Assessing the quality of hospitals

Hospital standardised mortality ratios should be abandoned

The quality of care provided by hospitals needs to be assessed objectively not only to stimulate clinicians and managers to make improvements but also to ensure public accountability, to enable patients to make informed choices, and to facilitate informed commissioning. Given the importance of all these activities, the measures used to assess quality must have sufficient validity and reliability. This is not true of the main measure being used in many countries, including the United Kingdom, the hospital standardised mortality ratio (HSMR). Before considering practical and methodological shortcomings in England, many of which are considered by Lilford and Pronovost in the linked article, the concept of using hospital deaths to judge the performance of a hospital needs to be considered.

A consequence of a failure to provide alternative forms of care has been that hospitals have taken on the role of providing a place for people to die. About half of us will end our days in a hospital bed. This makes it perverse to use a hospital’s mortality statistics to judge its quality of care, given that deaths are often an expected and accepted outcome. The incongruity of using mortality to assess a hospital is exacerbated by geographical variation in the proportion of deaths that occur in hospital (40–65%), which reflect not only the availability of alternative forms of end of life care, such as hospices and community palliative services, but also cultural, religious, and socioeconomic characteristics of the local population. It is no surprise to find that the higher the proportion of all deaths in a population that take place in hospital, the higher that hospital’s HSMR will be.

Aside from the inappropriateness of the concept of using death as a measure of hospital quality, several practical problems arise from shortcomings in the data used to derive HSMRs. The first results from variation in the diagnostic behaviour of doctors and hospitals. This leads to problems if the method of calculating the HSMR does not include all causes (or diagnoses) of death, as is the case with one approach, which excludes 20% of deaths. The resulting HSMR will partly depend on whether or not a death is ascribed to an included or excluded diagnosis.

Secondly, many secondary diagnoses (comorbidities), which are crucial for case mix adjustment, are commonly missing from hospital episode statistics, and those that are included often contain inaccuracies: in 2007–8, on average 17% were wrong, with an interquartile range of 8% to 26%.

The third, and most serious shortcoming of the data, is the failure of hospital episode statistics to recognise that many patients who die were admitted for end of life care. On average, hospital trusts report that only 4.5% of their patients who died were in this category, with many hospitals reporting none. Even the hospital that reported the most (22%) in 2007–8 may have underestimated this figure, because a detailed review of case notes at one trust showed that the true proportion was 37%. When this was taken into account its HSMR fell dramatically from 105 to 68.

Given these shortcomings in the data, it is no surprise to see how unstable HSMRs are as a measure. Recent reports that hospital mortality fell by an unbelievable 7% in only 12 months overall in England, and in some hospitals by more than 30%, shows the lack of validity of HSMRs. Their validity is also undermined by the finding that different methods for deriving HSMRs produce different results. For example, the mortality ratio for 2007–8 for Basildon and Thurrock Hospital derived by one company was 132 compared with 107 when derived by another.

Despite international support for using HSMRs to determine the quality of hospitals, particularly among policy makers and regulators, the validity of this measure has not been established. Indeed, it has barely been investigated. This could be done by comparison with more detailed in-depth methods of determining the quality of clinical care. Meanwhile advocates of HSMRs question whether its accuracy matters. They claim that, regardless of all the shortcomings, the publication of HSMRs is justified because it stimulates hospitals to improve their performance. To support this they cite examples of secular changes in HSMRs, ignoring the fact that these apparent improvements do not distinguish between data artefacts (such as changes in coding practice and admission and discharge policies) and real improvements. This cavalier approach ignores the danger of unjustified and unfair criticism of hospitals, with the attendant risks of damaging staff morale and public confidence. In addition, it may risk undermining staff and public confidence in quality assessment in general, encouraging scepticism about whether performance can ever be measured accurately.

