 DeMets DL. Data monitoring and sequential analysis—an academic perspective. *J Acquir Immune Defic Syndr* 1990; 3(suppl 2):S123-33.
3 ISIS-2 Steering Group. Intravenous streptokinase given within 0-4 hours of onset of myocardial infarction reduced mortality in ISIS-2. *Lancet* 1987;i:502.
4 Collins R, Peto R, Gray R, Parish S. Large-scale randomized evidence: trials and overviews. In: Weatherall DJ, Ledingham JGG, Warrell DA, eds. *Oxford textbook of medicine*. 3rd ed. Oxford: Oxford University Press, 1996:21-32.
5 Dickersin K, Min YI, Meinert CL. Factors influencing publication of research results: follow-up of applications submitted to two institutional research boards. *JAMA* 1992;263:374-8.

Caution may be warranted in releasing interim trial data

Editor—Interpreting trial data even at the end of a trial can be controversial and difficult. Though there may be arguments in some cases for releasing interim data,[1] depending on the type of trial and strength of findings, there are surely also strong arguments for patient participants and trialists keeping their nerve until all results are gathered in. Why else do we employ statisticians to undertake power calculations and provide recommendations of the cohort size needed to produce reliable data?

Visualising what recruitment by randomisation means has been facilitated by likening it to the uneven and random distri-

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bution of raindrops on a surface before complete coverage. My understanding is that earlier trials in a series for review, and interim results within a trial, can both be misleading in the apparent direction of results found.

Marketing pressure can also lead to premature stoppage of trials, where profit rather than patients is the prime motivation for the trials. This deprives not only "far term" but also "near term" participants of the satisfaction of finding out the long term benefits and the overall health benefits of an intervention already given to many near term participants. This was the case in the controversial stoppage of the American trial of tamoxifen for the prevention of breast cancer.[2] It is interesting that the European prevention trials did not follow suit; this was perhaps because of a more convergent and sensitive motivation of trialists and participants and joint determination to obtain long term data despite apparent interim findings in the United States.[3]

If the profession and patients collaborate in designing trials with agreed long term and short term objectives and aims, agreed stopping rules, and procedures for rapid and thorough dissemination of results (including both professional and lay interpretations) we might all derive full benefit and satisfaction from staying the course until the end. If patients are equal partners in devising such contracts with professionals, by being on trial steering committees and data monitoring committees, they will have equal opportunity to make decisions about whether or not to abandon the trial or release interim data.

Many participants join trials for altruistic reasons (23%) or trust in the doctor (21%), not for what benefit they hope to get from it.[4] Why then adopt a shortcut process that reduces the amount of learning, understanding, and benefit obtained from trials with participants who will have received an intervention that cannot be undone?

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2 Fisher B. Current controversies in cancer. Tamoxifen for the prevention of breast cancer: pro. *Eur J Cancer* 2000;36:142-50.
3 Thornton, H. Relationship of trial design to value of data for patient? *Eur J Cancer* 2000;36:1585-6.
4 Jenkins V, Fallowfield L. Reasons for accepting or declining to participate in randomised clinical trials for cancer therapy. *Br J Cancer* 2000;82:1783-8.

Several points are contentious

Editor—I have four objections to Lilford et al's proposal for monitoring clinical trials.[1]

Firstly, I object to the philosophy. Any people involved as subjects in a study are already being used as a means, not an end. The fact that they have volunteered for such a role is admirable and puts them on a par with firefighters and soldiers, who risk their lives more than other members of society in a way that benefits society. Concealing which treatment a person is receiving is perfectly acceptable and commonplace; therefore, perfect disclosure is not an absolute requirement for a morally justifiable trial. Trials are justified if there is insufficient valid information for an unbiased observer to make a decision.

Trials are shown to be valid when a well designed, well conducted study is published in an appropriate forum. Release of data effectively replaces the last stage with one that is less rigorous. This is not acceptable because (apart from the danger of mistaken conclusions) it is not what the researchers and subjects agreed to.