Some, although not all, of the shortcomings of HSMRs have been recognised by regulators who advocate their use, and by the recent inquiry into poor care at Mid Staffordshire NHS Foundation Trust. The proposed solution to methodological shortcomings is believed to lie in achieving a consensus among advocates on how to calculate HSMRs, while the problem of the public, managers, and the media misinterpreting the agreed measures is to be solved by improved understanding of their indicative rather than definitive role. Such caution is to be welcomed but is unlikely to be realised given the nature of the news media.

The inadequacies of HSMRs and the potential harm they may cause does not mean that we must abandon our attempts to measure the quality of hospital care. Instead we should turn to the increasing number of more specialised sources of data, in particular those established for national clinical background.
Each full time general practitioner in the United Kingdom has as many as 10 patients with chronic fatigue syndrome (CFS/ME) on their list. Many feel they have little to offer with regard to treatment. Patients in turn are often left feeling misunderstood and poorly cared for.

Currently, the only evidence based treatments for this condition reviewed in the Cochrane Library and recommended by the National Institute for Health and Clinical Excellence are cognitive behavioural therapy and graded exercise therapy, with cognitive behavioural therapy in specialist care having the larger evidence base. A primary care trial of brief cognitive behavioural therapy for CFS/ME offered by general practitioners who had received simplified training in the subject was unsuccessful. Few patients with CFS/ME receive specialist services, partly as a result of limited access, but also because many feel that psychological treatments delegitimise their condition. Thus, a treatment that includes aspects of the successful treatments, but in a more pragmatic fashion with less emphasis on psychology, is an attractive proposition. But does it work?

The linked randomised controlled trial by Wearden and colleagues, assesses pragmatic rehabilitation for CFS/ME offered in primary care. The rehabilitation consists of providing patients with detailed explanations for their symptoms combined with a carefully graded exercise programme, delivered by supervised general nurses after training. Patients randomised to this treatment became significantly less fatigued and depressed, and they slept better than patients who received usual care. However, one year later no significant difference was seen between the groups.

This suggests that pragmatic rehabilitation works, but only in the short term. Why then did an earlier randomised controlled trial of pragmatic rehabilitation with a single skilled therapist show large changes in fatigue and disability at one year of follow-up? Wearden and colleagues explain that their patients had more comorbidity and disability than patients in the earlier trial, and indeed most other trials. Increased disability is a recognised predictor of poor outcome of cognitive behavioural therapy in this condition. This may be even more relevant for a minimal intervention from less experienced practitioners. A recent trial found that guided self instruction cognitive behavioural therapy, accompanied by minimal support from a therapist, reduced fatigue and disability in patients with less severe rather than more severe CFS/ME. Therefore the best approach may be stepped care, in which patients with less disability are offered minimal intervention, whereas more severely affected patients are offered intensive specialist input. Alternatively, having more sessions of pragmatic rehabilitation for longer may build on initial improvements. In Wearden and colleagues’ trial, patients received fewer sessions (eight hours in total) than most successful trials of cognitive behavioural therapy and graded exercise therapy.

A further question is whether generalists are as successful as specialists in offering behavioural interventions. A large Dutch trial showed that 16 hours of cognitive behavioural therapy delivered by a range of recently trained health professionals was effective for at least a year, although the improvements were less than those obtained for highly skilled therapists. The effectiveness of these treatments may be a product of therapists’ skill and the number of sessions, with less experienced therapists needing more sessions.

To understand these interactions further, trials comparing short and longer term treatments with skilled and unskilled therapists are needed. These should also examine the cost effectiveness of different levels of therapeutic skill. The economic and personal burden of CFS/ME is large, yet data on cost effectiveness are scarce. Wearden and colleagues’ trial also investigated supportive listening therapy for CFS/ME. This approach is often used by
Prostate cancer and deprivation

Less radical treatment corresponds with higher deprivation, but the effect on survival differences is unclear

The Alma-Ata Declaration of 1978 states: “The existing gross inequality in the health status of the people particularly between developed and developing countries, as well as within countries, is politically, socially and economically unacceptable and is, therefore, of common concern to all countries.” Many studies have shown large disparities in the burden of cancer according to race or ethnicity and socioeconomic status. Indeed, socioeconomic factors such as poverty, inadequate education, and lack of health insurance are more important determinants than biological differences. In the linked study, Lytrasopoulos and colleagues use a population based cancer registry to assess variations in the management of prostate cancer in patients of different socioeconomic status.