Secondly, I object to practical aspects of the proposal. Some studies do not have data monitoring committees, and the committees that do exist may have very different ideas. Thus the scene is set for confusion on a grand scale. Lilford et al suggest that there could be guidelines. These are likely to be a great deal more complicated than the present situation. This proposal will also greatly reduce the weight of properly published evidence.

Thirdly, I object to the moral hazard. If I am a researcher planning a trial in which it will be difficult to recruit sufficient subjects to gain certainty then I may be tempted to go through the motions of applying for funding, ethical approval, etc on the basis of an unrealistically rapid recruitment schedule. I will do this in the knowledge that the data will get released anyway before the conclusion of the trial and a good trend will gain approval for the treatment.

Lastly, I object to the authors' misunderstanding of the role of data monitoring committees. I believe that their role is to stop trials that are causing undue adverse events and halt trials where the treatment effect has been underestimated—that is, where the number of subjects needed to show the effect is really much lower than initially thought. Inconclusive results at this stage represent a well designed study.

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Interim data are at least as important as interim analyses

Editor—Lilford et al make several points about the need to release interim results from clinical trials.[1] In discussing this, however, they write of "interim data," not clarifying the separation between making the results of interim analyses known and releasing the actual interim data.

Researchers are always enormously reluctant to release their data even after they have published the results of their research.[2] Given this, they are unlikely to consider releasing the data that were the basis of any interim analyses. The release of the actual data, however, should be considered at least as important as the release of interim analyses.

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2 Reidpath DD, Allotey PA. Data sharing in medical research: an empirical investigation. *Bioethics* 2001;15:125-34.

Latest data from START trial should be made available

Editor—The opinions expressed by Lilford et al regarding monitoring of clinical trials are relevant to a current trial in the United Kingdom of radiotherapy for breast cancer.[1] The international standard fractionation regimen consists of 50 Gy in 2 Gy fractions on five days a week, but the evidence base for this is tenuous. Many years ago it was suggested from reviews of treatment of advanced disease and skin metastases that fewer larger fractions might be more effective against breast cancer,[2] but radiotherapists have been reluctant to do this because of fear of increased late morbidity.

In 1986 two oncology centres embarked on a randomised trial comparing the standard 50 Gy with two schedules treating five times a fortnight, 39 Gy and 42.9 Gy, both in 13 fractions. Interim data were presented in 1994, showing a significantly lower morbidity for the 39/13 schedule: there was no difference in the rates of local recurrence of carcinoma, but there had been few recurrences at that time.[3] The trial closed in 1998 with 1400 patients enrolled. The schedules were continued as one of the arms of the multicentre standardisation of breast radiotherapy (START) trial[4] to obtain larger numbers and therefore more conclusive results. The trial data were taken over by the data monitoring committee and are being kept secret on the basis that their publication would prejudice recruitment to the trial. The final results of the trial will not be known for several years; meanwhile, 25 fractions remains the standard.

The median follow up of these 1400 patients is now eight years. If there is still no evidence of a significantly higher risk of recurrence from the 13-fraction schedule and the data were made publicly available, radiotherapists could reasonably offer women a course of treatment involving fewer hospital attendances and with fewer side effects rather than continuing to give the standard 25 fractions while awaiting results of the standardisation of breast radiotherapy trial. Other patients with cancer would also benefit from the consequent reduction in the workload and therefore shorter waiting lists in our hard pressed radiotherapy departments. The points raised by Lilford et al make a good case that it is now time to publicise the latest data from this trial.

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2 Cohen L. Radiation response and recovery. In: Schwarz EE, ed. *The biological basis of radiation therapy.* London: Pitman, 1966:208-16.
3 Yarnold JR, Bliss JM, Regan J, Broad B, Davison J, Harrington G, et al. Randomised comparison of a 13-fraction schedule with a conventional 25-fraction schedule of radiotherapy after local excision of early breast cancer: preliminary analysis. *Radiother Oncol* 1994;32 (suppl 1):S101.
4 START Trial Management Group. Standardization of breast radiotherapy (START) trial. *Clin Oncol* 1999;11:145-7.

Getting consent for necropsies

Perhaps we should seek consent to show necropsies to students

EDITOR—Sayers and Mair highlight the reasons for which hospital (consent) necropsies are performed and for which clinicians are now faced with the task of seeking informed consent—to confirm the cause of death, to answer diagnostic queries, and to obtain and retain material for research and teaching.[1] Another key use of a necropsy, not mentioned on the consent form, is in undergraduate teaching. Many medical students will encounter the necropsy during their training, either witnessing the whole procedure or as a demonstration of the pathological findings of the procedure in which organs and tissues are displayed (perhaps with the patient's body in the background) before their return to the body.

Should explicit informed consent be obtained to use necropsy in this way? The short report by Westberg et al in the same issue serves to highlight the importance of obtaining consent for students to witness invasive procedures such as a vaginal examination, even though most patients do not object.[2] Necropsy is no less invasive. Whether patients and relatives would object to a group of students viewing the body after death is not known. It is established, however, that "an important precondition for good education of medical students is that patients are prepared to participate in training."[3] Failure to obtain consent denies the autonomy of both the patient and the relatives.

Some people argue that, once death has occurred and the decision to allow a necropsy has been taken, the worst is over and therefore the presence of students at the necropsy is of no consequence and does not require consent. This denies relatives the opportunity to be altruistic and know of the benefits that come to students from the procedure. We should be as concerned that consent is adequate as we are with who obtains it.

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1 Sayers GM, Mair J. Getting consent for autopsies: who should ask what, and why? *BMJ* 2001;323:521. (1 September.)
2 Westberg K, Lynøe N, Lalos A, Löfgren M, Sandlung M. Getting informed consent from patients to take part in the clinical training of students: randomised trial of two strategies. *BMJ* 2001;323:488. (1 September.)
3 Lynøe N, Sandlung M, Westberg K, Duchek M. Informed consent in clinical training–patient experiences and motives for participating. *Med Educ* 1998;32:465-71.

Most relatives give consent once reasons for necropsy are explained

EDITOR—As pathologists performing a large number of perinatal autopsies, we read Sayers and Mair's personal view with a mixture of sadness and disbelief.[1] We do not want to increase the relatives' and (in our case) parents' grief with detailed descriptions of postmortem procedures. But current levels of information available mean that most already know the basics, and people want to have a choice. Most of the detailed explanations of what might happen to tissues and organs at a postmortem examination have been added to the consent form at the insistence of parents' pressure groups.

Teaching is essential for new doctors, all of whom need to learn at least the basics of pathology if they are going to be capable clinicians. Most of the research projects requiring postmortem tissues are clinicopathological studies. Almost all of them use tissues that will be retained for histological diagnosis anyway. Because we now need consent to retain even tissues used for diagnosis, clinicians could explain that this retention might help relatives in the future (including in future pregnancies and similar diseases in another member of the family).

Most pathologists retain full organs for teaching and training or research only at the specific request of a clinician. We are surprised that some doctors are prepared to give parents and relatives the consent form and let them deal with it by themselves in such a traumatic period.

Until recently there has not been much training in communications skills in medical schools, but surely opting out of the patient-doctor relationship at this time is not an answer. The main reasons for a hospital necropsy are to explain to the relatives what happened to the patient and to help the clinicians understand the disease process. It is not the pathologist who primarily benefits from a necropsy.

In our experience, most parents (and most hospital postmortem examinations are performed in perinatal cases) agree to the requests in the consent form for a postmortem examination once the reasons are explained to them, especially by a doctor they have met and trust. We are surprised that Sayers and Mair find it acceptable for a person whom the parents or relatives have never met before to come and talk to them at this time or at the time of the necropsy.

If clinicians want to discuss any aspect of the necropsy, including the reasons for requests other than diagnosis, we are all happy to help.

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Bereavement teams might ask for consent for necropsy

EDITOR—As we work in histopathology we have a keen interest in the process of hospital necropsy and getting consent for necropsies.[1] We can assure all clinicians that pathologists across the United Kingdom are acutely aware of the Alder Hey scandal, and caution abounds within the profession.