Prostate cancer is the most common non-cutaneous cancer in men in most industrialised countries. Stage at diagnosis and mode of treatment are the main determinants of the outcome for most cancers. Differences in survival from prostate cancer according to socioeconomic status, after adjustment for stage at diagnosis, are well documented. However, the effect of socioeconomic status on therapeutic decisions is less clear. A study of patients with prostate cancer in the United States found that those with the lowest socioeconomic status were less likely to receive surgery and radiotherapy (independent of age, ethnicity, disease stage, and geographical region). Similarly, a recent study in the United Kingdom found that men from more affluent areas were more likely to receive radical treatments.

Lytrasopoulos and colleagues assessed the relation between initial radical treatment (radiotherapy and radical surgery) and socioeconomic status, measured using a small area deprivation index. Incident cases of prostate cancer (35 171 men aged over 50 diagnosed 1995-2006) were identified from the population based cancer registry in Cambridge, which covers 5.5 million people. Information on cancer stage was available for 16 020 patients (45.5%). Radical treatment was less common in patients from the most deprived areas even after adjustment for stage at diagnosis. However, the effect of socioeconomic status on survival differences is less clear. A study of patients with prostate cancer in the United States found that those with the lowest socioeconomic status were less likely to receive surgery and radiotherapy (independent of age, ethnicity, disease stage, and geographical region). Similarly, a recent study in the United Kingdom found that men from more affluent areas were more likely to receive radical treatments.

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diagnosis. Among the most affluent, about 8% were treated with radical surgery and 29% with radiotherapy, whereas the corresponding figures were about 4% and 21% for the most deprived. These socioeconomic differences in odds of treatment use were also found in the multivariate analyses after adjustment for age, diagnosis period, and morphology. The authors concluded that the differences are unlikely to be artefactual and probably reflect true differences in clinical management.6

Their study confirms earlier findings that lower socioeconomic status is associated with less frequent use of radical treatment for prostate cancer.4,7 Possible explanations are behavioural (values, attitudes, health behaviour), social (communication skills, social support, economic resources, insurance), and clinical (comorbidity, choice of treatment, access to health care).5 Interpretation of the results should consider the potential limitations—individual socioeconomic status was not assessed, which could reduce differences, and no information was available on comorbidity or ethnicity.

The study provides no explanation for the variation in treatment seen. Factors involved in treatment decisions include contraindications for treatment (comorbidity and functional status), complications, and patients’ preferences. Furthermore, we do not know how eliminating these differences in treatment would reduce inequalities in survival. Strategies to reduce disparities in survival related to socioeconomic status must be based on an understanding of their cause.

One possible reason for variations in management by socioeconomic status is the lack of evidence about the relative merits of treatments. Several treatments are available (including surgery, radiation, cryotherapy, hormonal treatment, combination of these treatments, and expectant management) and few trials have compared them.8,9 Hence, treatment decisions cannot be made on evidence alone but require a doctor’s judgment and negotiation with the patient. Better educated patients may process information more easily, and doctor-patient communication may be more effective or fluent when doctor and patient have similar social backgrounds.10,11

Prostate specific antigen (PSA) testing has increased the detection of prostate cancer and resulted in overdiagnosis and overtreatment.2,12 Yet Lyraziopoulos and colleagues think of undertreatment as a potential problem in patients with a low socioeconomic status.13 The most deprived men could be having too few radical prostatectomies and radiation treatments or the most affluent could be having too many. Because the reasons for these socioeconomic disparities are unclear and the best way to reduce them is unknown, future studies should investigate the contribution of various prognostic factors to differences in survival. It would also be useful to evaluate such differences within the treatment arms of randomised trials.