Custom does indeed dictate that clinicians involved in patient care approach relatives to seek consent for necropsy, but, although the new consent forms may be overly detailed, the amount of information one is required to give relatives in order to obtain genuinely informed consent has not changed. The total time needed to achieve consent has not altered greatly, although a small amount of time is required to take the relatives through the layout of what can be a slightly confusing form.

The process of asking relatives whether they want some parts of the body or some specific organs left intact is unhelpful to them and also to the pathologist. Indeed, incomplete necropsies, without the option to take samples for microscopic examination or toxicology tests, often fail to give the definitive answers desired; the utility of doing only a partial necropsy should often be questioned. It is also unrealistic, when one considers the logistics involved, to suggest that pathologists should consult families (in the middle of the procedure) when something interesting is found that may require the results of histological tests to diagnose fully.

As Sayers and Mair state, doctors are expected to be sensitive, but therefore why do they propose that a pathologist—not previously known to the patient or family and therefore less able to empathise with their situation—should approach relatives for consent?[1] Staffing issues should also be considered. Clinicians are stretched for time, but moving the onus to pathology, which currently has the biggest consultant staffing crisis of any specialty, would only make matters worse.

Given the changes in the medicolegal climate, new, detailed consent forms are a necessity. Maybe the best way forward is to consider employing specially trained bereavement teams to deal with this process.

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Genetics mediate relation of birth weight to childhood IQ

EDITOR—Matte et al reported an association between birth weight and childhood IQ.[1] To control for confounding by maternal and family factors they examined this relation in sibships of the same sex and found an association between birth weight and IQ

Full IQ score at ages 5, 7, 10, and 12 of cotwins with lowest and highest birth weights in dizygotic and monozygotic twin pairs. Values are means (SD)

	Dizygotic twin pairs				Monozygotic twin pairs			
	No	Cotwin with lowest birth weight	Cotwin with highest birth weight	P*	No	Cotwin with lowest birth weight	Cotwin with highest birth weight	P*
All twins								
Birth weight (g)		2451 (436)	2804 (380)	0		2337 (427)	2545 (404)	0
Full IQ score:								
Age 5	77	99.4 (12.9)	102.6 (12.8)	0	81	102.9 (12.8)	105.3 (13.4)	0.01
Age 7	72	99.0 (13.9)	103.2 (14.5)	0	73	104.0 (15.1)	103.7 (14.0)	0.83
Age 10	75	104.1 (13.9)	106.8 (13.9)	0	75	108.0 (16.2)	107.6 (16.5)	0.70
Age 12	73	98.6 (12.8)	100.3 (14.1)	0.22	75	100.2 (13.9)	101.27 (12.5)	0.20
Gestational age >36 weeks								
Birth weight (g)		2550 (436)	2935 (333)	0	0	2535 (383)	2745 (353)	0
Full IQ score:								
Age 5	59	99.5 (12.7)	103.0 (11.9)	0	45	101.6 (11.7)	104.7 (13.3)	0.02
Age 7	56	98.2 (14.5)	104.0 (14.7)	0	42	101.1 (14.3)	101.3 (14.1)	0.90
Age 10	58	104.6 (13.7)	108.3 (12.2)	0	42	106.7 (15.1)	105.4 (16.1)	0.34
Age 12	56	98.7 (13.2)	101.73 (13.2)	0	41	97.4 (12.4)	98.3 (11.6)	0.39

*IQ differences between cotwins with lowest and highest birth weights were tested with paired *t* tests.

within male sibships. This association may be mediated by genetic factors.

The impact of genetic factors on this association can be determined through the investigation of birth weight and IQ in twin pairs. Differences within dizygotic twin pairs are a function of both genetic and non-genetic factors, whereas differences within monozygotic twin pairs are almost completely caused by non-genetic factors.[2] If genetic factors mediate the association between birth weight and IQ it is expected that for dizygotic twin pairs the association between intrapair differences in birth weight and IQ is positive, while for monozygotic twin pairs no association is expected.

In a Dutch longitudinal twin study the association between birth weight and IQ was measured in 170 twin pairs of the same sex.[3] Birth weight was obtained with a questionnaire, administered to the mother after the birth of the twins. Full IQ was obtained at ages 5, 7, and 10 with the revised Amsterdam child intelligence test (RAKIT), a Dutch intelligence battery, and at age 12 with the Wechsler intelligence scale for children.

Comparison between cotwins with lowest and highest birth weights showed that the dizygotic twins with the lowest birth weight had a lower IQ than their cotwin with the highest birth weight at ages 5 to 10 (table). This difference was not seen in the monozygotic twin pairs. Mean IQ was the same for the twins with the lowest and highest birth weights. When twin pairs with a gestational age of <37 weeks were excluded the results were similar. We also determined the association of intrapair differences in birth weight and IQ. At ages 7 and 10 this association was positive in dizygotic twin pairs ($r=0.29$, $P=0.01$; $r=0.27$, $P=0.02$) but not in monozygotic twin pairs ($r=-0.02$, $P=0.88$; $r=0.01$, $P=0.91$).

Our results suggest that genetic factors mediate part of the association between birth weight and childhood IQ, at least until age 10. We found an association between intrapair differences in birth weight and IQ in dizygotic twin pairs. As twin pairs share influences such as prenatal factors, socioeconomic status, parental smoking, and parental age, the influence of these confounders is negligible. In addition, in monozygotic twin pairs, in whom intrapair differences reflect only environmental influences, the association between intrapair differences in birth weight and IQ is absent.

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2 Philips DI. Twins studies in medical research: can they tell us whether diseases are genetically determined? *Lancet* 1993;341:1008-9.
3 Boomsma DI, van Baal GCM. Genetic influences on childhood IQ in 5- and 7-year old Dutch twins. *Dev Neuropsychol* 1998;14:115-26.

Quality of care for people with dementia

Change in attitude is needed

EDITOR—Are readers surprised by Ballard et al's findings that nursing homes are failing the needs of patients with dementia?[1] Probably not, especially if they spend any time in nursing homes either as a healthcare professional or as a relative or friend.

Ballard et al's conclusion that strategies to improve joint working between the agencies to provide integrated specialist services sounds good, but surely it's the day to day care that's failing people with dementia. Of course they need specialised services, but they need compassion, an understanding of their needs, appropriate activities, and human interaction. These things need time and a special kind of staff who enjoy working with elderly people with challenging problems.

Until relatively recently we were also failing children with severe learning disabilities. Now we understand these children's needs and rights to education, choice, and social interaction. People who work with these children are highly regarded in our society, if not well financially remunerated. It seems to me that until we start to apply the same ethos of care to our elderly people that we apply to our ill and disabled children we will continue to fail them. We must always remember that one day it may be us sitting in that chair with no way of communicating our distress.

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1 Ballard C, Fossey J, Chithramohan R, Howard R, Burns A, Thompson P, et al. Quality of care in private sector and NHS facilities for people with dementia: cross sectional survey. *BMJ* 2001;323:426-7. (25 August.)

Dementia care mapping is inadequate tool for research

EDITOR—Ballard et al draw conclusions from observing residents' activities in establishments providing care for people with dementia that few specialist professionals would disagree with: that standards are poor and must be raised.[1] Their methodology, however, is potentially misleading if service providers use the dementia care index alone as an indicator of improved quality of care.

Dementia care mapping measures the subjective experience of the service user across three dimensions (type of activity, degree of comfort, and time). Standardisation of data is achieved through thorough accredited training, and the dementia care index is derived from aggregation of observations. Typically in our experience, the activity is observed during the working hours of people other than nurses and rarely during early mornings, evenings, and nights.

The paper refers to a standardised six hours of mapping in each home in the study but fails to extrapolate general and relevant data on the quality of the services provided across a 168 hour week. When longitudinal studies have used the dementia care index as

a methodological tool it has been to measure the effect of training, empowerment, or other external dynamic factor rather than overall quality of life or care. As experienced managers and clinicians in acute and long stay dementia wards, we would be concerned if the quality of care provided could be generalised from observations in such a period.