How cognitive biases affect our interpretation of political messages

What we hear is often very different from what we are told

British readers of the BMJ will soon get to vote on the competing visions of the political parties at the general election. Although the mainstream parties each claim the middle ground, there are important differences in how they will approach the economic challenges that lie ahead, with potentially major implications for health and health care. How fast and how deep should cuts in public spending be? Are targets a good or a bad thing? What is the appropriate role of private healthcare providers?

Voters must decide which of the different answers they agree with, yet—as seen in recent disputes between leading economists about how to tackle the government deficit—it is possible for two well informed groups of people faced with the same evidence to reach completely different conclusions about what should be done. How do voters interpret such complex information and what influences them?

There is considerable evidence that people presented with balanced arguments place weight on those they already agree with,1 exhibiting what is termed confirmation bias.2 A recent study from the United States randomly allocated one of four versions of an authoritative news story about diabetes to people who had declared different political allegiances.3 Each story was identical except for how they described the cause of diabetes. One said nothing about the cause (the control), whereas the three others cited genes, individual lifestyle choices, and social determinants. They were then
Has the European Clinical Trials Directive been a success?

The academic community expresses concerns about its implementation

The laudable aims of the European Clinical Trials Directive (EU 2001/20/EC) were to improve the safety and efficiency of both commercial and investigator driven clinical trials and to provide the basis for improved European competitiveness. Unfortunately, even before the directive was finalised, concerns were voiced about potential adverse effects on studies designed to test and implement scientific discoveries in clinical practice (translational research) in Europe.1 2 Today, five years after implementation, evidence shows that the directive has had a negative effect on translational research.

The directive was designed to optimise patient safety, increase the numbers of patients entered into clinical trials, improve the efficiency of trial implementation, ensure best practice in ethical review and regulatory procedures, and harmonise these procedures across Europe. In fact, the implementation of the directive by individual EU member states has caused legislative differences between the different nations and obstacles to the conduct of clinical trials.3 Although practice has improved in some areas of Europe,4 in general the regulatory requirements are highly demanding and expensive, irrespective of the level of risk to which the patient will be subjected by participating in the study; trial implementation is now slower; and investigator (rather than drug company) driven studies are decreasing in number and complexity. All these effects are compounded in the context of multinational studies, where it has been impossible to comply

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Possible solutions to obstacles to clinical trials in Europe

Require only one clinical trials authorisation (CTA) for all multinational clinical trials, irrespective of the numbers of participating nations, either by development of a single CTA application across Europe or mutual recognition of authorisations by competent authorities

Simplify and harmonise the procedures for clinical trial approval (for example, use just one set of forms) and safety reporting (EudraVigilance and reporting rules)

Better define and harmonise the roles and review processes of ethics committees (achieve the so called single opinion) and competent authorities

Adopt a risk based approach—adapt the regulatory requirements to consider the risk associated with the trial with regard to safety reporting (for example, limited safety reporting for commercially approved drugs), data monitoring, insurance, application dossiers, substantial amendments

Allow co-sponsorship in the case of multinational trials, with the aim of facilitating collaboration between research groups

Better define terms and concepts (for example, investigational medicinal product (IMP), interventional study, substantial amendment)

Increase public financial support for investigator driven clinical trials

Harmonise insurance requirements—for example, uniform costs per country, minimum and maximum indemnity payments, total duration of coverage, and time to permit claims

Forum for Good Clinical Practice (at which the results of each were summarised, discussed, and prioritised with the aim of designing a proposal for consideration by the commission. The crucial factor in the success of this initiative was to engage all the key stakeholders (commercial and non-commercial sponsors, investigators from all areas of medicine, ethics committee members, competent authorities, funding bodies, and patients). The voice of academics was unusually silent during the development of the directive—now is the time to be heard.

2 Moulton B. Save European research campaign. BMJ 2004;328:286.