Increasing use should not be made of data from dementia care mapping as a comparative indicator of quality of care in units or for individuals. Incorporating a less subjective measure of quality of life to the study design, such as the dementia specific quality of life scale[2] or a user oriented framework,[3] would have added to the validity of the authors' findings.

Marshall's editorial highlights several structural and process deficits in places where dementia care is provided.[4] Externally set standards, expectations, resources, and training are all important in improving care. Each of these factors needs to be incorporated into the scrutiny of care quality for such research to have quantitative conclusions. Dementia care mapping can only presage qualitative discussions within teams.

We would be concerned if care homes began to market their services on the basis of a six hour observed rating, but this may be an outcome of such research methods. Clinicians and service managers need to clarify the minimum standards for care homes for older people.[5] The tools we use to develop and audit the quality of care must comprehensively reflect the multitude of needs of people with dementia.

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2 Gonzalez-Salvador T, Lysetkos CG, Baker A, Hovanec L, Roques C, Brandt J, Steele C. Quality of life in dementia patients in long term care. *Int J Geriatr Psychiatry* 2000;15:181-9.
3 Dabbs C. What do people with dementia most value in life? *J Dementia Care* 1999 July/August 16-19.
4 Marshall M. The challenge of looking after people with dementia. *BMJ* 2001;323:410-1. (25 August.)
5 Department of Health. *Care homes for older people. National minimum standards.* London: Stationery Office, 2001.

Registries charting epidemiological trends and benchmark outcomes are required

Editor—We have some reservations about the use of dementia care mapping (used in the paper by Ballard et al) for benchmarking the quality of care of people with dementia.[1] A fundamental problem is that health and social services have failed to chart the needs for the care of dementia and in consequence service commissioning has been inadequate. Ballard et al's report finds both the health service and the independent sector deficient. It is particularly damning for a health service that has had over 50 years to plan investment in services for people with dementia.

Care homes are the subject of intense policy development and escalating regulation. Commissioning, torn between "best practice" and "value," is dominated by financial constraints. Marshall, in the accompanying editorial, rightly promotes creatively designed environments for care,[2] but the necessary finance is not forthcoming.

We have seen a recent phenomenon in referrals for placement in a care home of frail elderly people currently in acute hospital beds. Assessment by care home staff shows these people to have dementia and to be commonly sedated, in an apparent act of containment. A rationale for this seems to be health authority rules that registered mental nurses must supervise residents with dementia in nursing care homes. An irreconcilable shortage of registered mental nurses has led to this regrettable "diagnostic denial." Assessments seem to say more about the needs of commissioners than the needs of the person needing placement.

Whole systems of integrated care have been proposed.[3] A recent report from the King's Fund highlighted the poor pay of care workers compared, for example, with supermarket employees.[4] Combine this with inadequate commissioning of basic and continuing training of care staff and lack of career progression for staff in dementia care and Ballard et al's observations become entirely understandable.

Good dementia care does exist in both the NHS and the independent sector, but usually as a result of enthusiastic champions rather than design. The dementia care literature reports many anecdotes of inadequacy and too infrequent evidence of innovation. Inclusive registries are required that chart epidemiological trends and benchmark outcomes. Such an approach would inform investment as well as regulation for dementia care, putting dementia on an equitable basis with conditions such as heart disease and cancer.

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1 Ballard C, Fossey J, Chithramohan R, Howard R, Burns A, Thompson P, et al. Quality of care in private sector and NHS facilities for people with dementia: cross sectional survey. *BMJ* 2001;323:426-7. (25 August.)
2 Marshall M. The challenge of looking after people with dementia. *BMJ* 2001;323:410-1. (25 August.)
3 Royal College of Physicians. *The health and care of older people in care homes. A comprehensive interdisciplinary approach.* London: RCP, 2000.
4 Henwood M. *Future imperfect. Report of the King's Fund care and support worker inquiry.* London: King's Fund, 2001.

Teenage pregnancy is not a public health problem

Editor—We agree with Smith and Pell's interpretation of their own and others' results that first teenage pregnancies are not associated with adverse outcomes, but we disagree with their conclusion that the associations they found between second teenage pregnancy and risk of preterm delivery and stillbirth indicate causation.[1] The most likely explanation is a combination of inadequate control for socioeconomic position, which the authors concede, and differences in the interval between pregnancies among teenage compared with older mothers.

Differences in pregnancy spacing cannot be rejected as an explanation, as the authors attempt to do, without its impact in this study being assessed. Furthermore, the authors do not consider the possible impact of differences in antenatal care between pregnant teenagers and older women in any of their analyses.

Health professionals should not accept without challenge the myth that teenage pregnancy is an important public health problem in the way that these authors do. There is no biological reason to suggest that having a baby before the age of 20 is associated with ill health. It is increasingly common for women to delay their first birth until they are in their 30s; the mean age at first birth for married women in England and Wales was 29.3 in 1999. This is despite the increased risk of chromosomal abnormalities and complications of pregnancy in this age group.

Women having babies in their 30s and 40s are not labelled a public health problem, and neither are women who have problems conceiving, even though their babies have an increased risk of perinatal death.[2] This so called public health problem of teenage pregnancy is really a reflection of what is considered to be socially, culturally, and economically acceptable in the United Kingdom.

Current policy in the United Kingdom aims, firstly, to halve the conception rate of the under 18s and set a downward trend in the rate for under 16s by 2010 and, secondly, to achieve a reduction in the risk of long term social exclusion of teenage parents and their children.[3] We would argue that the second of these goals is the appropriate public health aim, and yet most action is likely to be geared towards the first. A primary care group in Bristol received funds from the local health authority's inequalities budget to undertake work towards achieving the first of these targets only.[4]

Teenage pregnancy is not a public health problem; the cumulative effect of social and economic exclusion on the health of mothers and their babies, whatever their age, is.

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1 Smith GCS, Pell JP. Teenage pregnancy and risk of adverse perinatal outcomes associated with first and second births: population based retrospective cohort study. *BMJ* 2001;323:476-9. (1 September.)
2 Draper ES, Kurinczuk JJ, Abrams KR, Clarke M. Assessment of separate contributions to perinatal mortality of infertility history and treatment; a case-control analysis. *Lancet* 1999;353:1746-9.

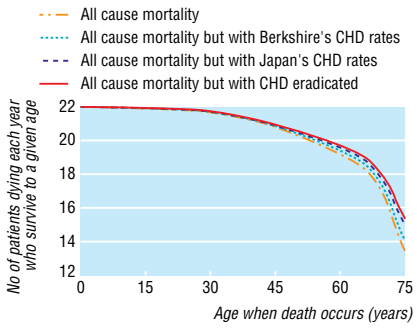
3 Social Exclusion Unit. *Teenage pregnancy*. London: Stationery Office, 1999.
4 Velleman G, Williams E. The role of the primary care group in promoting health. In: Scriven A, Orme J, eds. *Health promotion, professional perspectives*. New York: Palgrave (in association with Open University), 2001: 43-51.

National service frameworks

Framework's claim that GPs should devote more time to preventing coronary heart disease needs scrutiny

EDITOR—The national service framework for coronary heart disease states that "additional coronary heart disease prevention activities … will consume time, effort and resource. Primary care teams will have to give careful consideration to how resources used on lower value and lower priority activities might be redirected to the high priority, high value treatments identified."[1] The framework does not give any evidence justifying the claim that traditional services are low value or quantify the benefit of high value treatments.

I estimated the maximum benefit of activities aimed at reducing mortality by considering patients registered with a typical singlehanded general practitioner in northwest Lancashire because the area has the highest mortality from coronary heart disease in the United Kingdom.[2 3] Each year such a practice registers about 22 births and deaths.[3] Since the framework's objective is to reduce mortality among those under 75 I estimated the maximum impact of the activities by assessing how many more patients would survive to 75 if all of them were provided.[1] I used an actuarial life table method to prepare several survival curves for an annual birth cohort of 22 patients,[4] obtaining mortality and population data from the public health common dataset[3] and the Japanese Embassy (S Onishi, personal communication, 1999). I chose Berkshire's coronary heart disease rate because it is the lowest in the United Kingdom, and Japan's because it is the lowest in the world.



Survival curves for patients registered with typical singlehanded general practitioner in northwest Lancashire (1996 data). CHD=coronary heart disease. NW=northwest

The figure shows that if all cause mortality remains at 1996 levels and national service framework activities have no impact on coronary heart disease, 13.5 of the 22 patients dying each year will celebrate their 75th birthday; if coronary heart disease is eradicated, 15.5 patients will do so; if northwest Lancashire's coronary heart disease mortality is reduced to that of Japan, 15; and if the mortality is reduced to that of Berkshire, 14.

The maximum benefit that could result from all national service framework activities seems to be that two extra patients could survive to 75 annually, but this is unobtainable because the services are unlikely to eradicate coronary heart disease. Furthermore, since Lancastrians are unlikely to adopt the lifestyle of the Japanese, fewer than 1.5 extra patients can be expected to survive to 75. Lancastrians could acquire the behaviours and social and medical advantages of those in Berkshire, in which case an extra 0.5 patient could survive to 75 annually.

As general practitioner services are only a small proportion of all the framework activities the impact that a general practitioner could make will be modest. I believe that the framework's claim that general practitioners should devote more time to coronary heart disease prevention and less to traditional services is not compelling.

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1 Department of Health. *National service frameworks for coronary heart disease; standard four*. London: DoH, 2000.
2 Doll R. *The causes of cancer: quantitative estimates of avoidable risks of cancer*. Oxford: Oxford University Press, 1981.
3 Institute of Public Health. *Public health common data set*. Vol III. Surrey: IPH, 1996.
4 Mausner JS, Kramer S. *Epidemiology: an introductory text*. 2nd ed. Philadelphia: Saunders, 1985.

National service framework for older people is worth a try

EDITOR—More than three pages of critical letters from senior figures threaten to blow the national service framework for older people into oblivion.[1] Isn't it strange that such a quiet and sober document has generated such a response?

The document will do much for older people if we use it well. It is fearless in drawing attention to ageism and encourages us to consider older people as individuals. It looks at the systems that have developed in health care in recent years, and says that old people are not well served by being required to receive the same approaches as younger people with simpler health problems.

The framework considers some of the most common problems of old age, looking at the contributions of history, lifestyle, and family and recognising the differing and complementary strengths of social care, primary care, and secondary care. It encourages us to work across boundaries of mental and physical health and always to seek to promote good practice and achieve best health for older people.

This is a good attempt to help us do better; it should be given a chance.

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1 Correspondence. New beginning for care for elderly people? *BMJ* 2001;323:337-40. (11 August.)

Don't GPs have to be good clinicians any more?

EDITOR—I agree that the selection of doctors is far from perfect, but I am concerned that the emphasis shown by Patterson et al on key competencies for general practitioner registrars in Career focus will encourage the selection of politically correct candidates with little clinical acumen.[1]

Of the 11 key competencies quoted, only one, remarkably, related to clinical skills. The other 10 competencies, all management related, could easily have been condensed into two or three. Aren't professional integrity, coping with pressure, and empathy and sensitivity personal attributes in the same way as motivation and flexibility are? Aren't organising and planning skills, legal and political awareness, problem solving, and communication skills also part of team involvement and managing others? And what on earth is conceptual thinking? In this new world of general practitioner training I am already feeling deficient.

I see a similar trend in my own hospital's training days in the vocational training scheme, and I am concerned that the general practitioners of tomorrow will become clinically weakened as a result. I have noticed a similar trend in my own specialty, where the exit exam is now dominated by management and research, with only a quarter of it given to clinical acumen.

Surely clinical skills and expertise are more important now than ever; this worrying trend must be checked before it takes over the undergraduate curriculum as well.

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1 Patterson F, Lane P, Ferguson E, Norfolk T. Competency based selection system for general practitioner registrars [career focus]. *BMJ* 2001;323(7311, classified section):2. (1 September.)